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FROM THE EDITOR-IN-CHIEF'S DESK

Is it all water under the bridge or water over the dam now?

The Greek word for "return" is nostos.
Algos means "suffering".
So nostalgia is the suffering caused by an unappeased yearning to return.
— Milan Kundera, Ignorance

This quote was mentioned by Milan Kundera in his inimitable novel "Ignorance". Actually, no one, not even content, in a Kundera novel is happy since he takes such dizzying concepts as absence, forgetting and illusion. Last night, I was revisiting his book after decades, to face his petty and cruel characters again. All of a sudden, his quote on "nostalgia" seemed to strike the right note with me. That was a night for me to chill after a busy faculty schedule, in which I held a mid-term "reflection" session with medical students. I was trying to get over the disappointment I'd felt after the lecture, since the majority of the class declared their disinterest in surgical training. I've never been dismissive towards the generations that follow us. However, as a surgeon, I suddenly felt poetic and nostalgic about the good old days when surgical training and pursuing a career in surgery were extremely popular among doctors. I thought that the reason for declining interest in surgical training may be due to surgical residents' inevitable exhaustion, a reality which medical students can't help but notice. Unfortunately, from the outside, what they observe rings true.

It's not a coincidence that our new issue starts with the editorial by Prof. G. Karadeniz Cakmak with her stunning title "Winter is coming: Is the shine of surgery fading?" as she emphasized that the decreasing interest in surgery residency is a dynamic and multifaceted issue, stemming from work-life balance concerns, the emotional and physical burden of surgery, and shifting societal values around career goals and personal well-being. Kivratma et al. shared their results of an important survey on surgical training, where they found that the residents expressed low levels of satisfaction with the training and that improvements are vital in several areas concerning the training and working conditions of resident physicians. After scrutinizing the survey, I acknowledge that we should have stronger arguments than telling the trainees that everything gets better the senior they get, which is far from convincing.

As Ambroise Paré once said, "There are five duties of surgery: to remove what is superfluous, to restore what has been dislocated, to separate what has grown together, to reunite what has been divided, and to redress the defects of nature.". These tasks still remain divine for me and, despite all the challenges, I believe that to be a surgeon, we have to live and breathe it.

I'd like to thank all my colleagues in surgery for their devotion against all odds. And as always, thanks to our readers for their support.

Prof. M. Umit Ugurlu
TurkJSurg Editor-in-Chief

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EDITORIAL
Turk J Surg 2025;41(2):114-117

Winter is coming: Is the shine of surgery fading?

Güldeniz Karadeniz Çakmak

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INTRODUCTION

Becoming a surgeon is one of the most challenging and demanding decisions to be made at the very beginning of a young physician's career following a well-deserved graduation earned through years of dedication, perseverance and sacrifice. This lifelong, 24/7 journey requires not only technical skill but also resilience, patience, and a profound commitment to patient care in any circumstance. The education period never ends and involves years of rigorous training, a strong academic establishment, and the ability to cope with high-pressure situations and overwhelming stress. Becoming a surgeon means being able to work as a team member, developing excellent communication skills, and exercising empathy with patients, families, and colleagues. The fortune, however, is significant, as the act of a surgeon is both impactful and profoundly irreversible, providing the privilege to create a permanent influence on the life of a human being. Along with all these facts, the decline in enthusiasm for surgery residency and attrition has been a subject of concern and a pressing issue for the past decades globally (1-3). Various factors contribute to this trend, and several issues have been addressed as etiologic reasons. The correct question should not focus on the quantity of the surgery residents, or the medical students matching surgery, but rather on the quality of the education they receive.

The demanding hours, intense physical and emotional strain, and a high level of responsibility that come with surgery residency can be exhausting for many students, particularly when work-life balance is an important consideration today. To reverse the trend, it's crucial to not only identify these challenges but also to create a supportive environment that focuses on well-being, improving quality of life through rational and practical strategies. Since surgery is not only a profession but also a lifestyle that requires personal sacrifices in terms of both physical and psychological comfort, the current generation of medical students has concerns about choosing this way of life. It is indeed a heavy emotional burden, compounded by long working hours. For medical students applying to residency programs, choosing a medical specialty is a complex and critical process (4). For the majority of applicants, this choice determines their career trajectory and provides solid evidence regarding their character and attitudes towards life. Questions remain about how they navigate the available specialty options and which factors tend to influence their interest in each specialty. When we narrow the scope and examine the reasons why medical students do not prefer a surgical residency, or why resident attrition occurs, there are several key points that should be emphasized. As the preference decreases, it is not the quantity, but rather the academic quality of residents that unfortunately declines. When we analyze the match scores for general surgery in Türkiye, we identify four major problems that could lead to irreversible, serious consequences. One issue is the unmatched and less desirable residency programs, particularly in low-population geographic regions, with limited social life facilities. Another important point to consider is that medical school graduates with the lowest scores in the matching exam are secure spots in general surgery residencies. The third issue,

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which stems from and is compounded by the previous one, is that their motivation is not driven by ambition or passion, but rather by the need to find a final refuge that provides financial relief during this period. The final issue is resident attrition, which is higher than the presumed rate. Solutions to this phenomenon have been explored in Europe and the US in recent decades, focusing on the key factors contributing to the problem (1-4). To begin with, work-life balance is a crucial concern for young physicians. Surgery residency is known for longer hours on-duty, excessive stress, night shifts, and intense workload, which can lead to burnout. Many medical students are now prioritizing their private time and may be deterred by the perceived difficulty of maintaining it during surgical training. The impact on personal life, with long and unpredictable hours during residency, often leaves little time for personal activities or family time, prompting many medical students to consider other specialties that offer more predictable hours and less stress. Creating structured schedules that allow for regular time off, more flexible rotations, and ensure that residents have the opportunity to decompress and take care of their personal lives could be a step in the right direction. One question to be asked at the very beginning of the residency program should be: Do you live to work, or work to live? Since surgery means a lifetime of work, the answer might need to be more descriptive.

Economic prospects and financial considerations have long been key factors in residency choices. Surgical training often comes with a heavy financial burden due to extended years of education, the need for additional training in subspecialties, and relatively low salaries during residency. For many students, this financial burden is compounded by the high cost of medical school. Potential residents may also be dissuaded by the longer path to earning a higher salary, especially when compared to specialties with shorter training periods or more predictable financial outcomes. Additionally, malpractice verdicts and related concerns act as cautionary factors for young physicians, influencing them to pursue specialties with less risk and greater protective measures during their training and beyond.

Being a surgeon requires unique qualities to cope with high stress and the emotional toll. Surgery, particularly in specialties like trauma or oncologic surgery, involves high-stakes procedures with life-or-death outcomes, leading to significant stress and emotional fatigue. This emotional burden, combined with long working hours, contributes to higher levels of burnout among residents and may deter individuals who prefer specialties with fewer emotional and physical demands. Other issues to be addressed are the cultural and gender-related factors (5). Surgery has historically been a male-dominated field, and while this gender imbalance is changing, some medical students may still perceive surgery as less welcoming to women or other minority groups. In addition, the intense, competitive nature of surgery and the "macho" culture associated with it may discourage those who do not identify with this culture. Concerns about achieving gender equality and managing both career and family responsibilities during surgery residency are also major factors, particularly for female medical students (6,7). Surgery has traditionally been viewed as a high-stress, high-stakes profession with a somewhat rigid culture. Promoting diversity in gender, ethnicity, and career interests within the field could not only make surgery more appealing, fostering an environment with an inclusive culture, but also create a more collaborative and empathetic environment. Mentors and academicians should encourage female students to choose surgery. The presence of a role model has a significant positive influence on surgical career decision-making (8).

We recognize the evolving interests and expectations in the medical field. Today's medical students increasingly seek specialties that offer a balanced combination of intellectual challenges, patient interaction, and flexibility. Many find these qualities more prominent in fields such as internal medicine, dermatology, and family medicine. The rising popularity of lifestyle medicine and preventive care, along with advancements in medical technology, has led more students to pursue non-surgical specialties. Given the shifting expectations and values, surgery must be reframed to emphasize how it can be rewarding and impactful-not just in terms of patient outcomes, but also in terms of personal growth and contributions to the broader healthcare system. These changes will not be easy, but they have the potential to make surgery a more sustainable and desirable career path for future generations. On the other hand, the evolving nature of surgery, with minimally invasive surgery, robotics, and artificial intelligence, can be particularly impactful and appealing to a generation passionate about video games. A key factor to acknowledge is their capability and skill with these novel technologies, particularly their visuospatial abilities and hand-eye coordination (9). However, these advancements have led some to believe that surgery is becoming less "hands-on" or "traditional", which may make it less appealing to students interested in more physically demanding or technique-intensive practices.

From the perspective of mentors, our priority should be to engage in fearless and honest self-criticism. We must approach this with transparency, candor, and decisiveness to improve our training programs. One of the main areas for critique is the perceived lack of mentorship and support in some surgical residency programs, which can leave residents feeling unsupported or emotionally neglected. The hierarchical nature of surgical training (where more junior residents may feel isolated) can deter prospective candidates. Additionally, inadequate guidance on how to navigate the challenges of residency may contribute to a lack of interest in the field. Designing better support systems-ensuring access to mental health resources, mentorship programs, and

peer support networks—could help mitigate the emotional toll. Residency is a challenging time, and fostering a more supportive culture could lead to better retention rates. Another point with the potential to advance the field of surgery is the creation of a national blueprint for sustainable science in surgery. Being a surgeon-scientist should be promoted (10). Surgeon-scientists offer a distinct and innovative perspective in tackling critical scientific questions, blending clinical expertise with research-driven insights. The historic contributions of surgeon-scientists, including nine Nobel Prize laureates, highlight the unique perspective they bring to exploring critical questions about the biology and burden of disease (11). Surgeons possess a distinct approach and mindset that enables them to tackle key scientific challenges in innovative ways. Leaders in academic surgery must consider modernizing surgical training. We must adapt to the impact of generational changes on surgical residency applications, focusing on the preferences and values of millennial medical students, such as their desire for work-life balance, job satisfaction, and mental health support. Growth in mindset should be initiated by identifying a research focus in the decision-making process for a surgical career. Mentorship should be provided individually to each resident, which will reinforce the sense of belonging and prevent attrition.

All these factors are shaping the future of surgery residency programs. Our primary responsibility is not only to increase the quantity of surgical residency programs but also to enhance the fundamental academic quality of surgeon candidates. Simply increasing the number of surgical residency programs will not solve the problem if it is not accompanied by a focus on maintaining or improving the academic and clinical quality of surgeons. It is not just about producing more surgeons; it is about ensuring that those entering the field are well-prepared, compassionate, and capable of handling the complexities of modern surgery. Key approaches to improving the academic quality of surgical residency programs could include enhancing training standards and focusing on high-quality, evidence-based education in both the technical and non-technical aspects of surgery. This involves refining teaching methods, integrating simulation-based learning, and offering opportunities for residents to engage in research and innovation. The goal is to ensure that every resident is trained to the highest standards, equipped with both advanced skills and critical thinking capabilities. Additionally, designing individualized learning paths is essential, recognizing that surgical residents come from diverse backgrounds and have varying strengths and areas for growth. Tailoring training to individual needs through mentorship, assessments, and targeted learning could help residents develop more effectively in their specialties and reduce attrition.

While technical skills are crucial, the emotional and cognitive challenges of surgery are equally important. Building emotional and cognitive resilience, with a focus on stress management and decision-making skills, can better prepare surgeons for the challenges they will face on the ground. This could be integrated into the curriculum through formalized training in communication, leadership, and ethical decision-making. Furthermore, residents should not feel isolated or unsupported after graduation. Implementing lifelong mentorship policies within residency programs to create stronger relationships between residents and attending surgeons can help ensure that residents are not only mastering the technical aspects of surgery but also developing their professional identities as well-rounded healthcare providers. Mentors can assist residents in navigating the emotional and personal aspects of their career paths, such as managing burnout, stress, and work-life balance concerns. It is crucial to assess not only the clinical skills of residents but also their professional growth and overall well-being. Regular, continuous feedback and evaluations that are constructive, actionable, and focused on both personal and professional development can lead to better outcomes and the early identification of areas where residents may be struggling.

As mentors and faculty members, we must embrace the cultural shift in surgical education. A culture that emphasizes collaboration, diversity, and inclusion can help make surgery a more welcoming and accessible field. The surgical discipline is essential, but it can be approached with a more compassionate mindset. Encouraging open dialogue about mental health, work-life balance, and the stresses of residency can help transform the traditional, often tough, persona of surgery into one that recognizes the humanity of the individuals behind the scalpel. By changing our mindsets and approaches related to the expectations of residents, we can foster a more supportive and sustainable environment for their professional development. Residents should be encouraged to learn English, which is the lingua franca of science, to follow current literature updates. Cultivating a culture that prioritizes well-being and holistic growth will better prepare residents to navigate the inherent challenges of surgical training. Such a shift would not only enhance retention but also contribute to the creation of more compassionate, resilient, and proficient surgeons. Moreover, encouraging residents to participate in global health initiatives, collaborate with international colleagues, and engage in innovative surgical techniques and technologies can broaden their perspectives and offer new insights into their training. This, in turn, will drive quality improvements on a national scale. Moving away from old-school thinking and improving the academic quality of surgical residency programs is essential for cultivating skilled and visionary surgeons. By focusing on these key areas, we can ensure that we not only increase the quantity of surgeons but also significantly enhance the quality of care and innovation in surgery. As policymakers and faculty members, we must acknowledge the fundamental rule of

evolution—the survival of the fittest—which applies to the current state of surgery. If we wish to remain as a shining star in the future, as we were in the past when we were revered as the "hands of the gods on earth", we must adapt to the current ecosystem desired by the new generation and accept that change has already arrived in surgery. While surgery remains one of the most prestigious fields, the decline in interest is largely driven by lifestyle factors, including the desire for a more predictable and manageable work schedule and financial considerations. On a national basis, along with educational institutes' efforts, there remains a crucial responsibility of the Turkish Surgical Society, which is the most inclusive professional and umbrella organization encompassing surgeons in Türkiye. Turkish Surgical Society, should address the root causes of the problem and take urgent action to reverse the declining interest in pursuing surgical careers in our country. Turkish Surgical Society should initiate steps to address this issue, which has the potential to cause significant problems in the future. The designation of regional councils, including department heads and education coordinators, might be the first step forward. This would foster collaboration and cooperation, and determine the limits and strengths of each institute regarding the basic training of residents. Moreover, a web-based educational programme that includes essential educational content and information about being a surgeon medical students considering surgical residencies might be impactful. The curriculum should include educational modules and simulation-based basic surgical skills courses for medical students. The establishment of a committee of medical students aspiring to a career in surgery would foster interest in the field early on. The effect of surgical experience, including operation theater actions, involvement in operative procedures, welcoming attitudes of attendants and treating them as members of the team, has a great impact and serves as a motivator for student attitudes toward surgical careers (12). To open doors, like initiating shadowing a surgeon programme as a medical student, online meetings with well-known mentors, seminars on guidance for career planning in surgery, open question forum for medical student to reach surgical experts to receive accurate and comprehensive answers and lectures about what makes being a surgeon special and the reasons behind the mystery of surgery can help them to determine if surgery is the right path for her or him. The ultrastructure of the steps to be taken can be guided and revised with the recommendations and insights of educators from training institutions, and can be modified according to the requirements of each region across Türkiye. A task force hosted by the Turkish Surgical Society, with investment and engagement from various stakeholders, including academic surgeons, surgery department chiefs, governmental representatives, and funding institutes, can take the required deliberate action to transform the future of Turkish surgeon-scientists and pave the way for next-generation surgeons to possess not only theoretical and practical competence, but also research and ethics proficiency, ultimately, securing a well-deserved seat on the international platform of value-based surgical health care.

CONCLUSION

In summary, the decreasing interest in surgery residency is a dynamic and multifaceted issue, stemming from work-life balance concerns, the emotional and physical burden of surgery, and shifting societal values around career goals and personal well-being. Addressing these challenges—by improving residency conditions, offering better support systems, and showcasing a more diverse and inclusive surgical culture—could help reverse the trend and encourage more students to pursue a career in surgery.

Keywords: Excision, general surgery, incision

Footnotes

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EDITORIAL
Turk J Surg 2025;41(2):118-120

Artificial intelligence in surgical practice: Truth beyond fancy covering

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INTRODUCTION

In recent years, the role of artificial intelligence (AI) in surgical applications has been increasing, leading to significant changes in the healthcare field. AI is used in areas such as supporting surgeons' decision-making processes, evaluating surgical skills, and improving training processes. However, literature reviews on the applicability and effectiveness of this technology also show that integrating AI into surgical practice has some challenges.

When considering the application areas of AI in surgery, the main headings are as follows. In the preoperative period, diagnosis, clinical risk prediction, and selection of suitable patients for surgery, evaluation of the patient's preoperative data, identification and intervention of concomitant conditions that can be optimized, informing the patient about the surgery, presentation of appropriate written and visual materials, and AI contributions to the patient's education and consent process can improve the results. Intraoperatively, identifying surgical instruments and the stage of the operation and predicting procedural next steps may accelerate surgical decision-making and provide recommendations regarding possible outcomes. Additionally, perhaps after the development and integration of the operating room black box, one can envisage the operating theater of the future with access to dashboards updated with real-time data specific to the patient and surgical team. Developments in the fields of surgical robotics and automation are becoming increasingly important. The evaluation of intraoperatively obtained data streams and autonomous systems can be prepared based on these. The objective criteria and feedback produced through AI can improve the field of surgical training, and dynamic simulations can offer more realistic surgical training opportunities. During the postoperative period, monitoring patients via wearable device technology and sensors can improve many parameters, such as early warning, mobilization, and discharge. Prediction of complications can enable follow-up recovery. With the inclusion of mobile technologies, innovations toward the goal of remote monitoring are increasing and allow for a home-based recovery model (1,2).

Visual AI applications have also attracted attention as a part of surgical practice. In one study, an algorithm for predicting unwanted bleeding caused by surgical instruments during robotic and laparoscopic surgery was developed. This algorithm detects sudden movements of surgical instruments and predicts the possibility of bleeding. The authors state that such an early warning system can help surgeons work more safely (3).

The impact of AI on surgical decision-making processes is particularly evident at the intraoperative stage. In a review, AI-based systems offer functions such as accelerating intraoperative pathology and recommending surgical steps by increasing surgeons'

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access to information. AI-based decision support systems help surgeons better understand the current situation and thus enable them to make faster and more accurate decisions. These systems accelerate the decision-making processes of surgeons and contribute to better patient outcomes. Another study reported that AI allows surgeons to make more accurate predictions in decision-making processes and thus reduces the workload of surgeons. Such applications help surgeons work under less stress and achieve better patient outcomes (4,5).

Moreover, the potential of AI to reduce surgeons' workload is also noteworthy. In a review, the weaknesses of traditional clinical decision support systems are addressed, and how AI can be used to enhance surgical decision-making processes is discussed. The integration of AI into surgical decision-making has the potential to transform patient care by strengthening the decision to operate, the informed consent process, the identification, and mitigation of modifiable risk factors, decisions regarding postoperative management, and shared decisions regarding resource utilization (6).

A review evaluating the clinical applications of AI in robotic surgery revealed that AI modeling allows surgeons to improve intraoperative metrics such as force and touch measurements, better detect positive surgical margins, and even complete the automation of certain steps in surgical procedures. AI modeling applied to intraoperative surgical video streams and instrument kinematics data allows the creation of automated skill assessments. AI also holds promise for the creation and delivery of highly specialized intraoperative surgical feedback for training surgeons. However, further innovation raises important and complex ethical questions such as data privacy, the transparency of AI models, bias, accountability, and inappropriate models for financial incentives (7).

AI is emerging as a field with the potential to revolutionize surgical education and practice. One study discussed how AI can transform education, practice, and patient care. By addressing the current applications of AI and technological developments, the authors explain how these two fields can be combined in the future. In this context, the role of AI in surgical training is evaluated as an important tool that can help surgeons develop their skills and improve patient outcomes (8).

The increasing use of AI in healthcare services has also led to changes in the education of healthcare professionals. In a study addressing how AI affects clinical decision-making processes and how healthcare professionals should adapt to these new technologies, it is emphasized that training curricula should be updated to ensure that healthcare professionals gain knowledge and skills related to AI. This is important for surgeons to make more effective and reliable decisions when interacting with AI (9).

The potential of AI in surgical applications also faces some challenges. In this context, a study was conducted to demonstrate the feasibility of using a toolkit of deep neural networks simultaneously in the operating theatre for real-time assistance during laparoscopic cholecystectomy. This study suggested that predictions from AI tools could be used to improve surgical safety by providing information to surgeons, operating theatre staff, and administrators. However, the applicability of such systems is directly related to the level of surgeons' confidence and training in these technologies. There are also challenges to be solved, such as surgical safety, the need for multicenter datasets, data sharing and security, ergonomics, optimization of human-machine interfaces, and ethical problems related to AI assistance (10).

AI-powered analytics can help researchers increase efficiency through various big data analytics functions, such as code completion, automated machine learning, data visualization, and statistical testing. A large language model (LLM), a form of AI built to understand and produce human-like text, can facilitate surgical research. LLMs can provide benefits in many areas, such as identifying and refining research questions, conducting literature reviews, designing studies, and drafting and editing drafts during the writing process. These generative AI tools can help authors organize articles, improve readability, assist with grammar and translation, and perform administrative tasks such as citing references. However, there are limitations to the use of AI in scientific writing, such as potentially incorrect information due to hallucinations, a lack of human creativity, and the inability to understand complex scientific concepts. There is concern that scientists may over-rely on AI and use these tools to author entire papers with little supervision. Many surgical journals have provided guidance to authors and reviewers on the use of AI in the editorial process, stating the need for clear disclosure of the tools used and content generated, the importance of adhering to journal policies on confidentiality, and confirmation that authors and reviewers take responsibility for the content generated by AI (11-13).

Given the promise of AI and machine learning, the lack of knowledge about the nature, capabilities, and pitfalls of AI has led to anxiety. It is important not only to learn from and understand AI but also to recognize its potential limitations (14).

AI is a tool with the potential to transform many aspects of surgical practice. From training to patient care, a wide range of AI applications are helping surgeons develop their skills and improve patient outcomes. However, this transformation should aim to be realized with attention to the impact on healthcare and ethical practices, data privacy, and the humanitarian aspects of surgical practice.

Declaration of Generative AI and AI-Assisted Technologies in the Writing Process

The initial draft of this article was written in Turkish and later translated into English using DeepL Translator (deepl.com/en/translator). To enhance grammar, language quality, and proofreading, the author utilized Grammarly (app.grammarly.com) and Trinka AI (trinka.ai). After using these tools, the author thoroughly reviewed and edited the content and took full responsibility for its publication.

Keywords: Artificial intelligence, machine learning, perioperative care

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ORIGINAL ARTICLE
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Exploring the perspectives and challenges of general surgery residents in Türkiye: Insights from a survey on surgical training

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ABSTRACT

Objective: This study aimed to assess the perspectives of general surgery residents in Türkiye regarding the conditions and methods of their training, as well as the methods and circumstances under which their training is conducted

Material and Methods: The study involved 426 resident physicians undergoing training in general surgery at various institutions, including university hospitals, education and research hospitals, and foundation university hospitals, from January to March 2024. A web-based survey was distributed to the residents via email, containing 18 multiple-choice questions. The results were analyzed using the SPSS statistical software.

Results: The study revealed that 21.36% of the resident physicians had been in training for 0 to 1 year, while 20.19% had been in training for 2 to 3 years. A significant portion, 62.44%, was receiving their training in education and research hospitals, 36.38% in university hospitals, and only 1.17% in foundation university hospitals. In terms of training adequacy, 48.36% of the residents felt they did not receive enough practical training, and 81.22% believed they lacked sufficient theoretical training. Furthermore, 66.10% reported insufficient support for conducting academic research, and only 47.65% were aware of the core training program. Regarding work hours, 35.45% of residents were on duty every other day, 7.28% worked more than eight shifts per month, and 68.08% reported working 60 hours or more per week. Additionally, 91.31% of the residents deemed their salaries inadequate, and 71.36% experienced delays in receiving their on-call pay. Notably, only 55.63% expressed satisfaction with their experience as general surgery residents.

Conclusion: The findings of this research indicate that there is a lack of standardization in general surgery specialization training in Türkiye. The report reveals that both theoretical and practical training are insufficiently provided and not delivered in a systematic manner. Additionally, general surgery residents expressed low levels of satisfaction with the training they receive. It is evident that improvements are necessary in several areas concerning the training and working conditions of resident physicians

Keywords: General surgery, resident, education

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INTRODUCTION

In Türkiye, as in many other locations of the world, rapid technological advancements and innovations are driving change and transformation in the healthcare sector, paralleling trends in various other industries (1). The health sector is one of the areas where scientific knowledge is evolving most intensively (2,3). Increasing financial constraints within the healthcare system, alongside new medical developments and shifting expectations regarding service delivery, are the primary factors fueling this change. As this transformation unfolds, modifications in working environments, conditions, and relationships are occurring, which significantly affect the health and safety of employees (4,5).

Medical specialization training is a structured program designed for research assistants and residents, conducted under guidance and supervision. This organized training

not only fosters the personal and professional development of the residents but also ensures the delivery of safe and effective healthcare to patients (6). In Türkiye, the Turkish Surgical Society (TSS) established the Assistant Commission in 2009 to identify and address issues related to the professional and personal rights of resident physicians during their specialization training. This commission aims to enhance communication between residents and their peers, as well as with other official bodies within the TSS. Moreover, the education and personal rights of resident doctors are governed by the "Regulation on Specialization Training in Medicine and Dentistry", initially issued on April 26, 2014, and later amended on October 7, 2023. Additionally, initiatives and efforts to structure residency training programs in Türkiye have gained considerable momentum, with each specialty association developing a standardized curriculum for residency training within the framework of the Specialization Training Framework Program. Institutions offering specialization training educate resident doctors based on the established framework program. In Türkiye, authority and responsibility for specialty training are coordinated among the Ministry of Health (SB), the Council of Higher Education (YÖK), medical faculties, the Turkish Medical Association, and specialist associations (7). Specialist trainees, often working in isolation within their departments during their training, connect with the faculty administration twice a year through the "Assistant Orientation Program" for those newly entering specialty training. In this program, alongside faculty information advanced training is provided on topics such as ethical guidelines, professionalism, effective communication, stress management, health law, forensic medicine, malpractice, and effective consultation (8). According to the 2022 Health Statistics Yearbook Newsletter by the Ministry of Health in Türkiye, 45,391 of the total 194,688 physicians are resident physicians (9).

Today, many resident physicians, particularly those in surgical specialties, face challenging working conditions, limited educational resources, and a complex web of professional relationships. Establishing standardized guidelines for residency training across specialties is essential for both trainees and trainers. General Surgery Clinics, in particular, stand out as the most affected units in Türkiye, often struggling to complete training programs under especially difficult conditions. As of 2017, Türkiye has 123 institutions providing general surgery training, with 768 general surgery residents in training. These institutions include 9 city hospitals, 26 training and research hospitals, and 78 medical schools (13 of which are foundation institutions) (10). The primary goal of general surgery residency training is to equip residents with the professional competence, knowledge, and skills necessary for their practice, while also fostering lifelong learning and the ability to maintain their skills. General surgery residency training spans five years, with the Ministry of Health serving as the legal authority overseeing this specialist training (11).

General surgery residency today encompasses training in the treatment of the digestive system -including the esophagus, stomach, small and large intestines, liver, pancreas, and gallbladder- as well as diseases of the thyroid gland, parathyroid glands, adrenal glands, peripheral vascular diseases, hernias, skin, breast, and trauma care. General surgeons are trained to handle nearly all emergency surgical situations. Additionally, minimally invasive surgery and endoscopic procedures fall within the scope of general surgery (12).

Since the early 21st century, numerous developments have prompted changes in the nature and structure of general surgery training. In general surgery clinics, as in other surgical fields, challenges such as internal harassment (both horizontal and vertical), pressures on resident physicians, and the departure of trainers from educational institutions due to difficult working conditions are significant issues. The limited opportunities for career progression and the presence of incompetent or unqualified administrators hinder professional growth, creating a sense of a limited professional future. These conditions have contributed to increased migration out of the field and a growing sense of alienation among practitioners (13).

This survey study sought to assess the perspectives of residents working in general surgery clinics at university hospitals, foundation university hospitals, and training and research hospitals providing general surgery specialization training in Türkiye. The goal was to identify the conditions under which these residents train, understand the nature of their training, and develop a general approach for improvement. To achieve this, a survey was conducted among general surgery residents, aiming to create a more contemporary perspective, and enable a more thorough and accurate audit and evaluation process.

MATERIAL and METHODS

An online survey consisting of 18 multiple-choice questions was created for web-based completion, and the survey was distributed via email to 874 general surgery residents in 63 surgical clinics. Participants were informed that the average time required to complete the survey would be approximately 30 minutes. Four hundredt twenty-six resident physicians in general surgery training at university hospitals, education and research hospitals, and foundation university hospitals, responded to the survey and were involved in the study conducted between January and March 2024. The CROSS checklist has been completed for this study. Ethics committee approval was received from Ege University Ethics Committee Commission (decision no: 25-1.1T/40).

Statistical Analysis

The data collected in the study were analyzed using the SPSS 22 statistical software package (Statistical Package for the Social Sciences-IBM®). Descriptive statistics for the distribution of responses to the independent variables were presented as counts and percentages for categorical variables. The Kolmogorov-Smirnov test was employed to assess the normality of continuous variables. The chi-square test was used to examine relationships between categorical variables in both pairwise and multiple comparisons. For comparisons of quantitative variables across more than two groups, the Bonferroni test in post-hoc analyses was applied. Results were evaluated at a 95% confidence interval, with a significance level set at $p<0.05$.

RESULTS

The descriptive characteristics of the 426 general surgery residents participating in the study are presented in Table 1. Among the residents, 91 (21.36%) had been in training for 0-1 year, 98 (23.00%) for 1-2 years, and 86 (20.19%) for 2-3 years (Figure 1). Additionally, 265 residents (62.44%) were based in training and research hospitals, 155 (36.38%) in university hospitals, and 5 (1.17%) in foundation university hospitals (Figure 2).

While 220 residents (51.64%) believed they had received sufficient practical training, only 80 (18.78%) felt their theoretical training was adequate. The proportion of residents working in clinics that encourage academic activities was 33.90% (n=144). Conversely, 221 residents (66.10%) indicated that they did not receive adequate support for academic work.

Furthermore, 203 residents (47.65%) thought the education they received was sufficient for their specialization.

In the study, 203 residents (47.65%) reported being aware of the core education program, while 237 residents (55.63%) indicated that the resident report card application was implemented in their clinics. Additionally, 149 residents (34.98%) stated that they completed their other clinical rotations as officially specified. Furthermore, only 317 residents (74.41%) expressed that they were considering taking the proficiency exam administered by the TSS.

When examining the on-call status of the residents, 332 (77.93%) reported that they were able to use their leave rights after on-call duty. Additionally, 151 residents (35.45%) indicated that they were on-call every other day, while 31 residents (7.28%) stated they were on-call more than eight times a month. The majority of residents (68.08%; n=290) reported working 60 hours or more per week. Despite this demanding schedule, 389 residents (91.31%) felt their salaries were insufficient, and 304 (71.36%) noted delays in the payment of on-call fees. Furthermore, 262 residents (61.50%) expressed concerns about safety, while 237

Table 1. Descriptive characteristics of general surgery residents

		n	%
Do you think you received enough practical training during your residency?	Yes	220	51.64
	No	206	48.36
Do you think you received enough theoretical training during your residency?	Yes	80	18.78
	No	346	81.22
Are resident physicians encouraged to study academically in your clinic and are they provided with the necessary support in this regard?	Yes	144	33.90
	No	281	66.10
Do you consider your education sufficient for specialization?	Yes	203	47.65
	No	223	52.35
Do you have information about the core education program?	Yes	203	47.65
	No	223	52.35
Is there an assistant report card application in your clinic?	Yes	237	55.63
	No	189	44.37
Do you do your clinical rotations in the officially specified manner?	Yes	149	34.98
	No	277	65.02
Do you plan to take the Turkish Surgery Association proficiency exam?	Yes	317	74.41
	No	109	25.59
Do you use your leave right after duty?	Yes	332	77.93
	No	94	22.07
How many hours do you work per week?	40-50 hours	36	8.45
	50-60 hours	100	23.47
	60 hours and above	290	68.08
Do you work shifts every other day?	Yes	151	35.45
	No	275	64.55
Do you work more than 8 hours per month?	Yes	31	7.28
	No	395	92.72
Do you find resident physician salaries sufficient?	Yes	36	8.45
	No	389	91.31
Are there any delays in the payment of your duty fees?	Yes	304	71.36
	No	122	28.64
Do you have concerns about your life safety while serving in your clinic?	Yes	262	61.50
	No	164	38.50
Do you think you received enough practical training during your residency?	Yes	237	55.63
	No	54	12.68
	Undecided	135	31.69

residents (55.63%) reported being happy with their status as general surgery residents. Overall, these findings highlight the need for improvements in various aspects of the education and working conditions of resident physicians.

According to the results of the Bonferroni multiple comparison test, significant differences were identified between the groups regarding their perceptions of practical training adequacy. Specifically, it was found that 43.02% (n=114) of residents working in education and research hospitals felt they did not receive enough practical training during their residency, while this rate was slightly lower at 42.58% (n=66) among residents working in university hospitals. These findings indicate that both groups express similar levels of dissatisfaction regarding their practical training, highlighting a need for improvement in training programs across these hospital types. Additionally statistically significant differences were found regarding the question, "Do you think you received enough theoretical training during your residency?" based on the type of hospital where the resident physicians worked ($p<0.05$). The Bonferroni multiple comparison test revealed differences between residents in education and research hospitals and those in university hospitals. Specifically, 80.38% (n=213) of assistant doctors in education and research hospitals felt they did not receive adequate theoretical training, while this percentage was slightly higher at 83.23% (n=129) among those in university hospitals. In contrast, the study found no statistically significant differences regarding the question, "Do you have information about the Core Education Program?" among the different hospitals where the residents worked ($p>0.05$). This indicates that awareness of the Core Education Program was consistent across hospital types, despite the differences in perceptions of theoretical training adequacy.

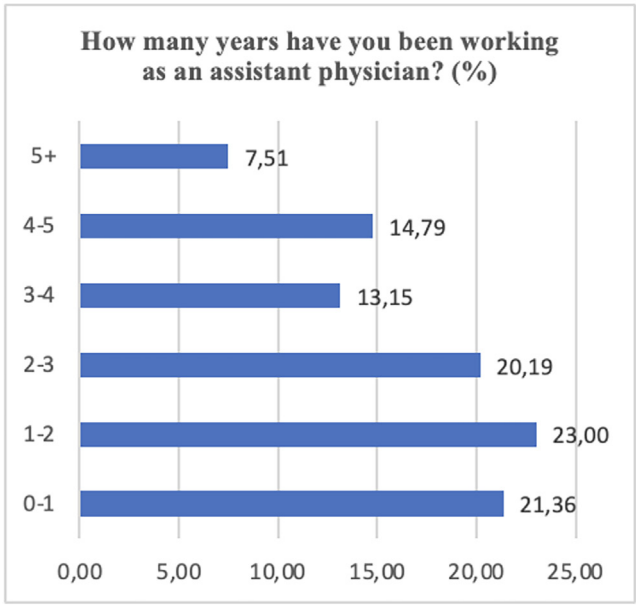

Figure 1. How many years have you been working as an assistant physician?

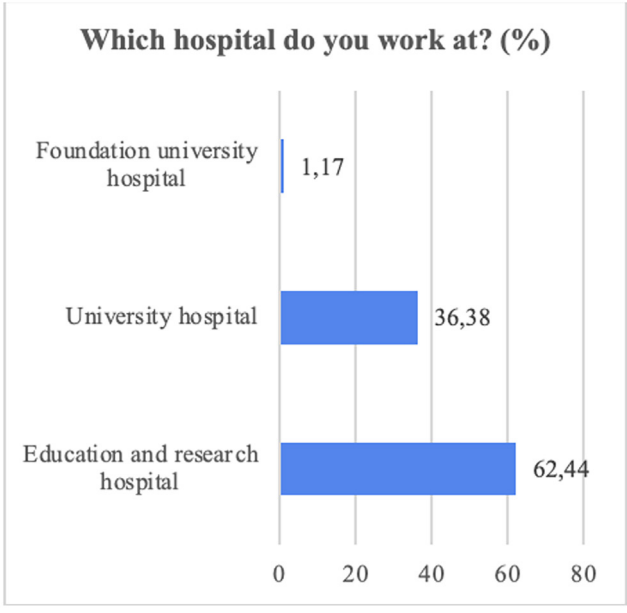

Figure 2. Which hospital do you work at?

DISCUSSION

The analysis of the survey results from 426 general surgery residents revealed a lack of standardization in the residency training process. It was found that both theoretical and practical training were insufficient and not delivered in an organized and structured manner. Furthermore, more than half of the residents reported dissatisfaction with the general surgery training they were receiving.

The role of hospitals affiliated with the Ministry of Health is crucial in general surgery employment. In our study, it was found that 62.44% of the residents were working in training and research hospitals 36.38% in university hospitals, and only 1.17% in foundation university hospitals. These findings contrast with the results of the "General Surgery Residents 2010 National Survey" conducted by the TSS Residents Commission, which indicated that, as of 2009, among the 1,005 physicians receiving specialization training in general surgery, approximately 58.4% were employed in university hospitals, 36.8% in training and research hospitals, and 4.9% in foundation university hospitals highlights the evolving landscape of general surgery training settings in Türkiye over the years (14). This discrepancy emphasizes a shift in the preference and distribution of general surgery residents across hospital types over the years, suggesting a growing emphasis on training and research hospitals rather than university hospitals in the existing training context.

In 2010, residents primarily favored university hospitals for their specialization, but in recent years, there has been a noticeable

shift towards training and research hospitals. One contributing factor to residents' dissatisfaction with general surgery training is low income. Training and research hospitals affiliated with the Ministry of Health typically generate higher revolving fund income, which may explain the increased preference for these facilities among residents. In our study, 48.36% of residents felt they did not receive adequate practical training, while 81.22% believed their theoretical training was insufficient. Additionally, only 33.90% of residents reported working in clinics that promote academic work, and 66.10% expressed that they do not receive enough support in this area. To improve these rates, an effective educational approach that addresses the learning needs of residents should be implemented in all general surgery clinics offering training. The first step is to standardize the general

Table 2. Comparison of resident physicians' opinions about their tenure and the practical, theoretical and core training they received during their residency

		How many years have you been working as a physician assistant?												Test
		0-1		1-2		2-3		3-4		4-5		5+		
		n	%	n	%	n	%	n	%	n	%	n	%	
Do you think you received enough practical training during your residency?	Yes	51	56.04	38	38.78	42	48.84	34	60.71	37	58.73	18	56.25	X^2: 10,86; **p=0.07**
	No	40	43.96	60	61.22	44	51.16	22	39.29	26	41.27	14	43.75	
Do you think you received enough theoretical training during your residency?	Yes	27_a	29.67	$14_{a,b}$	14.29	8_b	9.30	$15_{a,b}$	26.79	$9_{a,b}$	14.29	$7_{a,b}$	21.88	X^2: 16.83; **p=0.01***
	No	64_a	70.33	$84_{a,b}$	85.71	78_b	90.70	$41_{a,b}$	73.21	$54_{a,b}$	85.71	$25_{a,b}$	78.13	
Do you have information about the Core Education Program?	Yes	36	39.56	47	47.96	42	48.84	31	55.36	27	42.86	20	62.50	X^2: 7.18; **p=0.21**
	No	55	60.44	51	52.04	44	51.16	25	44.64	36	57.14	12	37.50	

Statistical significance, X^2: Chi-square test, note: There is a significant difference between different letters in the same row. Table 2 illustrates the comparison of resident physicians' perceptions regarding their tenure and the practical, theoretical, and core training received during their residency. The analysis revealed statistically significant differences regarding the question, "Do you think you received enough theoretical training during your residency?" in relation to the duration of their work as assistant physicians ($p<0.05$). The Bonferroni multiple comparison test indicated that the difference was between those who had worked for 0-1 year and those who had worked for 2-3 years. Specifically, 70.33% (n=64) of residents with 0-1 year of experience felt they did not receive sufficient theoretical training, whereas this rate increased to 90.70% (n=78) among those with 2-3 years of experience. In contrast, the study found no statistically significant differences regarding the questions, "Do you think you received enough practical training during your residency?" and "Do you have information about the Core Training Program?" in relation to the duration of their work as resident physicians ($p>0.05$) *:Significant p-value, a and b: It shows the results of the Bonferroni multiple comparison test.

Table 3. Comparison of residents' thoughts on their hospitals and the training received during their residency

		Education and research hospitals (n=265)		University hospitals (n=155)		Foundation university hospitals (n=5)		Test
		n	%	n	%	n	%	
Do you think you received enough practical training during your residency?	**Yes**	151_a	56.98	66_b	42.58	$2_{a,b}$	40	X^2: 221.88; **p=0.002***
	No	114_a	43.02	89_b	57.42	$3_{a,b}$	60	
Do you think you received enough theoretical training during your residency?	**Yes**	52_a	19.62	26_b	16.77	$2_{a,b}$	40	X^2: 215.12; **p=0.001***
	No	213_a	80.38	129_b	83.23	$3_{a,b}$	60	
Do you have information about the Core Education Program?	**Yes**	133_a	50.19	67_b	43.23	$3_{a,b}$	60	X^2: 16.67; **p=0.061***
	No	132_a	49.81	88_b	56.77	$2_{a,b}$	40	

Statistical significance, X^2: Chi-square test, note: There is a significant difference between different letters in the same row. The comparison of resident physicians' perceptions regarding the hospitals they work in and the practical, theoretical, and core training received during their residency is presented in Table 3. The analysis revealed statistically significant differences in responses to the question, "Do you think you received enough practical training during your residency?" based on the type of hospital ($p<0.05$). These findings suggest that the perceptions of practical training adequacy vary among resident physicians depending on the hospital setting in which they are training. Further analysis may help clarify the specific factors contributing to these differences in perceived training quality. *:Significant p-value, a and b: It shows the results of the Bonferroni multiple comparison test.

surgery training provided across the country and to expedite efforts for improvement. It is essential to recognize that training activities are as crucial as other professional responsibilities and should be restructured accordingly. Supporting our findings, Akçam et al. reported in their study that 57.7% of residents did not receive the theoretical course training provided by their trainers, while those who did received an average of only two hours of theoretical instruction per week. Additionally, the same study indicated that 26.9% of residents received no practical training, while those who did averaged eight hours of practical training per week (6).

In our study, 52.35% of residents reported that the education they received was insufficient for their specialization. In contrast, the "General Surgery Residents 2010 National Survey" indicated that only 32% of residents felt their specialization training was inadequate (14). Similar to our results, the study by Akçam et al. (6), which evaluated residents' perspectives on their surgical education involving 52 thoracic surgery residents across seven different hospitals, found that 39.5% of thoracic surgery clinics lacked resident education programs, 32.7% had insufficient periods for specialization training, and 78.8% reported experiencing stressful working conditions. According to a study by the Turkish Medical Association, half of the resident physicians expressed dissatisfaction with the medical specialization education they received (15). Similarly, in a study assessing the views of 204 residents training inthoracic and cardiovascular surgery in Türkiye, Çıtak and Altaş (16) reported that only 78.2% of the institutions had a resident training program, 59.1% provided adequate periods for specialization training, and 57.8% of residents considered their instructors to be sufficient. In contrast to our study, all resident physicians in basic medical sciences reported, according to Tan et al. (4), that a standard resident training curriculum was implemented in their departments, with nearly all of them indicating that the time allocated for continuing medical education was adequate. Allowing resident physicians to voice their opinions during the curriculum development process and to relay these opinions to the Medical Specialization Board or the YÖK through representatives appears to be a crucial step toward enhancing the quality of education and improving overall satisfaction rates. The TSS Qualification Board introduced the General Surgery Specialist Training Core Education Program (CEP) in 2006 to establish a standardized national curriculum (17). The TSS General Surgery CEP comprehensively outlines the purpose, goals, application principles, key measurement and evaluation points, and the concept of competence in general surgery training. It details the knowledge, skills, and attitudes required at various levels of seniority in both basic and specialized subjects. In the United States, the organization of resident training and working hours is managed separately by each specialty (18). The Accreditation Council for Graduate Medical Education (ACGME) plays a crucial role in standardizing medical specialty training by issuing periodic notifications (19). In our study, only 47.65% of residents were aware of the core education program, a figure slightly lower than the approximately 59% reported in the national survey conducted in 2010 (14). Despite the passage of 18 years, it is clear that challenges remain in both awareness and implementation of the TCD CEP, with some residents still unaware of its existence.

Being on duty is regarded as an integral part of education and service. However, in practice, the working hours and shift schedules for residents in educational institutions are often dictated more by the hospital's operational demands and the volume of clinical work than by the educational needs of the residents themselves. In our study, it was noted that 35.45% of residents were on duty every other day, 7.28% worked more than eight times a month, and 68.08% reported working 60 hours or more per week. This mirrors findings from the 2010 National Survey of General Surgery Residents, which revealed that 65% of residents in their first and second years were on duty every other day, 33% experienced block shifts lasting two or more consecutive days, and 11.3% had on-call duties exceeding ten times a month (14). Çıtak and Altaş (16) found that 59.8% of residents in thoracic and cardiovascular surgery worked nine or more shifts per month, often exceeding 90 hours per week. Similarly, Akçam et al. (6) reported that thoracic surgery residents in seven different hospitals averaged eight shifts per month, with a range of three to fifteen shifts. Unfortunately, this longstanding issue has remained unresolved for years, and the problem is being inadequately addressed. It's important to remember that excessive shifts and long working hours can hinder practical performance and increase the risk of medical errors (20,21).

In the United States, following the Libby Zion case on March 4, 1984, laws were enacted to prevent residents from working more than 80 hours a week and from being on call for more than 24 consecutive hours (22). In 2011, the ACGME implemented regulations that limited the total weekly working hours for residents to 80 and restricted shifts to a maximum of 16 hours (23). In 2017, the ACGME released a statement prioritizing residents' well-being and introduced various measures to address their mental health needs. The organization recognized that residents were facing issues related to depression and burnout, mandating that medical schools take necessary steps to ensure workplace safety, provide psychological support, offer adequate rest opportunities, and ensure safe transportation home after shifts (24).

In our study, 77.93% of residents reported that they were able to utilize their leave rights after shifts. This marks a significant change from previous practices, as residents historically did not have the option to take leave after their shifts. According

to the 2010 National Survey of General Surgery Residents, 99% of residents indicated that they did not have leave rights after shifts, and this issue was consistent across various institutions (14). Similarly, Akçam et al. (6) found that thoracic surgery residents in their study who were training in seven different hospitals did not exercise leave rights after their shifts. Additionally, Yılmaz et al. (25) conducted a study with 155 resident physicians and discovered that 85% of the residents lacked leave rights after their shifts, leading them to work continuously the following day. Similar findings were reported in the study by Rahman et al. (26), highlighting the urgent need for regulations regarding resident physicians' working hours. Another notable result from our research is that 389 residents (91.31%) felt their salaries were insufficient, and 304 residents (71.36%) indicated that they experienced delays in receiving their shift payments. This aligns with the "General Surgery Residents 2010 National Survey", in which 92% of residents expressed dissatisfaction with their salaries and revolving fund income and 20% reported taking on additional work to make ends meet (14). In our research, only 55.63% of residents expressed satisfaction with being a general surgery resident, a notable increase from around 43%, reported in the national survey conducted in 2010 (14). We attribute this 13% rise in satisfaction levels over the 15-year period to the implementation of a specialization training program that aligns with national laws and regulations and is based on internationally accepted standards in the institutions offering this training. This suggests that, despite the challenges they face, general surgery residents still have a passion for surgery and a desire to pursue careers as surgeons. Considering their demanding and complex workloads, enhancing the working conditions for general surgeons and addressing their personal rights could further boost resident satisfaction. Similarly, in the research conducted by, Yılmaz et al. (25), half of the participants believed that the specialty training they received was satisfactory, while one in three felt that improvements were needed in medical specialty training (25). In our study, only 34.98% of residents reported that they completed their clinical rotations as officially specified, compared to approximately 48% in the national survey conducted in 2010 (14). The primary reason for the 13% decrease in the adherence to rotation protocols in general surgery clinics between 2010 and 2024 is that these rotations are conducted based on the clinics' workload and manpower rather than the residents' needs. This lack of standardization and the prevalence of arbitrary practices contribute to the issue. Unfortunately, the failure to comply with legally mandated rotation regulations highlights the disorganization of general surgery specialization training in our country.

In 2006, the "Resident Surgery List Report Card", approved by the TSS Qualification Board Education, was implemented. This list outlines the surgeries that residents are expected to perform at least once during their training, with a requirement to complete a minimum of 350 surgeries, including 150 major procedures (27). In our study, 55.63% of residents reported that the resident report card application was used in their clinics. However, a national survey conducted in 2010 indicated that only 56% of surgical training clinics had a resident card system, and 66% of residents were unaware of the existence of the TSS resident card (14). Over the 14-year period, no significant change in application rates was observed.

Dissatisfaction among general surgery residents is prevalent across all levels of seniority. Primarily, the working hours of resident physicians should be regulated, training deficiencies should be identified, and the necessary financial support should be provided to the physicians. Mandatory weekly didactic sessions, national surgical training accreditation guidelines, periodic nationwide environment assessments, and the supervision of training centers with accreditation by competent authorities will enhance the quality of the education provided and ensure its standardization. We advocate for the establishment of a dedicated unit, along with a separate administrative support role, to oversee specialty training in general surgery departments and training clinics. This initiative could help mitigate training shortcomings, alleviate residents' workloads, and enhance the overall quality of their education.

Study Limitations

While this study offers valuable insights, it is important to acknowledge certain limitations. The validity and reliability of the survey were confirmed through factor analysis; however, there is a potential for selection bias, as residents who were more dissatisfied might have been more likely to participate. Additionally, the response rate of 48.7% raises concerns about non-response bias. Although inter-institutional comparisons were not the main focus, future studies should investigate differences in training quality and workload across various types of hospitals. Another significant point is the difference in perceptions of theoretical training among residents at different seniority levels. As surgical residents progress in their training, they gain more experience, which may lead them to identify deficiencies in their education, potentially explaining variations in their responses. Implementing structured training programs tailored to seniority levels may help address these concerns. Finally, while the study highlights the need for improvements in standardization and working conditions, future research should propose specific strategies for implementation.

CONCLUSION

Specialty training in surgical disciplines necessitates a multidisciplinary approach. This field is often chosen out of scientific curiosity, and passion, but it also demands a thorough examination of the challenges that can lead to attrition during or after residency. To restore the previous allure of surgical

specialties, it is crucial to identify the factors that diminish the quality of surgical training and to understand the expectations of resident doctors concerning their education.

When evaluating the survey results from our research, it became evident that general surgery residency training in our country suffers from significant deficiencies and lacks basic standards, leading to dissatisfaction among residents. Additionally, it was noted that residents endure long working hours with inadequate rest periods. This dissatisfaction is prevalent across all levels of seniority, particularly among final-year residents. To address these issues, it is crucial to organize working hours, identify and rectify training deficiencies, ensure the provision of necessary resources for academic pursuits, and offer financial support to resident physicians. Additionally, mandatory weekly didactic sessions, national surgical training accreditation guidelines, periodic nationwide environment assessments, and the supervision of training centers with accreditation by competent authorities will both enhance the quality of the education provided and ensure its standardization. We advocate for the establishment of a dedicated unit, along with a separate administrative support role, to oversee specialty training in general surgery departments and training clinics. This initiative could help mitigate training shortcomings, alleviate residents' workloads, and enhance the overall quality of their education.

Ethics

Ethics Committee Approval: This study was obtained from Ege University Faculty of Medicine Clinical Research Ethics Committee Decision no: 25-1.1T/40.

Informed Consent: Informed consent was obtained.

Footnotes

Author Contributions

Surgical and Medical Practices - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Concept - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Design - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Data Collection or Processing - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Analysis or Interpretation - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Literature Search - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.; Writing - H.G.K., B.Y., M.C.Ç., E.T., E.O., G.A., B.A., K.Ö., S.N.Ö., B.Y., Y.T., A.D.U., G.K.Ç., A.S.K.

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ORIGINAL ARTICLE
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Intergluteal fold depth has no influence on pilonidal sinus disease development

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ABSTRACT

Objective: The etiology of primary pilonidal sinus disease (PSD) remains unclear. Prior investigations suggest that sharp fragments from the occiput contribute to the formation of PSD. In 2009 a correlation between PSD and a deeper natal cleft was reported. We investigated the association between intergluteal fold (IGF) depth and PSD risk using a standardized five-step measuring protocol.

Material and Methods: Our clinical prospective study included 95 PSD patients and 105 non-PSD individuals, and measurements were taken from the glabella sacralis to the anus in a northern German population.

Results: The mean (± standard deviation) intergluteal depth progressively increased from the intergluteal opening from the sacral glabella at 9.1 (±3.4) mm to a maximum of 62.6 (±10.4) mm. Notably, the deepest point was consistently observed at the anus, where PSD occurrence is rare. No significant difference in IGF depth between PSD and non-PSD patients was found. Additionally, PSD predominantly developed in the proximal (cranial) third of the IGF, despite the maximum depth being in the distal region.

Conclusion: These findings suggest that IGF depth is not a risk factor for PSD.

Keywords: Intergluteal fold depth, natal cleft, pilonidal sinus, mechanism of disease, PSD

INTRODUCTION

The mechanism of primary pilonidal sinus disease (PSD) is unknown. Numerous theories about risk factors and prevention have emerged due to PSD's midline appearance in the lumbar region, glabella sacralis, and cranial opening of the intergluteal fold (IGF). Embryologic origins, such as remnants of the preen gland (1), residual human tail (2), neuro-cutaneous traction (3), faulty ectodermal closure (4), and gluteal muscle involvement (5), have been discussed and eventually dismissed. When more than 17,000 soldiers were taken out of action by PSD during World War II, Buie proposed that the disease was acquired from driving in hard seats on bumpy roads, coining the term "Jeeps disease" (6). Subsequent research disproved this theory (7).

This resulted in speculations about the acquired reasons for PSD: Higher body mass index (BMI), faulty hygiene, enhanced sweating and hormonal imbalances (8) have not been definitively proven. The folliculitis theory (9), in growing gluteal hair theory, or ruptured hair from other body regions piercing into the skin had to be discarded due to lack of supporting evidence. Recent studies by our group suggest that sharp hair fragments constitute the primary component of the pilonidal sinus nest (10), particularly from the occiput (11). Electron microscopy images (12) have captured hair strands erecting themselves and piercing the skin of the upper (cranial) IGF when a sharp edge is in proximity and hair scales point away from the skin. A hairy IGF seems to hold hair longer into position, suggesting that hairy individuals appear to have a higher susceptibility to PSD. We understand that many pilonidal sinuses

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are not found to contain hair, and a successful description of the complete PSD etiology must ultimately also address this issue.

In 2009, Akinci et al. (13) reported a correlation between PSD and deeper natal clefts after measuring the IGF depth, suggesting that surgical procedures to flatten the natal cleft, such as the Karydakis procedure, might reduce the risk of recurrence.

Understanding that a steeper upper natal cleft would cause hair to stand more upright, we wondered why a deeper natal cleft could significantly increase the risk of PSD. To investigate further, we developed a standardized measuring protocol to assess natal cleft depth in both PSD and non-PSD individuals.

Our study aims to address the key questions: the most reliable method for measuring the IGF depth, the presence of one or multiple "deepest points" within the IGF, and potential differences in maximum IGF depth between genders and PSD status. Ultimately, our goal is to determine if IGF depth is an independent risk factor in PSD. Our null hypothesis: There is no association between IGF depth and PSD risk, and IGF depth does not serve as an independent risk factor for PSD.

MATERIAL and METHODS

Patients

A total of 200 participants from a normal population in northern Germany were included in this study. The size of the study population was set, with the objective of creating a cohort double the size of the preceding study.

The PSD patients (95 individuals, 47.5%) were consecutively enrolled from the procto-surgery department who were from St. Marienhospital Vechta (no patient declined participation). One hundred-five (52.5%) non-PSD-patients were recruited from hospital workers, medical students, and patients with non-PSD-associated and non-inflammatory-related diagnoses (mainly traumatology). Participants were required to provide informed consent before being included in this study.

Measuring Tool

First, we tried to measure the depth of the intergluteal (natal) cleft without any mechanical influence of these soft tissues with laser light frame projection (14), but it was not possible. Despite being accurate down to 1/10 of mm, the intergluteal depth was not properly measured by this method due to buttock contact blurring the view of the sacral skin. Thus, we opted for mechanical measurement, modifying the method of Akinci et al. (13). To avoid the compression of the buttocks by heavy instrumentation and consequently lower IGF measurements, an electronic measurement tool from carbon fibre was procured (Kynup, digital caliper, Shenzeng Keyungu Network, Shenzen, China), and a lightweight aluminium plate (with a contact area of 20×3 cm) fixed below by our technical crew (with a total weight of 118 g). Upon calibration, the measuring device showed a deviation of no more than one millimeter across twenty measurements on a hard surface.

Measuring Procedure

To gauge IGF depth, the distance from the upper opening of the IGF (with a sub-3 mm diameter) to the IGF's end at the anus was evaluated. This span was split into four equal parts, resulting in five measuring points marked using a water-soluble pen. Measurements were taken at positions "a" (IGF opening), position "e" (anus), at the midpoint between a and e ("c", mid IGF), and at the midpoints between a and c ("b", 1/4), and c and e ("d", 3/4) (Figure 1). The procedure involved gently placing the tool's thin alloy plate over both buttocks without pressure as patients lay prone. The plastic lever was gently lowered until the midline's IGF depth was visually identified.

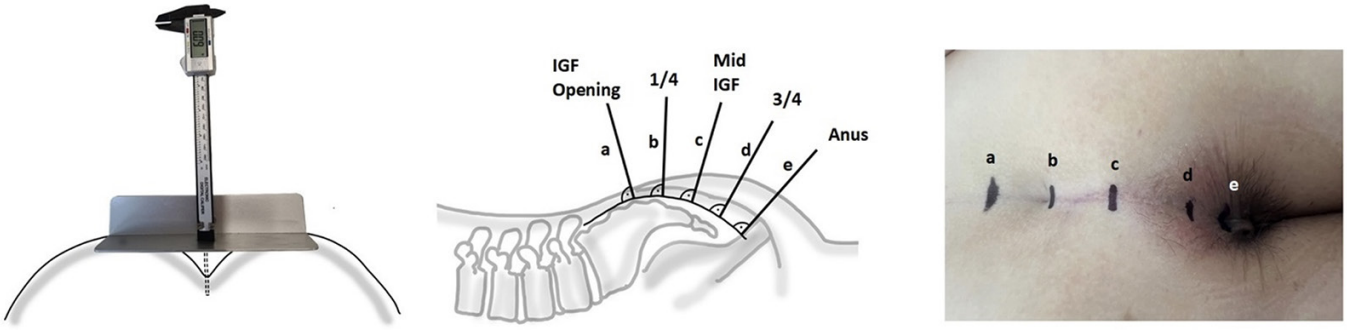

Figure 1. The left side of the figure shows a photo of the lightweight measuring tool used in the study. Please note that the numbers on the tool in the illustration are not correct and are for illustrative purposes only.

On the right side of the figure, there is an illustration demonstrating the measuring points. The measuring tool was positioned at a 90-degree angle to the sacral bone. The distance from the upper opening of the intergluteal fold (point A, with a diameter of less than 3 mm) to the end of the intergluteal fold at the anus (point E) was measured. This length was then divided into four equal parts, resulting in the identification of three additional points: B, C, and D.

IGF: Intergluteal fold

Measuring Protocol

All measurements were consistently conducted by the same investigator (LB) to avoid interobserver variability. For precision, each IGF depth at positions "a" to "e" underwent five measurements (with a variability of 1-3 mm per measurement). These measurements were recorded and the mean was used for analysis. The instrument was always positioned perpendicular to the sacral bone to measure skin-to-midline distance, as depicted in Figure 1.

Statistical Analysis

The study data were recorded in an Excel sheet (Excel 2016, Microsoft Corporation, Redmond, WA, USA). Continuous variables are presented as mean ± standard deviation (SD). Categorical variables are expressed as proportions and analyzed using Fisher's t-test. To assess differences between group means, we conducted an ANOVA. Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

Ethics: The study received approval from the Ethics Committee of Saarland (number: 59/22, date: 11.07.2022). The study was conducted in compliance with these guidelines and regulations, prioritizing the welfare and rights of the participants (15). The analysis done in this study did not contain any interventions that could potentially cause harm to human participants. Nevertheless, ethic approval was given by the Ethics Committee of the county Ethics chamber of the Saarland University Homburg/Saar 59/22 from 11th of July 2022 (Chair Prof. Dr. Grundmann) and by the Ethics Committee Hannover GRAE/151/2022 from 19th of August 2022 (Head Prof. Dr. Creutzig).

RESULTS

The study population consisted of 125 males (62.5%) and 75 females (37.5%). The age of the participants ranged from 16 to 81 years (PSD 16-77, non-PSD 16-81), with a mean (±SD) age of 37.7 (±15.5) years. The age and sex distribution between the PSD and non-PSD groups were not significantly different.

The participants' BMI had a mean (± SD) value of 27.2 (±5.1) kg/m^2. The range of BMI values was 17.8 to 50.6 kg/m^2.

The mean (± SD) length of the IGF from Glabella sacralis to anus was 16.3 (±2.5) cm in males and 15.3 (±2.5) cm in females. The mean IGF depth at different positions were as follows: 9.1 (±3.3) mm at the IGF opening (position a), 21.1 (±8.1) mm at ¼ (position b), 32.4 (±10.1) mm at mid IGF (position c), 45.6 (±10.0) mm at ¾ (position d), and 61.8 (±10.8) mm at the anus (position e). The largest IGF depth was observed between the gluteal muscles at the level of the anus. There were no statistically significant differences in IGF depth between males and females (p=0.816; t-test), or between PSD- and non-PSD patients (p=0.833; t-test; Figure 2).

A relationship between BMI and IGF depth was examined. There was a moderate increase in IGF depth with increasing BMI (slope 95% confidence interval: 0.01050 to 0.5088, R square =0.004163, p=0.041). The data indicate that the IGF depth moderately increases with BMI in our cohort at this time, measured with this method.

Age and its effect on body composition were found to affect BMI in the cohort, with a mean (± SD) increase in BMI over age, from the third decade of life (25.0±3.9 kg/m^2) to the ninth decade (28.5±5.3 kg/m^2).

The effect of age on IGF depth was analyzed between the third and ninth decades (Table 1). It was observed that IGF depth decreased at all five measuring points; with the largest decrease (by a factor of 1.7) observed in the mid region of the IGF (position c) (Table 1). This indicates a decrease in IGF depth with age at all measured points while BMI slightly increases, suggesting a less muscular contour effect.

Overall, these findings suggest that IGF depth is not significantly influenced by gender or the presence of PSD, but it shows a moderate association with BMI and a decrease with advancing age.

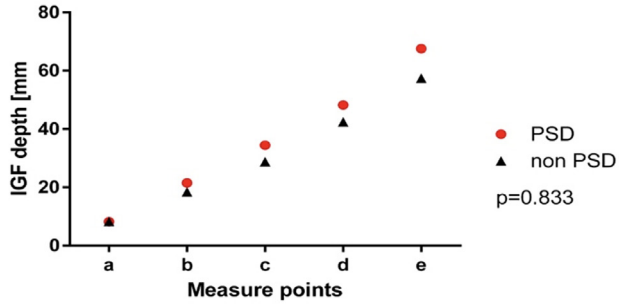

Figure 2. IGF depth for PSD versus non-PSD patients in predefined measuring points: (a) cranial opening of intergluteal fold (IGF opening), (b) proximal intergluteal fold, ¼ distance, (c) midpoint of the intergluteal fold (Mid IGF), (d) distal intergluteal fold, ¾ distance, (e) caudal end of intergluteal fold, anus.

IGF: Intergluteal fold, PSD: Pilonidal sinus disease

Table 1. Intergluteal fold depth [in mm] at five measuring points a-e, versus age decades 3-9

Age [decade]	a	b	c	d	e
20-29 [3]	1.55	2.91	4.27	5.73	7.00
30-39 [4]	1.48	2.78	4.03	5.55	7.10
40-49 [5]	1.33	2.82	3.98	5.20	7.00
50-59 [6]	1.21	2.33	3.29	4.75	6.42
60-69 [7]	1.28	2.64	3.56	5.04	6.40
70-79 [8]	1.05	1.89	3.00	4.42	6.16
80-89 [9]	1.00	2.25	2.50	3.50	5.75

Measuring points: (a) cranial opening of intergluteal fold; (b) proximal intergluteal fold; (c) mid intergluteal fold; (d) distal intergluteal fold; (e) caudal end of intergluteal fold close to anus

DISCUSSION

Although hair is not always found in pilonidal sinuses, the mechanism behind hair fragment insertion in PSD remains a key research subject. While factors such as increased axial hair force (positive) and sweating (negative) have been identified, further exploration is needed. After the 2009 publication suggested IGF depth as a potential risk factor, contrasting clinical findings led us to hypothesize that the IGF depth is not independently associated with PSD risk.

In our study, we conducted measurements using a standardized 5-point method with a lightweight tool in a larger cohort and found no significant difference in the depth of the natal cleft between PSD patients and the normal population. This raises doubts about the overall influence of IGF depth on the PSD development for several reasons. First, the maximum IGF depth occurs at the anus, where PSD is rare (16). Most PSD cases are found at the cranial opening of the IGF near the glabella sacralis (point A to B Figure 1), questioning the relevance of a region unaffected by PSD in the disease's genesis. Additionally, at the cranial opening, where PSD originates, IGF depth is minimal and seems unrelated to the disease's development. Prior studies have shown that sharp hair fragments tend to slide down the back and enter the skin at the cranial IGF opening. We assume that existing local hair helps hold the loose hair upright, allowing it to remain in position while gluteal muscle movement and the friction of the surrounding tissue drive it into the skin.

The differences between our findings and those of the previous Turkish study can be attributed to several factors. One potential explanation is the difference in populations. Our study focused on a northern German cohort, while the Turkish study involved a different population. Genetic, environmental, and lifestyle factors could affect the prevalence of PSD and its risk factors. Furthermore, the sample sizes in the two studies vary, which could impact the statistical power of the findings, with larger sample sizes generally producing more reliable results.

Methodological differences between the studies could also explain the inconsistent IGF depth measurements. Heavier measuring tools, for example, may compress the gluteal muscle and artificially reduce IGF depth. In our study, measurements in three of five positions exceeded the maximum depths recorded in the study by Akinci et al. (13). While body weight could theoretically explain this shallower IGF depth, we showed that reducing BMI from 50 to 20 kg/m^2, only decreases IGF depth by 25%. Therefore, the data suggest it's impossible for BMI to be a significant factor in reducing IGF depth by a factor of two in the Turkish cohort.

Age-related muscle atrophy is also unlikely to explain the discrepancy, as the Turkish cohort had a mean age of 27 years, while our cohort had a median age of 38 years, which suggests that IGF-related characteristics should have been more prominent in the younger Turkish population. Additionally, the Turkish study included 14% females, while our study had a much larger proportion of female participants (37.5%). While females in our study showed a trend toward lower BMI and smaller IGF depths, the smaller number of females in the Turkish study cannot fully explain the deviation in measurements. Given that differences in age, BMI, and gender composition do not account for lower IGF measurements, we propose that these discrepancies may be due to compression of the gluteal muscle during measurement, possibly caused by the use of a heavy tool or manual pressure. Such conditions may not provide accurate measurements of delicate soft tissues like the IGF.

Study Limitations

The study does acknowledge certain limitations. IGF depth was measured in prone patients, a position represents only one of the positions individuals adopt throughout the day. This prone position was necessary for comparison with the previous study. Additionally, the population cohort in our study focused on a northern German population, whose anatomical characteristics and predispositions may differ from those in other regions. This could limit the applicability of our findings to other populations. While our study suggests similarities in PSD genesis between developed countries like Germany and Türkiye, each region's unique contributing factors should be considered, and caution is needed when extrapolating findings to other populations.

The presence of migrants in the German cohort may also contribute to anatomical diversity, though the extent of this influence was not explicitly detailed. To validate and reconcile these findings, further research involving diverse populations, larger sample sizes, and rigorous methodologies will be necessary. Such studies could offer a clearer understanding of the potential link between IGF depth and PSD risk.

This study reveals that the deepest point of the IGF consistently is located distant from areas where PSD primarily occurs. Consequently, it can be inferred that IGF depth does not correlate with PSD development and does not impact PSD therapy. Given that most sharp hair fragments measure between 5 and 15 mm, any structure within this range could elevate hair fragments, causing the sharp end to potentially penetrate the skin irrespective of IGF's anatomical features.

Our study's findings provide evidence that IGF depth lacks an association with PSD risk. IGF depth does not emerge as an independent risk factor for PSD.

CONCLUSION

In conclusion, this study conducted on a northern German cohort offers compelling evidence that IGF depth is not linked to PSD development and does not act as an independent risk factor.

Ethics

Ethics Committee Approval: The analysis done in this study did not contain any interventions that could potentially cause harm to human participants. Nevertheless, Ethic approval was given by the Ethics Committee of the county Ethics chamber of the Saarland University Homburg/Saar 59/22 from 11th of July 2022 (Chair Prof. Dr. Grundmann) and by the Ethics Committee Hannover GRAE/151/2022 from 19th of August 2022 (Head Prof. Dr. Creutzig).

Informed Consent: Participants were required to provide informed consent before being included in this study.

Footnotes

Author Contributions

Concept - D.D.; Design - D.D.; Supervision - D.D.; Fundings - D.D.; Materials - D.D.; Data Collection or Processing - L.B., D.D.; Analysis or Interpretation - M.M., P.M., L.B., M.B-M., M.S., M.O., D.D.; Literature Search - M.M., P.M., L.B., M.B-M., M.S., M.O., D.D.; Critical Review - M.M., P.M., L.B., M.B-M., M.S., M.O., D.D.; Writing - M.M., P.M., L.B., M.B-M., M.S., M.O., D.D.

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ORIGINAL ARTICLE
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Comparison of the effects of epidermal growth factor mesenchymal stem cell and silver sulfadiazine on burn stasis zone

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ABSTRACT

Objective: This study investigates the effects of adipose tissue-derived mesenchymal stem cell (MSC), human recombinant epidermal growth factor (EGF) and silver sulfadiazine (SSD) on wound healing in the burn stasis zone by applying the comb burn model in rats.

Material and Methods: A comb burn model was used for the burns and 32 Wistar albino female rats were randomly divided into four groups (control, SSD, SSD+MSC, SSD+EGF). On the 1st day and the 21st day, the total burn area on the 1st day and the healed, healing, and non-healing burn area on the 21st day were calculated with the Image-J program. At the end of the 21st day, the pathology samples taken after euthanasia were scored semiquantitatively in terms of epithelization, inflammatory cell density, fibroblast density, collagen amount, and angiogenesis after hematoxylin-eosin staining.

Results: Histopathological analysis demonstrated that epithelialization scores were highest in the MSC (3.88±0.35, p<0.001) and EGF (3.63±0.52) groups, while the control group had the lowest values (1.50±0.53). Inflammatory cell density was significantly lower in the MSC (1.50±0.53, p<0.001) and EGF (1.88±0.64) groups than in the control group (3.75±0.46). Similarly, fibroblast density was lowest in the MSC (1.38±0.52, p<0.001) and EGF (1.75±0.71) groups, while the control group had the highest values (3.63±0.52). Collagen fibril density was significantly increased in the MSC (3.88±0.35, p<0.001) and EGF (3.50±0.53) groups compared to the control (1.63±0.74). Angiogenesis was highest in the EGF group (3.75±0.46, p<0.001), followed by the MSC group (3.00±0.53), while the control group had the lowest values (1.25±0.46). These results suggest that MSC and EGF play a significant role in wound healing, with MSC demonstrating superior epithelialization and EGF exhibiting the greatest angiogenic effect. Photo-analytical measurements showed that on day 1, burn area sizes were similar among all groups (p>0.05). By day 21, the healing burn area was significantly smaller in the MSC (3.19±0.98 cm^2, p<0.001) and EGF (4.33±0.48 cm^2) groups compared to the control (8.43±2.35 cm^2). The non-healing area was smallest in the EGF group (0.67±0.49 cm^2), followed by the MSC (1.06±0.49 cm^2, p<0.001) and SSD (1.91±0.75 cm^2) groups, whereas the control group had the largest non-healing area (7.29±2.20 cm^2). These findings suggest that MSC was the most effective treatment for promoting wound healing, followed by EGF and SSD.

Conclusion: We determined that both histologically and photo analytically, MSC and EGF provided faster wound healing in the burn stasis zone EGF gave better results than all groups in preventing necrosis.

Keywords: Burn, burn stasis zone, silver sulfadiazine, epidermal growth factor, mesenchymal stem cell

INTRODUCTION

Burn injuries remain a major clinical challenge, leading to significant morbidity and mortality worldwide (1). Current burn treatments primarily focus on infection control and symptom management rather than active tissue regeneration, leading to suboptimal outcomes in preventing tissue loss (2).

Among the three burn wound zones, the stasis zone is particularly critical due to its potential for tissue salvage. Without appropriate intervention, this area may progress to necrosis, making it a key target for burn treatment (3-5).

Conventional treatments have limited effectiveness in preventing tissue loss in the stasis zone. One of the most widely used topical agents in burn treatment is silver sulfadiazine (SSD), but SSD does not actively support tissue regeneration (6). Mesenchymal stem cells (MSCs) and epidermal growth factor (EGF) have shown promising results in wound healing. MSCs have been shown to accelerate wound healing, improve angiogenesis, shape the extracellular matrix (ECM) while inhibiting the inflammatory response and promote cutaneous wound healing (7-10). EGF contributes to wound healing by enhancing cellular proliferation and migration, promoting angiogenesis, regulating inflammation, and supporting the remodeling of the ECM (11-13).

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While MSCs and EGF have been studied in general wound healing, no prior study has systematically evaluated their direct effects in the burn stasis zone. By addressing this gap, our study provides critical insights into their potential for preserving tissue viability in burn injuries. We hypothesize that MSC and EGF treatments will significantly enhance tissue regeneration in the burn stasis zone by reducing inflammation, promoting epithelialization, and increasing angiogenesis compared to standard treatment. This study investigated the curative effects of adipose tissue-derived allogeneic MSCs and human recombinant EGF on the rat "burn stasis zone" by creating an experimental Comb burn model.

MATERIAL and METHODS

Ethical Approval and Animal Model

All animals used in this study were obtained from Sivas Cumhuriyet University Experimental Research Center, and all experimental procedures were approved by the Sivas Cumhuriyet University Ethics Committee (approval number: 65202830-050.04.04-351, date: 16.01.2020). All procedures complied with the Sivas Cumhuriyet University Experimental Animals Ethics Directive, which aligns with the Universal Declaration of Animal Rights, the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (European Treaty Series-no.123), the National Research Council of the USA, the United Nations Convention on International Trade in Endangered Species of wild fauna and flora (CITES), and the Bern Convention. This study also adheres to the animal research: Reporting of *in vivo* experiments guidelines (14). All procedures were performed under the supervision of a veterinarian.

Thirty-two female Wistar albino rats (200-250 g) were housed in a temperature-controlled environment (22-24 °C) with ad libitum access to food and water. The animals were randomly divided into four equal groups (n=8 per group). Euthanasia was performed on the 21st day using an overdose of pentothal sodium (200 mg/kg), and tissue samples were collected for analysis.

Burn Wound Model

The burn wounds were created based on an established comb burn model. The rats were anesthetized with an intraperitoneal injection of xylazine (10 mg/kg) and ketamine (40 mg/kg). After shaving the dorsal skin, the area was disinfected with povidone-iodine. A metal comb, heated in boiling water (100 °C) for three minutes, was applied perpendicularly to the dorsal skin for 30 seconds without exerting pressure to induce a second-degree burn. (Figure 1A-C). The depth of the burn injury was histopathologically confirmed (15).

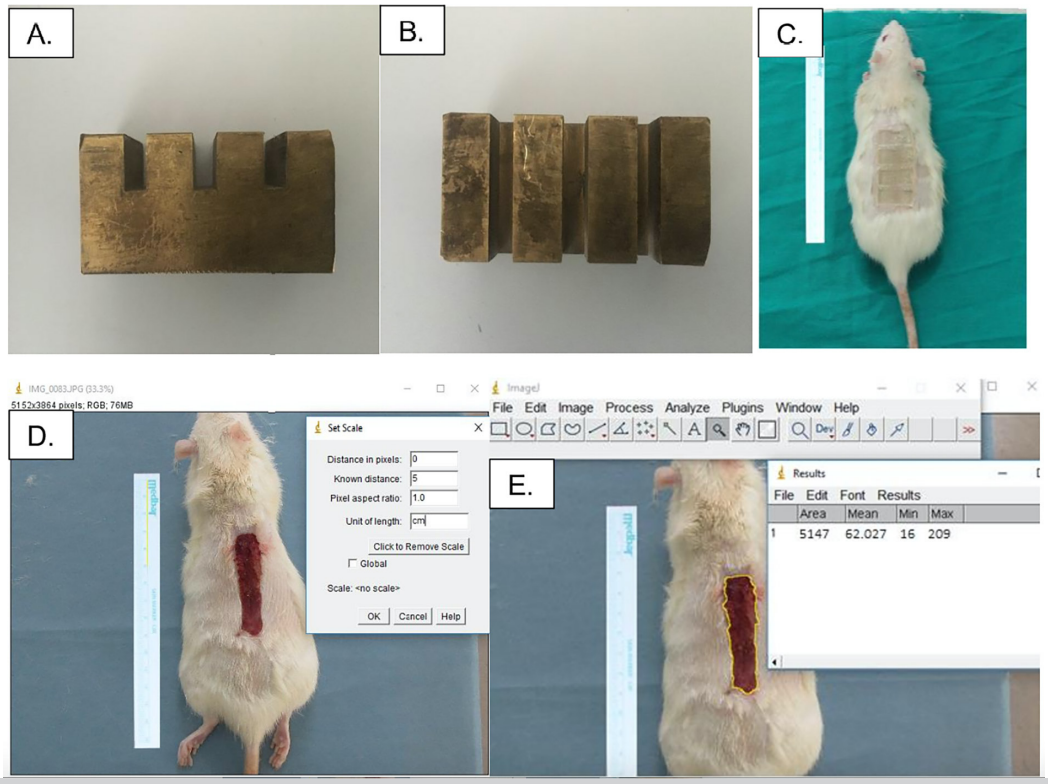

Figure 1. Creating a burn model with the comb and photo analysis of burnt areas. A, B. Brass plate prepared in accordance with the Comb burn model. C. The image created after the burn was made. D. Calibration was performed with the ImageJ program. E. The total burn surface area measurement on day 21 of a rat from the treatment groups was performed as an example using the ImageJ program.

Experimental Groups and Treatment Protocols

The animals were divided into four groups:

• **Control group (n=8):** No treatment was applied after burn injury.

• **SSD group (n=8):** SSD (Silverdin) was applied epidermally to the stasis zone once daily for 21 days.

• **MSC group (n=8):** Adipose-derived MSCs were injected subcutaneously into the stasis zone on days 1, 3, 7, and 14; and SSD was applied epidermally daily.

• **EGF group (n=8):** Reconstituted lyophilized recombinant EGF (75 µg) was injected intradermally into the stasis zone on days 1, 3, 7, and 14; and SSD was applied epidermally daily.

MSC Isolation and Culture

Adipose-derived MSCs were prepared at Kocaeli University Stem Cell and Gene Therapies Research Center following the protocol by Konno et al. (16).

• **Tissue source:** Adipose tissue was harvested from healthy Wistar rats via surgical excision under sterile conditions.

• **Isolation:** The tissue was digested with 0.1% collagenase type I for 45 minutes at 37 °C. The resulting cell suspension was filtered and centrifuged at 1.500 rpm for 10 minutes.

• **Culture conditions:** Cells were cultured in Dulbecco's modified eagle medium supplemented with 10% fetal bovine serum (FBS) and 1% penicillin/streptomycin at 37 °C with 5% CO_2.

• **Passage and expansion:** Cells were expanded until 80-90% confluence and passaged using trypsin. Passage numbers 2 to 3 of cells were used for the experiment.

• **Injection protocol:** Each rat received 100,000 MSCs (1×10^5 cells) diluted in 100 µL PBS, injected subcutaneously at four points 0.5 cm from the burn stasis zone on days 1, 3, 7, and 14.

EGF Preparation and Administration

A lyophilized recombinant EGF (75 µg) was reconstituted in 1 mL sterile saline. The solution was intradermally injected at four points within the stasis zone on days 1, 3, 7, and 14 using a 30 G insulin syringe. The total injected volume was 0.1 mL per injection site per rat.

Photoanalysis of Burn Areas

Photographs were taken on days 1 and 21 with a standardized distance of 50 cm and a guide ruler. Image analysis was performed using ImageJ software, and total burn area (cm^2) and non-healing area (coagulation necrosis) were calculated separately (Figure 1D, E).

Histopathological Evaluation

At the end of the study, rats were sacrificed using CO_2 inhalation euthanasia. The epidermis, dermis, adjacent healthy skin, and wound area were excised and fixed in 10% neutral buffered formalin for 48 hours. The tissues were processed with graded ethanol (70%, 80%, 96%, 100%) and embedded in paraffin. 5-µm-thick sections were obtained using a Leica RM2245 microtome. Hematoxylin-eosin staining was performed, and the samples were evaluated under a light microscope (Olympus BX51).

A semi-quantitative scoring system was used to assess epithelialization, inflammatory cell density, fibroblast cell density, collagen fibril density, and angiogenesis (Table 1).

Statistical Analysis

Statistical analyses were performed using GraphPad Prism. Two-Way analysis of variance (ANOVA) was used for repeated measures in the same group over time (burn area changes between days 1 and 21). One-Way ANOVA followed by Tukey's post hoc test was used for comparisons between groups. The Kruskal-Wallis test was applied for non-parametric data. A power analysis was conducted using G*Power software to determine the minimum sample size required for a power of 0.8 and α=0.05.

RESULTS

Histopathological Evaluation

Sections taken from the groups were stained with hematoxylin-eosin. The tissues of all groups were examined under the light microscope and evaluated by semi-quantitative scoring. Significant morphological damage was observed in the

Table 1. Semi-quantitative scoring of the tissue samples

Epithelialization	Inflamatuar cell density	Fibroblast cell density	Collogen fiber density	Angiogenesis
0: None	0: None	0: None	0: None	0: Very rare formation of new vessels
1: Epithelialization 30%	1: A few inflamatuar cells	1: A few fibroblast cells	1: A few collogen fibers	1: Rare formation of new vessels
2: Epithelialization 30-50%	2: Medium level inflamatuar cell density	2: Medium level fibroblast cell density	2: Medium level collogen fiber density	2: Medium level formation of new vessels
3: Epithelialization 50-85%	3: Lots of inflamatuar cell density	3: Lost of fibroblast cell density	3: Lots of collogen fiber density	3: Numereus formation of new vessels
4: Epithelialization 85-100%	4: High level inflamatuar cell density	4: High level fibroblast cell density	4: High level collogen fiber density	4: Intense formation of new vessels

epithelial tissue of the control group (Figure 2A-A'). When the treatment groups were examined, it was observed that the epithelialization improved morphologically in the MSC, EGF, and SSD groups compared to the control group (Figure 2B-B', C-C', D-D'). In the control group, it was observed that the number of inflammatory cells due to the burn wound was quite high (Figure 2A-A'). Inflammatory cell density was significantly reduced in the EGF and SSD groups compared to the control group (Figure 2B-B', D-D'). The group with the least number of inflammatory cells was identified as the MSC group (Figure 2C-C'). It was determined that fibroblast cell density was quite high in the control group and gradually decreased in the treatment groups, (MSC, EGF, and SSD in order of fibroblast cell density from low to high). Collagen fibrils were determined most intensely in the control group and decreased in the SSD, EGF, and MSC groups, respectively. Angiogenesis, from the lowest to the highest among the groups, respectively; EGF, MSC, SSD, and control group (Figure 2A-A', B-B', C-C', D-D').

Comparison of Histopathological Data According to Experimental Groups

In the analysis of histopathological data, it was determined that there was a statistically significant difference between the groups. At the end of the 21st day, the experimental groups were evaluated in terms of epithelialization, inflammatory cell density, fibroblast cell density, collagen fibrous density, and angiogenesis, which we determined as histopathological parameters. Inflammatory cell density was higher in the control group. However, inflammatory cell density was significantly decreased in the MSC and EGF group compared to the control group (**p<0.01, ****p<0.0001) (Figure 3A). Fibroblast cell density was higher in the control group. However, fibroblast cell density was significantly reduced in the MSC and EGF groups compared to the control group. However, fibroblast cell density detected in MSC and EGF groups was also found to be significantly lower than in the SSD group (**p<0.01, ****p<0.0001) (Figure 3B). Angiogenesis rates were compared between the groups. Angiogenesis was significantly increased in MSC and EGF groups compared to control and SSD groups (**p<0.01, ***p<0.001,****p<0.0001) (Figure 3C). Collagen fibril density was found to be significantly lower in the control group compared to the other groups. Collagen fibril density was significantly increased in the MSC and EGF groups compared to the control and SSD groups (**p<0.01, ****p<0.0001) (Figure 3D).

The group with the best epithelization recovery was the MSC group. Similarly, epithelialization was significantly higher in the EGF group than in the control group (*p<0.1, **p<0.01) (Figure 3E).

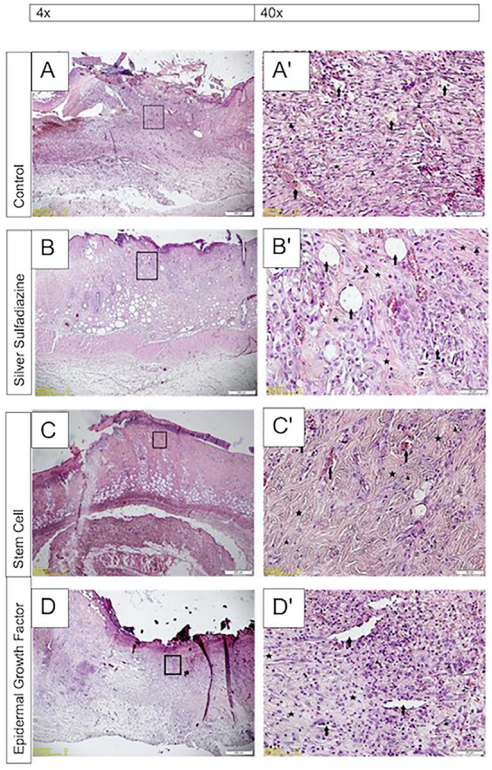

Figure 2. Morphological images for control and treatment groups. All specimens were investigated at 4x and 40x magnification with hematoxylin eosin under the light microscope. Sections from A-A': control group, B-B': Silver sulfadiazine group, C-C': Stem cell group, and D-D': Epidermal growth factor group. Blood vessels are indicated by the black arrow; collagen fibers are indicated by stars; fibroblasts are indicated by the arrowhead.

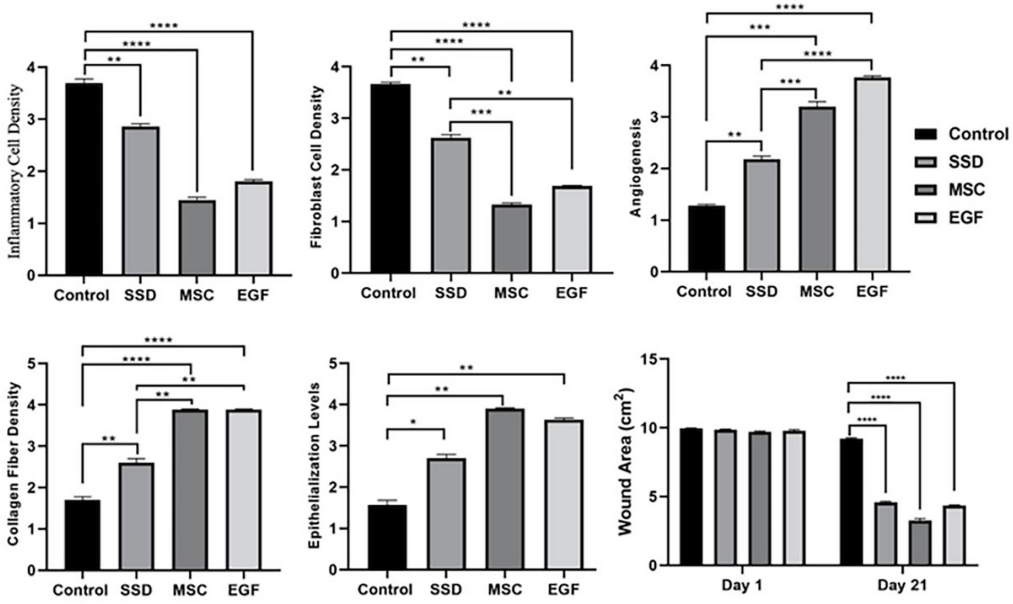

Figure 3. Comparison of epithelialization levels, inflammatory cell density levels, fibroblast cell density levels, collagen fiber density levels, angiogenesis levels, wound area, and non-healing area of experimental groups. (*p<0.1,**p<0.01,***p<0.001,****p<0.0001).

Using the photo analytical results, the one-day burn area and the 21-day burn area were calculated. In addition, at the end of the 21st day, the non-healing area in the burn area with irregular wound healing and necrosis was calculated. For calculations, photographs were taken from a distance of 50 cm using a guide ruler, and the ImageJ program was utilized. The groups were evaluated in terms of burn area on the first day. It was determined that the created burn area was not significantly different between the groups. Burn areas where healing continued on the 21st day were compared. It was observed that the area in the SSD, MSC, and EGF groups, was significantly reduced compared to the control group, (****p<0.0001) (Figure 3F).

On the 21st day, the groups were compared in terms of regular healing in the burn area, areas without regular epithelialization, and areas with necrosis. The non-healing area was found to be significantly smaller in the SSD, MSC, and EGF groups compared to the control group (**p<0.01, ***p<0.001, ****p<0.0001) (Figure 3F).

DISCUSSION

This study is one of the first to compare the effects of MSCs and EGF on the burn stasis zone. Our results demonstrate that MSCs are more effective in promoting epithelialization, while EGF is superior in preventing necrosis. These findings suggest that MSCs and EGF have distinct but complementary roles in burn wound healing.

Burn wound progression significantly impacts morbidity by increasing necrosis, infection risk, and the need for surgical interventions. Our results indicate that intradermal EGF administration significantly reduced necrotic areas, whereas MSCs contributed more to epithelialization. These findings support the potential therapeutic role of MSCs and EGF in burn treatment.

Although MSC therapy has been widely studied in burn healing, no prior research has specifically evaluated the effects of subcutaneous adipose-derived MSC injection on the burn stasis zone. Consistent with previous findings, our results suggest that MSCs promote vascularization, reduce oxidative stress, and enhance tissue repair (17-21). EGF, a well-known mitogenic factor, demonstrated a significant reduction in necrosis, likely through its pro-angiogenic effects (22). However, MSCs exhibited broader paracrine activity, potentially explaining their greater impact on epithelialization.

Study Limitations

This study was conducted in a rat model, and further clinical studies are required to determine its applicability in human patients. The small sample size, lack of standardized dosing, and absence of a combined MSC-EGF treatment group are limitations. Additionally, the long-term effects of MSC and EGF remain unknown.

CONCLUSION

Given these findings, MSCs and EGF may offer promising therapeutic options for severe burns. Their ability to prevent burn wound progression could reduce infection risk, limit the need for debridement and grafting, and improve functional and cosmetic outcomes in burn patients. Future studies should focus on optimizing treatment protocols, evaluating combination

therapies, and conducting clinical trials to establish their role in standard burn care.

Ethics

Ethics Committee Approval: All animals used in this study were obtained from Sivas Cumhuriyet University Experimental Research Center, and all experimental procedures were approved by the Sivas Cumhuriyet University Ethics Committee (approval number: 65202830-050.04.04-351, date: 16.01.2020).

Informed Consent: As this study involves animals, consent is not required.

Footnotes

Author Contributions

Conception - S.S.; Design - S.S.; Supervision - S.S.; Data Collection and/or Processing - Ö.K.; Analysis and/or Interpretation - S.S., Ö.K.; Literature Review - Ö.K.; Writer - Ö.K.; Critical Review - S.S., Ö.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Predictive score for conversion in laparoscopic cholecystectomy - a prospective study

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ABSTRACT

Objective: 2-15% of laparoscopic cholecystectomy gets converted to an open procedure due to various factors. The aim of this study was to identify pre-operative risk factors that could predict the conversion of laparoscopic cholecystectomy to open surgery. Pre-operative prediction would help in reducing the morbidity.

Material and Methods: Adult patients undergoing elective laparoscopic cholecystectomy at a tertiary institute were included in the study. The parameters analysed were age, gender, body mass index, total count, liver function test, gall bladder size and wall thickness, impacted stone in Hartmann's pouch and common bile duct (CBD) diameter on ultrasonography. Intra-operative findings and the total number of conversions to open surgery were documented. Statistical analysis was done using SPSS 16.0 Inc., IBM system. A univariate regression analysis was used to find the significant risk factors followed by multivariate linear regression.

Results: Twenty-one of the 222 (9.5%) patients who underwent laparoscopic cholecystectomy, were converted to open cholecystectomy. Six variables were found significant on univariate analysis: Age, sex, total count, gallbladder wall thickness and size and diameter of the CBD. On logistic regression analysis, gall bladder wall thickness and size were found to be significant, and were used in the scoring system, wherein 1 point was given to each variable. The predicted risk of conversion was 0.5%, 1.8% and 7.2% for a score of zero, one and two respectively.

Conclusion: The most significant factors predicting conversion of laparoscopic cholecystectomy to open surgery were gall bladder size and wall thickness. This prediction can be used to minimize the time to conversion and reduce the morbidity.

Keywords: Laparoscopic cholecystectomy, conversion, ultrasonography, gallbladder wall thickness, risk factors

INTRODUCTION

Cholelithiasis is an important disease in developed countries, affecting 10 to 15% of the adult population (1). In India, the prevalence of cholelithiasis varies from 3.1 to 6.12% with higher prevalence among women (2,3). The prevalence of gallstones increases with age and is a common cause of upper abdominal pain (4). Ultrasonography of the abdomen is the investigation of choice for diagnosis.

The gold standard treatment for cholelithiasis is laparoscopic cholecystectomy. On average, 2-15% of laparoscopic cholecystectomies have to be converted to an open surgery due to various reasons (5). Conversion is known to prolong the operative time and increase the complication rates, length of hospital stay and hospital charges (6).

The reasons for conversion could involve patient factors, surgeon factors, or rarely equipment failure. The need to convert should be considered an attempt to avoid complication and not as a failure. It would be useful if one could predict the need to convert pre-operatively, as these patients can be converted early, thus avoiding the morbidity associated with prolonged dissection and anesthesia.

This study was planned with the idea of formulating a pre-operative scoring system that could be used to predict the conversion of laparoscopic cholecystectomy to open. We aimed to examine the impact of the various pre-operative factors on the conversion rate and then we planned to devise a scoring system.

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MATERIAL and METHODS

Aim of the Study

1. To identify the clinical as well as ultrasonic features that predict the conversion of laparoscopic cholecystectomy to open cholecystectomy.

2. To formulate a predictive score for conversion using regression analysis method.

After obtaining approval from Sri Ramachandra University Institutional Ethics Committee, patients undergoing elective laparoscopic cholecystectomy were included in the study (approval number: CSP-MED/14/OCT/19/195, date: 14.10.2014). The patients were enrolled in the study after obtaining written informed consent.

Inclusion Criteria

All patients above 18 years of age with an ultrasound diagnosis of cholelithiasis who were electively planned to undergo laparoscopic cholecystectomy were included in the study.

Exclusion Criteria

Patients with a history of previous upper abdominal surgeries, obstructive jaundice, acute cholecystitis, and recent endoscopic retrograde cholangio-pancreatography were excluded from the study.

The clinical and ultrasound features of the patients were taken into consideration in predicting the conversion of laparoscopic to open cholecystectomy.

The clinical factors were age, body mass index, and liver function tests. The demographic data of the patients were taken into account.

Ultrasonography of the abdomen was done using GE-Logiq P5, Probe-Convex 3.5CS (2-5 MHz) 128 elements, 38 mmR. The gallbladder was scanned with right subcostal oblique and intercostal section views.

The imaging features that were studied were:

- Gallbladder wall thickness,
- Size of the gallbladder,
- Presence of impacted stone in Hartmann's pouch,
- Common bile duct diameter.

After routine investigations and assessment, all patients underwent standard laparoscopic cholecystectomy using four ports under general anesthesia. The critical view of safety was demonstrated in all cases. If the procedure was converted into an open cholecystectomy, then the reasons for conversion were noted. The post-operative course of the patient in the hospital was also documented, especially the duration of stay.

Statistical Analysis

All the data were entered in a Microsoft Excel sheet and analysed using statistical package for the social sciences 16.0, an international business machines statistical system. Descriptive statistics of quantitative data were presented as mean and standard deviation. A univariate regression analysis was used to find the significant risk factors. These significant factors were then analysed using a multivariate linear regression model.

We then developed a pre-operative predictive scoring system for conversion, based on independent factors derived from multivariate analysis, followed by logistic regression analysis.

RESULTS

Among the 222 patients who underwent elective laparoscopic cholecystectomy during the period 2014-2016, 21 patients were converted to open surgery. Therefore, 9.5% of the study population had conversion to open cholecystectomy.

On analysing the demographic details, most of the patients in our study were in the age group 51 to 60 years. The mean age of patients who underwent laparoscopic cholecystectomy was 48.2 years, whereas the mean age of patients converted to open cholecystectomy was 60.29 years. This was statistically significant at a p-value of 0.001.

43.2% of the study population was male. Among patients who underwent successful laparoscopic cholecystectomy, 39.8% were male and 60.2% were female. Among 21 patients who underwent conversion, 76.2% were male. This was statistically significant (p-value of 0.001).

When comparing body mass index (BMI) in laparoscopic and converted cases, the mean BMI was the same in both groups and was not statistically significant.

An elevation was observed in the total white blood count in patients who were converted, with a mean total count of 11,671.43, which was statistically significant (p-value of 0.014).

The most common reason for conversion was frozen Calot's triangle. The other causes were adhesions, mucocele of the gallbladder, hemorrhage and fibrosis of the gallbladder (Figure 1).

Analysis of the ultrasonographic findings in both group of patients yielded the following results: The mean gallbladder wall thickness in converted cases was 8.5 mm, which was statistically highly significant (p-value of 0.001).

The mean diameter of the common bile duct was 6.45 mm in the converted cases, and this was significant with a p-value of 0.001.

11.9% of patients who underwent laparoscopic cholecystectomy had a contracted gallbladder. On the contrary, 76.20% of patients

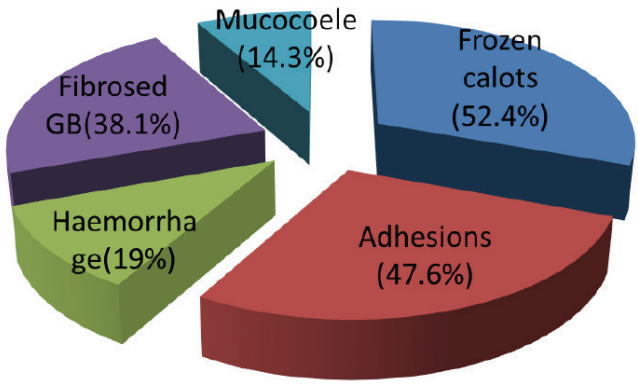

Figure 1. Reasons for conversion to open cholecystectomy.

who were converted to open cholecystectomy had contracted gallbladder, which was statistically significant (p-value=0.001).

13.4% of patients who underwent laparoscopic cholecystectomy had stone impaction in Hartmann's pouch. Impaction of stone in Hartmann's pouch was present in 23.8% of patients who underwent conversion to an open procedure, and this was not statistically significant.

The mean duration of hospital stay was 11.33 days for the converted cases and 3.44 days for the laparoscopic cases, which was statistically highly significant.

Univariate Analysis

The table below shows the six variables, which were found significant in univariate analysis, which were then subjected to logistic regression analysis for the scoring system (Table 1).

Logistic Regression Analysis

By logistic regression analysis, gallbladder wall thickness and size of the gallbladder was found to be significant factors associated with conversion to open cholecystectomy. These factors were therefore used to arrive at the pre-operative scoring system for conversion of laparoscopic cholecystectomy to open cholecystectomy. One point was given for each parameter. For example, if gallbladder thickness was more than 4 mm, then 1 point was given. If a contracted gallbladder was seen, then 1 point was given.

Statistical Analysis

Patients who scored zero have a risk of 0.5% for conversion to open cholecystectomy with a significant p-value of 0.001.

There is a 1.8% risk of conversion to an open procedure for patients who scored 1 with a p-value of 0.001, which is statistically significant.

Patients with a score of 2 have a likelihood of conversion to open by 7.2%, which is statistically highly significant with a p-value of 0.0001 (Table 2).

DISCUSSION

Prevalence rates of gallstone disease in Asian populations vary from 5-20% and among Black Americans it ranges from 5.3% of men to 13.9% of women (1). In India, the prevalence of gallstone disease varies from 3.1-6.12% with a higher prevalence among women.

Ultrasonography of the abdomen is the gold standard investigation for the diagnosis of cholelithiasis. Since the advent of minimally invasive surgery, laparoscopic cholecystectomy has become the gold standard treatment for symptomatic and asymptomatic cholelithiasis.

Laparoscopy is minimally invasive and is associated with less morbidity, shorter hospital stay, reduced postoperative pain and wound complications, decreased incidence of postoperative ileus, earlier oral intake, early ambulation, quicker return to normal activity, and improved cosmesis (7).

Despite these advantages, conversion to open surgery is necessary in some cases. Approximately 2-15% of attempted laparoscopic cholecystectomies have to be converted to open cholecystectomies due to different reasons (8,9). There are numerous factors responsible for conversion to an open procedure: Aberrant or altered anatomy, ductal or vascular anomalies, and/or acute or chronic inflammation (10). Excessive bleeding, accidental injuries of the biliary tract, inability to perform lateral traction of the gallbladder due to thickened gallbladder wall, presence of dense adhesions, frozen Calot's triangle, and mucocele of the gallbladder are the patient-related factors responsible for conversion (11,12).

Concise knowledge about these preoperative variables for conversion helps the operating team to plan for the surgery appropriately (13). This conversion should not be taken as

Table 1. Univariate analysis of patient factors

	Score	Df	Sig. (p-value <0.5)
Age	10.712	1	0.001
Sex	10.258	1	0.001
TC	5.991	1	0.014
Gallbladder wall thickness	103.613	1	0.000
Size of gallbladder	53.136	1	0.000
Diameter of CBD	47.281	1	0.000

CBD: Common bile duct

Table 2. Statistical analysis of the scoring system

Score	Conversion	Relative risk (95% CI)	p-value
0	0.5%	0.84 (0.11-0.612)	0.001
1	1.8%	0.215 (0.075-0.619)	0.001
2	7.2%	27.687 (11.182-68.555)	0.0001

CI: Confidence interval

a failure of surgery or inexperience of the surgeon; rather, it is a wise decision to avoid intraoperative injuries to the vital structures and associated morbidity and mortality. The ability to accurately identify an individual patient's risk for conversion based on preoperative information can result in accurate preoperative counselling, improved operating room scheduling, grading of risk for technical difficulty appropriate assignment of surgical assistance, and may improve patient care by reducing the time to conversion (14).

In our study, out of the 222 patients who underwent elective laparoscopic cholecystectomy, 21 patients (9.5%) were converted to open cholecystectomy.

On reviewing the world literature, the conversion rate of laparoscopic cholecystectomy to open varies from 2% to 15% (15). A study conducted by Al-Mulhim (16) stated that the conversion rate of lap cholecystectomy was 1.8%. In our study, we found the incidence of conversion to be 9.5%. This is in accordance with literature, which states that the average conversion rate of laparoscopic to open surgery is in the range of 1.8-27.7% (8).

In a study by Chauhan et al. (17), seven hundred and sixtyfour patients (539 females and 225 males) were taken-up for laparoscopic cholecystectomy; 33 (4.31%) of them were converted to open cholecystectomy. The most common reason for conversion was dense pericholecystic adhesion (51.5%), leading to either non-progression of surgery or inability to reach the Calot's triangle safely. Frozen Calot's triangle was the second most common reason (18.8%) for conversion.

Saber et al. (18) reported a conversion rate of 7.35%. The most common reasons for conversion were acutely inflamed gallbladder, frozen Calot's, aberrant anatomy, and bleeding. This was similar to our experience, where the most common reason for conversion was a frozen Calot's triangle.

Predictive Factors

Age

In our study, the mean age of patients who underwent laparoscopic cholecystectomy was 48.2 years, and the mean age of patients converted to open cholecystectomy was 60.29 years. This variable is statistically highly significant with p-value of 0.001. Philip Rothman et al. (8) found age to be a significant risk factor in the conversion of laparoscopic cholecystectomy to open, with an age range of 60 to 65 years. Another study by Reddy and Balamaddaiah (7) also showed age more than 60 as a significant compounding factor for conversion of laparoscopic cholecystectomy to open cholecystectomy.

In the study by Saber et al. (18) regarding preoperative prediction of difficult laparoscopic cholecystectomy with 204 patients, they found that age over 50 years, was an independent risk factor for the conversion of the procedure to the open technique.

Gender

In our study, 43.2% of the participants were male and 56.8% were female. 76% of the cases that were converted from laparoscopic to open surgery were male. Analysis of these data showed a p-value of 0.001, which was statistically significant.

Philip Rothman et al. (8), in their meta-analysis, found that out of 31 studies, male gender was a significant risk factor in 21 studies. The study by Yol et al. (19) found that in patients with symptomatic gallbladder stones, inflammation and fibrosis were more severe in men than in women. These findings are likely to explain the higher rates of conversion in men. O'Leary et al. (20), Agrawal et al. (9), and other studies conducted worldwide showed male sex as a significantly associated factor for conversion of laparoscopic cholecystectomy to open, which is similar to our study.

Size and Wall Thickness of the Gallbladder

Ultrasonography of the abdomen is the preoperative investigation of choice for the diagnosis of cholelithiasis (21,22). In our study population, 76.2% of the converted cases had a contracted gallbladder, which was statistically significant, and the mean gallbladder wall thickness in converted cases was 8.5 mm, which was statistically significant.

This is in accordance with the meta-analysis by Philip Rothman et al. (8), who found a gallbladder wall thickness of more than 4 mm and contracted gallbladder that is less than 2 cm as a contributory factor in the conversion of laparoscopic cholecystectomy to open.

The theory postulated for conversion in these patients is that the thickened and contracted gallbladder makes it difficult to hold the gallbladder neck to allow adequate retraction, which is very essential to perform safe dissection in the Calot's triangle. It also reduces the extent of the anatomical definition leading to more injuries of the anatomical structures and uncontrollable bleeding thereby acting as a risk for conversion to open surgery to manage the complication. Studies done by Saber et al. (18), Gupta et al. (11), Agrawal et al. (9), Nidoni et al. (10), Chandio et al. (23) have also identified thickened gallbladder wall, and contracted gallbladder as significant factors responsible for the conversion.

Scoring System

There are several pre-operative risk scoring systems formulated, to calculate the risk of conversion from laparoscopic to open cholecystectomy. On analysing the various factors that are predictive of conversion to an open cholecystectomy, we have formulated a scoring system including the two significant predictors, namely, gallbladder wall thickness greater than 4 mm, and contracted gallbladder.

In comparison to other scoring systems, which include factors such as previous hospital admission, palpable gallbladder, impacted gall-stone, pericholecystic fluid, previous surgery, male sex, gallbladder thickness, obesity, contracted gallbladder, and the presence of an abdominal scar, our scoring system proves to be easier, as the only investigation needed for the scoring is an ultrasound (24,25). As other biochemical and clinical parameters were insignificant, it is therefore not necessary to analyse these to determine the conversion rate.

A similar scoring system to ours predicts the likelihood of conversion using a scale of 0 to 3 points, with 1 point given for each of the following: Male gender, gallbladder wall thickness more than 4 mm, and the presence of a contracted gallbladder on ultrasound. A score is defined as significant if it has two or more points (significant p-value), but a score of less than 2 showed no statistical significance in relation to the percentage of conversion (20). However, in our study, there were only two ultrasonic variables that were significant and a score of 1 had a 1.8% chance of conversion (p-value of 0.001) and a score of 2 had a 7.2% chance of conversion (p-value of 0.001). If both these ultrasonic features were absent, a score of 0 was given, which had a 0.5% chance of conversion (p-value of 0.0001), meaning that these patients still had a small chance of conversion.

The variables in our scoring system are readily available, as ultrasound is the primary modality of investigation in the diagnosis of gallbladder disease, thus eliminating the need for additional imaging . This predictive score has to be validated in a future study.

Study Limitations

One limitation of our study was that not all cases were operated on by the same surgeon. Cases were taken from four surgical units which had surgeons of varying experience in laparoscopic surgery. The other limitation was that only elective cases were included. These limitations can be overcome by including patients undergoing both elective and emergency laparoscopic cholecystectomy, performed by a single surgeon.

CONCLUSION

Conversion to an open cholecystectomy shows a strong association with gallbladder characteristics on ultrasound, which are available preoperatively. The need to convert should be considered as an attempt to avoid complication and not as a failure. Our scoring system is simple and will help the surgeon to be better prepared for technical difficulties that are expected to be encountered on the table. As this scoring system is both easy to follow and inexpensive, it can be used as pre-operative tool to predict accurately, the need for conversion during laparoscopic cholecystectomy.

Ethics

Ethics Committee Approval: After obtaining approval from Sri Ramachandra University Institutional Ethics Committee, patients undergoing elective laparoscopic cholecystectomy were included in the study (approval number: CSP-MED/14/OCT/19/195, date: 14.10.2014).

Informed Consent: The patients were enrolled in the study after obtaining written informed consent.

Footnotes

Author Contributions

Concept - R.R., S.T.V.; Supervision - R.R.; Fundings - J.P.S., R.R.; Materials - R.R.; Design - R.R.; Data Collection or Processing - S.T.V., J.P.S.; Analysis or Interpretation - S.T.V., R.R.; Literature Search - R.R., S.T.V., J.P.S.; Critical Review - R.R., S.T.V., J.P.S.; Writing - R.R., S.T.V., J.P.S.

Conflict of Interest: No conflict of interest was declared by the authors.

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Comparison of enhanced view-totally extraperitoneal technique and totally extraperitoneal technique in S1 scrotal hernia repair

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ABSTRACT

Objective: The treatment of scrotal hernias may vary according to the surgeon's experience. Although open anterior approaches are mostly preferred, specialized hernia surgeons prefer laparoscopic approaches. The study evaluated the safety and efficacy of the laparoscopic enhanced view-totally extraperitoneal (eTEP) technique and the laparoscopic totally extraperitoneal (TEP) technique in treating scrotal hernias.

Material and Methods: The retrospective cohort study compared patients with unilateral scrotal hernia who underwent eTEP or TEP from November 2022 to October 2023. The two groups were compared in demographic characteristics and operative and postoperative data. The main result of this study was the recurrence rate.

Results: A study analyzed 54 patients: 30 underwent the eTEP technique, and 24 underwent the TEP technique. No significant difference was observed between the groups regarding recurrence rates, incidence of chronic pain, time of the surgical procedure, length of stay, time taken to resume daily activities, pneumoperitoneum occurrence, and complications, particularly hematoma and seroma formation. Patients were followed up for an average of 19 months (±5.2).

Conclusion: The comparison of the eTEP technique to traditional TEP for scrotal hernia repair has not demonstrated any conclusive evidence of the superiority of eTEP. The outcomes associated with the eTEP technique were found to be comparable to those of TEP, with an average follow-up period of 19 months. Similar to TEP, the eTEP technique demonstrates both safety and feasibility in the management of scrotal hernias. Furthermore, it is necessary for prospective randomized studies to compare these two techniques directly, specifically in the realm of scrotal hernia repair.

Keywords: Laparoscopic scrotal hernia repair, scrotal hernia, enhanced view-totally extraperitoneal

INTRODUCTION

A scrotal hernia is defined as an inguinal hernia that has migrated into the scrotum. Köckerling et al. (1) found a 2.7% rate of scrotal hernia in 98,321 inguinal hernia patients. Whether the scrotal hernia is reduced or whether the hernia is giant can pose a challenge for the surgeon (2). Although open techniques are mostly preferred in scrotal hernia repairs, laparoscopic techniques can also be used (3).

Köckerling et al. (1) reported higher rates of postoperative complications after scrotal hernia repair, complication-related reoperations, and overall complications such as bleeding/seroma formation, ileus, wound site infections, and bowel injury (1). The management of scrotal hernias is recommended to be managed by teams, including specialized abdominal wall hernia surgeons, due to the high complications and complexity of scrotal hernias (3).

Total extraperitoneal (TEP) and transabdominal preperitoneal (TAPP) are the most commonly performed laparoscopic techniques for scrotal hernia repair. If laparoscopic repair of the scrotal hernia is to be performed, Bansal et al. (4) recommended TEP if the hernia can be reduced; otherwise, they recommended TAPP. The primary advantage of TEP repair is the reduced risk of intraperitoneal organ injury and the formation of intra-abdominal adhesions. Additionally, unlike TAPP repair, TEP does not necessitate the use of a peritoneal flap for closure (5,6). Laparoscopic scrotal hernia repairs can also be performed with the enhanced view-totally extraperitoneal (eTEP) method described by Daes (7). With the eTEP technique, the extraperitoneal space appears

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larger, the working ports are more ergonomic, and accidental pneumoperitoneum can be tolerated more easily. Daes (8) has indicated that the eTEP technique offers significant advantages in the repair of large hernias and scrotal hernias, highlighting its potential effectiveness in this surgical procedure. However, there is no literature study comparing the eTEP technique with other laparoscopic techniques in scrotal hernias. Based on this point, we compared the eTEP technique with the TEP technique in scrotal hernias. This is the first study comparing eTEP and TEP techniques for scrotal hernia repairs.

MATERIAL and METHODS

A retrospective cohort study was conducted at a single-center. A flow diagram is shown in Figure 1. The study included patients with unilateral scrotal hernia after anterior repair who underwent eTEP or TEP between November 2022 and October 2023. Data were collected retrospectively from medical records and entered into a database. Following data collection, a comparative analysis of the results of the two techniques was performed. Patients are divided into the eTEP group and the TEP group. We recorded and compared demographic characteristics such as age, gender, ASA scores, body mass index (BMI), and smoking habits across both groups. Operative and postoperative data were recorded and compared in both groups.

Patients with reducible unilateral scrotal hernia, and aged 18-65, were included. As the European Hernia Society (EHS) recommended, S1 hernias were included, and S2 and S3 hernias were excluded (3). Patients under 18, and over 65 years of age,

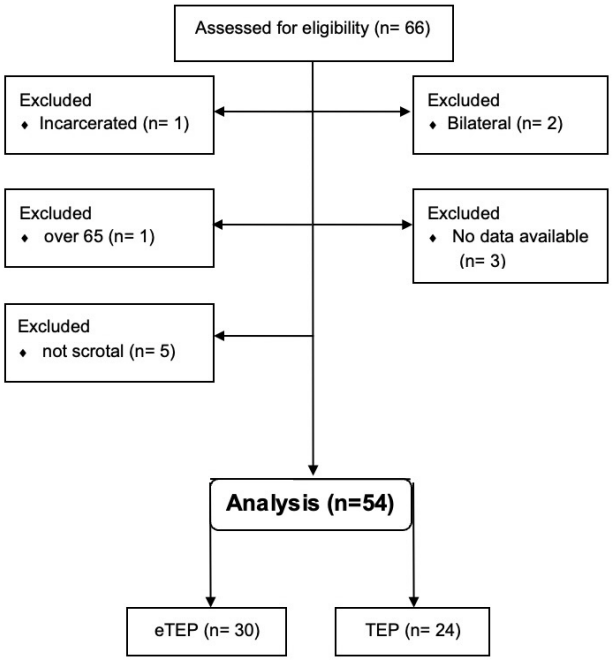

Figure 1. Flow diagram.
eTEP: Enhanced view-totally extraperitoneal, TEP: Totally extraperitoneal

individuals with complex inguinal hernias such as incarcerated, strangulated, or recurrent hernias, along with those having bilateral hernias, were excluded. Patients with obesity (BMI ≥30) and those who are pregnant were also excluded.

Hernia repair procedures were conducted by a single surgeon who specializes in laparoscopic inguinal hernia repair. This surgeon possesses extensive experience with the eTEP and TEP techniques, having successfully performed these methods in a minimum of 250 cases.

The Ethics Committee of the University of Health Sciences Türkiye, Van Training and Research Hospital approved the study (date: 29/11/2024, no: GOKAEK-2024-01-05), and written informed consent was obtained from the participants. All procedures conducted in studies involving human participants adhered to the ethical standards established by the institutional research committee, as well as the principles outlined in the 1964 Helsinki Declaration and its subsequent amendments or comparable ethical standards.

Surgical Methods

All patients underwent the surgical procedure under general anesthesia. Prior to the operation, each patient received an infusion of 1 gram of intravenous cefazolin as a prophylactic measure. In the postoperative period, to ensure effective pain management, a standardized intravenous dose of 1 gram of paracetamol, along with tramadol administered at a dosage of 1-2 mg/kg, was provided to each patient. In our study, urinary catheterization is not routinely performed in scrotal hernia repairs. Each patient underwent placement of a polypropylene mesh measuring 15x12x10 cm.

eTEP Procedure

Following the establishment of a sterile field and positioning of the patient in the supine orientation, an incision was made 4 cm lateral and 4 cm superior to the umbilicus on the contralateral side of the hernia. Upon completing the skin incision, the posterior rectus sheath was identified, and access to the retromuscular space was achieved using a 0-degree telescope in conjunction with an optical trocar. The 0-degree telescope was replaced with a 30-degree one. Insufflation was effectively established at a pressure of 12 mmHg, and telescopic blunt dissection was initiated with precision. A 5 mm secondary trocar was successfully inserted at the junction of the semilunar line and the arcuate line on the contralateral side of the hernia. The retrorectus space, particularly near the midline, was expertly dissected using an energy device. The posterior rectus sheath was thoroughly divided under clear visualization with laparoscopic scissors, starting from its medial attachment at the arcuate line and advancing to the umbilical level. Trocar placement and arcuate line division are shown in Figures 2, 3. In this way, the extraperitoneal area was further dissected with the energy device, and the field of view was widened. A third 5 mm

trocar from the umbilicus was inserted into the extraperitoneal area. After trocars' insertion, the steps to establish a critical view of the myopectineal orifice were achieved (9). Preperitoneal dissection was achieved medially until 3-4 cm inferior to the pubic bone, and laterally or into the Bogros cavity until the psoas muscle was seen. The hernia sac was dissected from the cord, and its elements, and testicular vessels. The hernia sac was first opened in the middle part, revealing no structure inside, and was then transected. The proximal hernia sac was tied. The distal sac was left untouched. The peritoneal loop (10) was divided, and the peritoneum was dissected above the iliac vessels, and retracted. Thus, the iliac vessels, the cord with its structures, and the psoas muscle were better visualized. The polypropylene mesh was placed to overlap direct, indirect, and femoral hernia sites by at least 3-4 cm and at least 2-3 cm below the pubis. The mesh was not fixed. While performing desufflation under direct visualization, care was taken to prevent mesh displacement.

TEP Procedure

After establishing a sterile field and positioning the patient supine, an incision was made in the ipsilateral side of the hernia adjacent to the umbilicus. Following the initial skin incision, the rectus sheath was identified and subsequently incised. The rectus muscle was retracted laterally using a retractor, allowing visualization of the posterior rectus sheath. A 10 mm trocar was then introduced. Insufflation was achieved with 12 mmHg pressure, and telescopic blunt dissection was begun from the midline to the pubic bone. In the midline, the second trocar was positioned three fingerbreadths below the umbilicus, while the third trocar was placed three fingerbreadths below the second trocar under direct visualization. Following the insertion of the trocars, the procedure continued in the same manner as the eTEP technique.

Outcomes

All demographic data (age, gender, BMI of the patients, smoking history, and ASA scores) were recorded. Hernia size classification, use of tackers, the duration of the operation (from the incision through the skin closure), pneumoperitoneum (PP), and method of hernia sac division were recorded. Postoperative complications such as hematoma and seroma, length of hospitalization, time taken to resume daily activities, chronic pain, and recurrence were recorded.

Hernia classification was performed according to EHS (2).

Chronic pain is characterized as moderate pain persisting no less than three months, thereby impacting daily activities.

Time taken to resume daily activities is defined as returning to work for the employed person who does not do heavy work, and doing all household chores without any outside help for the person at home.

The primary objective of this study was to assess the recurrence of hernias, while the secondary objectives encompassed both operative and postoperative findings.

Statistical Analysis

Before conducting further analyses, the Kolmogorov-Smirnov and Shapiro-Wilk tests were employed to evaluate the normality of the variables. If the data were normally distributed, parametric tests were used. An independent sample t-test was used to compare parametric values. Subsequently, the Mann-Whitney U test was utilized to compare the non-parametric measurements between groups. The relationships or differences between groups concerning categorical variables were analyzed using

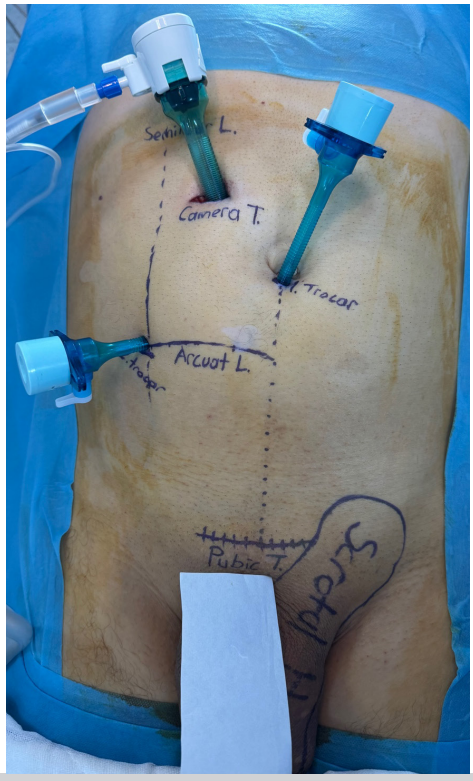

Figure 2. eTEP trocars.
eTEP: Enhanced view-totally extraperitoneal

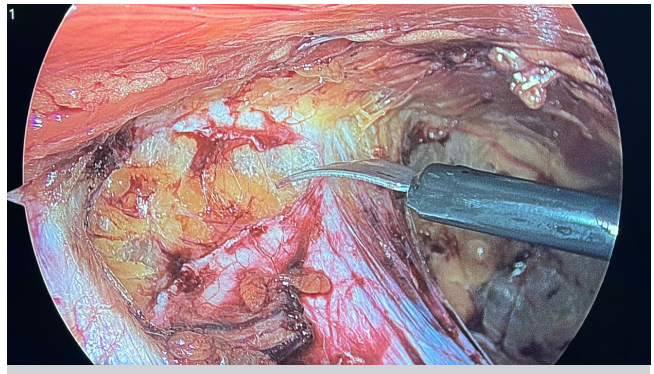

Figure 3. Arcuat division.

chi-square and Fisher's exact tests. Comparative results related to other demographic characteristics were presented as ratios of qualitative variables, while quantitative variables were reported as means accompanied by standard deviations. Statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS), version 22.0 (SPSS Inc., Chicago, IL, USA). In all analyses, a p-value of less than 0.05 was regarded as statistically significant.

RESULTS

A total of 54 patients were analyzed. A flow diagram is shown in Figure 1. Thirty patients were in the eTEP group, and twenty-four patients were in the TEP group. The median age was 31.5 (range 20-64) in the eTEP group and 37 (range 18-64) in the TEP group (p=0.95). The ASA scores were similar in both groups (p=0.92). The mean BMI scores were 26.3 (±3.5) in the eTEP group and 26.2 (±2.6) in the TEP group (p=0.47). Smoking was similar in both groups (p=0.54). Demographic characteristics are shown in Table 1. In no patient was the surgical technique converted to TAPP or open repair.

The mean operative time was 55.3 (±13.7) minutes for eTEP and 54 (±15.2) minutes for TEP (p=0.76). Hernia classification was similar between the groups (p=0.93). In the eTEP group, L1 was 5 (16.7%), L2 was 21 (70%), and L3 was 4 (13.3%). In the TEP group, L1 was 5 (20.8%), L2 was 21 (66.7%), and L3 was 3 (12.5%). The use of a tacker was absent in both groups. Pneumoperitoneum was 100% in both groups. In the eTEP group, the hernia sac was divided using LigaSure™ in 5 (16.7%) patients and a pretied suture loop in 25 (83.3%) patients. In the TEP group, the LigaSure™ was used to divide the hernia sac in 4 (16.7%) patients, and a pretied suture loop was utilized in 20 (83.3%) patients. Operative data are shown in Table 2.

All patients were followed up for a mean of 19 (±5.2) months (eTEP group 19.9±5 and TEP group 18.1±5.5, p=0.22). Postoperative complications were similar in both groups (p=0.96). Hematoma occurred in 4 cases (13.3%) in the eTEP group and 3 cases (12.5%) in the TEP group. Seroma was observed in 3 (10%) among the eTEP group and 3 (12.5%) among the TEP group. No patient reported complications such as inferior epigastric vessel injury, surgical emphysema, enterotomy/serosal injury, bladder injury, scrotal edema, cord edema, skin ecchymosis, urinary retention.

Chronic pain was seen in only 1 (3.3%) patient in the eTEP group. The length of stay was 1 day in both groups. The median time taken to resume daily activities was 7 (range 3-15) days in the eTEP group and 7 (range 3-14) days in the TEP group (p=0.96). No recurrence was noted in any patient in either group. Postoperative data are shown in Table 3.

Table 1. Demographic characteristics

	eTEP (n=30)	**TEP (n=24)**	**p**
Age median (range) *	31.5 (20-64)	37 (18-64)	0.95
Gender (male/female)	30/0	24/0	-
ASA n (%)			0.47
I	17 (56.7%)	10 (41.7%)	
II	12 (40%)	12 (50%)	
III	1 (3.3%)	2 (8.3%)	
BMI (kg/m^2) mean ± SD **	26 (±2.8)	24.6 (±3.5)	0.11
Smoke n (%)	8 (26.7%)	7 (29.2%)	0.54
Hernia classification n (%)			0.93
L1	5 (16.7%)	5 (20.8%)	
L2	21 (70%)	16 (66.7%)	
L3	4 (13.3%)	3 (12.5)	

ASA: American Society of Anaesthesiologists, BMI: Body mass index, *: Mann-Whitney U test was used, **: Independent sample t-test was used. SD: Standard deviation, eTEP: Enhanced view-totally extraperitoneal, TEP: Totally extraperitoneal

Table 2. Operative datas

	eTEP (n=30)	**TEP (n=24)**	**p**
Use of tacker n (%)			-
Yes	0	0	
No	30 (100%)	24 (100%)	
PP n (%)	30 (100%)	24 (100%)	-
Sac division n (%)			0.64
LigaSure™	5 (16.7%)	4 (16.7%)	
Pretied suture loop	25 (83.3%)	20 (83.3%)	
Operation time (min.) mean ± SD **	55.3 (±13.7)	54 (±15.2)	0.76

PP: Pneumoperitoneum, **: Independent sample t-test was used. SD: Standard deviation, eTEP: Enhanced view-totally extraperitoneal, TEP: Totally extraperitoneal, SD: Standard deviation

Table 3. Postoperative datas

	eTEP (n=30)	**TEP (n=24)**	**p**
Follow-up (month) mean ± SD **	19.9 (±5)	18.1 (±5.5)	0.22
Complication n (%)			0.96
None	23 (76.7%)	18 (75%)	
Hematoma	4 (13.3%)	3 (12.5%)	
Seroma	3 (10%)	3 (12.5%)	
Chronic pain n (%)	1 (3.3%)	0 (0%)	0.56
Length of stay (day)	1	1	-
Time taken to daily activities (day) median (range) *	7 (3-15)	7 (3-14)	0.96
Recurrence	0	0	-

*: Mann-Whitney U test was used, **: Independent sample t-test was used. SD: Standard deviation, eTEP: Enhanced view-totally extraperitoneal, TEP: Totally extraperitoneal

DISCUSSION

In our study, the demographic characteristics of the patients in both groups exhibited a similar distribution, indicating that the patient groups were homogeneous (Table 1). During a mean follow-up of 19 months, the eTEP technique showed results similar to the TEP technique for scrotal hernia repair.

Open repairs for scrotal hernias are recommended when the hernia is irreducible or large (11). The specialized hernia surgeon can safely perform laparoscopic techniques for scrotal hernias (3). The advantages of minimally invasive techniques, such as faster recovery and cost-effectiveness, are also observed in scrotal hernias (11). The selection of the laparoscopic technique is determined by the surgeon's level of expertise and the specific characteristics of the scrotal hernia. Bansal et al. (4) recommended the TEP technique if the scrotal hernia can be reduced, with a 25% conversion rate to TAPP (4). Köckerling et al. (1) reported that TAPP is the safest technique for irreducible scrotal hernias. Daes (7) described an enhanced totally extraperitoneal (eTEP) technique for the management of large scrotal hernias. This approach involves the division of the hernia sac and the fixation of the distal end laterally to the posterior inguinal region, aimed at minimizing the risk of seroma formation (7).

There are very few studies comparing TEP and TAPP in scrotal hernias (1,4). There are also no studies in the literature comparing the eTEP technique with other laparoscopic techniques in scrotal hernias. Our study is the first. Laparoscopic scrotal hernia repair is mostly concerned with reducing seroma formation (7,12-14). Various techniques have been described in laparoscopic approaches to reducing seroma formation. Daes (7) described an eTEP technique in 6 patients with scrotal hernias, ligating the proximal end and pulling up the edges of the distal sac, which are then fixated lateral to the posterior inguinal canal 5-7 cm superior to the ilio-pubic tract to avoid seroma formation. This was assisted by lowering insufflation pressure, pulling the testis down, and external pressure to the ipsilateral scrotum, with care taken to avoid cord structures (7). A recent review revealed that transection of the indirect hernia sac is associated with a higher incidence of seroma but does not increase the occurrence of other complications (15). In our study, no intraoperative auxiliary techniques were used to reduce seroma.

The eTEP technique has many advantages over TEP. The eTEP technique has been found to be particularly advantageous in the management of scrotal hernias, bilateral hernias, incarcerated hernias, patients with obesity, and those with a short distance between the umbilicus and the pubic tubercle. In addition, the eTEP technique tolerates pneumoperitoneum very well, as it creates more extraperitoneal space, compared to TEP (8), which contributes to better tolerance. Considering the more ergonomic port placement and better-tolerated pneumoperitoneum, however, the operation time was similar in both groups. The fact that demographic characteristics were similar, the classification of the scrotal hernia was the same (Table 1), the scrotal hernia was reducible, and the scrotal hernia was not giant (not S2, S3 in EHS classification) was associated with similar operation times in both groups.

Mesh fixation is still a controversial issue in inguinal hernias. Research indicates that the avoidance of mesh fixation may lead to a reduction in postoperative pain as well as a decrease in operative time in laparoscopic inguinal hernia repair (16). There are no studies evaluating mesh fixation, especially in scrotal hernias. According to the HerniaSurge Group International Guideline, mesh fixation is recommended only in large direct hernias in TAPP or TEP repair to reduce the possibility of recurrence (11). Considering that mesh fixation may increase chronic pain (17), in our study, no patient underwent mesh fixation because all patients had lateral hernias, even though some had large defects (L3).

In our study, pneumoperitoneum was present in all patients in both groups (Table 2). The hernia sac was divided after it was partially opened, and its contents were clearly seen. The hernia sac division was usually performed in its narrowest part. The hernia sac division performed in our study is similar to the Primary Abandon-of-the-Sac technique (12) applied in the extraperitoneal space. In both groups, the hernia sac division was performed using a pretied suture loop (18) and LigaSure™. LigaSure™ was shown to be effective in an experimental rat study (19) and is useful for peritoneal defect closure. Both methods were applicable and effective in a short time.

Regardless of whether the surgical approach is open or laparoscopic, the incidence of complications is elevated in cases involving scrotal hernias compared to non-scrotal hernias (1,3). Transection of the hernia sac may increase seroma formation in the scrotal hernia (20). A randomized study found that sac transection or reduction did not increase seroma formation (21). Leibl et al. (22) reported that approximately 10% of seromas form in aspirates from scrotal hernias. Nikolian et al. (23) found hematoma/seroma formation in 23.9% of the participants in their prospective study and reported spontaneous healing without aspiration. In our study, hematoma/seroma formation was similar between groups, and the rate was similar to that of the studies in the literature. After 3 months of follow-up, hematoma/seroma healed without intervention in both groups.

The risk of complications was higher in scrotal hernias than in non-scrotal hernias, but chronic pain did not fall into this category. Chronic pain at 1 year was less in patients with scrotal hernias compared to those with other types of hernias (3). Considering the advantage of laparoscopy in reducing chronic pain and enabling rapid recovery, laparoscopic repair

of scrotal hernias, chronic pain is expected to be very low. Our study supports this finding. Chronic pain occurred in one patient in our study, and this finding is similar to observations to observations in scrotal hernia studies in the literature (13,21). The range of lengths of stay for scrotal hernias is 0.93 to 5.5 days (20). Significant complications, including injuries to organs and vascular structures, have a direct impact on the duration of hospitalization. Since our patient population included reduced scrotal hernias and S1 hernias (not S2 and S3 in EHS classification) with very low complication rates, the length of stay was one day in both case groups.

Laparoscopic repairs are known to result in an earlier return to work than open repairs (11). However, no literature study compares laparoscopic repairs in scrotal hernias, in terms of return to work. It is believed that patients with uncomplicated scrotal hernias return to work earlier than those with complicated hernias. In our study, since patients had uncomplicated scrotal hernias (S1, reducible and not recurrent), the time taken to resume daily activities was similar in both groups.

Although the recurrence rate of scrotal hernias is higher than non-scrotal hernias, no recurrence occurred in our study subsequent to an average follow-up duration of 19 months. The most important reason for the absence of recurrence was that all steps of critical view of the myopectineal orifice, which must be performed in laparoscopic hernia repair, were completed. The mesh size was adequate and overlapped 3-4 cm above all potential hernia areas. A specialized hernia surgeon performed all cases. It was observed that the peritoneum covered the mesh during CO_2 desufflation to prevent mesh folding or displacement.

Study Limitations

Our study's major limitation is that it is retrospective. This field is open to surgeons interested in laparoscopic scrotal hernia repair, and prospective studies will significantly contribute to the literature. Another limitation is that 19 months is a short follow-up period for hernia recurrence. However, scrotal hernia repairs with short follow-up periods have also been observed in the literature. The follow-up period was sufficient to evaluate the feasibility of eTEP and TEP techniques in scrotal hernias.

CONCLUSION

The eTEP technique showed results similar to those of the TEP technique in scrotal hernias. Both eTEP and TEP techniques are safe and feasible. In addition, prospective randomized studies are clearly needed for laparoscopic repairs of scrotal hernias.

Ethics

Ethics Committee Approval: The Ethics Committee of the University of Health Sciences Türkiye, Van Training and Research Hospital approved the study (date: 29/11/2024, no: GOKAEK-2024-01-05).

Informed Consent: Informed consent was obtained from all participants who were included in this study.

Footnotes

Author Contributions

Concept - A.H.Y.; Fundings - A.H.Y.; Materials - M.E.U.; Supervision- A.H.Y.; Design - A.H.Y.; Data Collection or Processing - M.E.U.; Analysis or Interpretation - A.H.Y.; Literature Search - M.E.U.; Critical Review- A.H.Y.; Writing - A.H.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Could the HALP score indicate poor prognosis in colorectal cancer patients?

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ABSTRACT

Objective: Colorectal cancer (CRC) is a major health problem worldwide. According to estimates for the year 2030, cancer will be the number one cause of death for both genders. CRC is the third most common type of cancer and the second most common cause of cancer-related deaths. Various parameters are needed to provide information about the course and prognosis of the disease.

Material and Methods: The study included 103 patients diagnosed with CRC between 2017 and 2023. The patients' HALP scores were retrospectively analyzed together with clinical data. The relationship between survival times, disease stage, and treatment response was examined.

Results: The obtained data showed that low HALP scores were associated with worse overall survival. Although the HALP score cut-off value was found to be different in various studies conducted on benign or malignant diseases, a low HALP score indicates a poor prognosis. In our study, a HALP score below 23 was found to be associated with low overall survival.

Conclusion: This study suggests that a low HALP score is associated with poor prognosis and could serve as a valuable prognostic marker in the clinical management of CRC patients. However, certain limitations must be considered. While albumin is a marker of systemic inflammation and nutritional status, its specificity is limited in acute and chronic inflammatory conditions, which may impact the prognostic value of the HALP score. Further investigation into the biological mechanisms underlying this relationship and the potential of the HALP score in predicting treatment response would enhance its clinical applicability.

Keywords: Colorectal cancer, HALP score, prognosis, survival

INTRODUCTION

Cancer is a significant health problem worldwide. Estimates for 2030 predict that cancer will be the number one cause of death for both genders (1). Colorectal cancer (CRC) is the third most common type of cancer and the second most common cause of cancer-related deaths (2). The American Cancer Society predicts that approximately 153,020 people will be newly diagnosed with CRC in 2023 (2).

The most commonly used method for staging colon CRC is tumour, node, metastasis (TNM) staging. TNM staging is a scoring system that evaluates the invasion of the tumor into the colon layers, the number of metastases to the lymph nodes of the relevant colon segment, and whether there is metastasis to distant organs (3,4). The stage of the disease is still the most important prognostic factor for CRC. Nevertheless, recent research has focused on different prognostic factors for CRC.

It is well known that systemic inflammation and nutrition play a role in the proliferation of cancer cells, local invasion, and metastasis to lymph nodes or distant organs (5). Deficiencies in immunity and nutrition have been associated with cancer cells exhibiting aggressive behavior. In previous studies, blood cells such as platelets, monocytes, neutrophils, and lymphocytes have been associated with tumor proliferation, invasion, and distant organ metastasis, and have been found to be significant (6). Attempts have been made to obtain information about the course

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of cancer by comparing different inflammatory markers. Several inflammatory markers, such as neutrophil to lymphocyte ratio, platelet-lymphocyte ratio and systemic inflammation response index, have been defined and used to predict prognosis in various types of cancers (6-9). The hemoglobin, albumin, lymphocyte, platelet score (HALP) index, which was first described by Chen et al. (10), includes a combination of hemoglobin, albumin, lymphocyte, and platelet values. This index indicates nutritional status and systemic inflammation, and provides information about the patient's prognosis. HALP score has been used to determine the prognosis of patients in intensive care units with various types of cancer, such as prostate, breast, and lung cancer (11-16).

In this study, we investigated whether the HALP index can be used as a prognostic marker for CRC.

MATERIAL and METHODS

A retrospective analysis was conducted on data from patients who underwent CRC surgery between 2017 and 2023 at University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital General Surgery Clinic. Patients who were admitted to our clinic, but whose HALP score could not be calculated due to lack of data and whose disease stage could not be determined, were excluded from the study. Patients' demographic data, radiological images, pathology records, operative notes, and laboratory values were recorded.

Clinical and pathological variables of all included patients were collected from electronic medical records. These included age, gender, comorbid diseases, tumor characteristics (location, degree of differentiation, presence of lymphovascular/perineural invasion, and staging features), presence of mismatch repair mutation, type of surgery performed, total number of lymph nodes removed, number of positive nodes, and information on complications. In addition, preoperative serum albumin, hemoglobin, lymphocyte, and platelet values were collected for all patients to calculate the HALP index. All patients were staged according to the 8th edition American Joint Committee on Cancer TNM staging system (17).

HALP index was calculated with the following formula: Hemoglobin level (g/L) × albumin level (g/L) × lymphocyte count (/L) / platelet count (/L) (10). To investigate the prognostic impact of the HALP score, we determined a cut-off value, calculated by the receiver operating characteristics (ROC) analysis, obtained from the study group. The HALP score cut-off value was calculated as 23. The threshold based on the Youden index (sensitivity + specificity - 1) was chosen to estimate sensitivity and specificity. The cohort of the study was analyzed in two groups according to the determined HALP cut-off.

The primary outcome of this study was to evaluate whether HALP has a prognostic value for CRC.

The secondary outcomes involved evaluating whether HALP predicts early hospital mortality in patients undergoing CRC surgery.

This study was approved by the Ethics Committee of the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital (no: 2023-200, date: 27.11.2023), and it was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was obtained from all patients.

Statistical Analysis

SPSS version 24.0 (SPSS Inc. IBM, Chicago, U.S.) was used for statistical analysis. The continuous data were presented as mean ± standard deviation, median, and interquartile range, and categorical data were presented as numbers and frequencies. The proportion or frequency was compared between the two groups using Fisher's exact test or the χ^2 test, and differences in continuous variables were evaluated using the Student's t-test and the Mann-Whitney U test for non-parametric values. Survival curves were compared using the Kaplan-Meier method and the log-rank test. Cox regression analysis was used for univariate and multivariate overall survival (OS) analysis.

RESULTS

In our center, 245 patients underwent CRC surgery between January 2017 December 2023. One hundred forty-two patients were excluded from the study because of loss of follow-up, and lack of data. A total of 103 patients were included in the study.

According to ROC analysis, the HALP score cut-off value was calculated as 23. Group 1: HALP score <23. Group 2: HALP score >23 (Figure 1).

The HALP <23 group yielded 60 patients, while the HALP >23 group included 42 patients. Patient demographics such as age, gender, and comorbid disease were similar between the groups. However, the mean hemoglobin level, the mean albumin level, the mean lymphocyte count, and the median platelet counts were significantly different in both groups, as expected (Table 1).

Postoperative outcomes are summarized in Table 2. Only one perioperative mortality case was observed in each group, and the result was not statistically significant. Tumor localization and pathological outcomes were also similar between the two groups.

Univariate and multivariate Cox regression analyses were performed to evaluate prognostic factors for CRC. In the univariate analysis, age, comorbid disease, stage M, and the HALP score were found to be significant in CRC prognosis. However, in

the multivariate analysis, only stage M and the HALP score were poor independent prognostic factors for CRC patients' prognosis (Table 3).

The five-year OS was 68.4% in the HALP <23 group, while the OS was 83.3% in the HALP >23 group. The Kaplan-Meier analysis showed that the HALP <23 group has worse survival outcomes than the HALP >23 group, with a significant result (log-rank: 0.012). Survival curves of the two groups are shown in Figure 2.

DISCUSSION

The HALP index is a criterion that can be used to determine prognosis and survival in cancer patients. It is easy, cheap to calculate. It is calculated using only four parameters, with all parameters examined for all patients preoperatively. Systemic inflammation plays a crucial role in tumorigenesis. Growing evidence indicates the critical role of lymphocytes, especially in tumor suppression. Moreover, hemoglobin, lymphocytes, and platelet values reflect the synthesis ability of the hematopoietic system. However, its reliability as a prognostic marker in CRC should be carefully interpreted, considering certain limitations. Albumin is a negative acute phase reactant. It varies in inflammatory conditions in the body and in the presence of cancer. Low albumin values are observed in long-term malnutrition. Although albumin is commonly used as a marker of nutritional status and systemic inflammation, its specificity is limited in both acute and chronic inflammatory conditions. This variability may weaken the prognostic significance of the HALP score in CRC patients, where chronic inflammation is a hallmark of disease progression (18). Therefore, the HALP score can be a guide prognosis and survival, not only in malignant but also in benign diseases. Studies on the HALP score are available not only in malignant diseases but also in benign diseases. In a study conducted by Tian et al. (19), they associated low HALP scores with acute ischemic stroke and recurrence within 90 days. In a meta-analysis published by Li et al. (20), high platelet and low lymphocyte values were associated with poor prognosis and OS in cancer patients with an impaired platelet-lymphocyte ratio. A study conducted by Gasparyan et al. (21) found that a high platelet-lymphocyte ratio and a high platelet count in patients are highly predictive of rheumatic disease.

There are limited numbers of studies that investigate the HALP score in relation to CRC prognosis. Different cut-off values for the HALP score have been found in various studies. In the study conducted by Calderillo Ruiz et al. (14) on hispanic-based colon cancer patients, the cut-off value for the HALP score was calculated as 15. Guo et al. (22) reported that HALP score is an important prognostic factor in their study on patients with metastatic prostate cancer. And in this study, the HALP

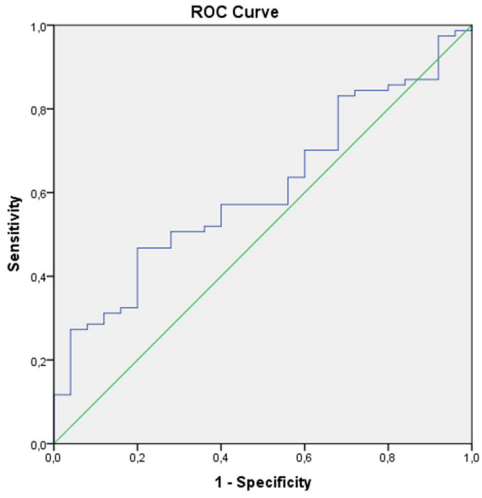

Figure 1. ROC curve analysis for the HALP score.

Area	Std. error	Asymptotic sig. Lower bound	Asymptotic 95% confidence interval	
			Upper bound	
0.607	0.060	0.108	0.490	0.725

Table 1. Basic characteristics between lower and higher HALP groups

n=103	HALP <23 (n=60)	HALP >23 (n=42)	p
Age (mean ± SD)	65.1 (±12.8)	63.7 (±13.3)	0.588
Gender (%) Male Female	 33 (55%) 27 (45%)	 30 (71%) 12 (29%)	0.091
Comorbid diseases Presence Absence	 42 (70%) 18 (30%)	 27 (64%) 15 (36%)	0.544
Pre-operative hemoglobin (g/dL) (mean ± SD)	10.6 (±1.9)	12.6 (±1.9)	<0.001
Pre-operative albumin (g/dL) (mean ± SD)	3.5 (±0.5)	4.1 (±0.6)	<0.001
Pre-operative lymphocyte (mL) (mean ± SD)	1.3 (±0.7)	2 (±0.7)	<0.001
Pre-operative platletel (cells*10^9L) [median (IQR)]	349 (IQR: 165)	256 (IQR: 124)	<0.001

IQR: Interquartile range, HALP: Hemoglobin, albumin, lymphocyte, platelet score, SD: Standard deviation

score cut-off value was determined as 32.4. In the study by Güç et al. (23) on patients with non-small cell lung cancer, the HALP score cut-off value was found to be 23.24. In our study, the cut-off value for the HALP score was found to be 23. In the study conducted by Ekinci et al. (12) on patients with renal cell carcinoma, the HALP score cut-off value was determined to be 27.7, and an HALP score below 27.7 was associated with poor prognosis. In a study by Zhai et al. (7), the HALP score cut-off value in patients with non-small cell lung cancer was considered 48, and a low HALP score was found to be associated with lower OS. Zhang et al. (24) examined various biomarkers and scores in patients with intrahepatic cholangiocarcinoma. In their study, the HALP score cut-off value was 43.6 and the HALP score was found to be associated with intrahepatic recurrence and lymph node metastasis (24). Farag et al. (11) reviewed studies including various types of cancer, such as gastric, gastrointestinal, lung, esophageal, pharyngeal, bladder/urothelial, prostate, and gynecological cancers, and mentioned HALP scores. In the analyses, the HALP score cut-off value was between 20-49. Duran et al. (25) in their study on breast cancer patients, reported the HALP score to be 29.01. Although the HALP score alone was not sufficient to predict axillary lymph node positivity, it was found to be associated with advanced or aggressive tumors (25).

Albumin is a negative acute phase reactant. Many different factors affect serum albumin levels, and it has been shown to lack sensitivity and specificity as an indicator of nutritional status. Specifically, acute and chronic inflammatory conditions affect serum albumin levels by altering hepatic protein metabolism and

Table 2. Pathological outcomes in both groups

n=103	HALP <23 (n=60)	HALP >23 (n=42)	p
B			
Right colon	17 (28%)	13 (31%)	
Transverse colon	6 (10%)	1 (2%)	
Left colon	9 (15%)	8 (19%)	0.616
Sigmoid colon	10 (17%)	8 (19%)	
Rectum	16 (27%)	9 (22%)	
FAP*/synchrone	2 (3%)	3 (7%)	
Operation			
Right hemicolectomy	23 (38%)	13 (31%)	
Left hemicolectomy	9 (15%)	9 (21%)	
Anterior resection	6 (10%)	5 (13%)	0.552
Low anterior resection	15 (25%)	11 (26%)	
Abdominoperineal resection	5 (9%)	1 (2%)	
Total colectomy	2 (3%)	3 (7%)	
Hospital mortality	1	1	0.797
Stage T			
T1	3 (5%)	2 (5%)	
T2	3 (5%)	4 (10%)	0.637
T3	29 (48%)	23 (55%)	
T4	25 (42%)	13 (30%)	
Stage N			
N0	31 (52%)	20 (48%)	0.670
N1	19 (32%)	12 (29%)	
N2	10 (16%)	10 (23%)	
Stage M			
M0	53 (88%)	38 (90%)	0.731
M1	7 (12%)	4 (10%)	
Pathological stage			
Stage I	5 (8%)	5 (12%)	
Stage II	23 (38%)	16 (38%)	0.933
Stage III	25 (42%)	17 (40%)	
Stage IV	7 (12%)	4 (10%)	
MSI			
High	9 (15%)	6 (14%)	0.920
Low	51 (85%)	36 (86%)	
Harvested lymph nodes [median (IQR)]	21 (20)	20 (16)	0.151
Tumor positive lympph nodes (mean ± SD)	2.3 (±4)	2.4 (±4.4)	0.904

IQR: Interquartile range, HALP: Hemoglobin, albumin, lymphocyte, platelet score, SD: Standard deviation, FAP: Familial adenomatous polyposis, MSI: Microsatellite instability

Table 3. Univariate and multivariate overall survival analysis for colorectal cancer

n=124	HR	95% CI	p	HR	95% CI	p
Gender	1.272	0.549-2.950	0.576			
Age	1.061	1.023-1.100	**0.001**	1.039	0.997-1.084	0.070
Comorbid diseases	7.771	1.827-33.054	**0.006**	2.473	0.872-7.013	0.089
Tumor localization	0.904	0.675-1.334	0.419			
Operation type	0.978	0.568-1.996	0.841			
Stage T (T1-T2 vs. T3-T4)	5.140	0.489-54.024	0.173			
Stage N (N0 vs. N+)	1.309	0.594-2.885	0.504			
Stage M	3.303	1.190-9.764	**0.022**	5.287	1.170-23.888	**0.030**
MSI	1.291	0.386-4.332	0.678			
HALP	0.327	0.130-0.821	**0.017**	0.314	0.123-0.793	**0.014**

HR: Hazard ratio, CI: Confidence interval, MSI: Microsatellite instability, HALP: Hemoglobin, albumin, lymphocyte, platelet score

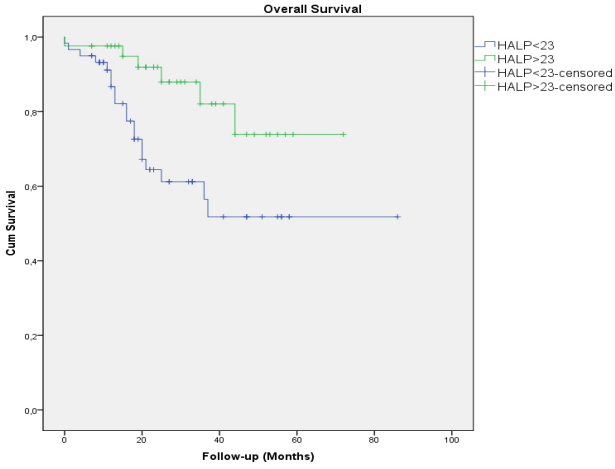

Figure 2. Overall survival in HALP <23 and HALP >23 groups. (Log-rank: 0.012).

HALP: Hemoglobin, albumin, lymphocyte, platelet score

inducing capillary leakage. This being the case, serum albumin is no longer considered a reliable nutritional marker in inflammatory states but rather a marker for disease severity (26). It is seen often in hospitalized patients and is associated with a poor clinical cours (27). There are many factors that affect serum albumin levels. Although it provides information about nutritional status, its specificity is low (28). The real reason for low serum albumin levels has been a subject of debate for a long time. It is known that malnutrition is related to hypoalbuminemia (29). Albumin levels have also been found to be low in acute and chronic inflammation. Therefore, it seems logical to include the albumin multiplier in the calculation of the HALP score because CRC patients are associated with both chronic inflammation and malnutrition.

Hemoglobin is responsible for carrying oxygen in the blood. It is found in red blood cells, and one of its building blocks is iron. In colorectal cancers, blood may be present in the stool due to spontaneous bleeding of the cancer. Low hemoglobin may be associated with colorectal cancers in older ages (30). In addition, anemia may be seen in conditions such as chronic inflammation (31). There is a hemoglobin multiplier in the HALP score calculation, so a low HALP score may be associated with a low hemoglobin value.

Study Limitations

This study has some limitations as well. First, its retrospective design might lead to some selection biases. Second, the relatively small number of patients might affect the strength of the statistical analysis. Finally, this study was conducted in a single center; hence, this may affect the generalizability of the results.

CONCLUSION

HALP score is an easy and inexpensive method to calculate. In CRC cases, poor HALP score is associated with low OS. Therefore, using the HALP score in CRC cases can provide information about OS.

Ethics

Ethics Committee Approval: This study was approved by the Ethics Committee of the University of Health Sciences Türkiye, İzmir Bozyaka Training and Research Hospital (no: 2023-200, date: 27.11.2023), and it was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Informed Consent: Informed consent was obtained from all patients.

Footnotes

Author Contributions

Concept - Ö.Ç, H.Y., A.C.Y., Y.Ç.,B., S.T., E.O., A.M.Ö., M.Y.; Design - Ö.Ç, H.Y., A.C.Y., Y.Ç.,B., S.T., E.O., A.M.Ö., M.Y.; Data Collection or Processing - Ö.Ç., Y.Ç.B., A.C.Y.; Writing - H.Y., S.T., E.O.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Assessing and managing benign breast lesions leading to mastalgia: A review of 840 patients

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ABSTRACT

Objective: Mastalgia often raises malignancy concerns. This study explores its link to benign breast conditions, and cancer.

Material and Methods: This retrospective study included 840 patients presenting to the surgical clinic with breast disease between January 2016 and January 2023.

Results: This study included 840 patients (800 female, 40 male) presenting with mastalgia, either as an isolated symptom or in combination with other complaints. In 350 cases (41.6%), pain alone was reported; in 410 cases (48.8%), pain with a lump; and in 18 cases (2.1%), pain with nipple discharge. Non-cyclic pain (51.5%) was more common than cyclic pain (42.5%), with pain most frequently localized to the right breast (53.5%), followed by bilateral (23.8%) and left breast (17.8%) pain ($p<0.001$). A significant association was observed between mastalgia and neck/shoulder pain (10.7%, $p<0.001$). A family history of breast cancer was present in 16.6% of patients. Histologic analysis revealed fibrocystic changes (42.2%), fibroadenoma (21.1%), and ductal ectasia (11%) as the most common diagnoses. Malignancy was detected in 6 cases (1.3%, including 1 male patient), with a significantly higher prevalence in the pain + lump group ($p<0.001$). Other findings included mastitis (9 cases), abscess (53 cases), and fat necrosis (4 cases). Patients with suspected malignancy underwent biopsy based on radiologic suspicion (BIRADS 2-4a) and physical examination.

Conclusion: Mastalgia is predominantly a benign condition, but non-cyclic pain, particularly when associated with a lump, warrants thorough evaluation to exclude malignancy. The link between mastalgia and fibrocystic changes shows that research is needed into the causes and consequences. It is not a malignancy indicator, accurate diagnosis requires histological and radiological assessments.

Keywords: Breast pain, malignancy risk, fibrocystic changes, atypical mastalgia

INTRODUCTION

Mastalgia is a prevalent symptom experienced by most women at some point in their lives, often resolving on its own. A thorough history, physical examination, and specific imaging can help pinpoint the underlying cause of mastalgia, aiding in the selection of suitable treatment options. Various factors have been recognized as potential contributors to the physiological causes of mastalgia, including hormonal changes, dietary habits, stress, medications, and poorly fitting bras. While breast cancer is a rare reason for breast pain, it should still be considered and investigated as a potential diagnosis. Various therapeutic methods exist to alleviate breast pain, such as providing reassurance, implementing supportive measures, adjusting diet, administering non-steroidal anti-inflammatory drugs, and hormonal interventions. Pain may range from mild to severe, may come and go, and may last all day, affecting quality of life (1,2). Mastalgia can be associated with premenstrual syndrome, fibrocystic disease and, in rare cases, breast cancer. Moreover, studies have shown that breast pain is not associated with an increased risk of cancer (3). The aim of this study was to characterize and manage benign breast conditions causing mastalgia and to examine the relationship between mastalgia and malignancy.

MATERIAL and METHODS

Study Design and Setting

This retrospective observational study included 840 patients who presented with mastalgia (breast pain) between January 2016 and December 2022. The study was

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conducted in the only tertiary care hospital in a city located in the western part of the Black Sea Region, Türkiye. Due to the absence of alternative secondary or tertiary centers, this hospital serves as the primary referral facility for patients with breast complaints in the region. This centralized healthcare model allowed for the comprehensive collection of clinical data from a well-defined population.

Data Collection Process

Data were retrieved from the hospital's electronic medical record (EMR) system, which archives patient demographics, clinical notes, radiological images, and reports, operative records, pathology results, and laboratory tests. A trained research team accessed and reviewed the data in a structured format using standardised data abstraction forms to ensure consistency. Data validation techniques included cross-referencing imaging findings with pathology results and independently verifying diagnostic codes related to breast disease. Missing or ambiguous records were reviewed by a second investigator to improve accuracy and reliability.

The EMR system utilized in this hospital is integrated with diagnostic imaging and pathology databases, enabling researchers to follow the patient journey from presentation to diagnosis and management. Only complete and verifiable patient records were included in the analysis.

Inclusion and Exclusion Criteria

Patients were included if they presented to the surgical outpatient department specifically with mastalgia during the study period. Patients whose primary complaint was not breast pain (e.g., palpable mass without pain, nipple discharge, or systemic symptoms) were excluded from the study to maintain a focused dataset relevant to mastalgia-related breast lesions.

Histopathological Evaluation

Breast tissue samples were obtained for histopathological assessment via core needle biopsy, excision biopsy, incision biopsy, or simple mastectomy, depending on the clinical and radiological findings. The choice of biopsy method was guided by lesion characteristics and anatomical accessibility.

- Core needle biopsy was preferred for both palpable and non-palpable lesions with suspicious imaging findings, particularly breast imaging-reporting and data system (BI-RADS) category 4 and 5.
- Excision biopsy was used in cases where core biopsy was unsuitable, such as in lesions with ambiguous borders, difficult locations, or inadequate sample yield.
- Mastectomy specimens were evaluated in patients who underwent surgical treatment for persistent or complex lesions.

Histopathological classification was performed by experienced pathologists according to the World Health Organization classification of breast tumors, distinguishing between benign, atypical, and malignant lesions.

Diagnostic and Imaging Approach

A stepwise diagnostic algorithm was employed for evaluating breast pain:

1. Ultrasound was used as the first-line imaging modality for all patients.
2. The BI-RADS classification was applied to standardize reporting and inform next steps.
3. Mammography was used for patients over 40 years of age, or those with suspicious findings on ultrasound.
4. Breast magnetic resonance imaging (MRI) was reserved for inconclusive cases or for further characterization of complex lesions.
5. Hormonal profile assessments (including estrogen and prolactin levels) were conducted selectively, particularly in premenopausal women or patients with cyclic pain.

No specific pre-intervention medications or procedures were applied. The diagnostic and management process followed national clinical guidelines and evidence-based practice, ensuring a standardized approach across all cases.

Ethical Approval

All procedures followed ethical standards and the principles outlined in the Declaration of Helsinki. The study commenced after obtaining approval from the Bartın University Medical Faculty Clinical Research Ethics Committee (ethical no: 2023-SBB-0914). Patients' demographic and clinical characteristics were evaluated. Given the retrospective nature of the study, the need for written informed consent from the patients was waived.

Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were assessed for normality using the Shapiro-Wilk test. Data with normal distribution are expressed as mean ± standard deviation, whereas non-normally distributed data are presented as median (interquartile range).

To compare continuous variables between two independent groups, the independent samples t-test was used for normally distributed data, and the Mann-Whitney U test was applied for non-normally distributed data. Categorical variables were summarized as frequencies and percentages (%) and compared using the chi-square (χ^2) test. When expected cell counts were <5, Fisher's exact test was applied.

A p-value <0.05 was considered statistically significant for all analyses.

To enhance interpretability and data transparency:

• Key results were presented in tables, including descriptive statistics, p-values, and effect sizes where applicable.

All analyses were independently reviewed by a biostatistician to ensure methodological rigor and compliance with good statistical practice in clinical research.

RESULTS

Demographic and clinical data for these 840 patients can be found in Tables 1-3.

During the study period, a total of 840 patients presented to the breast clinic. Out of these, 350 patients reported breast pain either as their sole symptom or in combination with other symptoms. The ages of the patients ranged from 15 to 65 years, with a mean age of 32.5 years.

The presenting complaints were categorized as follows:

• Pain alone in 350 patients (41.6%)

• Pain with a lump in 410 patients (48.8%)

• Pain with nipple discharge in 18 patients (2.1%)

The pain was identified as non-cyclical in 412 patients (51.5%). The distribution of pain by the affected breast was:

• Right breast in 450 patients (53.5%)

Table 1. Patient characteristics

Main category	Subcategories	Frequency	Percentage
Age; m (SD) Range: 15-65			
Menstrual status	Menstruating	520	65
Menstrual cycles	Menopausal	280	35
	Regular	460	57.5
Lactation status	Lactating	170	21.25
	Non-lactating	180	22.5
Nipple discharge	History of lactation	580	72.5
	Yes	110	13.75
	No	620	77.5
Family history of breast cancer (female, male)	Positive family history of breast cancer	140	16.6
	Negative family history of breast cancer	700	83.3

SD: Standard deviation

Table 2. Pain analysis

Main category	Subcategories	Frequency	Percentage	z-value/chi-square value	p-value
Type of pain	Cyclical	340	42.5	-2.477*	0.013
	Non-cyclical	412	51.5		
Site of pain (female, male)	Right breast	450	53.5	67.627**	<0.001
	Left breast	150	17.8		
	Bilateral	200	23.8		
Pain in other sites (neck and shoulder) (female,male)	Yes	90	10.7	-12.457*	<0.001
	No	640	76.1		

*: z-value, **: chi-square value

According to the results of the analysis in Table 2, in terms of the type of pain, non-cyclic pain (51.5%) was more common than cyclic pain (42.5%) and this difference was statistically significant (z=-2.477, p=0.013).

In terms of localisation of pain, pain was most commonly reported in the right breast (53.5%) and less frequently in the left breast (17.8%). In addition, the rate of bilateral breast pain was found to be 23.8%. The difference observed in the analysis of localisation was statistically significant (χ^2=67.627, p<0.001).

In addition, while the rate of those who reported pain in other regions such as neck and shoulder was 10.7%, the rate of those who did not report pain was 76.1%. This difference was statistically significant (z=-12.457, p<0.001).

These findings indicate that non-cyclic breast pain is more common, that pain is most commonly seen in the right breast, and that the relationship with pain in the neck-shoulder region is significant

• Left breast in 450 patients (53.5%)

• Both breasts in 200 patients (23.8%)

Non-cyclic breast pain is more common than cyclic pain, with the right breast being the most commonly affected. There is a significant association between breast pain and pain in the neck and shoulder region (p<0.001).

This study highlights the frequency and distribution of breast pain among patients presenting to the clinic and provides insights into the nature of their symptoms.

According to the BI-RADS classification, the distribution of mass lesions among the patients was as follows:

- 46.5% of patients had BI-RADS 1 mass lesions
- 40.2% had BI-RADS 2 mass lesions
- 8.4% had BI-RADS 3 mass lesions
- 2.5% had BI-RADS 4 and 5 mass lesions (Figure 1).

Patients with BI-RADS 5 mass lesions reported non-cyclical and severe pain, typically in the post-menopausal period. These patients also had palpable masses along with persistent pain. The mammography and ultrasonography findings were assessed using the BI-RADS classification system, as described by the Radiological Society of North America.

The histological diagnoses (Table 4) among the patients were as follows:

- Fibrocystic changes: 190 cases (43.1%)
- Fibroadenoma: 95 cases (21.5%)
- Ductal ectasia: 50 cases (11.3%)

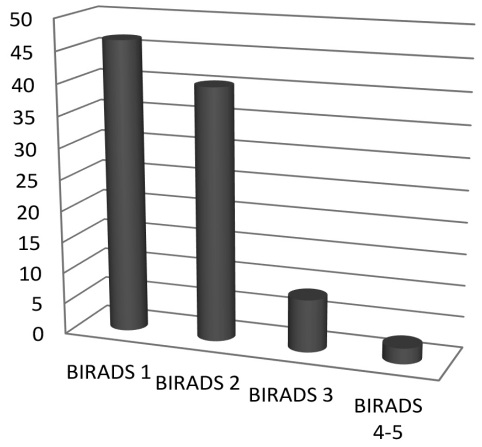

Figure 1. Percentage distribution of patients based on BIRADS classification.

BIRADS: Biopsy based on radiologic suspicion

Table 3. Primary symptom evaluation of benign breast changes

Symptom	Breast changes	Percantage of total patients
Pain	**Cysts** **-Fibrocystic breast disease** **- Hyperplasia of the breast** **- Mastitis** **- Postoperative changes**	88.8%
Palpable mass	Cysts - Fibrocystic breast disease - Fibroadenoma - Lipoma - Hamartoma - Intramammary lymph nodes	48%

Table 4. Histological diagnosis of breast pain

Main category	Frequency	Percantage	Chi-square test value	p-value
Fibrocystic changes	190	42.22	471.316	<0.001
Fibroadenoma	95	21.11		
Ductal ectasia	50	11.11		
Hamartoma	12	2.67		
Mastittis, abscess (M&F)	53	11.78		
Fat necrosis	11	2.44		
Carcinoma (both female and male)	6	1.33		
Non	33	7.33		

According to Table 5, it was examined whether there was a difference in breast pain rates between the groups. Accordingly, the difference in breast pain rates between groups is significant (p<0.001). The group with the highest breast pain is the fibrocystic changes group

Table 5. The patients clinically diagnosed with breast cancer, the presenting complaints

Patient group	Total number of patients	Malignancy rate (%)
Pain only	350	22.3%
Pain + lump	350	68.5%
Pain + nipple discharge	350	14.7%

- Hamartoma: 12 cases (2.7%)
- Mastitis/abscess: 53 cases (11.7%)
- Fat necrosis: 11 cases (2.4%)
- Carcinoma: 6 cases (1.39%)
- No specific diagnosis: 33 cases (7.3%).

Among patients clinically diagnosed with breast cancer, the presenting complaints were:

- Pain only: 22.3%
- Pain with nipple discharge: 14.7%
- Pain with a lump: 68.5% (Table 5).

According to Table 5, a difference in breast pain rates between the groups was examined. Accordingly, the difference in breast pain rates between groups is significant ($p<0.001$). The group with the highest breast pain is the fibrocystic changes group.

The difference in malignancy rate between groups was examined with the chi-square test. According to the results, the malignancy rate of the pain + lump group was higher than the other two groups ($p<0.001$).

Moreover, 70% of patients histologically diagnosed with cancer reported experiencing both pain and a palpable lump. Nearly all patients diagnosed with cancer, either clinically or histologically, exhibited a palpable breast lump during clinical breast examination. Mastalgia alone is not significantly associated with malignancy, but its presence alongside a mass increases the malignancy risk.

Patient Follow-up and Clinical Implications

Patients with BI-RADS 3 or higher, non-cyclical pain, and palpable masses were subjected to follow-up for 6 to 12 months, encompassing scheduled imaging procedures and clinical examinations. Those with histopathologically confirmed benign lesions received tailored follow-up based on risk profile, symptom persistence, and radiological findings.

For high-risk groups, including postmenopausal women with unilateral, persistent, non-cyclical mastalgia and BI-RADS 3-5 lesions, closer monitoring and early tissue diagnosis are recommended. The importance of integrating routine ultrasound and timely biopsy for unresolved symptoms cannot be overstated when it comes to avoiding delayed malignancy diagnosis.

DISCUSSION

Common Causes of Mastalgia

Mastalgia, characterized by pain in the nipple and breast tissue, is a common complaint among women, with approximately 70% experiencing it at some point in their lives. Although often self-limiting, it can significantly impact quality of life due to concerns about malignancy. However, breast pain alone is rarely indicative of breast cancer (4). A study by Khan and Apkarian (5) detected malignancy in only 0.63% of 5.463 patients with mastalgia, whereas our study found a slightly higher rate of 1.3%. This difference may be due to the smaller range of our study population. A 2018 meta-analysis (6) also found no significant association between mastalgia and malignancy, a finding supported by our results.

Mastalgia is broadly classified into cyclical and non-cyclical types. Cyclical mastalgia, linked to hormonal fluctuations, is more common in younger women and typically presents as bilateral, intermittent pain. Non-cyclical mastalgia, often unilateral and persistent, is more prevalent in postmenopausal women and may occasionally be associated with underlying pathology, including malignancy (7,8). Our study found that non-cyclic breast pain was more common than cyclic pain, with the right breast being the most frequently affected. Additionally, a significant association was observed between breast pain and pain in the neck and shoulder region ($p<0.001$). Preece et al. (9) noted that breast cancer-related pain often exhibits a cyclical pattern. However, our findings suggest that non-cyclic mastalgia in postmenopausal women may have a significant association with malignancy, which requires careful evaluation. This difference may be due, for example, to study populations or methodologies. Several recent studies, including a 2024 systematic review by Tomar et al. (10), have emphasized the diagnostic challenge of distinguishing benign mastalgia from early breast malignancy, especially in postmenopausal women, supporting our findings on the need for careful evaluation in high-risk groups. There is ongoing debate about whether mastalgia is purely psychoneurotic in origin. However, most cases have physiological or pathological causes rather than psychological ones (11). A significant association was found between mastalgia and fibrocystic changes, non-lactating history, and a family history of breast cancer, while no direct association was identified with other factors studied (Tables 1-3). The estimated probability of developing breast cancer in patients presenting with mastalgia alone ranges between 0.8% and 2.7% (12). Although mastalgia may occur in advanced breast cancer, primary evaluation should focus on ruling out malignancy through appropriate diagnostic tools to reduce patient anxiety.

Among benign breast conditions, fibrocystic changes and hyperplasia were most common, particularly in patients over 35 years of age. Palpable masses were identified in 48% of patients (Table 3). No significant association was found between breast pain and nipple discharge (13). However, 11.25% of patients had pain originating from musculoskeletal sources, which responded well to analgesics and local steroid injections. Recognizing musculoskeletal pain is essential for distinguishing it from mastalgia and ensuring appropriate management (14). Our study identified a significant association between mastalgia and fibrocystic changes, a novel finding not clearly reported in previous studies. The observed association between fibrocystic changes and mastalgia is corroborated by the large-scale study (15), which additionally found a significant correlation between dense breast tissue and non-cyclical pain. Emphasizing the low risk of malignancy in patients with mastalgia may help reduce unnecessary anxiety and enable clinicians to adopt a more targeted approach.

Diagnostic Evaluation and Imaging Findings

All patients underwent a thorough clinical examination, with routine mammography for those over 40, and an ultrasound for nearly all patients. Additional imaging, including MRI (16), was performed when initial findings were inconclusive. The mean age of patients was under 40 years, consistent with existing literature, and the mean duration of painful symptoms was five days per month. This comprehensive imaging approach provided a more detailed assessment than previous studies (16), supporting the notion that routine further imaging in patients with mastalgia may be unnecessary. This finding suggests that clinicians can optimize resource utilization. A 2020 cohort study by Holbrook (17) demonstrated that over 62% of patients with non-cyclical mastalgia had benign imaging findings, echoing our conclusion that breast pain alone often does not indicate malignancy.

According to the BI-RADS classification, 46.5% of masses were BI-RADS 1, 40.2% BI-RADS 2, 8.4% BI-RADS 3, and 2.5% BI-RADS 5 (Table 4). Patients with BI-RADS 5 masses reported persistent non-cyclic postmenopausal pain associated with palpable masses. Histological analysis (Table 5) revealed fibrocystic changes (43.1%), fibroadenoma (21.5%), ductal ectasia (11.3%), hamartoma (2.7%), mastitis/abscess (11.7%), adiposis (2.4%), cancer (1.3%), and non-specific findings (7.3%). Among clinically diagnosed breast cancer patients, 22.3% presented with pain alone, 14.7% with pain and nipple discharge, and 68.5% with pain and a lump (Table 5). Almost all cancer cases had a palpable mass on clinical examination, with histopathological findings predominantly consistent with invasive ductal carcinoma. Our results align with recent data from the UK Breast Screening Programme, which reported that mastalgia, in the absence of a mass or radiological abnormality, has a cancer detection rate of less than 1% (18). Yıldırım et al. (19) found no significant correlation between BI-RADS categories and type of mastalgia, suggesting that breast pain alone, without radiological or physical findings, does not increase cancer risk, which is consistent with our study.

Implications for Malignancy Risk

Although mastalgia is rarely a direct indicator of breast cancer, it can sometimes be the first symptom of non-cyclic pain, particularly in postmenopausal women. In our study, 20 patients initially presenting with mastalgia were diagnosed with early-stage breast cancer. This finding underscores the importance of a comprehensive assessment despite the low overall risk of malignancy. While Preece et al. (9) suggested that breast cancer-related pain is typically cyclical, our study found a stronger association between non-syndromic mastalgia and malignancy in postmenopausal women. This discrepancy may be due to the broader age range of our study population.

The literature (20) indicates that approximately two-thirds of mastalgia cases are cyclic and related to hormonal fluctuations (21), whereas non-cyclic mastalgia is more common in women over 40 years and is usually unilateral (21). Studies (22) suggest that breast cancer-related pain is typically unilateral and persistent, in contrast to cyclic mastalgia (23). Our study reinforces that postmenopausal women with non-cyclic mastalgia may have a higher risk of malignancy, highlighting the need for further focused research on this subgroup.

In a study (24) women found no link between breast pain and cancer, and most patients were not diagnosed with malignancy. However, some postmenopausal women with non-cyclic mastalgia may develop breast cancer. Consistent with the existing literature, non-cyclic mastalgia is more common in postmenopausal women, whereas cyclic mastalgia is more common in younger patients. As the classification is based on patient history, there is a potential bias (25). Further research is needed to assess cancer risk and to better understand the subtypes and causes of mastalgia. Kızılkaya et al. (8) suggested that premenopausal patients with non-cyclic breast pain might have malignancy. Some studies (26,27) have linked mastalgia with obesity, nulliparity, smoking, and high caffeine consumption, but our study found no association between pain intensity and malignancy risk. This supports the notion that pain alone is not a definitive indicator of malignancy.

There's been much debate in the literature about the connection between non-cyclic mastalgia and breast cancer, with some studies pointing towards a link, but the overall risk is considered low. For example, a study in the American Journal of Roentgenology (28) found breast cancer incidence in patients with breast pain as their only symptom to be between 0% and 2.3%. Similarly, research in the American Family Physician (29) journal stated that after normal clinical breast examination and

mammography, the risk of malignancy in patients with non-cyclic breast pain is about 0.5%.

The discrepancies in findings may be attributed to differences in study populations, diagnostic criteria, and methodologies. Some high-risk studies or specialist breast clinic patients may overestimate cancer risk. The lack of definitions or imaging differences further complicates comparison. Our study found no significant difference in malignancy rates between cyclic and non-cyclic mastalgia. Clinical/radiology evaluation remains essential for diagnosis, not just pain patterns.

Treatment options for mastalgia include tamoxifen, danazol, gamma-linolenic acid, and Fructus Agni Casti (30). However, these treatment modalities remain controversial (31). In our clinic, consistent with the literature, pharmacological intervention is generally avoided. Mastalgia often resolves spontaneously, though persistent cases may benefit from NSAIDs such as diclofenac or paracetamol (32). Hormone therapy is reserved for select cases due to its potential side effects.

Clinical Implications and Follow-up

Our findings suggest that a stepwise, symptom-based approach to mastalgia management is both effective and resource-efficient. In cases of mastalgia without other clinical or radiological abnormalities, reassurance and short-term follow-up may be sufficient. For patients with risk factors such as age over 40, non-cyclical pain, or a palpable mass, a more aggressive diagnostic approach, including biopsy, is warranted.

We propose a follow-up protocol based on mastalgia type, age, and physical findings:

- Low-risk (cyclical, <40 years, no lump): Observation and symptomatic treatment.
- Moderate-risk (non-cyclical, <40 years, family history): Imaging and 3-6 month follow-up.
- High-risk (non-cyclical, >40 years, lump or BI-RADS 3-5): Immediate biopsy and specialist referral.

Such stratification can be instrumental in reducing patient anxiety and improving diagnostic accuracy. This stepwise approach is further supported by Siddique et al. (33), who highlighted the value of structured risk models in mastalgia evaluation to minimize unnecessary intervention while ensuring early detection.

Suggestions for Future Research

This study contributes to the growing body of literature supporting the low likelihood of malignancy in mastalgia, particularly when it occurs in isolation.

Further research needs to be done:

- Long-term outcomes of patients with mastalgia and BI-RADS 3 lesions can be investigated.
- The role of hormonal and lifestyle factors in chronic mastalgia can be assessed.
- Predictive models or scoring systems can be developed to identify patients at higher risk of malignancy.
- Investigating the psychosocial impact of mastalgia and management strategies can provide insights into quality of life, where the presence of clinical symptoms may be an early sign of malignancy.

Our study provides valuable insights into the low malignancy risk associated with mastalgia and emphasizes the importance of a comprehensive evaluation to rule out underlying pathology. While mastalgia is predominantly physiological, persistent or atypical cases -particularly in postmenopausal women- warrant further investigation. Imaging modalities such as ultrasound and mammography remain crucial for identifying underlying pathological causes, while histological analysis remains the gold standard for definitive diagnosis.

The relationship between mastalgia and obesity, smoking, and caffeine consumption is underexplored in the literature. Future research could focus on analyzing these factors in detail.

This study demonstrates that although mastalgia is often associated with benign conditions such as fibrocystic changes, it can also be linked to other medical issues. The findings emphasise the importance of a structured diagnostic approach, including clinical assessment, imaging and histopathology for effective patient management.

Recommendations for Practice

- Clinicians should maintain a high index of suspicion for malignancy in patients with persistent mastalgia and concurrent breast masses.
- A graded follow-up algorithm should be applied, especially for BI-RADS 3+ lesions and non-cyclical pain, in older age groups.
- Developing a risk stratification tool for mastalgia cases based on imaging and clinical features may aid resource allocation and reduce unnecessary anxiety in low-risk patients.

The risk-based approach proposed in this study is consistent with current clinical practice guidelines, including those issued by the American College of Obstetricians and Gynecologists and the National Institute for Health and Care Excellence, which emphasise individualised assessment and stratification based on clinical and imaging findings. By means of patient categorization according to risk profiles, clinicians can more accurately determine the necessity for further investigation or intervention, thereby minimizing unnecessary imaging in low-risk cases while ensuring early diagnosis in high-risk presentations. This strategy has the potential to enhance the utilisation of resources and to provide reassurance to patients, particularly in settings where access to advanced diagnostic tools is limited.

Study Limitations

This study has several inherent limitations due to its design: Data were collected from patient records, which may have contained inaccuracies, and the study also lacked long-term follow-up due to the absence of standardisation. Additionally, as the study was conducted across a single centre, the findings may not be generalisable. Finally, the study did not assess key contributing factors.

CONCLUSION

In conclusion, while mastalgia is predominantly a benign and self-limiting condition, a comprehensive evaluation is essential to rule out malignancy and other underlying causes, particularly in high-risk subgroups. Emphasizing the low malignancy risk and adopting a tailored diagnostic approach can optimize patient care and resource utilization.

Ethics

Ethics Committee Approval: All procedures followed ethical standards and the principles outlined in the Declaration of Helsinki. The study commenced after obtaining approval from the Bartın University Medical Faculty Clinical Research Ethics Committee (ethical no: 2023-SBB-0914).

Informed Consent: Due to the retrospective nature of this study, written informed consent was not obtained.

Footnotes

Author Contributions

Concept - Y.D., A.M.D.; Design - Y.D., A.M.D., M.Ç., S.S.Ç.; Supervision - E.C.D., Y.D., M.Ç., S.S.Ç.; Materials - Y.D., A.M.D., M.Ç., S.S.Ç.; Data Collection or Processing - E.C.D., M.Ç., S.S.Ç.; Analysis or Interpretation - Y.D., E.C.D., A.M.D.; Literature Search - Y.D., A.M.D., M.Ç., S.S.Ç.; Writing - Y.D., E.C.D., M.Ç.

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ORIGINAL ARTICLE
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A comparative analysis of preoperative, intraoperative, and tumor characteristics in emergency and elective right-sided colonic surgery

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ABSTRACT

Objective: This study aimed to compare preoperative, intraoperative, and tumor characteristics between patients undergoing emergency and elective surgery for right-sided colon cancer. Despite the worsened prognosis of emergency colorectal cancer cases, studies on right colon cancer remain limited.

Material and Methods: This retrospective study included 356 patients who underwent surgery for right-sided colon cancer between January 2015 and April 2023. Patients were categorized into emergency (n=93) and elective (n=263) groups. Demographic data, tumor characteristics, and surgical details were analyzed. Binary logistic regression was applied to identify independent predictors of emergency surgery.

Results: Age (p=0.435) and gender distribution (p=0.853) were similar between groups. However, American Society of Anesthesiologists (ASA) scores were higher in the emergency group (p=0.001), while Charlson comorbidity index (CCI) scores showed no significant difference (p=0.169). T4 (p<0.001), N1 (p=0.008), and M1 stages (p<0.001) were significantly more frequent in the emergency group, along with higher tumor perforation rates (34.4% vs. 1.9%, p<0.001). Open surgery was more common in the emergency group (p=0.005). While total lymph node yield was similar (p=0.501), the number of metastatic lymph nodes was higher in the emergency group (p=0.008). Logistic regression identified higher ASA score, advanced T, N, M stages, tumor perforation, and tumor size as predictors of emergency surgery.

Conclusion: Patients undergoing emergency surgery for right colon cancer have more advanced disease, higher tumor perforation rates, and poorer prognostic factors. Laparoscopic surgery was less utilized, which indicates technical challenges. Early diagnosis and screening strategies may reduce emergency interventions and improve outcomes.

Keywords: Right-sided colon cancer, emergency surgery, elective surgery, tumor stage, tumor perforation, prognostic factors

INTRODUCTION

Colorectal cancer is among the most frequently diagnosed malignancies worldwide, significantly contributing to cancer-related morbidity and mortality. According to GLOBOCAN 2022 data, it is the third most commonly detected cancer globally (1). Similarly, in Türkiye, colorectal cancer ranks as the third most prevalent malignancy (2). Despite continuous advancements in diagnostic techniques and therapeutic interventions, a substantial number of cases still present as emergencies, which are associated with poorer clinical outcomes (3).

Right-sided and left-sided colorectal cancers exhibit distinct biological and pathological characteristics (4,5). Research indicates that right-sided colon cancers are often diagnosed at more advanced stages and are associated with worse prognoses, including lower five-year survival rates compared to left-sided tumors (6-8). Differences in molecular pathways, tumor progression patterns, and symptom onset between these subtypes contribute to their diverse clinical presentations and prognostic implications.

The objective of this study is to investigate the differences between emergency and elective surgeries in patients with right-sided colon cancer, with a specific focus on preoperative demographic characteristics, intraoperative findings, and tumor pathology. While the adverse outcomes of emergency colorectal cancer surgeries have been well documented, there remains a lack of specific data on emergency right-sided colon cancer cases. This study aims to fill that gap by identifying prognostic

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factors and key distinctions between emergency and elective surgeries, thereby contributing to improved clinical decision-making and patient management strategies. We hypothesized that patients undergoing emergency surgery for right-sided colon cancer would present with more advanced tumor stages, higher tumor perforation rates, and worse prognostic indicators compared to those undergoing elective surgery.

MATERIAL and METHODS

This research was designed as a retrospective observational study and carried out in the general surgery department of a tertiary-level university hospital. The study population included patients who underwent surgery due to right-sided colon tumors between January 2015 and April 2023. Ethical approval was obtained from the Ethics Committee of Gazi University Faculty of Medicine in accordance with the principles outlined in the Declaration of Helsinki (approval no: 17.07.2023-597, date: 17.07.2023).

A total of 392 patients were initially identified. Clinical data were gathered through hospital digital record systems and patient charts. After reviewing the dataset, 36 patients were excluded based on the following criteria: Patients younger than 18 years or older than 90 years, patients with missing preoperative clinical or pathology data, and patients who underwent surgery for non-malignant indications. This process resulted in a final study group of 356 patients.

Among the participants, 93 patients (25.7%) underwent emergency surgery, while 263 patients (72.7%) had elective operations. Emergency surgery was defined as operative intervention needed within 48 hours of hospital admission, typically due to acute clinical presentations such as bowel obstruction, gastrointestinal perforation, or significant bleeding. Elective surgeries were performed following standard preoperative evaluation and optimization protocols, including imaging and staging workup.

For each patient, data on demographics [age, gender, ASA classification, Charlson comorbidity index (CCI)], tumor characteristics (anatomical site, histological subtype, differentiation, TNM stage), and surgical parameters (approach, procedure type, lymph node evaluation) were systematically collected and compared between the two groups.

Statistical Analysis

All statistical analyses were performed using SPSS version 26.0. Since the data did not follow a normal distribution, non-parametric tests were used. Continuous variables were reported as median (min-max) and compared with the Mann-Whitney U test. Categorical variables were summarized as counts and percentages, and comparisons were made using the chi-square test.

To identify factors independently associated with emergency surgery, binary logistic regression was conducted. Only variables with $p<0.05$ in univariate analysis were included in the model. A significance threshold of $p<0.05$ was applied for all statistical tests.

RESULTS

Out of 356 patients, 93 (26.12%) underwent emergency surgery and 263 (73.87%) underwent elective surgery. There were no significant differences in age (p=0.435) or gender distribution (p=0.853). Emergency cases had significantly higher ASA scores (p=0.001), while CCI scores were comparable (p=0.169) (Table 1).

Tumor localization did not differ significantly (p=0.067), but poorly differentiated tumors were more frequent in emergency cases (p=0.001). T4, N1, and M1 stages were significantly more common in this group (p<0.001, p=0.008, and p<0.001, respectively), as was tumor perforation (34.4% vs. 1.9%, p<0.001). No difference was found for angiolymphatic (p=0.054) or perineural invasion (p=0.950) (Table 2).

Open surgery was more frequent in the emergency group (p=0.005), whereas the use of laparoscopy was lower. Although

Table 1. Demographic and clinical characteristics of patients undergoing emergency and elective surgery

	Total	Emergency (n=93)	Elective (n=263)	p
Age, median (range), year	64 (22-90)	66 (24-89)	63 (22-90)	0.435
Sex, n (%) Female Male	 133 (37.6%) 223 (62.6%)	 34 (36.6%) 59 (63.4%)	 99 (37.6%) 164 (62.4%)	 0.853
ASA, n (%) I II III IV	 87 (24.4%) 140 (39.3%) 122 (34.3%) 7 (2.0%)	 18 (19.4%) 33 (35.5%) 36 (38.7%) 6 (6.5%)	 69 (26.2%) 107 (40.7%) 86 (32.7%) 1 (0.4%)	 **0.001**
CCI, median (IQR)	3 (1-6)	3 (1-6)	3 (1-6)	0.169

n: Number, p: Value, CCI: Charlson comorbidity index, IQR: Interquartile range, ASA: American Society of Anaesthetiologist, bold values indicate statistically significant p-values (p<0.05)

total lymph node yield was similar (p=0.501), metastatic node count was higher in emergency cases (p=0.008). Median tumor size was also larger (7 cm vs. 5 cm, p<0.001) (Table 3).

Multivariate analysis showed that higher ASA score, advanced T, N, M stages, tumor perforation, tumor size and operation performed were independently associated with emergency surgery (Table 4).

DISCUSSION

Although emergency-diagnosed colorectal cancer cases are known to have worse prognoses, studies focusing specifically on this patient population remain relatively scarce. In this study, we analyzed right-sided colon cancer patients by comparing preoperative clinical characteristics, intraoperative findings, and pathological outcomes between emergency and elective surgery groups. Through this comparison, we aimed

Table 2. Tumor characteristics and staging in emergency and elective surgery groups

	Total	Emergency (n=93)	Elective (n=263)	p
Localization Cecum Ascending colon Hepatic flexura	 124 (34.8%) 145 (40.7%) 87 (24.4%)	 28 (30.1%) 34 (36.6%) 31 (33.3%)	 96 (36.5%) 111 (42.2%) 56 (21.3%)	 0.067
Tumor differentiation, n (%) Well differentiated Moderately differentiated Poorly differentiated	 153 (43.0%) 165 (46.3%) 38 (10.7%)	 30 (32.3%) 44 (47.3%) 19 (20.4%)	 123 (46.8%) 121 (46.0%) 19 (7.2%)	 **0.001**
T stage, n (%) T1 T2 T3 T4	 15 (4.2%) 51 (14.3%) 183 (51.4%) 107 (30.1%)	 0 (0.0%) 2 (2.2%) 47 (50.5%) 44 (47.3%)	 15 (5.7%) 49 (19.6%) 136 (51.7%) 63 (24.0%)	 **<0.001**
N stage, n (%) N0 N1 N2	 162 (45.5%) 141 (39.6%) 53 (14.9%)	 31 (33.3%) 49 (52.7%) 13 (14.0%)	 131 (49.8%) 92 (35.0%) 40 (15.2%)	 **0.008**
M stage, n (%) M0 M1	 304 (85.4%) 52 (14.6%)	 66 (71.0%) 27 (29.0%)	 238 (90.5%) 25 (9.5%)	 **<0.001**
Angiolymphatic invasion, n (%) Negative Positive	 188 (52.8%) 168 (47.2%)	 41 (44.1%) 52 (55.9%)	 147 (55.9%) 116 (44.1%)	 0.054
Perineural invasion, n (%) Negative Positive	 294 (82.6%) 62 (17.4%)	 77 (82.8%) 16 (17.2%)	 217 (82.5%) 46 (17.5%)	 0.950
Tumor perforation, n (%) Negative Positive	 319 (89.6%) 37 (10.4%)	 61 (65.6%) 32 (34.4%)	 258 (98.1%) 5 (1.9%)	 **<0.001**

n: Number, p: Value, bold values indicate statistically significant p-values (p<0.05)

Table 3. Comparison of surgical techniques, lymph node dissection, and operative findings

	Total	Emergency (n=93)	Elective (n=263)	p
Operation performed, n (%) Right hemicolectomy Right hemicolectomy+ileostomy İleostomy, no resection	 319 (89.6%) 32 (9.0%) 5 (1.4%)	 58 (62.4%) 30 (32.3%) 5 (5.4%)	 261 (99.2%) 2 (0.8%) 0 (0.0%)	 **<0.001**
Surgical access, n (%) Laparoscopic Open Laparoscopic converted to open	 29 (8.1%) 299 (84.0%) 28 (7.9%)	 4 (4.3%) 75 (80.6%) 14 (15.1%)	 25 (9.5%) 224 (85.2%) 14 (5.3%)	 **0.005**
Total lymph nodes, median (range), number	35.5 (12-82)	34 (15-68)	36 (12-82)	0.501
Metastatic lymph nodes, median (range), number	1 (0-31)	1 (0-31)	0 (0-16)	**0.008**
Tumor size, median (range), cm	5.2 (0.3-19)	7 (2.8-11.5)	5 (0.3-19)	**<0.001**

n: Number, p: Value, cm: Centimetres, bold values indicate statistically significant p-values (p<0.05)

Table 4. Independent risk factors associated with emergency surgery (logistic regression analysis results)

	B	p	Exp (B)	CI	
ASA	-1.618	**<0.001**	0.198	0.094	0.417
Tumor differentiation	0.007	0.985	1.007	0.492	2.059
T stage	-1.020	**0.005**	0.361	0.177	0.734
N stage	0.924	**0.044**	2.520	1.025	6.192
M stage	-1.427	**0.014**	0.240	0.077	0.745
Tumor perforation	-5.021	**<0.001**	0.007	0.002	0.025
Operation performed	-6.253	**<0.001**	0.002	0.000	0.015
Surgical access	-0.877	0.141	0.416	0.130	1.336
Metastatic lymph nodes	-0.080	0.261	0.923	0.802	1.062
Tumor size	-0.220	**0.008**	0.803	0.683	0.943

p: Value, CI: Confidence interval, ASA: American Society of Anaesthetiologist, bold values indicate statistically significant p-values (p<0.05)

to identify factors that may influence prognosis and surgical outcomes.

Our findings indicate that 26.12% of patients undergoing right-sided colon cancer surgery required emergency intervention, which aligns with prior studies (9-11). The median age of our study population was 64 years (range: 22-90), with female patients accounting for 37.6% of the total. No significant differences were observed between the emergency and elective groups regarding age and gender distribution, which is consistent with the results of Banks et al. (9). However, previous studies suggest that elderly patients are more prone to emergency colorectal cancer presentations due to late-stage symptom onset and delayed diagnosis (12).

In terms of preoperative characteristics, we found that ASA scores were significantly higher in the emergency group, whereas CCI scores did not differ significantly between the groups. Banks et al. (9) reported similar findings regarding CCI scores, while noting no significant differences in ASA scores, which could be attributed to demographic variations among different study populations. A similar trend has been observed in studies conducted in Western European cohorts (13).

Surgical approaches differed significantly between the groups. In the elective surgery cohort, right hemicolectomy was the primary procedure (99.2%), whereas the rate of ileostomy procedures was notably higher in emergency cases (p<0.001). Regarding surgical access, emergency cases exhibited a higher frequency of open surgeries and a lower utilization of laparoscopic techniques (p=0.005). Additionally, laparoscopic-to-open conversion rates were higher among emergency surgeries. These findings align with established surgical trends, as emergency cases often present technical challenges that limit the feasibility of minimally invasive approaches. Conversely, laparoscopic surgery is more commonly performed in elective procedures due to enhanced preoperative preparation and patient optimization. Vallance et al. (14) reported a progressive increase, reaching 30%, in laparoscopic colorectal surgeries over six years, while in our study, the laparoscopic surgery rate among emergency cases was 19.35%, indicating relatively low utilization.

Lymph node dissection plays a critical role in colorectal cancer surgery. Although total lymph node counts did not differ significantly between groups, metastatic lymph node counts were significantly higher in the emergency cohort (p=0.008). Azin et al. (15) previously highlighted the higher likelihood of inadequate lymph node dissection in emergency colorectal surgeries. While our findings did not indicate a disparity in the total number of retrieved lymph nodes, the increased presence of metastatic lymph nodes in emergency cases suggests a more advanced disease state in these patients. Similar patterns have been observed in prior research (16). The absence of a difference in total lymph node counts between the groups may indicate a high level of surgical proficiency at our institution.

When tumor staging was analyzed, T4 tumors were significantly more prevalent in emergency cases (p<0.001), with higher frequencies also observed for N1 (p=0.008) and M1 stages (p<0.001). These findings are consistent with prior studies, which have demonstrated that emergency-diagnosed colorectal cancer cases are more likely to present at an advanced stage due to delayed detection (17,18). Interestingly, no significant difference was observed in CCI scores and perineural invasion rates between the emergency and elective groups. This finding suggests that the acute clinical presentation of right-sided colon cancer may be more closely associated with tumor aggressiveness and anatomical complications than with baseline comorbid status or perineural spread.

Our findings indicate that emergency colorectal cancer patients not only have lower survival rates but also exhibit higher frequencies of advanced tumor stages and metastatic disease. Most patients undergoing emergency surgery present with

complications such as intestinal obstruction, perforation, or severe bleeding, which delay diagnosis and worsen prognosis (19,20). Furthermore, inadequate lymph node dissection in emergency settings has been reported as a key factor negatively impacting survival outcomes (20). From a public health perspective, these findings underscore the importance of implementing effective colorectal cancer screening programs. Early detection through screening may reduce emergency presentations and allow for more favorable outcomes through timely elective interventions.

These results suggest that both the late-stage diagnosis of emergency colorectal cancer cases and the constraints of urgent surgical intervention contribute to poorer prognoses (12). Early detection remains a critical factor in reducing emergency surgeries and improving patient outcomes. Tumor perforation rates were markedly higher in emergency cases (34.4%) compared to elective cases (1.9%) ($p<0.001$), consistent with previous findings by Banks et al. (9).

Binary logistic regression analysis identified several independent factors significantly associated with emergency surgery. A higher ASA score was a strong predictor of emergency intervention [$p<0.001$, odds ratio (OR): 0.198, 95% confidence interval (CI): 0.094-0.417]. Additionally, advanced T stage ($p=0.005$, OR: 0.361, 95% CI: 0.177-0.734) and higher N stage ($p=0.044$, OR: 2.520, 95% CI: 1.025-6.192) were significantly correlated with emergency presentation. The presence of metastatic disease (M stage) was also associated with an increased likelihood of emergency surgery ($p=0.014$, OR: 0.240, 95% CI: 0.077-0.745). Tumor perforation was the strongest predictor of emergency surgery ($p<0.001$, OR: 0.007, 95% CI: 0.002-0.025). Additionally, the type of surgical procedure performed was found to be significantly linked to the likelihood of emergency intervention ($p<0.001$, OR: 0.002, 95% CI: 0.000-0.015). Lastly, larger tumor size was also associated with an increased need for emergency surgery ($p=0.008$, OR: 0.803, 95% CI: 0.683-0.943).

This study has several notable strengths and limitations. One of its key strengths is the relatively large sample size (n=356), which enhances statistical power. Additionally, it provides a comprehensive comparison of emergency and elective colorectal surgeries, focusing not only on clinical factors but also on pathological outcomes, thereby making a significant contribution to the literature. The inclusion of multivariate logistic regression analysis further strengthens the study by identifying independent risk factors associated with emergency surgery, offering valuable insights into high-risk patient profiles.

Study Limitations

The study also has certain limitations. As a retrospective analysis, it is inherently susceptible to selection bias and potential missing data. Moreover, the study was conducted at a single center, which may limit the generalizability of its findings. Another significant limitation is the lack of long-term oncologic outcomes, as survival data were unavailable. Consequently, the impact of emergency and elective surgical approaches on long-term prognosis remains unclear. Future prospective, multicenter studies with extended follow-up periods are needed to validate these results and provide deeper insights into emergency colorectal cancer management.

CONCLUSION

This study highlights the differences in clinical, intraoperative, and pathological outcomes between emergency and elective right-sided colon cancer surgeries. Patients undergoing emergency surgery had more advanced tumors, higher rates of tumor perforation, and greater metastatic lymph node involvement. Additionally, laparoscopic surgery was significantly less common, while open surgery was more frequently performed in emergency cases. These findings suggest that right-sided colon cancer patients requiring emergency intervention present with worse prognostic features and pose greater challenges in surgical management.

According to multivariate analysis, higher ASA score, advanced T, N, M stages, tumor perforation, tumor size and the type of surgical procedure performed were significantly associated with emergency surgery. These results emphasize the importance of optimal surgical techniques, even in cases where emergency intervention is unavoidable.

Early detection of colorectal cancer can significantly improve survival and oncologic outcomes by reducing the proportion of patients requiring emergency surgery. The implementation of regular screening programs and optimized management of high-risk patients can enhance surgical outcomes and long-term prognosis. Future prospective, multicenter studies are necessary to validate these findings and explore additional strategies for improving emergency colorectal cancer management.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Ethics Committee of Gazi University Faculty of Medicine in accordance with the principles outlined in the Declaration of Helsinki (approval no: 17.07.2023-597, date: 17.07.2023).

Informed Consent: Signed informed consent forms were obtained from all patients.

Footnotes

Author Contributions

Surgical and Medical Practices - Y.F.A., E.G., Ç.B., M.A.; Concept - Y.F.A., Ç.B., M.A.; Design - E.G., Ç.B.; Data Collection or Processing - Y.F.A., E.G.; Analysis or Interpretation - Y.F.A., Ç.B.; Literature Search -Y.F.A., E.G., Ç.B.; Writing - Y.F.A., E.G.

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ORIGINAL ARTICLE
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Co-expression of Stem Cell Markers CD133 and CD44 as Predictors of Metastatic Potential of Colorectal Carcinoma

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ABSTRACT

Objective: One of the most prevalent cancers in the world is colorectal carcinoma (CRC). Aggressive cancer forms and a poor prognosis are linked to cancer stem cell (CSC) markers. The study aimed to determine whether the co-expression of the CSC markers CD133 and CD44 could predict an increased risk of metastasis in colorectal cancer.

Material and Methods: Our study included 90 patients with CRC. All patients were divided into two subgroups: Metastatic CRC and non-metastatic CRC. Initially, tumor samples were examined using conventional histological techniques, and then immunohistochemical analysis with monoclonal antibodies against CD133 and CD44 markers was performed.

Results: High co-expression of CD133 and CD44 was observed in 71.4% of patients with metastatic disease, compared to 37.9% in patients without distant metastases. Discordant expression of both markers was found in 8% of the subgroup with metastatic CRC and 13.4% of the subset without metastatic CRC. Statistical analyses showed a significant association of increased expression of CD133 and CD44 with the disease stage, T- category, and N- nodal status. With multiple regression analysis, the stage of disease was singled out as the factor with the greatest and statistically significant influence on the expression of CD133 ($p<0.0001$) and CD44 ($p<0.0001$).

Conclusion: Co-expression of CD133 and CD44 plays an essential role in predicting the metastatic form of CRC. Both stem cell markers can be implemented in standard pathohistological diagnostics and can be useful markers for pre-therapeutic oncology screening.

Keywords: Colorectal carcinoma, stem cells, CD133+, CD44+, metastatic potential

INTRODUCTION

Colorectal cancer (CRC), with about 10% of all cancer cases, is the second most common cause of cancer-related deaths globally and the third most common type of cancer overall. The majority of cases affect individuals 50 years of age and older. Several lifestyle factors, including a sedentary lifestyle, obesity, smoking, excessive alcohol use, a high intake of processed meats, and a poor intake of fruits and vegetables, may increase the risk of CRC (1). The most frequent risk factor CRC, after advancing age, is family history. Less than 5% of cases of CRC are caused by the two most prevalent familial cancer syndromes, hereditary nonpolyposis and familial adenomatous polyposis (2). Most cases of CRC occur as a result of pre-existing dysplastic adenomatous polyps. The process of carcinogenesis includes a few steps: inactivation of various genes that suppress tumor growth, repair of DNA and simultaneous activation of oncogenes. These processes lead to selective growth of colorectal epithelial cells, then transformation of normal epithelium to adenomatous polyps, eventually leading to invasive CRC (3). Progression from adenoma to cancer and metastatic disease requires simultaneous disruption of protective mechanisms, including adenomatous polyposis coli, p53, and transforming growth factor β, as well as induction of oncogenic pathways, such as renin-angiotensin-system (4,5). Traditional tumorigenesis models imply that every cell in the tumor population can initiate and propagate tumors. The recently discovered cancer stem cells (CSCs) model indicates that only a tiny percentage of cells can spread malignancies. This hypothesis raises the question of the effectiveness of current diagnosis and therapy, suggesting

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that the CSCs model can be used to rationally develop new and robust diagnostic, therapeutic, and monitoring strategies (6,7). About 90% of patients with CRC die as a result of metastatic dissemination of the primary tumor, which implies researching new markers that can predict the metastatic potential in colorectal carcinoma (8). This study aimed to ascertain if CD133 and CD44 CSC markers might indicate an increased risk of CRC metastasis by performing immunohistochemistry examination of surgical material taken from individuals with the disease.

MATERIAL and METHODS

Subjects

This retrospective cohort study included ninety (n=90) patients who underwent surgical treatment at the University Clinic for Digestive Surgery in Skopje, North Macedonia, with a primary clinical diagnosis of CRC. Patients were divided into two groups: metastatic CRC and non-metastatic CRC. Before surgery, the patients were not treated with chemotherapy, radiation therapy, or immunotherapy. The clinical and pathological features included as covariates were age, gender, histological grade, and disease stage. The Ethical Committee of the Medical Faculty in Skopje, North Macedonia (number: 03-2039/5) approved the study protocol on 25 May 2016.

Pathohistological and Immunohistochemical Analysis

Macroscopically processed postoperative material and tissue samples for histological investigation were preserved in 10% neutral formalin for 18 to 24 hours as part of the dissection routine for colorectal cancers. The material was molded into paraffin blocks following a series of xylene and alcohol processing steps. Hematoxylin-eosin staining was performed on slides after applying paraffin blocks cut from 5-micron tissue samples. Light microscopy (Olympus) was used for investigation. The histological type and grade of the cancer and its local invasiveness, lymph nodal status, vascular invasion, distant metastases, and disease stage were all ascertained using histological investigation. Representative samples of tumor tissue were immunohistochemically analyzed using monoclonal antibodies against CD133 and CD44. The primary antibodies used were anti-CD133 rabbit monoclonal antibody (Miltenyi, Germany; clone AC133, dilution 1:11) and anti-CD44 mouse monoclonal antibody (Novocastra, UK; clone DF1485, dilution 1:50). For antibody visualization, a modified Avidin-Biotin Immunoperoxidase Complex method was employed, utilizing the EnVision detection system (Dako, Denmark). To ensure specificity and exclude nonspecific staining, an internal control system was implemented. Negative control samples consisted of identical tissue sections processed in the same staining chamber using the same protocol, but without the application of the primary antibody. Positive controls provided by the manufacturer were used for each antibody staining procedure. Tissue pretreatment was performed in the DAKO PT Link system, with buffers of appropriate pH values according to the manufacturer's recommendations. The staining protocol included the application of primary antibodies, followed by secondary antibodies conjugated with biotin, and the avidin-biotin peroxidase complex reaction. The chromogenic detection was performed using 3,3'-diaminobenzidine tetrachloride. Pathohistological and immunohistochemical analyses were performed at the Institute of Pathology, Medical Faculty in Skopje.

Scoring of CD133 and CD44 Expression

For each antibody, five visual fields at medium magnification (10×) were analyzed, including both peripheral and central regions of the tumor tissue in each case. The expression levels of CD133 and CD44 were semi-quantitatively classified as low when more than 50% of tumor glands or cells were negative, and high when more than 50% were positive. CD133 positivity was defined by apical-luminal staining of glandular epithelium or intraglandular cellular debris, while CD44 positivity was defined by membranous staining of tumor cells. The intensity of staining was not evaluated for either marker. CD44 and CD133 expression was defined with scoring systems that assessed the percentage of positive cells and a histochemical or overall score. CD44 and CD133 expression levels are the median values of our series of staining.

Statistical Analysis

The software SPSS was used for the statistical analysis of the obtained data. The following tests were used: Spearman's rank-order correlation, the Student's t-test, the Kolmogorov-Smirnov test, the Shapiro-Wilk W test, the Mann-Whitney U test, the One-Way Analysis of Variance (ANOVA), the Kruskal-Wallis test, and multiple regression analysis (multiple correlation coefficient, or R). The threshold for statistical significance was set at $p<0.05$.

RESULTS

Patient Clinicopathological Parameters

The patients' clinicopathological parameters are compiled in Table 1. Of the 90 patients in the study, 53 were between 50 and 70 years, and 27 were older than 71 years. There were 52 cases involving males and 38 involving females. The left colon (44.5%) had the highest tumor localization, followed by the rectum (31.1%) and the right colon (24.4%). There were no statistically significant variations in disease location between male and female patients (Mann-Whitney U test, $Z=1.578$, $p=0.11$). Age groups and illness location did not significantly differ (Kruskal-Wallis ANOVA: $H=5.796$, $p=0.1219$). Nonetheless, at more advanced stages of the disease, especially in patients with metastatic colorectal cancer, elevated expression of CD133 and CD44 was noted.

CD133 and CD44 Co-expression and Its Correlation with Metastasis

Compared to 37.9% of patients without metastatic disease, 71.4% of patients with metastatic disease had high levels of CD133 and CD44 co-expression. 13.4% of patients with non-metastatic colorectal cancer, and 8% of patients with metastatic colorectal cancer, had a discordant expression of both markers. According to statistical analysis, the illness stage, T-category, and N-nodal status strongly correlated with significant co-expression of CD133/CD44. By multiple regression analysis, the illness stage was found to be the most critical factor impacting CD133 ($p<0.0001$) and CD44 ($p<0.0001$) expression. Stage III and IV tumors showed the highest expression levels, which were associated with a higher risk of metastasis. Tables 2 and 3 present the respective findings.

Statistical Correlation of CD133/CD44 Expression

• **Tumor stage:** High expression of CD133 was significantly associated with stage III (79.5%) and stage IV (84.6%) tumors compared to stage I (0%) and stage II (4%) ($p<0.0001$). A similar trend was observed for CD44.

• **T-category:** CD133 expression was significantly higher in T3 (51.1%) and T4 (64.3%) tumors compared to T1 (20%) and T2 (8.3%) tumors ($p<0.01$). A similar distribution was noted for CD44 ($p<0.05$).

• **Nodal status:** High CD133 and CD44 expression correlated significantly with N2 status ($p<0.05$ for CD133; $p<0.01$ for CD44).

• **Tumor differentiation (G grade):** Significant differences in CD133 ($p<0.05$) and CD44 ($p<0.05$) expression were found across different differentiation grades.

Frequency of High and low Co-expression of CD133/CD44 in Subgroups of Patients According to Stage of Disease

According to results from multiple regression analysis, which suggest that the stage of the disease is the most significant factor in the expression of CD133 and CD44, we performed an analysis of differences in the co-expression of CD133/CD44 among subgroups of patients according to the stage of disease

Table 1. Patients' clinicopathological parameters

Variables	Number of patients
Age (years)	
<30	1
31-50	9
50-70	53
>71	27
Sex	
Male	52
Female	38
Localization	
Right colon	22
Left colon	40
Rectum	28
T-category	
T1	5
T2	12
T3	45
T4	28
Nodal status	
No	41
N1	24
N2	25
Tumor status	
G1	6
G2	72
G3	12

Table 2. Correlation between CD133 and independent factors using multiple regression analysis

Independent variables	**R=0.71 R^2=0.51 F=9.27 p=0.000001**				
	Beta in	**Partial correl.**	**Tolerance**	**t (80)**	**p-level**
Sex	0.0064	0.0085	0.8515	0.076	0.939152
Age	-0.0781	-0.0484	0.1886	-0.433	0.665494
Age groups	0.1529	0.0939	0.1866	0.844	0.400973
Localization	-0.0347	-0.0467	0.8871	-0.418	0.676953
Stage	-0.6884	0.5850	0.5374	-6.451	**0.000001**
T-category	0.0343	0.0391	0.6401	0.350	0.726851
Nodal status	-0.0740	-0.0953	0.8195	-0.856	0.394240
G differentiation	-0.1106	-0.1442	0.8505	-1.303	0.196046
Distant metastasis +	0.0908	0.1109	0.7398	0.998	0.321036

and presence of distant metastasis. The first subgroup consisted of patients at stages I and II, and the second subgroup consisted of patients at stages III and IV of the disease. The results showed statistically significant differences between subgroups of patients (Pearson's chi-square: χ^2=55.36; df=1; p<0.00001). The results are shown in Figure 1.

DISCUSSION

CEA and CA 19-9 are widely used markers in gastrointestinal malignancies, but their low sensitivity and specificity limit their prognostic value in CRC. CD133 and CD44 have recently been identified as key markers for colorectal CSCs, with their high co-expression linked to poor prognosis. A meta-analysis by Chen et al. (9) identified CD133 as a significant prognostic marker in CRC, correlating with advanced tumor stage, nodal involvement, and vascular invasion. Jing et al. (10) found CD44 to be an independent prognostic factor, more reliable for predicting hepatic metastases and survival than CD133. Khelwatty et al. (11) reported that while CD133 alone predicts poor survival, combining CD133 and CD44 enhances risk stratification. Tsunekuni et al. (12) observed that patients expressing both markers had significantly shorter survival, suggesting their combined analysis could aid treatment decisions and follow-up strategies. Another study suggested that CD133 expression may be related to sensitivity to radiotherapy or chemotherapy in colorectal cancer. Still, the presence of CD133-positive cancer cells alone cannot support the concept of CSCs in colorectal cancer. In the same study, other molecules, such as CD44, have been proposed as additional putative markers for CSCs in CRC (13). Our study identified an association between distant metastases and high expression of the cell markers CD133 and CD44, consistent with literature. Recent data showed a high correlation between CD133/CD44 co-expression and liver metastases in patients with colorectal carcinoma (14). In this study, CD44 expression was identified as an independent marker associated with patient survival. It was a more precise prognostic marker for liver metastases, metastatic disease, and survival than CD133. Horst et al. (15) demonstrated that CD133 expression does not correlate with CD44 and that

Table 3. Multiple regression analysis-correlation between CD44 and independent variables

Dependent variables	**R=0.73 R^2=0.53 F=10.24 p=0.000001**				
	Beta in	**Partial correl.**	**Tolerance**	**t (80)**	**p-level**
Sex	0.0902	0.1213	0.8515	1.092	0.277807
Age	-0.1129	-0.0718	0.1886	-0.643	0.521513
Age groups	0.1781	0.1121	0.1866	1.009	0.315861
Localization	0.1184	0.1614	0.8872	1.463	0.147422
Stage	-0.6749	0.5874	0.5374	-6.493	**0.000000**
T-category	0.0937	0.1093	0.6401	0.983	0.328228
Nodal status	-0.1397	-0.1824	0.8196	-1.659	0.100917
G differentiation	-0.1628	-0.2151	0.8505	-1.971	0.052225
Distant metastasis +	0.0732	0.0920	0.7398	0.826	0.410866

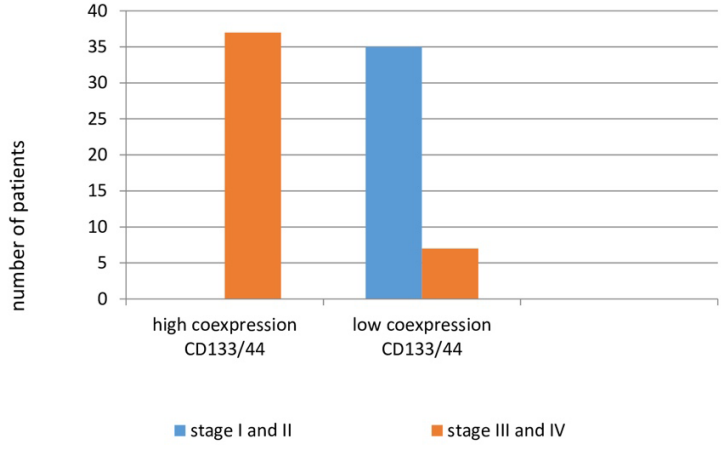

Figure 1. Frequency of high and low co-expression of CD133/CD44 in groups of patients according to stage of disease.

CD133 is the best individual marker for poor survival prognosis. In contrast, combined analysis of both markers may have greater prognostic power in patients with colorectal carcinoma. In another study, CD133 expression was observed in 69% of patients with metastatic disease, while increased expression of CD44 was observed in 61% of patients (16). In our study, high expression of both markers was detected in 69% of patients. Statistical analysis in our study showed a significant association of increased expression of CD133 and CD44 with disease stage. High expression of CD133 was found in tumors at stage III (79.5%) and stage IV (84.6%), compared to tumors at stage I (0%) and stage II (4%). A similar immunohistochemical expression distribution was observed for CD44, with 71.8% high expression in stage III tumors and 92.3% in stage IV tumors; compared to stage I (0%) and stage II (8%) tumors. These results correlate with findings from recent studies (13,17). Regarding the variations in CD133 and CD44 immunohistochemical expression in tumors belonging to distinct T categories, our analysis revealed that CD133 was significantly more expressed in T3 (51.1% high expression) and T4 (64.3% high expression) tumors than in T1 (20%) and T2 (8.3%) tumors. Compared to T1 (20%) and T2 (8.3%), tumors, CD44 expression was found to be similarly distributed in T3 (51.1%) and T4 (60.7%) cancers. In a meta-analysis of CD133 as a colorectal CSC marker, Chen et al. (9) discovered a substantial association in patients with colorectal cancer. According to their research, in patients with colorectal cancer, elevated CD133 expression was substantially linked to worse clinical outcomes and specific clinicopathological characteristics, including T3 and T4 categories, N category, and vascular invasion. In contrast to the findings of Chen et al. (9) and our findings, we did not find a favorable association between higher T-category (T3) and high CD133 expression in our earlier study (15). Their study only compared T2 and T3 tumors, unlike ours, which included T1 and T4 tumors. Their study followed patients for 10 years post-surgery and demonstrated significantly lower survival rates correlated with high CD133 expression. Regarding differences in CD133 and CD44 expression in tumors with different nodal statuses, our study showed significantly higher CD133 expression in tumors with N2 nodal status, than in others (N0 and N1). The statistical significance was greater for CD44 in tumors with N2 nodal status than in N0 and N1. CD133/CD44 showed the highest co-expression frequency in tumors with N2 nodal status compared to N0 and N1 status. In our study, the expression and co-expression of the examined markers were strongly correlated with high nodal status (N2). This supports established gold standards in colorectal surgery, such as complete mesocolic excision (CME) and total mesorectal excision (TME). In N1-2 tumors, complete loss of CD44 expression was predominant than its high expression in the N0 category. Differences may arise from their study fusing N1 and N2 statuses into a single category, while our study considered N0, N1, and N2, separate groups. The results are similar to previously published data (18). Our study showed a significant difference in the expression of CD133 and CD44 across tumors with different differentiation grades (G). Given the small size of G1 (6 samples) and G3 (12 samples), statistical analysis between individual groups was not performed. However, in the G1 group, low CD133 expression predominated (83.3%), while in G2, the difference was less significant (54.2% low expression vs. 45.8% high expression), and in G3, high CD133 expression was predominant (75%). A similar distribution was observed for CD44 expression. Our study found that in patients with metastatic disease (stages III and IV), CD44 and CD133 expression was increased compared to patients without metastases (stages I and II) (11,13).

Study Limitations

Our study had several limitations that should be acknowledged. The first limitation is the study's small sample size, single-center setting, and retrospective design. The second limitation was that some subgroups of patients (those with G1 tumors) are underrepresented, which affects statistical robustness. This is the result of the lack of prior specific case selection, as the cohort was composed of a consecutive case series. The decision to include consecutive cases was necessitated by the limited time frame allocated for data collection, which restricted the possibility of applying more selective inclusion criteria. Another limitation of the study is the absence of disease-free subjects and results on overall survival outcomes, which limits determining its true prognostic utility. These were the result of the financial limitations of the study. Thus, a larger prospective study is needed to establish the true prognostic value of both markers as predictors of the metastatic potential of colorectal carcinoma.

CONCLUSION

Our findings support the notion that CD133 and CD44 are helpful prognostic indicators, strongly correlated with the course of the disease and survival in individuals with colorectal cancer. We conclude that higher or lower CD44 expression is linked to higher or lower CD133 expression, but not vice versa. Low expression of CD44 does not always indicate low expression of CD133. Early diagnosis, patient monitoring, and tailored therapy selection may benefit from understanding the molecular pathways behind colorectal CSCs and identifying particular markers like CD44 and CD133. Analysis of stem cell markers may change conventional treatment approaches and help lower the risk of CRC metastases and local recurrence. The following essential findings from this investigation led to the conclusion:

• Elevated CD133/CD44 co-expression was considerably more prevalent in the group with metastatic disease than in the group without metastatic disease.

• Stages III and IV carcinomas had higher CD133/CD44 co-expression levels than stages I and II.

• In the individual analysis of CSC markers, high vs. low carcinoma expression incidence, varied significantly according to the tumor T-category, nodal status, and differentiation grade.

• The N status analysis supports the gold standards for TME CME, which are already established in colorectal surgery.

• A cut-off value for identifying CSC marker expression must be established to produce more trustworthy results.

• These markers should be correlated with other parameters impacting cancer aggressiveness and chemoresistance to provide future opportunities for broader applicability and a better understanding of CSCs. The objective is to include them as a pre-treatment oncological screening tool, a standard prognostic marker, and a commonly used pathohistological diagnostic tool.

Ethics

Ethics Committee Approval: The Ethical Committee of the Medical Faculty in Skopje, North Macedonia (number: 03-2039/5) approved the study protocol on 25 May 2016.

Informed Consent: Retrospective study.

Footnotes

Author Contributions

Concept - O.K., I.K., R.J.; Design - O.K., I.K., R.J.; Materials - O.K., I.K., R.J.; Data Collection or Processing - O.K., I.K., R.J.; Analysis or Interpretation - O.K., I.K., R.J.; Literature Search - I.K.; Critical Review - O.K., I.K., R.J.; Writing - I.K.

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ORIGINAL ARTICLE
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Evaluation of efficacy of ultrasound guided erector spinae plane block (ESPB) for post-operative analgesia in patients undergoing laparoscopic cholecystectomy

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ABSTRACT

Objective: The objective is to assess the clinical efficacy of erector spinae plane block (ESPB) for post-operative analgesia in patients undergoing laparoscopic cholecystectomies.

Material and Methods: This prospective, interventional, quasi-randomized single-blind study was approved by institutional ethical committee. Total 82 patients undergoing laparoscopic cholecystectomy were allocated into two groups, ESPB and control group. Postoperatively, the total tramadol consumption in 24 hours, the visual analogue scale (VAS) at various time intervals and time to rescue analgesia in both groups were monitored.

Results: The requirement of tramadol in first 24 hours was significantly more in controls as compared to cases (p=0.005). The mean VAS at rest, coughing and at movement was significantly lower in the immediate period, at 2nd hour and 4th hour after being shifted to post-operative area, in case group as compared to control. The time to rescue analgesia was statistically significantly more in ESPB group (p=0.002).

Conclusion: ESPB for laparoscopic cholecystectomy is a safe and effective technique of multimodal analgesia which provides better pain relief, reduced opioid requirement, lower post-operative pain scores, reduced total post-operative analgesic consumption along with prolonged time to rescue analgesia.

Keywords: Erector spinae plane block, multimodal analgesia, post-operative analgesia, rescue analgesia, visual analogue scale

INTRODUCTION

Laparoscopic cholecystectomy is now considered the gold standard for treatment of Gall stone disease, as it has been proven to cause less surgical trauma, better tissue healing, and faster recovery. Even though laparoscopic cholecystectomy is a minimally invasive procedure, post-operative pain, especially at port sites, remains a problem to be solved. Post-operative pain after laparoscopic surgeries is related to surgical manipulations, diaphragmatic irritation and indwelling abdominal trocars. Visceral pain after laparoscopic surgery may be due to stretching of the peritoneum, insufflation of gases intraoperatively, or post-operative residual pneumoperitoneum (1).

Various analgesic strategies, as a part of multimodal analgesia, exist for the management of post-operative pain. Regional anaesthetic techniques are prevalent in clinical practice and have a promising role in the management of post-operative analgesia after laparoscopic abdominal surgeries (2). Several techniques such as transversus abdominis plane block (3), serratus anterior plane block (4), and intraperitoneal insufflation of local anaesthetic (5) have been proven to reduce the post-operative analgesic requirement after abdominal surgeries.

The erector spinae plane block (ESPB) was first described by Forero et al. (6) for neuropathic pain resulting from metastatic lesions to the ribs and from the malunion of multiple rib fractures. The ultrasound-guided ESPB, effective for both somatic and visceral pain, is a recent interfascial block described for post-operative analgesia (6).

The role of ESPB as a better analgesic modality in reducing 24-hour opioid consumption has recently been established for post-operative analgesia in breast surgeries (7), video-assisted thoracoscopic surgery (8), and cardiothoracic

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surgeries (9). The use of this modality for post-operative analgesia in abdominal surgeries are few and are mostly case-reports and case series (10-12).

The purpose of this study was to assess the efficacy of ESPB versus conventional analgesia in post-operative pain relief after laparoscopic cholecystectomy. Recently, few studies with small sample sizes have been conducted to evaluate the role of ESPB in laparoscopic cholecystectomies, with administration of 0.25-0.5% bupivacaine. A reduction in post-operative analgesic score and 24-hour opioid usage was found by Aksu et al. (13) and Tulgar et al. (14). Our prospective study was conducted on patients undergoing laparoscopic cholecystectomies with 0.375% ropivacaine, as ropivacaine is associated with less cardiovascular and neurological toxicity. Ropivacaine provides better sensory-motor dissociation, hence enhancing the recovery of the motor component, thus assisting in early patient movement (15).

MATERIAL and METHODS

Study Design

The present study was approved by the Institutional Ethical Committee of Dr. Ram ManoharLohia Institute of Medical Sciences (IEC no- 149/20) as a prospective, interventional, quasi-randomized, single-blind study, conducted in patients undergoing laparoscopic cholecystectomy with general anaesthesia.

Patients between the age groups of 18 to 65 years, with an American Society of Anesthesiologists physical status classification score of 1 or 2 and body mass index (BMI) between 20-30 kg/m^2, were included in the study.

Patients on anticoagulants, having local sepsis, pre-existing peripheral neuropathies or chronic pain conditions, having any contraindication to regional anaesthesia administration; or those who refused to give consent were excluded from the study.

After taking an informed consent, a total of 82 patients were included in this study. The patients were divided into two groups -ESPB receiving case group and a control group that received conventional analgesia- with 41 patients each.

Patient Grouping

After screening for eligibility, participants were allocated alternately to each group (quasi-randomisation), such that there were 41 participants in each group.

In the preoperative area, patients were instructed on the usage of 10-cm visual analogue scale (VAS) for assessment of pain, graded from 0 (no pain) to 10 (most severe pain). An intravenous line was inserted, and a crystalloid was started.

In group A, the block was not performed, and the patient was shifted to the operation theatre (OT). A placebo was not administered via the ESPB technique due to its invasiveness, which made it ethically incorrect to administer placebo this way. In group B, the patient underwent ultrasound-guided ESPB 30 minutes prior to surgery.

Preoperative ESPB

All patients were monitored for their oxygen saturation, heart rate, blood pressure (non-invasive) and ECG. The group B patients received 15 mL of 0.375% ropivacaine, at the level of T8 vertebrae, bilaterally in either prone or sitting position under USG (Sonosite) guidance using high frequency linear probe (l7-12 Hz). The procedure was performed by a single senior anesthesiologist with expertise in ultrasound-guided procedures.

Details of procedure: After part preparation and under all aseptic conditions, the lower border of the scapula (corresponding to the T7 vertebra) was traced, and the T8 vertebra was localized by moving caudally. The USG linear probe was placed longitudinally, 3-cm lateral to the T8 spinous process. After identification of trapezius and erector spinae muscles superficial to the hyper-echoic transverse process (TP), a 22-gauge, 100 mm insulated, facet-type needle was introduced in a cephalo-caudal orientation. The needle was advanced until it gently hit the TP of T8 vertebra (Figure 1a, 1b). The needle was then retracted slightly, and normal saline (1-2 mL) was administered to check for adequacy of the plane by hydrodissection. After confirmation of the correct location of the needle tip, local

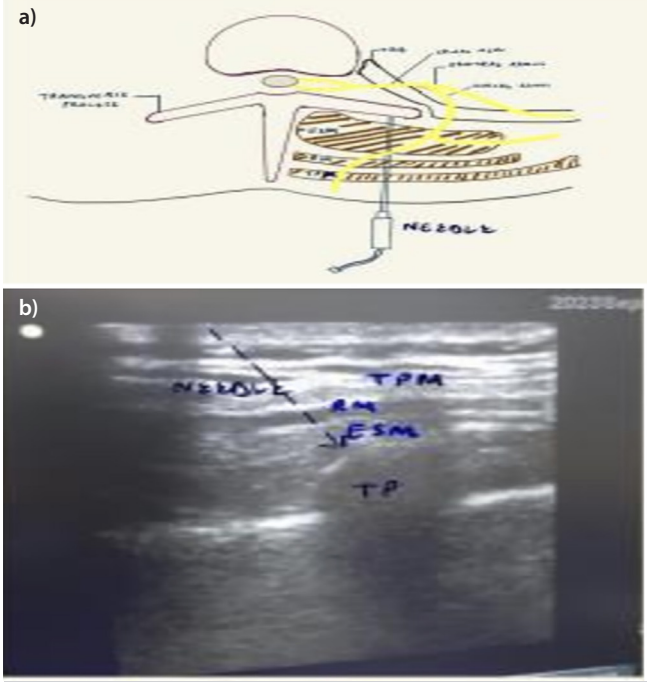

Figure 1. 1a) Line diagram depicting needle localization of needle at T8 transverse process beneath erector spinae muscle, 1b) USG guided image depicting localization of needle at T8 transverse process beneath erector spinae muscle.

TPM: Trapezius muscle, RM: Rhomboid muscle, ESM: Erector spinae muscle, TP: Transverse process

anesthetic agent, ropivacaine 15 mL in 0.375% concentration, was administered (Figure 2a, 2b). The procedure was repeated on the other side. After 15 minutes of block administration, the sensory level was assessed by pin prick 2 levels above and below the administration site, i.e., from T6-T10 vertebral level. If no sensory loss was observed, it was considered a block failure and the case was excluded from the study.

The patient's vitals were assessed every 5 minutes for 30 minutes for any hemodynamic changes and/or any other adverse effects, such as pneumothorax, bradycardia, or hypotension. In the absence of any post procedure, the patient was shifted to the OT.

General Anaesthesia

In the operation theatre, after the standard monitoring devices were connected, patients were given IV midazolam 0.02 mg/kg and fentanyl (0.02 mg/kg) as premedication. Induction was with IV propofol (1.5 mg/kg) and vecuronium (0.08-0.1 mg/kg). All patients were intubated with appropriately sized endotracheal tubes, connected to mechanical ventilators, and maintained on inhalational isoflurane, oxygen, and air. At the completion of surgery, an intravenous dose of ondansetron at 0.1 mg/kg was administered, and isoflurane was discontinued.

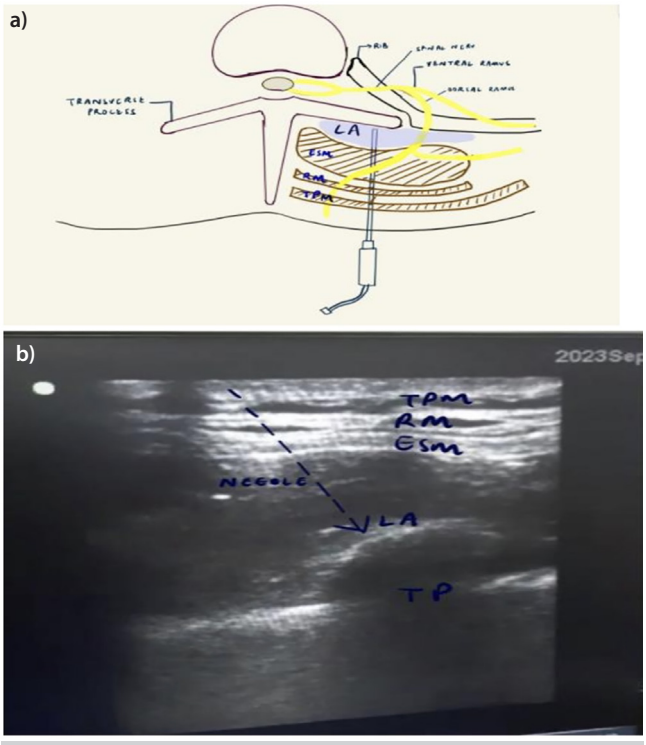

Figure 2. 2a) Line diagram depicting spread of local anaesthetic agent at T8 transverse process beneath erector spinae muscle, 2b) USG guided image depicting spread of local anaesthetic agent at at T8 transverse process beneath erector spinae muscle.

TPM: Trapezius muscle, RM: Rhomboid muscle, ESM: Erector spinae muscle, TP: Transverse process, LA: Local anesthetic

The neuromuscular blockade was reversed with neostigmine 0.05 mg/kg and glycopyrrolate 0.01 mg/kg.

Intraoperatively, for patients of both groups, the standard protocol for analgesia included IV fentanyl (2 mcg/kg) at the time of induction, and repeated as required. Total intraoperative fentanyl consumption was recorded as a marker for adequacy of nerve block. Paracetamol 1 gm IV and inj. tramadol 100 mg (slow over 10 minutes in 10 mL normal saline) were given 15 minutes prior to extubation.

Post-operative Monitoring and Outcome Measures

In the post-operative recovery room, the hemodynamics of patients, of both groups, were monitored. Post-operative multimodal analgesia with IV paracetamol 15 mg/kg every 6 hours was given in all patients. The VAS was assessed by a medical health professional, who was blinded to the grouping of the patients. VAS score was measured at rest (Figure 3a), on coughing (Figure 3b) and on movement (Figure 3c) immediately after being shifted to post-operative area and then at the 2nd hour, 4th hour, 8th hour, 12th hour and in the 24th hour of the post-operative period.

Inj. tramadol 100 mg was given as first line treatment for rescue analgesia if VAS >4 and/or at the patient's request. If pain still failed to subside, injection diclofenac 75 mg, IM was given.

The primary outcome measure of the study was the frequency of tramadol and other analgesic modalities requirements in the first 24 hours of the post-operative period.

Secondary outcome measures were time to rescue analgesia, VAS score as measured at rest, on coughing and on movement in the immediate 1st hour following extubation and then at the 2nd hour, 4th hour, 8th hour, 12th hour and in the 24th hour of the post-operative period along with occurrence of any post procedural side effect.

RESULTS

Age distributions, averageweight, height, and BMI, are shown in Table 1. No statistically significant difference with regard to these parameters was noted between the two groups. Vitals

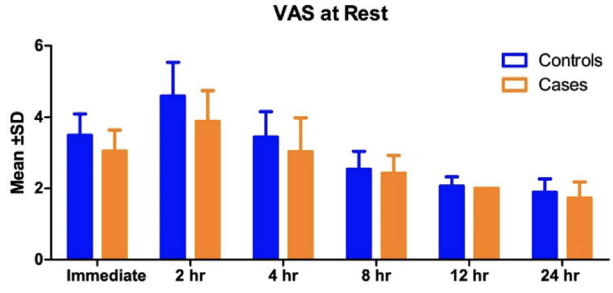

Figure 3a. Bar chart show the mean VAS at rest in control and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

of patients in both groups were comparable and ESPB did not result in any post-procedure hemodynamic instability.

Nausea was significantly more prevalent in the control group than in the case group, and no complications such as pneumothorax or hematoma formation were seen with the ESPB.

Table 2 demonstrates the comparison of frequencies regarding the requirement of tramadol as 0 (not required), 1 (single dose), 1+1 (two doses), and other analgesics during the 24-hour post-operative period, along with intraoperative fentanyl consumption, between controls and cases. The requirement of tramadol (p=0.005), other analgesics (p=0.006) in the post-operative period, as well as intraoperative fentanyl consumption (p=0.015), were significantly more in the control group (group A) as compared to the cases (group B).

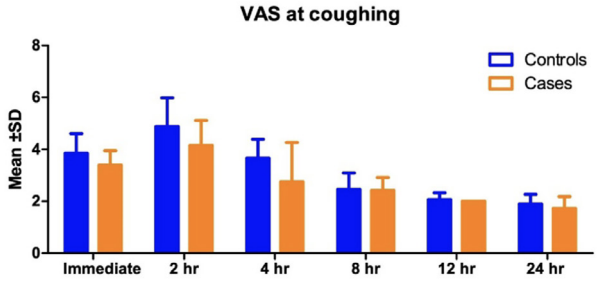

Figure 3b. Bar chart shows the mean VAS at coughing in between controls and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

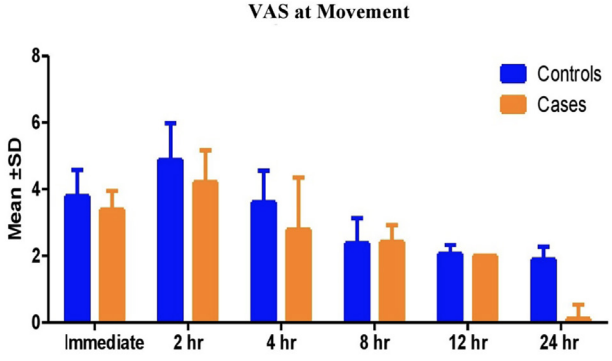

Figure 3c. Bar chart shows the mean VAS at movement in between controls and cases at immediate, 2 hr, 4 hr, 8 hr, 12 hr and 24 hr.

VAS: Visual analogue scale, SD: Standard deviation

The association of the mean time to rescue analgesia (hours) between the control group (group A) and the case group (group B) is shown in Table 3. The mean time required for administration of rescue analgesia was significantly more in group B (p=0.002).

DISCUSSION

Regional anaesthesia and pain management have experienced advances in recent years, especially with the advent of fascial plane blocks. The present study was carried out to assess the efficacy of ESPB for post-operative analgesia in patients undergoing laparoscopic cholecystectomy.

In our study, it was found that the mean duration of rescue analgesia was 1.67±0.42 hr in controls and 2.16±0.54 in cases, and this duration was statistically significantly higher in the ESPB group compared to the control group. Our findings were in agreement with other studies, which used ESPB in various other surgeries. Krishna et al. (16), who performed ESPB using 3 mg/kg 0.375% ropivacaine in patients undergoing elective cardiac surgery with cardiopulmonary bypass, reported the time to first rescue analgesia was 6 hours in the control group vs. 10 hours in the ESPB group. However, they did not conduct a statistical analysis, hence significance through the p-value could not be analyzed.

The exact mechanism of action of ESPB is still not clear. However, the rationale for the statistically significant longer duration of rescue analgesia demand in patients receiving ESPB could possibly be due to the spread of the local anesthetic agent in the paravertebral space, leading to effective analgesia for somatic and visceral pain (17). Studies, comparing the efficacy of ESPB with other blocks in breast surgeries have shown varying results. Sinha et al. (18), who conducted a study to compare efficacy of ESPB and pectoral nerve block (PECS) in patients posted for modified radical mastectomy found that mean duration of analgesia in patients of PECS block group was 7.26±0.69 hours while that in the ESPB group was 5.87±1.47 hours. However, when compared with the control group, fewer scores and lower morphine usage were found in patients receiving ESPB preoperatively in MRM surgeries. It was speculated that

Table 1. Comparison of age, weight, height and BMI between cases and control group

	Controls (n=41)		Cases (n=41)		t	p-value
	Mean	± SD	Mean	± SD		
Age (years)	37.37	11.43	40.95	12.26	-1.37	0.175
Weight (kg)	61.41	7.14	62.71	6.90	-0.83	0.407
Height (cm)	160.78	6.66	158.59	5.50	1.63	0.108
BMI (kg/m^2)	23.74	2.22	24.13	3.06	-2.14	0.035

SD: Standard deviation, BMI: Body mass index.

Table 2. Comparison of frequencies of requirement of tramadol, requirement of other analgesic (inj. diclofenac) in 24 hours and intra-operative fentanyl consumption in between controls and cases

Tramadol frequency	Controls (n=41)		Cases (n=41)		Chi-sq.		[1]p-value
	n	%	n	%			
0a	14	34.15	26	63.41	10.60		0.005*
1b	21	51.22	15	36.59			
1+1c	6	14.63	0	0.00			
Other analgesic inj. diclofenac							
Required	17	41.46	5	12.20	7.52	0.006*	
No requirement	24	58.54	36	87.80			
	Controls (n=41)		Cases (n=41)		t	[1]p-value	
	Mean	± SD	Mean	± SD			
Intra-op fentanyl consumed in miligram	162.80	24.45	151.83	14.13	2.49	0.015*	

*: Significant, [1]: Independent t-test, 0a: -(no requirement), 1b: (single dose), 1+1c: (two doses), SD: Standard deviation.

Table 3. Association of mean duration of rescue analgesia (hr) in between controls and cases

	Controls (n=41)		Cases (n=41)		t	[1]p-value
	Mean	± SD	Mean	± SD		
Time to rescue analgesia (hour)	1.67	0.42	2.16	0.54	-3.24	0.002*

*: Significant, [1]: Independent t-test, SD: Standard deviation.

the better analgesic profile with PECS block was due to the blockade of the medial and lateral pectoral, long thoracic, and thoracodorsal nerves (median and lateral pectoral nerves have been implicated in post-mastectomy surgical pain).

In our study, VAS score was significantly higher in the control group till 0-4th hour after surgery as compared to the case group receiving ESPB. There was no significant difference in VAS score between the two groups from the 8th hour till 24 hours after surgery. The findings of our study are supported by previous studies, like Tulgar et al. (14), who also observed in their study that numerical rating scale (NRS) values were higher and statistically significant in the control group for the first 3 hours after surgery. NRS scores at rest, at the 20th minute, 40th minute, 1st hour, and the 3rd hour were statistically significantly lower in the ESPB group ($p<0.0045$).

We found a statistically significant reduction in total intra-operative fentanyl consumption in the ESPB group. The mean intra-op fentanyl consumed was 162.80±24.45 in controls and 151.83±14.13 in cases. Our results are supported by the study conducted by Sethi and Garg (19), who observed that mean fentanyl requirement during surgery was statistically comparable for the two groups. Therefore, with the administration of ESPB, the intraoperative requirement of opioids is reduced, which further reduces post-operative nausea and vomiting and aids in a smoother recovery for the patient.

No complications such as pneumothorax or hematoma formation were seen with ESPB in the present study, although Ueshima (20) and Hamilton et al. (21) reported pneumothorax as a complication following ESPB.

Most authors affirm that ESPB is a technique that has great advantages over other blocks performed close to the neuronal axis. El Ghamry and Amer (22). Thoracic epidural analgesia, paravertebral block, and quadratus lumborum block are alternative approaches that are used to block somatic and visceral pain for post-operative analgesia. However, these approaches involve difficult and time-consuming techniques.

Study Limitations

Our study is limited by a small sample size; therefore, we were unable to reach enough power to analyze less common side effects. The study was a quasi-randomized study, hence there was an inherent risk of selection bias, however, it provides a possible insight for planning large-sample, well-designed RCTs to draw definitive conclusions. Since ESPB is an invasive procedure, sham placebo was not administered, and therefore, the absence of such a group is a limitation of this study. At the

end of surgery, 1 gm paracetamol and 100 mg tramadol were administered to all the patients, including the case and control groups, and could arguably have affected the initial hour pain scores and time to rescue analgesia. However, the bias due to this was controlled by standardizing the amount of drugs and administering them at the same designated time point in both the case and control groups.

CONCLUSION

ESPB for laparoscopic cholecystectomy is an easy-to-perform, relatively less time-consuming, effective, and safe technique for multimodal anaesthesia, which provides better pain relief, reduced opioid requirement, lower post-operative pain scores, and reduced total post-operative analgesic consumption, with prolonged time to rescue analgesia.

Optimal dose and drug concentration to achieve adequate analgesia are still not clear. Hence, further research and more comparative trials with other regional anaesthetic techniques are required.

Ethics

Ethics Committee Approval: The present study was approved by the Institutional Ethical Committee of Dr. Ram ManoharLohia Institute of Medical Sciences (IEC no- 149/20) as a prospective, interventional, quasi-randomized, single-blind study, conducted in patients undergoing laparoscopic cholecystectomy with general anaesthesia.

Informed Consent: Informed consent was obtained.

Footnotes

Author Contributions

Concept - M.H., S.C., A.G.; Design - M.H., S.C., A.G.; Materials - S.C.; Data Collection or Processing - M.H., S.C., M.K.G., A.G.; Analysis or Interpretation - M.H., S.C., M.K.G., A.G.; Literature Search - M.H., S.C., A.G.; Critical Review - M.H., S.C., M.K.G., A.G.; Writing - M.H., S.C., A.G.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
Turk J Surg 2025;41(2):186-192

Surgical procedure and retrospective comparative series of Microport's AnteriorPath® vs. AMIS® in total hip arthroplasty. Preliminary findings from a single institution

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ABSTRACT

Objective: In recent years, the paradigm of surgical approaches for total hip arthroplasty (THA) has evolved, with portal-assisted techniques emerging as a promising avenue for increasing precision and minimizing invasiveness. The purpose of this study was to compare early experience with the Microport anterior percutaneously (MAP) assisted THA system, with the established AMIS direct anterior approach (DAA).

Material and Methods: A retrospective chart analysis was performed on 200 consecutive patients who underwent DAA or MAP at our institution in 2022. The research was conducted in accordance with the Declaration of Helsinki (as revised in 2013), and was approved by the institutional review board of the University Duisburg-Essen (23-11274-BO).

Results: Two hundred patients were enrolled (100 DAA and 100 MAP; time to follow-up 1.7 years ±88 days). The mean operative time was 81 minutes (MAP) and 67 minutes (DAA, p>0.05). The mean cup tilt angle was 39° (MAP) and 40° (DAA; p>0.05). The mean cup anteversion angle was 13° (MAP) and 16° (DAA; p>0.05). The mean postoperative hemoglobin (Hb) decrease was 2.6 mg/dL ±0.9 mg/dL (MAP) and 2.5 mg/dL ±0.9 mg/dL (DAA; p>0.05). No major complications were documented in any of the 200 cases during the observation period. Additional screw fixation was performed in 7 cases and hybrid stem cementation was performed in 3 cases due to lack of rotational stability. All 10 cases were in patients with DAA. In only one of the 200 cases, two units of RBC were transfused postoperatively in a DAA case after a postoperative decrease of 5.7 mg/dL Hb.

Conclusion: Anterior Path® has been demonstrated to provide reliable results, despite the presence of a steep learning curve. The employment of a working cannula has been shown to enhance the surgeon's perspective during the preparation of the acetabulum. In relation to skin incision, the bikini line incision, which is regarded as advantageous due to its alignment with the cleavage lines, has been identified as a notable benefit that is acknowledged by the patient.

Keywords: AMIS, arthroplasty, bikini incision, DAA, Microport, Medacta, total hip arthroplasty

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INTRODUCTION

Traditional total hip arthroplasty (THA) techniques have shown remarkable success rates in relieving pain, improving function, and enhancing patients' quality of life. However, the invasiveness of conventional procedures can lead to prolonged recovery periods and increased morbidity (1).

In recent years, a growing emphasis on minimally invasive surgical techniques has emerged within the orthopedic community (2). These approaches aim to achieve the same therapeutic goals as traditional THA while minimizing surgical trauma, reducing postoperative pain, shortening hospital stays, and facilitating faster rehabilitation. Consequently, surgeons have been exploring innovative techniques to refine and advance the field of minimally invasive total hip arthroplasty (MI-THA) (2-5).

MI-THA using the direct anterior approach (DAA) has been shown to have advantages over other approaches, such as the posterolateral approach (PLA) and

the SuperPath® (SP) approach (6). Studies have shown that DAA results in less intraoperative bleeding, less muscle damage, and a lower incidence of hip dislocation (7). In addition, DAA has been shown to be an appropriate approach for primary THA in patients with complex acetabular deformities, such as coxa profunda and protrusio acetabuli (8). Recent evidence suggests that DAA is also effective in obese patients, with relatively low complication rates and satisfactory clinical outcomes (9). In addition, DAA has been shown to have comparable radiographic parameters to other minimally invasive approaches, such as the SP approach (10). Overall, the DAA is a safe and effective approach to THA, with advantages in terms of reduced intraoperative bleeding, muscle damage, and postoperative recovery, as well as comparable radiographic parameters and clinical outcomes to other approaches. The MAP technique used in this study involves smaller incisions, less soft tissue disruption, and a modified surgical approach. In addition to the well-known percutaneously assisted Microport approaches already described in the literature, MAP is a percutaneously assisted system for MI-THA that allows skin incision along the cleavage lines (11-15).

Through this innovative approach, we aim to minimize surgical trauma, reduce blood loss, and expedite the recovery process without compromising the accuracy and longevity of the implant. The authors are not aware of any studies comparing conventional DAA and Microport's AnteriorPath® (MAP; AnteriorPath, MicroPort Orthopedics Inc., Arlington, TN, USA) for MI-THA. In this study, we provide an overview of the surgical technique, patient selection criteria, and a comprehensive analysis of early results observed in a cohort of patients who underwent the recently applied MAP procedure compared with those of patients who underwent a well-established DAA at our institution.

MATERIAL and METHODS

This study presents the early results and radiographic outcomes of the newly applied MAP procedure, which combines the principles of minimally invasive surgery with the technical demands of THA. Patients enrolled in this study presented with degenerative osteoarthritis for elective primary THA after failure of non-operative management. Patients were divided into two groups (MAP and DAA). The evaluation included cup orientation, operative time, blood loss, complications that may have occurred during the follow-up period, length of hospital stay, and opiate use. Cup position was measured on scaled standard radiographs by a board-certified surgeon. Approved measurement techniques were used to measure anteversion and abduction of the cup (16).

Statistical Analysis

Data collection was performed by a board-certified surgeon. Statistical analysis was performed using Microsoft Excel (Microsoft Corp., Redmond, WA, USA). Evaluation was carried out with descriptive statistics. For numerical data, means, standard deviations, medians, and quartiles were calculated depending on the distribution. A p-value <0.05 was deemed significant. The cumulative average of surgery time was used to evaluate the learning curve. The Mann-Kendall trend test was used because it does not depend on the normal distribution of the data and is suitable for time series data. The research was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the institutional review board of the University Duisburg-Essen (23-11274-BO).

Preoperative Planning/Patient Positioning

Preoperative digital templating was performed from a standardized anteroposterior radiograph of the pelvis using a radio-opaque size marker. Offset and the presence of any leg length discrepancy were accounted for in the placement of the templated components. The distance from the tip of the greater trochanter to the shoulder of the femoral component was measured as a reference for planned intraoperative placement. The patient was positioned in supine position on the operating table. The skin incision line is marked before disinfecting the surgical area between the costal arch and the median plane of the abdomen, including the entire ipsilateral leg (Figure 1). A straight line is drawn between the proximal patellar pole and the anterior superior iliac spine. Another line is drawn at a 90° angle to the previously drawn line from the anterior superior iliac spine to the dorsolateral side. A third line is drawn from the tip of the greater trochanter at a 90° angle to the first line drawn. This creates a square with the inguinal crease, which serves as another landmark for placement of the skin incision (Figure 1).

Surgical Procedure

All surgeries were performed by two experienced hip surgeons (HH performed MAP; UH performed DAA). A digitalized planning tool (mediCad®, HECTEC™ GmbH, Landshut, Germany) was used for preoperative planning. After the skin incision is made in the bikini line (Figure 1), the subcutaneous preparation is continued to the thigh fascia (Figure 2). In some cases, branches of the lateral femoral cutaneous nerve may be found in the medial area of the skin incision and should be protected. Laterally, the tensor fasciae latae muscle shimmers through the fascia, with a fat-filled interval visible medially. The fascia is split longitudinally at the belly of the tensor fasciae latae muscle, and the muscle is bypassed medially; the muscle interval is bluntly dissected

deeply with the surgeon's finger. A blunt Hohmann retractor can now be placed laterally onto the proximal femur (Figure 2c). The sartorius muscle is medialized with a round hook to ligate or coagulate the palpable perforator vessels in the muscle interval, to achieve cranial dissection. Once the surgeon's finger can pass ventrally around the neck of the femur, a MIS Hohman hook can be placed cranially on the neck of the femur (Figure 2d). Another MIS hook is placed caudally on the femoral neck (Figure 2b) after adhesions of the ventral capsule have been loosened with the Cobb raspatory, and a fourth MIS hook is placed on the ventral acetabulum (Figure 2a). The hip joint capsule is now visibly stretched (Figure 2b). After the ventral capsule has been removed and the hooks on the femoral neck have been moved intracapsularly, the double femoral neck osteotomy is performed. A medial osteotomy is performed on the anatomic collum, and a second wedge-shaped osteotomy is performed on the surgical collum. After removal of the bone wedge, the femoral head can now be removed from the acetabulum (Figure 3). It is helpful to screw the corkscrew in at the transition to the cartilaginous surface of the femoral head or within the cartilaginous surface of the femoral head (Figure 3A). This may prevent the corkscrew from being torn out of the cancellous femoral bone when removing the femoral head. The percutaneously assisted targeting instrument set is inserted, and the working cannula is inserted through a stab incision (Figure 4). The first reamer may be inserted through the skin incision for medial opening of the acetabulum, if desired. All following reamers are then inserted into the acetabulum through the bikini incision and reamed through the percutaneous working sheath until the desired size is reached. The original cup is also delivered through the working cannula (Figure 4). To prepare the femoral shaft, a slit is made in the peritrochanteric musculature dorsolateral to the tip of the greater trochanter using a monopolar electrocautery blade to position the femoral elevator at this point. The patient's leg is then lowered, adducted, and externally rotated to achieve extension of the hip (Figure 5). In conjunction with adduction of the operated leg and external rotation, and elevation of the proximal femur by the assistant using the Femoral elevator hook, stem preparation can now be performed as usual.

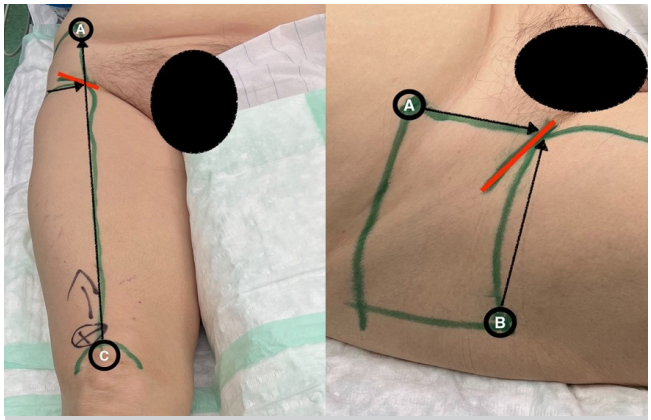

Figure 1. Sketch of landmarks for bikini incision (red line). A: Anterior superior iliac spine. B: Tip of the greater trochanter. C: Proximal patellar pole.

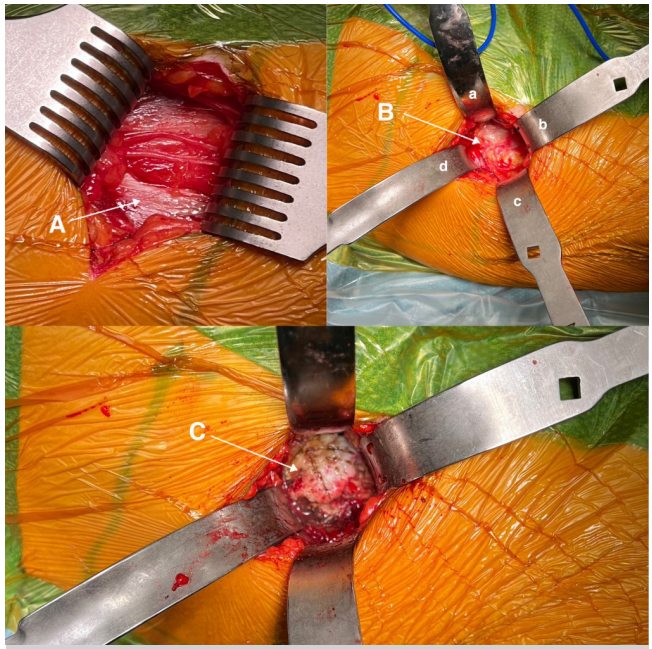

Figure 2. Illustration of the surgical situs after subcutaneous preparation with exposure of the fascia lata (A), after opening the muscle interval and positioning the 4 hooks on the anterior acetabular rim (a), on the caudal femoral neck (b), laterally on the greater trochanter (c), and on the cranial femoral neck before (B), and after (C) removal of the joint capsule.

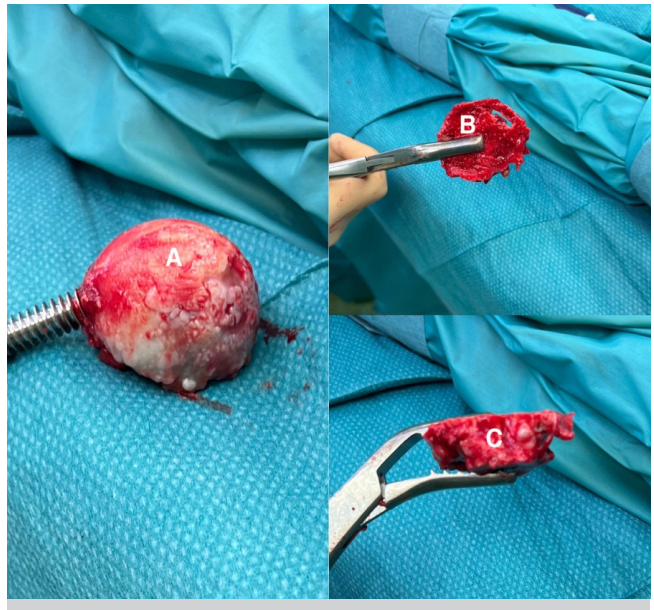

Figure 3. View of the femoral head (A) and femoral neck disc removal from an axial view (B) and lateral view (C) after double osteotomy.

RESULTS

Two hundred patients were enrolled: 100 patients received 100 patients received a DAA and 100 received an MAP. The mean age in both groups was 68 years (±11 y.). 59% (MAP) and 72% (DAA) of the patients were women. The mean body mass index (BMI) was similar in both groups, with a mean BMI of 26.96 kg/m^2 in the (MAP) group and 27.64 kg/m^2 in the (DAA) group. The average time to follow-up in both groups was 1.7 years (±88 days). The mean operative time was 81 minutes (MAP) and 67 minutes (DAA), p>0.05. The average cup tilt angle was 39° (MAP) and 40° (DAA; p>0.05). The average cup anteversion angle was 13° (MAP) and 16° (DAA), p>0.05. The mean postoperative hemoglobin (Hb) decrease was 2.6 mg/dL ±0.9 mg/dL (MAP) and 2.5 mg/dL ±0.9 mg/dL (DAA, p>0.05). Additional screw fixation of the cup was performed in 7 cases and cementation of the stem was performed in 3 cases due to lack of intraoperative rotational stability. All 10 cases involved patients in the DAA group. In only one of 200 cases, two units of RBCs (approximately 600 mL) were transfused postoperatively after the patient lost 5.7 g/dL Hb intraoperatively. This transfusion case also involved a patient in the DAA group. Our results showed that there is a steep learning curve within the first MAP. Analysis of the learning curve showed that the average operating time for the first 5 MAPs was 140 minutes, with the operating times decreasing over time and leveling off at an average of 81 minutes within the first 100 MAPs studied (τ=0.093; p=0.17, Figure 6).

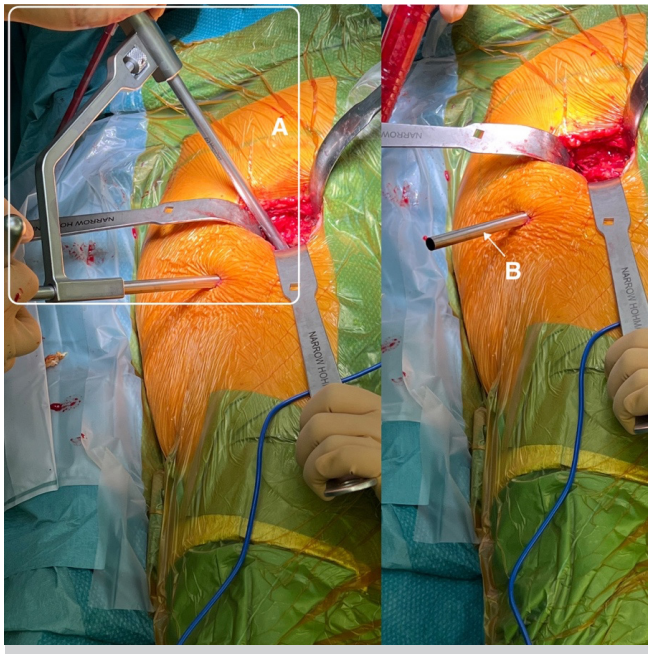

Figure 4. Positioning of target instrument set (A) and remaining working cannula (B) after target instrument set removal.

DISCUSSION

In this comparative study of 200 cases, 100 underwent a DAA and the remaining 100 underwent anterior path (MAP). Both cohorts had a mean age of 68 years, although the DAA group had a higher proportion of female patients. BMI was similar in both groups. The study found that, on average, procedures performed with the DAA technique were completed more quickly than those performed with the MAP technique. In addition, there were only slight differences in the surgical placement of the prosthetic cup between the two methods. In addition, hemoglobin levels decreased at a similar rate after surgery in both cohorts. Notably, there were no reported complications in the overall patient

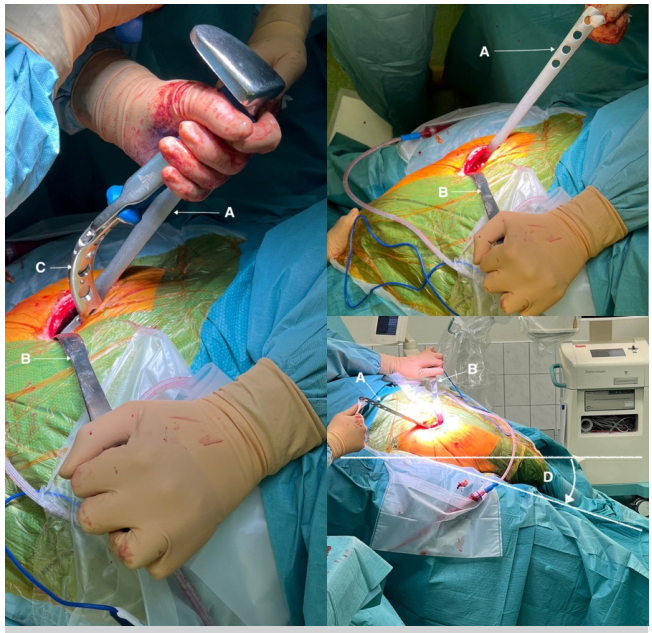

Figure 5. A femoral elevator (A) is placed laterally under the greater trochanter, and another hook (B) is placed on the medial calcar for better exposure. The proximal femur is now exposed by adduction and external rotation as the table legs are lowered.

Figure 6. Learning curve analysis of AnteriorPath surgeries over the course of 100 procedures (X-axis: duration of surgery; Y-axis: date of surgery).

population, although some additional surgical procedures were required in selected DAA cases (screw fixation of the cup, stem cementation). The study also highlighted a learning curve associated with the MAP technique, with notable improvements in operative time observed following the initial procedures.

Operative Time and Complication

The shorter operative times associated with the DAA observed in this study are consistent with findings from the literature suggesting that the DAA may be associated with efficient surgical technique and potentially faster recovery; although, the difference in operative times requires further investigation to establish clinical significance (10,13). Both MAP and DAA demonstrated similar short-term outcomes and postoperative hemoglobin decline. This finding is consistent with studies reporting no difference in blood loss or transfusion rates between another Microport percutaneously assisted MI-THA approach (SuperPath) and DAA, as reported in studies (12,17). Regarding the very low transfusion rate of 0.5% (1 in 200 patients) found in our study, a clear reduction in the need for transfusion can be seen when comparing the results of the present study with the transfusion rate of Penenberg et al. (3). They published a comparable study of 226 patients who underwent the PATH technique, also developed by Microport, showing a transfusion rate of 10% (3). The need for additional screws and cementation in the DAA group, as seen in this study, may indicate a need for increased intraoperative stability, which has also been noted in the literature (3,11).

Implant Positioning

We found no significant difference in cup orientation between the two groups. However, the clinical implications of the observed differences in cup tilt and anteversion angles between the two approaches are not entirely clear and warrant further investigation to determine their significance on patient outcomes (12,13). The recommendation for acetabular cup placement in THA is a general guideline aimed at achieving optimal alignment and stability. Individual patient characteristics and pre-existing conditions may require personalized adjustments to these guidelines. An example of this is flat back syndrome, which can affect pelvic tilt and may require a different cup orientation.

Dennis et al. (17) indicated that customizing the position of the cup based on spinopelvic (SP) mobility patterns can result in a significant reduction in the incidence of prosthetic impingement. The incidence rate was found to be as low as 9%, in contrast to the range of 18-61% observed with non-individualized positions. However, cup placement had no effect on bone impingement, which occurred in approximately one-third of patients regardless of cup orientation. In addition, the study highlighted specific risk factors associated with impingement during flexion and extension, including age, lumbar flexion, pelvic tilt, pelvic rotation, and functional femoral stem anteversion. These findings strongly suggested that performing a preoperative SP analysis to determine an individualized cup orientation can effectively reduce the occurrence of prosthetic impingement. However, it is important to remember that bone impingement remains an important consideration in THA planning (18). Another study by Danaei and McPhee (18) presented an optimization approach based on a model of acetabular cup orientation in THA. This approach uses patient-specific motion capture data to calculate hip contact forces and the relative orientation of the femur and pelvis through a musculoskeletal model. Two measures, angular impingement distance and angular edge loading distance, were defined to quantify the risk of impingement and edge loading at different cup orientations. The optimization framework used three criteria to determine the optimal cup orientation, thereby addressing the trade-off between impingement and edge-loading risks. This approach is particularly noteworthy because it eliminates the need for force plate measurements by estimating ground reaction forces and moments, making it more practical and cost-effective. The results highlight the importance of patient-specific factors, such as pelvic tilt, in determining optimal cup alignment, particularly affecting cup anteversion values. The results suggest that deviations from the Lewinnek safe zone may be necessary to achieve individually optimal results. The low computational complexity of the method made possible by the use of analytical formulas, makes it suitable for real-time application in both preoperative and intraoperative settings (19,20). In conclusion, both MAP and DAA are effective surgical approaches to MI-THA, each with different operative timeframes and technical considerations. The choice of approach should take into account patient-specific factors, surgeon experience, and the nuanced differences highlighted in the literature, such as (11-13,17).

Skin Incision

Skin incisions aligned with the cleavage lines (also known as Langer lines) are generally considered superior due to reduced scarring, faster healing, and improved cosmetic results, such as with the bikini incision. These lines correspond to the natural orientation of collagen fibers in the dermis, and incisions made along them tend to be less disruptive. Studies support that following these lines can minimize the tension on the wound, resulting in a more aesthetically pleasing and functional scar (15,21-23).

Patient Reported Outcome Measures (PROM)

The absence of PROMs in the current investigation can be attributed to the limited duration of the study, which only

provided short-term results. A comprehensive examination and meta-analysis (published in 2019 in the esteemed Journal of Arthroplasty) meticulously compared the PROMs associated with DAA and other conventional THA techniques, as well as minimally invasive THA (MI-THA) procedures. The authors of this study discovered that there were no discernible disparities in PROMs, encompassing pain levels, functional capabilities, and postoperative complications, among the aforementioned surgical approaches. Nevertheless, it is imperative to acknowledge that the authors expressed some reservations, highlighting that the studies encompassed within their systematic review exhibited a level of quality that ranged from substandard to moderate, thereby necessitating the inclusion of further high-quality investigations to substantiate their conclusions (24).

This study, along with the Penenberg et al. (3) PATH study and the Ramadanov et al. (11) SuperPATH study, collectively serves to further the understanding and knowledge in the field of minimally invasive (MI-THA). These studies highlight that different surgical techniques can effectively achieve comparable goals of joint stability and accurate placement of hip components. Each technique has unique considerations and potential advantages that enhance the adaptability and overall success of MI-THA. These valuable contributions play a critical role in expanding the range of surgical options available to orthopaedic surgeons, ultimately leading to improved patient outcomes in hip replacement surgery (3,4,11-13).

Potential Limitations

Limitations include the retrospective design, potential selection bias, and reliance on short-term follow-up data that may not fully capture long-term outcomes or rare complications. In addition, the comparative analysis of DAA and MAP approaches was limited to the experience of a single institution, which may affect the generalizability of the findings. It is recommended that future studies validate these preliminary results and investigate the impact of individualised cup orientation on patient-specific outcomes in MI-THA.

CONCLUSION

Anterior path has been demonstrated to provide reliable results, despite the presence of a steep learning curve. The employment of a working cannula has been shown to enhance the surgeon's perspective during the preparation of the acetabulum. In relation to skin incision, the bikini line incision, which is regarded as advantageous due to its alignment with the cleavage lines, is recognized by patients as beneficial.

Ethics

Ethics Committee Approval: The Mann-Kendall trend test was used because it does not depend on the normal distribution of the data and is suitable for time series data. The research was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the institutional review board of the University Duisburg-Essen (23-11274-BO).

Informed Consent: All authors have given a written declaration of consent for publication of the data obtained in this study.

Footnotes

Author Contributions

Concept - H.H., P.G.; Design - H.H.; Supervision - S.F., P.G.; Data Collection or Processing - A.G., J.G.; Analysis or Interpretation - A.G., M.M.; Literature Search - P.G., R.N.; Critical Review - H.H., M.D.; Writing - P.G., S.F., R.N.

Conflict of Interest: No conflict of interest was declared by the authors.

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ORIGINAL ARTICLE
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Endoscopic management of post-cholecystectomy cystic duct stump biliary leakage: Single-centre experience

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ABSTRACT

Objective: Biliary leakage from the cystic duct stump following cholecystectomy is a significant postoperative complication. Endoscopic retrograde cholangiopancreatography (ERCP) with stenting has become the preferred treatment due to its minimally invasive nature and high success rates.

Material and Methods: This study retrospectively evaluates the efficacy of ERCP for managing cystic duct stump leakage. A total of 29 patients treated between February 2017 and April 2024 were analyzed. Inclusion criteria included patients with confirmed cystic duct leakage. Primary and secondary success rates were defined as bile leakage cessation and absence of biliary fistula after stent removal, respectively.

Results: The group consisted of 20 females and 9 males, with an average age of 64.14 years and median body mass index of 27.7 kg/m^2. Cholelithiasis without acute cholecystitis was the primary surgical indication in 48% of cases. ERCP was the first-choice treatment for 89.7% of patients, using stents based on common bile duct width. Initial success was achieved in 89.7% of cases, with a mean drain removal time of 14.3 days. Secondary success was seen in 96.4% of patients. Complications, such as pancreatitis and stent migration, occurred in 13.8% of cases.

Conclusion: The study highlights the effectiveness of ERCP in managing cystic duct leaks, with high success and acceptable complication rates, confirming it should be the treatment of choice for this condition.

Keywords: Cholecystectomy, biliary leakage, endoscopy

INTRODUCTION

Cholecystectomy, a surgical removal of the gallbladder, has evolved significantly over the past few decades, with laparoscopic techniques becoming the gold standard due to their minimally invasive nature. However, despite advancements, the risk of bile duct injuries and leaks remains a pertinent issue (1,2).

Bile leakage after cholecystectomy, particularly from the cystic duct stump, is a significant postoperative complication that can lead to considerable morbidity. The incidence of bile leaks ranges from 0.3% to 2.7% and is often associated with increased hospital stay, readmissions, and a need for additional interventions (1,3). The pathophysiology of cystic duct stump leaks involves incomplete closure or ischemic necrosis of the cystic duct remnant, leading to persistent biliary drainage into the peritoneal cavity (1,2). Early identification and management of this condition are crucial to prevent complications such as bile peritonitis, sepsis, and long-term biliary fistula formation (1). While surgical re-intervention was traditionally the mainstay of treatment, endoscopic approaches have shown superior outcomes in terms of patient recovery and complication rates (1,2,4). Endoscopic retrograde cholangiopancreatography (ERCP) with stenting has emerged as the preferred treatment modality due to its minimally invasive nature and high success rates (1).

Current literature emphasizes the importance of early ERCP intervention to manage bile leaks effectively. Studies have shown that timely ERCP can significantly reduce morbidity and improve patient outcomes compared to delayed interventions (1,2,5). Nowadays, clinicians are focused on optimizing ERCP techniques, including the development of more advanced stents and improved imaging modalities to enhance the detection and management of biliary leaks (1,4).

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Aim

This study aims to evaluate the efficacy and safety of endoscopic transpapillary drainage using ERCP for managing postoperative cystic duct stump leaks after cholecystectomy.

MATERIAL and METHODS

Twenty-nine consecutive patients with biliary leakage from the cystic duct stump after cholecystectomy, with no evidence for choledocholithiasis or cystic duct stones treated in our department between February 2017 and April 2024 were enrolled in the study. The data from the electronic medical records of the patients was collected and analysed. Due to the retrospective character of the study, it was not subject to the assessment of the institutional review board. Inclusion criteria: patients with cystic duct stump leakage confirmed by cholangiography (during ERCP) (Figure 1), clinical assessment (typical content and drainage volume of the external drain placed at the time of surgery), and abdominal ultrasonography, who underwent ERCP with stenting of the biliary tract, were included in the study. In all patients, the cystic duct was closed with two metal clips and drainage of the peritoneal cavity was performed during the primary surgery.

The initial success of the endoscopic procedure was defined as the reduction of bile leakage confirmed by clinical examination and ultrasound assessment, which indicated cessation of bile leakage and an absence of abdominal fluid collections, resulting in removal of the percutaneous drain.

The secondary success of the endoscopic procedure was defined as the lack of the fistula after removal of the biliary stent.

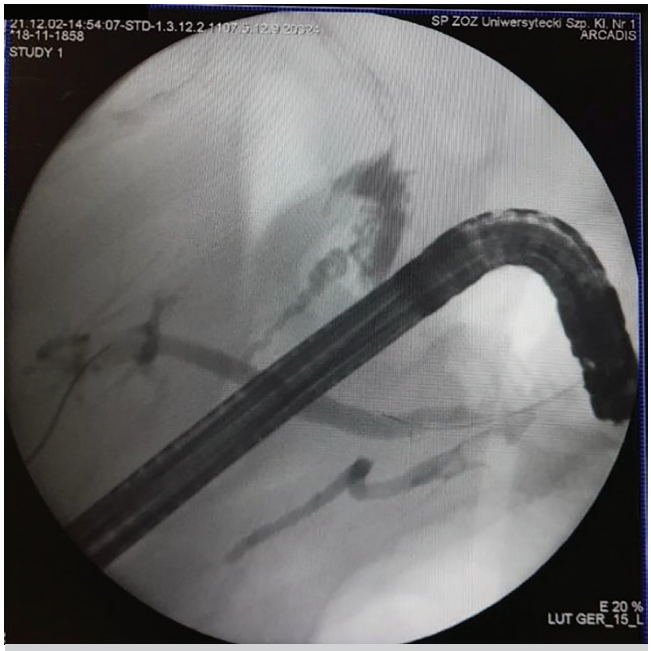

Figure 1. Cholangiogram showing cystic duct stump leakage.

Statistical Analysis

Descriptive statistics were used to summarize patient demographics, clinical characteristics, and treatment outcomes. Continuous variables were presented as means with standard deviations and medians with ranges, while categorical variables were reported as frequencies and percentages. Success rates and complication rates were calculated as proportions.

RESULTS

The study group consisted of 29 patients, with a gender distribution of 20 females (69%) and 9 males (31%). The average age of the patients was 64.14 years, with a median age of 66 years, ranging from 24 to 86 years. The average body mass index (BMI) of the patients was 28.53 kg/m^2; the median BMI was 27.7 kg/m^2, ranging from 21.8 to 38.9 kg/m^2 (Table 1).

The indication for primary surgical treatment (cholecystectomy) was cholelithiasis without acute cholecystitis in 14 patients (48%), gangrenous acute cholecystitis in 7 patients (24%), acute cholecystitis without gangrene in 5 patients (17%), chronic cholecystitis in 2 patients (7%), and empyema of the gallbladder in 1 patient (3%). Laparoscopic cholecystectomy was the treatment of choice in these patients. In 5 cases (17.2%), the technique was changed to laparotomy intraoperatively due to difficult surgical conditions caused by inflammation during the procedure (3 cases of acute cholecystitis without gangrene, 1 case of gangrenous cholecystitis, 1 case of empyema of the gallbladder) (Table 2).

An endoscopic procedure was the first choice for the treatment in 26 patients (89.7%), 2 patients had previously undergone laparotomy with an unsuccessful attempt to close the fistula due to clinical instability in the course of peritonitis and sepsis, and 1 patient had undergone percutaneous ultrasound-guided drainage of the biloma. All the ERCP procedures were performed in a surgical theatre under intravenous sedation using midazolam (5 milligrams) and fentanyl (200 micrograms). During the procedure, the patients had their heart rate and oxygen saturation monitored and remained under intensive care 1 hour after the procedure.

Table 1. Patient characteristics

Characteristic	p-value
Total patients	29
Gender distribution	20 females (69%), 9 males (31%)
Average age (years)	64.14±14
Median age (years)	66 (24-86)
Average BMI (kg/m^2)	28.53
Median BMI (kg/m^2)	27.7 (21.8-38.9)

BMI: Body mass index

During the procedure, each patient underwent successful sphincterotomy or precutting of the ampulla of Vater. Self-expandable metallic stents (SEMS) and Amsterdam biliary stents were used in 20 patients (69%) and 9 patients (31%), respectively. In the SEMS group, additional implantation of double pigtail plastic stents (7 Fr, 12 cm) was performed in 2 patients to achieve proper management of the leakage. Stent type was chosen depending on the width of the common bile duct (CBD). Amsterdam-type straight plastic stent was implanted in CBD ≤4 mm, SEMS for CBD 4-8 mm and SEMS with double pig-tail drainage biliary catheter for CBD >8 mm (Table 3).

The mean time from cholecystectomy to ERCP was 12.4 days, with a median of 5 days (ranging 1-63 days). Only two patients waited for ERCP longer than 35 days (55 and 65 days respectively); this was caused by technical difficulties and transfer from other hospitals. Excluding these patients, the mean time decreases to 9 days, and the median remains the same, which ranges from 1 to 35 days. The waiting time for the procedure was dictated by the patient's stable clinical condition, the time needed to perform imaging diagnostics, and the technical capabilities of the endoscopy facility.

Initial Success

Initial endoscopic success, confirmed through ERCP (fixing the distal stent ring above the leakage site), clinical examination (the bile leakage stopped), and ultrasound (no fluid collection in the abdominal cavity), was achieved in 26 patients (89.7%) (Figure 2). In this group of patients, a external drain was removed between 3 and 40 days after ERCP (mean 14.3 days, median 10 days).

In the group of patients with no initial endoscopic success (persistent bile leakage despite proper stent placement), all underwent the ERCP procedure again. The mean time was 5.6 days and the median was 6 days (ranging from 3 to 8 days). In all these patients, bile leakage was stopped after the second ERCP with stent reimplantation, which allowed the removal of the external drain 12-14 days (median 14 days) after the second endoscopic intervention.

Secondary Success

Secondary success was evaluated during the cholangiography after endoscopic removal of the biliary stent. Twenty-eight patients underwent this procedure 30-180 days after successful biliary stenting (mean 78 days, median 62 days). One patient died during the follow-up due to non-surgical causes. No signs of persistent biliary fistula were found in 27 patients (96.4%) (Figure 3). In one patient (3.6%) signs of a biliary fistula were found despite maintaining the plastic biliary stent (Amsterdam 10 Fr 9 cm) for 50 days. This patient underwent reimplantation of the biliary stent and remains in follow-up (Table 4).

Table 2. Indications for primary surgical treatment

Indication	Number of patients (%)
Cholelithiasis without acute cholecystitis	14 (48%)
Gangrenous acute cholecystitis	7 (24%)
Acute cholecystitis without gangrene	5 (17%)
Chronic cholecystitis	2 (7%)
Empyema of the gallbladder	1 (3%)

Complications

Four patients (13.8%) presented complications resulting directly from ERCP. Two of them were diagnosed with acute pancreatitis (successfully treated conservatively), and in two cases the biliary stent migrated proximally or distally, resulting in failure to achieve the initial success, which required further endoscopic procedures.

Six patients (20.7%) were diagnosed with complications caused by primary surgical condition and treatment. Surgical site infection requiring additional treatment and prolonged hospitalisation occurred in 3 patients (10.4%). Additionally, enteroenteric fistula occurred in 1 patient, and acute appendicitis occurred in 1 patient. One patient developed respiratory failure due to sepsis, requiring intensive care unit hospitalization (Table 5).

DISCUSSION

The findings of this study reinforce the efficacy of endoscopic transpapillary drainage using ERCP in managing cystic duct stump leaks after cholecystectomy. The initial success rate of 89.7% aligns with existing literature, which reports success rates ranging from 85% to 95% for ERCP in treating postoperative bile

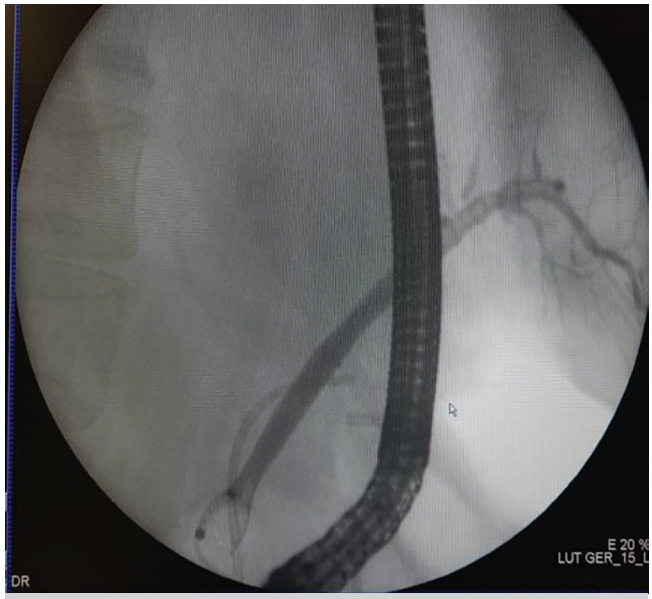

Figure 2. Initial endoscopic success (no bile leakage) after SEMS implantation.

SEMS: Self expandable metal stent

leaks (2,6,7). This high success rate underscores the reliability of ERCP as a first-line treatment, particularly when compared to more invasive surgical options (2,8).

When compared to other treatment modalities, such as surgical re-intervention, ERCP offers several advantages. It is less invasive, has a shorter recovery time, and is associated with fewer complications. For instance, a study by Baron and Harewood (1) demonstrated that ERCP had a higher success rate and a lower complication rate compared to surgical approaches (2,7). Additionally, the use of SEMS improved the outcomes, especially in patients with wider CBDs (2,7-9).

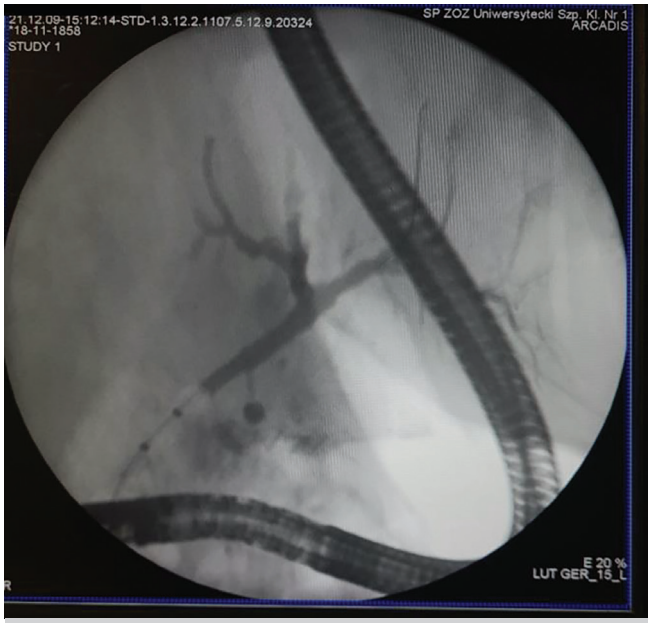

Figure 3. Secondary success-no bile leakage after removal of the stent.

Table 3. ERCP treatment details	
Variable	**p-value**
Patients treated with SEMS	20 (69%)
Patients treated with Amsterdam biliary stents	9 (31%)
Additional DPT plastic stents in SEMS group	2
Mean time from cholecystectomy to ERCP (days)	12.4 (median 5, range 1-63)
SEMS: Self expandable metal stent, BMI: Body mass index, DPT: Double pig-tail	

Table 4. Initial and secondary success rates	
Success rate	**p-value**
Initial success	26 patients (89.7%)
Secondary success	27 patients (96.4%)
No persistent biliary fistula	27 (96.4%)

Table 5. Complications	
Complication	**Number of patients (%)**
Acute pancreatitis	2 (6.9%)
Stent migration	2 (6.9%)
Surgical site infection	3 (10.4%)
Enteroenteric fistula	1 (3.4%)
Acute appendicitis	1 (3.4%)
Respiratory failure due to sepsis	1 (3.4%)

Despite its high success rate, ERCP is not without challenges. Complications such as acute pancreatitis and stent migration are well-documented risks associated with the procedure (2,10). The incidence of these complications in our study (13.8%) is comparable to other reports, suggesting that while ERCP is effective, it requires careful patient selection and management to mitigate risks (2,10). Furthermore, the need for repeating ERCP in a subset of patients highlights the importance of close follow-up and the potential for multiple interventions to achieve optimal outcomes (2,8,10).

The management of postoperative bile leaks is inherently complex and often requires a multidisciplinary approach. Collaboration between surgeons, gastroenterologists, and radiologists is essential to ensure comprehensive care. For example, the involvement of interventional radiologists can be crucial for managing complications such as bile collections and abscesses that may arise during treatment (2,9,11). Additionally, the role of nursing and supportive care in monitoring and managing patients post-ERCP cannot be overstated (2,12).

CONCLUSION

In conclusion, this study confirms that endoscopic transpapillary drainage is a highly effective and relatively safe treatment for cystic duct stump leaks following cholecystectomy. Given its minimally invasive nature and high success rates, ERCP should be considered the treatment of choice for this complication. Future research should focus on optimizing patient selection criteria and procedural techniques to further enhance outcomes and minimize complications.

Ethics

Ethics Committee Approval: This retrospective study is not a medical experiment or a clinical trial performed on a patient, therefore it did not require a ethics committee approval.

Informed Consent: Retrospective study.

Footnotes

Author Contributions

Concept - W.C., T.K., P.H.; Design - J.S.; Supervision - A.D., J.S., P.H.; Materials - T.K.; Data Collection or Processing - W.C., T.K.; Analysis or Interpretation - W.C., T.K.; Literature Search - W.C., A.D.; Critical Review - A.D., J.S.; Writing - W.C., P.H.

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ORIGINAL ARTICLE
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Video-assisted mitral valve reoperation through a right minithoracotomy: A single-center experience

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ABSTRACT

Objective: The study aim was to determine our results of minimally invasive technique without aortic cross clamping for mitral valve surgery after previous cardiac surgery.

Material and Methods: We performed 24 consecutive mitral valve surgeries between January 2015 and December 2018 in patients with a history of previous cardiac surgery. The procedure was performed using video-assisted right minithoracotomy, femoro-femoral bypass, a temperature of 26 °C, and cardiopulmonary bypass without aortic cross-clamping.

Results: Mitral valve replacement was performed in 12 (50%) of these patients, and mitral valve repair was performed in the same number (50%). The mean ejection fraction was 46.08±6.52% and the mean age was 61.52±11.48 years. Eighteen patients (75%) had previous coronary artery bypass graft surgery, and six patients (25%) had previous mitral valve surgery. In terms of postoperative complication frequencies that patients have experienced, one of the patients (4.1%) had postoperative low cardiac output syndrome. Two patients (8.3%) had renal failure; 2 patients (8.3%) had pneumonia, and stroke was seen in one patient (4.1%) postoperatively, whereas 2 patients (8.3%) had reoperation for bleeding. The mean postoperative packed red blood cell transfusion requirement at 48 hours was 1.00±1.10 units. The mean length of hospital stay was 10.54±4.37 days.

Conclusion: Minimally invasive port access procedure via right thoracotomy may be a safe and effective option in selected patients who need mitral surgery and have a history of prior sternotomy.

Keywords: Reoperation, ventricular fibrillation, mitral valve surgery

INTRODUCTION

Redo cardiac surgeries are associated with a significantly higher risk of complications and death during the perioperative period, especially when involving reoperations on the mitral or tricuspid valves (1). Individuals with open or functioning coronary bypass grafts, with prior aortic valve replacements, or a heavily calcified aorta present additional technical challenges. Conventional median sternotomy in these cases is complicated by dense adhesions, heightened bleeding risk, potential graft injury, and suboptimal valve exposure-factors that collectively increase procedural complexity. In these cases, a right-sided thoracotomy serves as a viable alternative to the traditional median sternotomy approach (2). Minimally invasive mitral valve reoperation using video assistance offers a strategic alternative, mitigating many risks associated with repeat sternotomy. This approach minimizes trauma to mediastinal structures, reducing the likelihood of damage to the heart, major blood vessels, phrenic nerve, and existing bypass grafts. Enhanced visualization and controlled dissection decrease intraoperative hemorrhage and postoperative complications (3). Furthermore, the technique provides superior visualization of the mitral valve anatomy achieved with minimal to moderate retraction, facilitating precise surgical repair while preserving thoracic stability. In most cases, the mitral valve is readily accessible through the right side of the chest. Although the distance to the valve is considerable, it can be managed effectively with the use of extended surgical instruments. This approach also allows access to the superior and inferior vena cava, as well as entry into the right atrium, enabling the performance of additional procedures on the right side of the heart.

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For many years, hypothermia-induced ventricular fibrillation has been utilized as a method of myocardial protection during coronary surgery. This technique is grounded in the understanding that a decompressed heart in ventricular fibrillation at a temperature of 26 °C requires significantly less energy. In this study, we aimed to share our experience of minimally invasive mitral valve surgery without aortic cross clamping after previous cardiac surgery.

MATERIAL and METHODS

A total of 24 consecutive redo minimally invasive mitral valve surgeries with insignificant or minimal aortic insufficiency, performed between January 2015 and December 2018, were retrospectively analyzed. The study protocol was approved by the İstanbul Bilim University Ethics Committee (date: 07.06.2017, no: 44140529/2017-66). Preoperative computed tomography (CT) angiography was routinely performed in all patients to evaluate the suitability of femoral arterial and venous cannulation for cardiopulmonary bypass (CPB). Imaging assessment focused on aortoiliac patency, vascular caliber, and anatomic variations that could preclude safe peripheral cannulation.

The presence of significant aortic insufficiency (grade 2+ or more) was an exclusion criterion as it limits the visibility of the surgical field and may cause coronary malperfusion. If coronary artery disease cannot be effectively treated with percutaneous coronary intervention (PCI), a sternotomy may still be necessary to provide surgical access. The presence of pectus excavatum would also be an exclusion criterion, because of the difficulty of mitral valve exposure due to displacement of the cardiac chambers by the malformed sternum. Also, individuals with pleural adhesions and thickening were excluded from the study. Antithrombotic drugs were discontinued in patients undergoing PCI one week before the procedure, and the surgery was postponed 3 months after PCI. The EuroSCORE risk model provides standardized preoperative risk quantification for in-hospital mortality and severe morbidity following cardiac surgery, supporting surgical decision-making and patient counseling. The EuroSCORE algorithm incorporates multiple preoperative variables including patient demographics (age, gender), cardiovascular history, and significant comorbidities to generate individualized risk estimates for postoperative mortality and major adverse cardiac events. The updated EuroSCORE II version enhances predictive accuracy through the inclusion of additional clinical parameters and the application of contemporary statistical modeling techniques.

Surgical Procedure Description

The patients were placed in the 30-degree lateral decubitus position following the induction of general anesthesia and single-lumen endotracheal intubation. Intraoperative transesophageal echocardiography (TEE) was systematically performed in all cases, with comprehensive assessment of biventricular function, valvular morphology/hemodynamics, and exclusion of intracardiac pathology prior to cannulation. The surgical technique utilized two thoracic ports along the anterior axillary line for the video camera, cardiotomy vent, and CO_2 insufflation (2 L/min), in addition to a 4-6 cm incision made in the right fourth intercostal space.

A 4-cm longitudinal skin incision was performed on all patients in the femoral region, centered medial to the femoral pulse at the inguinal crease. The direct arterial cannulation method was used. The femoral artery was encircled with a snare proximally, positioned over the cannula, and secured with a clamp distally.

Cannulation and CPB Establishment

Femoro-femoral CPB was achieved through percutaneous insertion of a 17 Fr arterial cannula (Medtronic, MN, USA) and a 30/33 Fr multistage venous cannula (Medtronic) via the femoral vessels. Venous drainage was augmented with a 17 Fr bicaval cannula (Medtronic) placed percutaneously in the right internal jugular vein under ultrasound guidance. All procedures incorporated an intraoperative cell salvage system (Cell Saver Elite+, Haemonetics, MA, USA) for autologous blood recovery.

Minimally Invasive Access

Surgical access was obtained through:

1. Two 5-mm thoracic ports placed along the anterior axillary line (3rd and 5th intercostal spaces) for:

- 3D videoscope (Stryker 1688, 4K resolution)
- CO_2 insufflation (2 L/min flow rate)
- Cardiotomy vent

2. A 4-6 cm right anterolateral thoracotomy at the 4th intercostal space, utilizing a soft-tissue retractor (Estech Flex A) and specialized rib spreader (Estech Riblift II).

Surgical Technique

Following systemic cooling to 26 °C nasopharyngeal temperature:

1. The pericardium was opened 2 cm superior and running alongside to the phrenic nerve

2. Left atriotomy was performed via Sondergaard's groove

3. Mitral valve exposure was achieved using a dynamic atrial retractor (Estech MitraFlex).

Physiological Management

CPB parameters were maintained at:

- Mean arterial pressure: 70-80 mmHg
- Pump flow: 2.4-2.8 L/min/m^2
- Mixed venous saturation >70%

Patient positioning included:

- 15° trendelenburg
- 20° right lateral decubitus tilt

Ventricular fibrillation was permitted during cooling, with electric cardioversion reserved for persistent fibrillation after rewarming. Air was carefully expelled from the left ventricle, and a catheter was inserted through the valve under increased CO_2 insufflation (8 L/min).

Closure and Rewarming Protocol

Following completion of the mitral valve procedure, the left atriotomy was closed in two layers using a continuous 4-0 polypropylene suture (Prolene, Ethicon). A final TEE assessment confirmed:

- Absence of atrial air
- Competent valve function
- Normal ventricular filling

Systemic rewarming was initiated with a graded protocol:

1. Temperature gradient maintained at ≤10 °C between blood and core temperature

2. Rewarming rate of 0.25-0.5 °C/min to prevent microbubble formation

3. Target nasopharyngeal temperature of 36.5 °C before weaning CPB

After confirming the absence of left ventricular air during the TEE, patients were weaned off CPB.

Post-CPB Resuscitation and Closure Protocol

1. Defibrillation and Rhythm Management

- External defibrillation was performed using 30-50 J biphasic shocks (ZOLL M-Series) to achieve sinus rhythm
- Two temporary epicardial pacing wires (Medtronic 6500) were secured to the right ventricular anterior wall.

· Unipolar ventricular lead for backup pacing

· Atrial lead available for sequential pacing if needed.

2. Drainage and Hemostasis

- Two 28 Fr straight chest tubes (Atrium Medical) were placed under direct vision:

· Pericardial tube positioned posterior to the heart

· Right pleural tube placed along the diaphragmatic surface

- Meticulous hemostasis was verified with Valsalva maneuver at 30 cm H_2O.

3. Structured Chest Closure

- Pericardium was loosely reapproximated with interrupted 2-0 Vicryl sutures
- Ribs were reapproximated using #5 FiberWire pericostal sutures
- Layered soft tissue closure:

· Muscle: Continuous 0 Vicryl

· Subcutaneous: 2-0 Vicryl

· Skin: Staples or subcuticular 4-0 Monocryl.

Statistical Analysis

The distribution of continuous variables was formally evaluated for normality using the Shapiro-Wilk test (W statistic) with α=0.05 threshold for significance. Continuous variables were expressed as mean ± standard deviation when normally distributed, and as median with interquartile range, when the distribution was non-normal. Categorical variables were summarized using counts and percentages. All data are reported accordingly.

RESULTS

A total of twenty-four patients, 14 males and 10 females, were evaluated. Patients had a mean age of 61.52±11.48. Fifteen patients (62.5%) had hypertension, 5 patients (20.8%) were diabetic, 12 patients (50%) had hyperlipidemia, and 2 patients (8.3%) had chronic renal failure. Six patients (25%) were in functional class II, fourteen (58.3%) were in functional class III, and four (16.7%) were in class IV. Twenty patients (83.3%) had a mild level of tricuspid regurgitation (TR) whereas 4 patients (16.7%) had a severe level of TR (Table 1).

Eighteen patients (75%) had previous coronary artery bypass graft (CABG) surgery and 6 patients (25%) had previous mitral valve surgery. Mitral valve replacement was performed in 12 (50%) of these patients and mitral valve repair was performed in 12 (50%) of them. Neochordae replacement and annuloplasty ring were used for all mitral repair patients. There was no residual mitral regurgitation before discharge, at early and midterm follow-up, for repair patients.

The mean interval between the initial surgery and subsequent reoperations was 7.16±4.93 years. The mean EuroSCORE was 8.4±1.67. The mean durations of ventricular fibrillation and CPB were respectively, 82.95±12.08 minutes and 142.91±30.60 minutes. Mean hospital stay was 10.54±4.37 days, whereas intensive care unit stay was 2.70±3.40 days (Table 2). We did not convert the surgery to sternotomy in any patient.

In terms of postoperative complication frequencies that patients have experienced, one of the patients (4.1%) had postoperative low cardiac out syndrome. Two patients (8.3%) had renal failure, two patients (8.3%) had pneumonia postoperatively, and two patients (8.3%) underwent reoperation for bleeding. Postoperative stroke was observed

in one patient. There were two deaths in our study due to multi-organ failure.

The average packed red blood cell transfusions 24 hours postoperatively were 0.87±0.99, and 48 hours postoperatively were 1.00±1.10 units.

Table 1. Patients instead of patient

		Mean ± SD
Age (years)		61.52±11.48
EF (%) **EuroSCORE**		4.08±6.52 8.4±1.67
		n (%)
Gender	**Female**	10 (41.7)
	Male	14 (58.3)
HT		15 (62.5)
DM		5 (20.8)
HL		12 (50)
CRF		2 (8.3)
PAD		2 (8.3)
COPD		6 (25)
NYHA	2	6 (25)
	3	14 (58.3)
	4	4 (16.7)
TR	Mild	20 (83.3)
	Severe	4 (16.7)

SD: Standard deviation, EF: Ejection fraction, HT: Hypertension, DM: Diabetes mellitus, HL: Hyperlipidemia, CRF: Chronic renal failure, PAD: Peripheral arterial disease, COPD: Chronic obstructive pulmonary disease, NYHA: New York Heart Association, TR: Tricuspid regurgitation

Table 2. Operative data of patients

	Mean ± SD/n (%)
Operation interval (year)	7.16±4.93
Fibrillatory arrest (min)	82.95±12.08
CPB (min)	142.91±30.60
ICU stays (day)	2.70±3.40
Hospital stays (day)	10.54±4.37
Packed RBC transfusions-24 h post-op. (U)	0.87±0.99
Packed RBC transfusions-48 h post-op. (U)	1.00±1.10
Stroke	1 (4.1%)
Renal failure	2 (8.3%)
LCOS	1 (4.1%)
Pneumonia	2 (8.3%)
Reoperation for bleeding	2 (8.3%)

SD: Standard deviation, CPB: Cardiopulmonary bypass, ICU: Intensive care unit, RBC: Red blood cell, LCOS: Low Cardiac Output Syndrome

DISCUSSION

Redo surgeries performed via median sternotomy pose a heightened risk for patients with patent coronary bypass grafts. Injury to a patent graft can be life-threatening. To reduce complications, enhance recovery time, and improve cosmetic results, various alternatives to traditional sternotomy have been developed. These include partial sternotomy, mini right anterolateral thoracotomy—conducted either with direct visualization or video assistance—and robotic approaches to mitral valve surgery. Such procedures often utilize extended conventional instruments along with compact retractors. The right anterolateral thoracotomy approach helps avoid manipulation of patent grafts, thereby lowering surgical risk. Myocardial protection during these operations can be maintained without aortic cross-clamping by employing hypothermia and inducing ventricular fibrillation.

This method has also been used for reoperative mitral valve surgery in the presence of a patent left internal mammarian artery (LIMA)-left anterior descending artery (LAD) graft (4,5). In our study, 18 patients (75%) had previous CABG surgery with patent LIMA-LAD graft.

The presence of concomitant coronary artery disease, which would normally require concurrent coronary artery bypass surgery, would be a contraindication for minimally invasive valve surgery. However, the use of PCI could advantageous in such scenarios, by circumventing the need for CABG and allowing the minimally invasive valve procedure to be performed. Concurrent PCI was successfully utilized in 8.3% of the present patients. Performing PCI in a diseased graft or native coronary artery avoids the necessity for reoperative coronary artery bypass surgery. To perform concurrent coronary bypass surgery, the entire heart must be exposed, placing any patent grafts at risk.

Repair can be carried out under fibrillatory arrest or with the beating heart in such circumstances. Both beating heart and fibrillatory-arrested heart procedures have been confirmed to be safe in several studies (6,7).

Umakanthan et al. (8) highlighted the safety of using ventricular fibrillation combined with hypothermia and without aortic clamping during minimally invasive mitral valve surgeries. The study involved 195 patients who underwent this myocardial protection technique in cardiac surgery procedures. In patients with prior cardiac surgery, dense pericardial and mediastinal adhesions pose a significant obstacle to minimally invasive approaches. These adhesions not only complicate dissection but also critically limit access to key structures, particularly the aorta, making safe cross-clamping extremely challenging. Our findings indicated a 30-day mortality rate of 8.4%, with low output syndrome and stroke

occurring in 4.1% of cases, which aligns with the outcomes reported by other studies utilizing myocardial protection with aortic clamping (9,10). The low incidence of inotropic support in our cohort supports the literature, which suggests that this technique offers effective myocardial protection (11). Limited surgical dissection reduces the risk of excessive bleeding and the need for transfusions. Furthermore, this minimally invasive approach causes less tissue damage and is associated with lower postoperative pain levels (12). Patients also experience the benefit of earlier mobilization due to the enhanced stability of the bony thorax. The observed reductions in postoperative ventilation duration, intensive care unit stay, and overall hospitalization period may be attributed to the less invasive surgical approach. This correlation suggests that minimally invasive techniques enhance recovery kinetics in this patient cohort, potentially due to reduced surgical trauma, diminished systemic inflammatory response, and preserved respiratory mechanics compared to conventional sternotomy approaches. Bolotin et al. (13) however, observed no significant difference in mortality or CPB times, though their study showed notable reductions in postoperative intubation duration, blood transfusion requirements, and hospital stay. Onnasch et al. (14) reported their experience with 39 patients undergoing redo mitral valve surgery through port access. They concluded that this technique is safe for use in reoperations. The practical advantages of this approach include avoiding sternal reentry, minimizing cardiac dissection, and preventing dissection of patent grafts. Additionally, it leads to lower transfusion rates, fewer wound complications, reduced overall morbidity, and shorter hospital stays. Our findings are consistent with those of other studies regarding postoperative blood loss, the lengths of stay in both the intensive care unit and the hospital, and the amount of red blood cells transfused (14).

Svensson et al. (15) documented a 7.5% incidence of stroke in patients undergoing right thoracotomy. The elevated stroke rate noted in our cohort may be attributed to several contributing factors. In cases of repeat surgery, mediastinal adhesions can displace the left ventricular apex toward the outflow tract, which may increase the risk of complications, including the entrapment of air emboli. To mitigate this risk, we utilize intraoperative strategies such as manually agitating and compressing the chest and employing TEE to ensure effective de-airing of the left ventricle. We believe our comparatively low stroke rate is a result of maintaining arterial pressure above 40 mmHg during CPB, using a cannula for continuous aspiration from the left ventricle, and delivering a steady flow of carbon dioxide into the operative field throughout the procedure. In our research, postoperative stroke occurred in one patient (4.1%).

A comprehensive preoperative evaluation of the aorta, iliac, and femoral arteries using imaging modalities such as CT or angiography is crucial to minimize the potential for dislodging thrombi or atheromatous plaques during retrograde perfusion. Importantly, we observed no complications related to cannulation in our series.

Our observed in-hospital mortality rate was 8.4%, which aligns with outcomes reported in other studies involving mitral valve reoperations performed via either right thoracotomy or median sternotomy (15,16).

In right minithoracotomy approaches, fibrillatory arrest is generally favored, as operating on a beating heart can compromise mitral valve visualization—particularly when aortic regurgitation is present—and may heighten the risk of air embolism (17). Additional research would be valuable to further assess the comparative outcomes of fibrillatory arrest versus beating heart techniques in redo mitral valve surgery.

The beating heart method is typically reserved for situations where aortic clamping is not feasible, such as in cases of porcelain aorta or prior proximal aortic surgery. Moreover, the presence of mild or greater aortic regurgitation precludes the use of this technique, in which case an aortic endo-balloon becomes a suitable alternative.

CONCLUSION

In summary, minimally invasive mitral valve reoperations performed under hypothermia and ventricular fibrillation without aortic cross-clamping can be conducted safely in carefully selected patients, with a low rate of associated complications.

Ethics

Ethics Committee Approval: The study protocol was approved by the İstanbul Bilim University Ethics Committee (date: 07.06.2017, no: 44140529/2017-66).

Informed Consent: A written informed consent was obtained from the parents and/or legal guardians of the patients.

Footnotes

Author Contributions

Surgical and Medical Practices - M.E., K.O., A.S., K.T.S., B.A.; Concept - M.E., K.O., A.S.; Design - M.E., K.T.S., B.A.; Data Collection or Processing - M.E., K.O., A.S.; Analysis or Interpretation - M.E., A.S., K.T.S.; Literature Search - M.E., K.T.S.; Writing - M.E., K.O., A.S., K.T.S., B.A.

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CASE SERIES
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The initial experience of natural orifice specimen extraction surgery in laparoscopic colorectal surgery

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ABSTRACT

Natural orifice specimen extraction surgery (NOSE) is an extension of minimally invasive colorectal surgery. NOSE was introduced into the unit in January 2024 in selected group of patients. The aim of this study was to evaluate the initial experience of NOSE surgery in minimally invasive surgery colorectal surgery in terms of feasibility and safety outcomes. Prospective data was collated for all cases of NOSE in colorectal surgery from Jan 2024 to Dec 2024. Data collected included patient demographics, comorbidities, underlying pathology, pre-, intra- and post-operative outcomes. There were 17 cases considered for NOSE surgery. Eight cases had successful transvaginal NOSE and six cases had successful transanal NOSE. The median age was 68.5 years (range 36-87 years). The median ASA was 3 (range 1-4). All the transvaginal NOSE were performed with laparoscopic right hemicolectomy for neoplasia. Of the six transanal NOSE, four were performed for benign and two for malignant indications. There were no intraoperative complications with no conversion to open surgery. There were no post-operative complications especially anastomotic leak, ileus, wound infection, and extraction-site related complications in transvaginal NOSE cases. There was one anastomotic leak in transanal NOSE that required laparoscopic washout and defunctioning ileostomy. All the neoplasia cases achieved satisfactory oncological outcomes (R0 resection & adequate lymph node yield). The median follow-up was 6 months (range 2-11). The early experience of NOSE in colorectal surgery is safe and feasible in well selected group of patients. It avoids abdominal wall trauma from extraction with reduction of wound infection, pain and long-term risk of incisional hernia.

Keywords: Colectomy, NOSE, MIS, morbidity, outcomes 31

INTRODUCTION

Minimally invasive surgery in colorectal surgery has evolved significantly in the last few decades. The laparoscopic techniques are established in most centres. Laparoscopic colorectal resections usually involve laparoscopic mobilization of the colon followed by a mini-laparotomy for exteriorization to complete the anastomosis. Despite the overall improvement over open surgery, this approach still carries some morbidities ranging from ileus, wound infections and long-term development of incisional hernias (1,2). There is recent interest to embark on intracorporeal anastomosis (ICA) to reduce the ileus rates (3) and this allows off-midline extraction which has a reduced wound infection and hernia rate (4).

Natural orifice specimen extraction surgery (NOSE) has been around for some time (5). It is seen as a bridge between conventional laparoscopic surgery and natural orifice endoscopic transluminal endoscopic surgery (NOTES) (6). NOTES is technically challenging (6) whereas in NOSE surgery, the whole surgery is performed as usual techniques apart from the extraction. NOSE can be performed through the anus (Ta), vagina (Tv) or transcolonic (Tc) in the setting of colorectal surgery (7). It has the advantage of avoiding any potential abdominal wall morbidities and reduces post-operative pain (8,9). This approach is only limited to a few centres and only a handful of Australian units have adopted this approach (10,11). Our unit has adopted ICA in colorectal resections routinely and started to offer NOSE in selective cases.

The aim of this study was to evaluate the initial experience with feasibility and safety of NOSE in laparoscopic colorectal surgery in our unit.

MATERIAL and METHODS

This was a review of the prospectively maintained database of all NOSE surgery performed from January 2024 to December 2024. Ethics approval (670/24) was obtained from the ethics committee. The patients' demographics, the comorbidities,

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previous abdominal surgery, colorectal pathology, the pre-, intra- and post-operative details, histopathology and follow-up were collated. The last clinic follow-up was considered the last follow-up in this study.

Patient Selection

The cases were carefully selected for their suitability. The inclusion criteria for transvaginal NOSE were female patients, consenting to transvaginal extraction, T0-T3 tumors, size of tumour <6 cm, no peritoneal disease and elective cases. The exclusion criteria were: T4/perforated tumours (Figure 1), metastatic disease, emergency cases, child-bearing age females, large mutilfocal fibroids (Figure 2) inhibiting easy access to the posterior vagina and previous pelvic radiation/gynaecological cancers.

The inclusion criteria for transanal NOSE were benign cases including diverticular disease, sigmoid volvulus and for malignant cases of resected malignant left colonic polyp. The details of the operation were explained in the clinic and informed consent was obtained from the patient. If NOSE was not feasible intraoperatively, a pfannenstiel incision was then performed.

Technique for Transvaginal NOSE

Our technique has previously been published (12). Briefly, the patient is placed in a lithotomy position with reverse Trendelenburg and right tilt position. A beanbag is used to ensure the patient does not slip down on the table. Bilateral calf compressors are used.

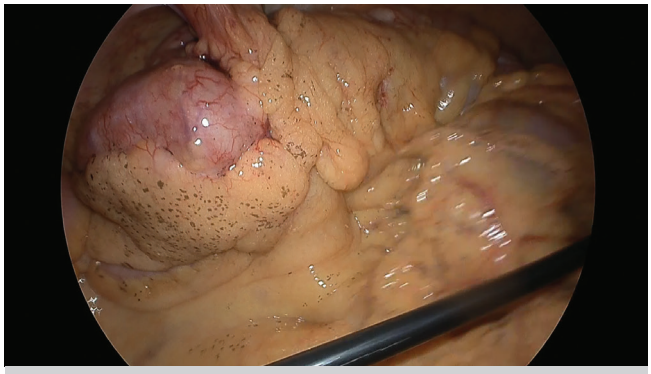

Figure 1. An example of intraoperative finding of large caecal tumour with potentially T4 disease.

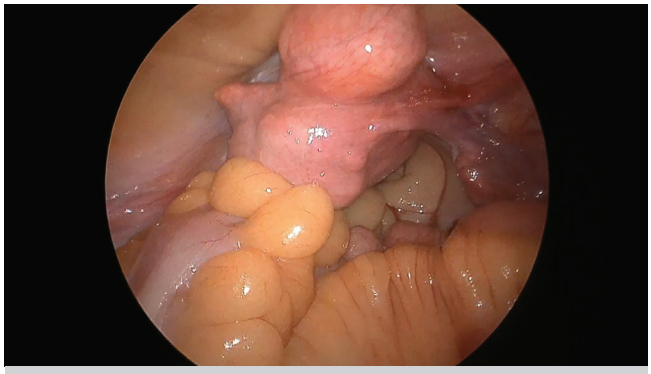

Figure 2. Large multifocal uterine fibroid precluding easy access for transvaginal natural orifice specimen extraction.

Indwelling catheter is used. Standard prophylactic intravenous antibiotics (2 g cephazolin and 500 mg metronidazole) were given.

The vagina is examined for any strictures and irrigated with povidone-iodine solution prior at the start of the case.

A 5 mm optical entry at the Palmer's point is utilized. Further two 5 mm and one 12 mm ports are placed under vision. Bilateral transabdominis plane blocks are performed with 20 mLs of 0.75% ropivocaine diluted into 60 mLs. The right hemicolectomy is performed in the conventional approach. ICA is performed.

The pelvis is examined for any adhesions which are divided sharply. The uterus if present is hitched up transabdominally to allow easy access to the posterior vagina.

The assistant irrigates the vagina again with povidone-iodine solution. A rectal sizer is inserted to guide the posterior fornix of the vagina. Posterior colpotomy is performed with diathermy laparoscopically. A small Alexis wound retractor is placed through the vagina.

A Rampley's forceps is used to extract the specimen through the vagina. The wound retractor is removed, and a temporary pack is inserted into the vagina to allow re-establishment of pneumoperitoneum. The vagina is closed with 3/0 absorbable V-Loc suture. The vagina is examined to ensure there is no residual defect.

A vagina pack soaked in Povidone-iodine is placed in the vagina overnight.

Technique for Transanal NOSE

Our technique has previously been demonstrated (13). The positioning is similar to the aforementioned except for a left tilt position.

An on-table colonoscopy is performed to confirm the diagnosis and perform washout with povidone-iodine (14).

Three 5 mm and one 12 mm ports are used. The left colon is mobilized in the usual manner.

The splenic flexure is routinely mobilized in all cases. For malignant polyp cases, a high ligation of the inferior mesenteric artery is performed. For benign cases, a low ligation is performed with preservation of the superior rectal artery.

The upper rectum is stapled off with an endoscopic stapler. The proximal mesocolon is ligated with an energy device. The proximal colonic margin is determined and divided with an endoscopic staple. The rectal staple line is removed.

A small Alexis wound retractor is placed through the rectum. The anvil of the circular stapler is introduced through the anus into the peritoneal cavity. The assistant then uses a Rampley's forceps to extract the specimen. For bulky diverticular disease specimen, the mesentery is separated from the colon. In certain cases, the colon needs to be removed in piecemeal.

The wound retractor is removed. The rectal stump is closed with an endoscopic stapler. Indocyanine green is performed to assess for the perfusion of the colonic conduit and the rectum. A purse-string of the conduit is created intra-corporeally with 3/0 V-Loc. The anvil is inserted and further secured with a PDS endoloop. An end-to-end colorectal anastomosis is created with a circular stapler.

Alternatively, the anvil inserted into the colonic conduit following removal of the staple line and the spike is delivered through the antimesenteric border. The colostomy is closed off with an endoscopic stapler. A side-to-end colorectal anastomosis is created with a circular stapler.

A flexible sigmoidoscopy is performed to assess the colorectal anastomosis and pneumatic test. All the cases were performed by the fellow (ZN) who has had prior experience in laparoscopic NOSE surgery under the supervision of the consultant surgeon (SW).

Post-operative Care

Enhanced recovery after surgery (ERAS) principles were followed. Nasogastric tube or drains were not placed. Free fluids were given immediately post-operation. A full diet was allowed on day 1.

The vagina pack and the indwelling catheter were removed at 6.00 am on day 1. Patients were advised to have no sexual intercourse for 6 weeks post-operation. Patient was followed up in clinic in two weeks' time for clinical review (Figure 3).

The pain score was recorded based on the last documentation prior to discharge. The pain score was assessed by the nursing staff.

RESULTS

Demographics

During the study period, a total of 17 patients were considered for NOSE. Of the 17 patients, 10 were considered for NOSE-Tv and seven for NOSE-Ta. Eight patients underwent laparoscopic right hemicolectomy with NOSE-Tv (Table 1) and six underwent laparoscopic anterior resection with NOSE-Ta (Table 2). The median age was 68.5 years (range 36-87 years). All NOSE-Tv were female patients. For NOSE-Ta, there were four males and two females. The comorbidities were listed in the table. The median ASA was 3 (range 1-4). The median BMI was 27.5 (18.8-40.3) for NOSE-Tv and 28.4 (23.1-50) for NOSE-Ta respectively.

NOSE-Tv

The surgery was performed for neoplasia in all cases; four cancers, three malignant polyps and one advanced polyp. Conventional D2 laparoscopic right hemicolectomy was performed in four patients and complete mesocolic excision with central vascular ligation was performed in four patients. All the ICAs were performed in an isoperistaltic side-to-side stapled configuration.

Two cases required adhesiolysis in the pelvis from previous hysterectomy. A wound retractor was used in all cases. There was no conversion to open surgery. There were no intraoperative complications. The remaining two cases considered for NOSE-Tv were found to have larger tumour and hence a pfannenstiel incision was performed instead.

The median operative time was 188.5 min (range 137-247 min). One patient had planned intensive care unit (ICU) for observation overnight due to underlying comorbidities of liver cirrhosis. One patient had unplanned ICU admission due to asymptomatic hypotension from the spinal anaesthesia (for chronic pain). There were no anastomotic leaks. The median time to flatus and bowel movements were 1 day (range 0-3) and 1 day (range 1-3) respectively.

The median pain score prior to discharge was 0 (range 0-5). The median length of stay was 2.5 days (range 23 hours-8 days). One patient was clinically cleared for discharge on day three but waited for rehabilitation on day eight for underlying frailty and malnutrition.

On clinic follow-up, there were no wound-related complications. There were no extraction-site related complications on follow-up.

Histopathology results are detailed in Table 1. All the specimens had R0 and clear resection margins. The median lymph node

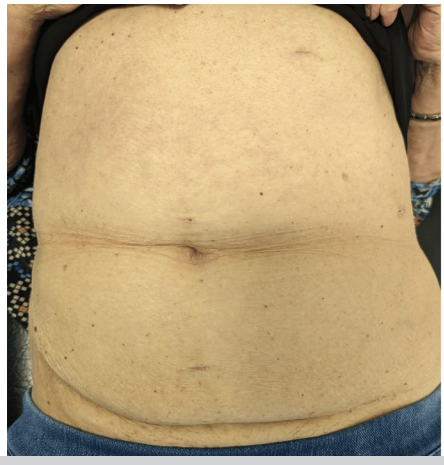

Figure 3. Clinic review of the patient's abdomen 2 weeks after laparoscopic right hemicolectomy with transvaginal NOSE.

NOSE: Natural orifice specimen extraction surgery

Table 1. The peri-operative details of patients that underwent NOSE-Tv

Case	Sex	Age (years)	Comorbidities	ASA	Previous abdominal surgery	BMI	Pathology	Surgery	Operative time (mins)	Day to flatus
1	Female	60	Necrotising myopathy on rituximab and prednisolone	2	Hysterectomy	24	Malignant ascendinzg colon polyp (polypectomy)	RH	168	3
2	Female	79	Heart failure, COPD, AF, CKD 3	3	Nil	29.3	Malignant caecal polyp (EMR)	RH	207	2
3	Female	72	CKD 2	2	Open appendicectomy	26.7	Caecal cancer	RH	247	1
4	Female	71	Liver Cirrhosis Childs Pugh A from alcohol, Heart Failure, Malnutrition, Pulmonary embolism on therapeutic anticoagulation, legally blind	3	Nil	18.8	Hepatic flexure cancer	RH	190	2
5	Female	73	Chronic back pain	3	Hysterectomy	29.2	Malignant hepatic flexure polyp (EMR)	RH	137	1
6	Female	86	CKD 3, Fatty liver, AF, OSA, Type 2 diabetes	3	Hysterectomy	40.3	Caecal cancer	RH	230	0
7	Female	66	Marginal zone lymphoma	3	Caesarean section	22.5	Hepatic flexure cancer	RH	187	1
8	Female	87	CKD 3, AF, previous rectosigmoid cancer	4	High anterior resection	29	Large recurring caecal polyp	RH	160	1

Day to bowel movement	Pain score on discharge	Length of stay (day)	Size of tumour (mm)	Histopathology	Lymph node	R0/ Margins	Comments
3	2	3	-	Nil residual cancer	0/24	Clear	-
2	0	4	Incidental neuroendocrine tumour 11x10	Nil residual adenocarcinoma. Incidental terminal neuroendocrine tumour	4/25 (neuroendocrine)	Clear	-
1	0	23 hours	50x33	T2/N0	0/18	Clear	-
2	0	8	27x20	T3/N0	0/17	Clear	Clinically ready for discharge day 3, awaited rehabilitation for malnutrition
1	0	3	-	No residual cancer	0/32	Clear	Rural patient
0	1	2	25x16	T2/N0	0/16	Clear	-
1	5	2	40x26	T3/N0	0/24	Clear	No pick up available on day 1
1	1	2	16x12	Tubular adenoma with high grade dysplasia	0/15	Clear	Rural patient

COPD: Chronic obstructive pulmonary disease, CKD: Chronic kidney disease, AF: Atrial fibrillation, OSA: Obstructive sleep apnea, EMR: Endoscopic mucosal resection, RH: Right hemicolectomy, NOSE: Natural orifice specimen extraction surgery

Table 2. The peri-operative details of patients that underwent NOSE-Ta

Case	Sex	Age (years)	Comorbidities	ASA	Previous abdominal surgery	BMI	Pathology	Operative time (min)	Day to flatus	Day to bowel movement	Pain score on discharge	Histopathologoy	Lymph node	R0/ Margins
1	M	37	Ex-smoker	2	Lap Morgagni hernia repair	30.4	Recurrent sigmoid diverticulitis	232	1	1	2	Complicated diverticulitis	--	-
2	M	86	Ex-smoker	3	Nil	26	Recurrent sigmoid volvulus	140	1	2	0	Sigmoid volvulus	-	-
3	M	54	Asthma	2	Laparoscopic lavage	26.3	Recurrent sigmoid diverticulitis	288	2	2	2	Complicated diverticulitis	-	-
4	F	57	Nil	1	Open right nephrectomy	33.6	Malignant sigmoid polyp	178	1	1	1	Nil residual cancer	0/23	Clear
5	F	36	Morbid obesity	3	Nil	50	Malignant sigmoid polyp	175	1	1	2	T3/N2	7/28	Clear
6	M	40	Smoker	3	Nil	23.1	Recurrent sigmoid diverticulitis	227	1	2	2	Complicated diverticulitis	-	-

BMI: Body mass index, NOSE: Natural orifice specimen extraction surgery

yield was 21 (range 15-32). In the median follow-up of 6 months, there was no local or distant recurrence.

NOSE-Ta

The surgery was performed for recurrent sigmoid diverticulitis in three patients, recurrent sigmoid volvulus in one patient and malignant polyp in two patients. Five patients had end-to-end and one had side-to-end colorectal anastomosis. A wound retractor was used in all cases. There was no conversion to open surgery. There was no intraoperative complication. Of the seven cases considered for NOSE-Ta, one required conversion to a lower midline laparotomy for frozen pelvis from chronic sigmoid diverticulitis.

The median operative time was 202.5 min (range 140-288 min).

There was a case of small anastomotic leak on day three that required a return to theatre for laparoscopic washout and defunctioning loop ileostomy. The patient since had a healed colorectal anastomosis and reversal of loop ileostomy five months later. The median time to flatus and bowel movement were 1 day (range 1-2) and 1.5 days (range 1-2) respectively.

The median pain score prior to discharge was 2 (range 0-2). The median length of stay was 4 days (range 1-17). On clinic follow-up, there were no wound-related complications.

There were no extraction-site related complications on follow-up. Histopathology results are detailed in Table 2.

DISCUSSION

This study has demonstrated the initial experience of laparoscopic colorectal surgery with both transvaginal and transanal NOSE procedures.

The application of NOSE is significantly easier as compared to NOTES which has unfamiliar views and clash of instruments. NOSE retains all the familiarity of the established laparoscopic colorectal techniques with 5-12 mm port placements (6). The published literature in Australia is mainly limited to a single centre publication with large experience in both Tv- and Ta-NOSE surgery (10,14).

Earlier small series suggest that NOSE-TV is safe in laparoscopic right hemicolectomy (15-17). An earlier systematic review of 90 cases of NOSE-Tv found two cases of colonic/rectal injury sustained during NOSE-Tv (18). This could be avoided with careful selection of cases and meticulous extraction techniques as shown in our experience. An updated 2023 international guidelines on NOSE published the indications for different NOSE techniques (7).

The safety of NOSE in malignant cases often raises concerns. It is important to emphasize that the oncological resection principles are not compromised (19). We showed that all the malignant cases achieved R0 resection and adequate lymph

node yield. The potential for seeding in the vagina or rectum/anus during extraction is akin to the initial reports of port sites malignant recurrence during the initial adoption of laparoscopic surgery (20). The key aspects to protect against this are the use of a wound protector for extraction, gentle traction of the specimen and irrigation with povidone-iodine.

For NOSE-Ta cases, we strictly select only cases of resected malignant polyps and benign indications although it can be done for left colonic malignancy (9,21). We do not recommend debulking the mesentery or colon for malignant indications. For NOSE-Tv cases, we assess intraoperatively. In cases where there is doubt about the size of the tumour, a ruler can be used to measure intraoperatively (Figure 4). A study found that mean tumour size 6.5 cm+/- 4.2 cm failed in NOSE (22). Different tumour sizes have been published as cut-off for NOSE-Tv. Our experience has been similar to Seow-En et al. (23) where the width of the pelvic outlet and vaginal conduit need to be considered as well. In scenarios where there are significant pelvic adhesions requiring prolonged adhesiolysis or large subserosal fibroids precluding easy access to the posterior vagina, NOSE can be abandoned. Pre-operative evaluation of the endoscopic images of the primary tumour and CT images of the primary tumour and uterus (Figure 5) are important for operative planning. Larger series of NOSE-Tv have not found any local recurrence cases (22). Local recurrence in the vagina has been limited to a case report.

Another concern for following NOSE-Tv is on the sexual function. The studies have shown that there was no impact on the long-term sexual function following NOSE-Tv (8,23-25).

We have not offered NOSE-Tv to child-bearing age females in keeping with most centres' exclusion criteria (15-17). For NOSE-Ta, studies have shown there is no impairment of the anorectal function (19,21). We have not observed that but will require a long-term survey to assess that.

There are a few technical details to discuss. To perform NOSE, the clinician should be proficient in ICA techniques. In Tv-NOSE for laparoscopic right hemicolectomy, the ICA is performed as usual technique as it is not linked to the extraction aspect of the procedure.

There was a case of small anastomotic leak early on in NOSE-Ta which could be related to technical factor while creating the purse-string. It is vital to have full thickness decent bites of the bowel during purse-string. The anvil should also be secure and snugged. We do not think it was secondary to a rectal injury from the NOSE-Ta extraction. An alternative way is to perform a Baker-type anastomosis (side-to-end) which precludes the need for intracorporeal purse-string. For NOSE-Tv, using a larger needle such as 2/0 is easier to close the posterior colpotomy. Alternatively, this can be performed extra-corporeally.

The average length of stay following colonic surgery remains around 3-4 days despite the routine practice of ERAS (26). The next challenge is to bridge the gap between ERAS and ambulatory colectomy (27). The two factors that often concern patients and/or clinicians from discharge are ability to tolerate diet and post-operative pain (28). We did not have a comparison group to demonstrate the reduction in post-operative ileus rates but can be reflected in the median time to return of bowel movement and flatus (median one day). With NOSE, the patients had low median post-operative pain and need of opioids on discharge. The benefits extend even further to obese (10) and comorbid patients.

This study is limited by the small numbers as a report of initial experience. The operative time may not be fully reflective

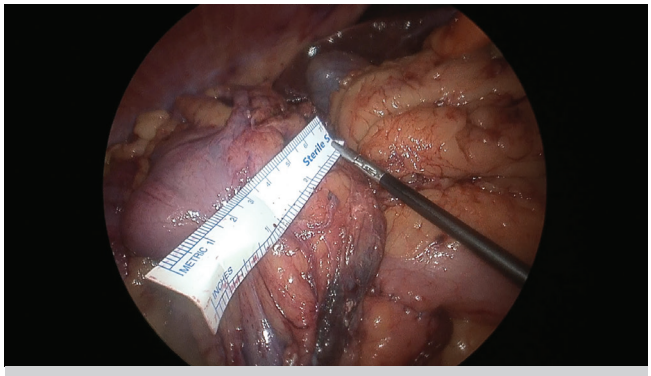

Figure 4. Intraoperative measurement of the tumour size with a ruler and abandoning transvaginal NOSE.

NOSE: Natural orifice specimen extraction surgery

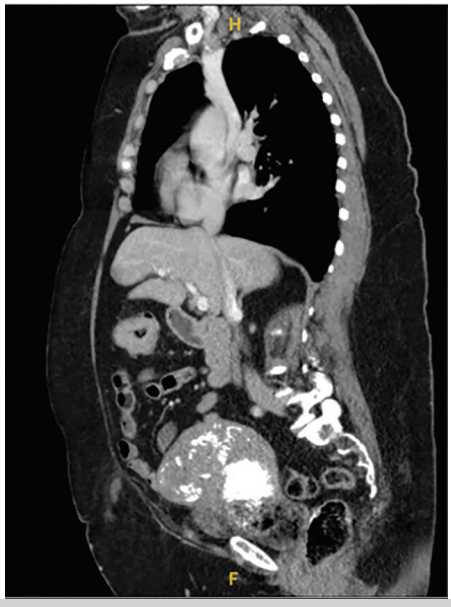

Figure 5. Preoperative sagittal view of CT scan for assessment of the uterus where the large fibroid made transvaginal NOSE not suitable.

NOSE: Natural orifice specimen extraction surgery, CT: Computed tomography

as the author was initially on the learning curve of ICA followed by complete mesocolic excision in laparoscopic right hemicolectomy. In some of the cases of NOSE-Ta, the operative time included the time for cystoscopy and bilateral ureteric catheters insertion for the diverticular disease cases. Nevertheless, the operative time is comparable to larger series (8,10,14). A learning curve analysis for NOSE surgery was not possible due to the small numbers but with appropriate mentoring, this study has demonstrated its feasibility even in the hands of a fellow.

CONCLUSION

The introduction of NOSE in laparoscopic colorectal surgery is safe and feasible in our early experience. NOSE surgery in a well-selected group of patients offers additional benefits of reduced post-operative pain, and post-operative complications related to abdominal wall extraction of specimen. The techniques of NOSE surgery will continue to evolve and mature.

Ethics

Informed Consent: Informed consent was obtained from the patients.

Footnotes

Author Contributions

Concept - Z.Q.N., S.W.; Design - Z.Q.N., S.W.; Fundings- Z.Q.N., N.L., C.M.; Materials - Z.Q.N., N.L., C.M., S.W.; Data Collection or Processing - Z.Q.N., C.M.; Analysis or Interpretation - Z.Q.N., N.L., C.M., S.W.; Literature Search - Z.Q.N., N.L., C.M.; Writing - Z.Q.N., N.L., C.M.

Conflict of Interest: No conflict of interest was declared by the authors.

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LETTER TO THE EDITOR
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The double burden: Family, career, and gender discrimination in surgery

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Keywords: Women surgeons, disparity, gender differences,equality, surgery, academic surgery

Dear Editor,

We read with great interest the article by Bozkurt et al. (1) titled "A questionnaire on the perception of social and academic discrimination against female general surgeons in Türkiye". This research underlines the gender-specific issues that female surgeons encounter in Türkiye, while illustrating the stereotypes and gaps that continue to exist in a field dominated by men, which is a rather masculine-oriented domain. It is equally impressive how the authors seek to combat gender bias and advocate for an inclusive culture for the next generation of trainees and graduates. This study aligns well with other studies conducted worldwide that continue to highlight the challenges women face in surgery. For example, Lyons et al.'s (2) study from the United Stated of America (USA) confirmed that female surgeons undergo discrimination, harassment, and inequality in employment opportunities, which corresponds to the narratives of female surgeons in Türkiye. Likewise, Lim et al.'s (3) approach to a qualitative systematic review uncovered a great deal of gender discrimination in surgery and the undue burden it places on women in terms of family life versus their surgical career. These findings corroborate the study by Bozkurt et al. (1), in which a significant percentage of respondents (66.7% male and 65% female) acknowledged that family responsibilities hinder women's participation in general surgery. Moreover, the analysis conducted by Chen et al. (4) showed that female surgeons receive fewer complex cases than their male counterparts, a finding that parallels the perception of 45.6% of female respondents in Bozkurt et al.'s (1) study, who felt that female surgeons are given fewer cases and responsibilities. Furthermore, Schlick et al. (5) reported that many female surgical residents in the USA suffer from gendered harassment, which involves belittling comments and sexualized attention. This finding is consistent with the high rates of degrading acts of femininity and harassment experienced by female surgeons in Türkiye (53.4% and 57.3%, respectively). With all these challenges, the study conducted by Bozkurt et al. (1) also stresses the positive impact of female role models and mentors who work to help empower women to pursue and succeed in their surgical careers. This was also shown by Yorozuya et al. (6) that female mentors in Japan played an important role in leading women surgeons in the heavily masculine-dominated world. In the same way, the #ILookLikeASurgeon movement, discussed by Logghe et al. (7), has helped to dispel negative stereotypes and widen the scope of surgery, which accentuates the importance of women in the profession. In conclusion, the study by Bozkurt et al. (1) significantly contributes to the understanding of gender discrimination in the surgical community, particularly in the context of Türkiye. These results highlight the importance of systemic change in

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acknowledging and addressing gender bias, facilitating work-life balance, and providing better supportive networks for female surgeons. This is just the beginning, and we hope that this study will encourage more research and policy changes to ensure a fair and inclusive space for all surgeons, irrespective of gender.

Footnotes

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LETTER TO THE EDITOR
Turk J Surg 2025;41(2):214-215

Comment on: "Comparative evaluation of P-POSSUM and NELA scores in predicting 30-day mortality following emergency laparotomy: A prospective observational study"

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Keywords: Gastrointestinal surgery, general surgery, laparotomy

Dear Editor,

I read with interest the article by Lodha et al. (1), "Comparative evaluation of P-POSSUM and national emergency laparotomy audit (NELA) scores in predicting 30-day mortality following emergency laparotomy: A prospective observational study". This study contributes to an important discussion on perioperative risk stratification; however, several methodological limitations weaken its conclusions.

The authors state that NELA outperforms P-POSSUM in predicting 30-day mortality but do not perform statistical testing to compare area under the curve (AUC) values. Without formal comparison, such as DeLong's test (2), it is unclear whether the difference is significant, limiting their ability to conclude that "the NELA score outperforms the P-POSSUM score". Previous studies report higher AUCs for both scores (0.84 for NELA and 0.81 for P-POSSUM) (3), compared to 0.699 and 0.687 in this study. It remains uncertain whether this discrepancy reflects population differences or study design flaws.

The inclusion criteria also raise concerns. The study only included patients undergoing laparotomy via a midline incision of ≥5 cm, excluding laparoscopic and laparoscopically assisted procedures that meet NELA inclusion criteria (4). Furthermore, case distribution is broadly categorised as "perforation peritonitis", "acute intestinal obstruction", and "miscellaneous", leaving uncertainty over whether inappropriate cases (e.g., open appendicectomy) were included while relevant ones (e.g., hernia repair with bowel resection) were excluded. Future studies should align with NELA criteria to ensure comparability with existing data.

Another limitation is the lack of adequate follow-up. Both NELA and P-POSSUM predict 30-day mortality, yet this study followed patients only until discharge. With a mean postoperative stay of 9.94 days, late mortalities may have been missed. While the reported 9.7% mortality rate aligns with existing data, the absence of structured follow-up raises concerns about validity. Future studies should actively follow patients for at least 30 days.

The study also reports significantly higher NELA and P-POSSUM scores in patients requiring intensive care unit (ICU) admission. However, given that these scores influence clinical decision-making and clinicians were not blinded, high scores themselves may have contributed to more ICU admissions rather than reflecting

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independent predictive accuracy. NELA guidelines recommend ICU admission for high-risk patients (≥5% predicted mortality) (4), meaning the study may be capturing appropriate use of NELA in clinical decision-making, rather than validating predictive performance.

Finally, the study overlooks newer, more accurate scoring models. The Hajibandeh index, ASA grade, Sarcopenia model has demonstrated superior discrimination, with an AUC of 0.96 for 30-day mortality (5). The omission of newer models is an important oversight, particularly given the increasing recognition of sarcopenia as a prognostic factor.

While the study supports NELA's use, the lack of statistical comparisons, potential selection bias, incomplete follow-up and omission of newer models weaken its conclusions. Future research comparing risk stratification scores for emergency laparotomy should include formal statistical testing, adhere to standardised inclusion criteria, ensure adequate follow-up, and consider alternative scoring models to improve predictive accuracy.

Footnotes

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