



The retrospective documentation of legal cases with bile duct injury that were submitted for consideration to İstanbul Forensic Medicine Institute by the courts between 2008-2012

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ABSTRACT

Objective: The aim was to evaluate the parameters that were considered by Forensic Medicine in bile duct injury as well as the issues that the physicians were found to be faulty.

Material and Methods: The following parameters were investigated in 21 files that were referred to İstanbul Forensic Medicine Institute with request of expert opinion between 2008-2012; expert decisions, patient's age, gender, written patient consent, diagnosis, type of first surgery, surgical complications, timing of complication diagnosis within the scope of complication management, patient's referral timing, troubleshooting procedures and mortality rate.

Results: Physicians were found to be faulty in all files. The reason for physician fault was failure to show the necessary professional care and attention in one (4.7%) file, late recognition of injury and late transfer of the patient in 20 (95.3%) files. Written consent had not been obtained in any of the files. Thirteen patients were female (61.9%) and 8 (30.1%) were male, with a mean age of 43.3 years. Nineteen patients had cholelithiasis (90.4%), and two patients (9.5%) had a mass in the head of the pancreas. Cholecystectomy was performed laparoscopically in 15 patients (78.9%), and with open surgery in 4 patients (21.1%). The Whipple procedure was performed in two patients. The diagnosis was made during the operation in one patient (4.7%), and in the post-operative period in 20 patients (95.3%). The time to diagnosis after surgery was between 3-6 days. All of the patients had been referred to third level health care facilities. The timing of transfer was 1 day in the patient who was diagnosed during the operation, and ranged between 4-10 days in those who were diagnosed postoperatively. Reasons for late referral were delays related to pending test results in 12 patients, vague signs in 3 patients, and following-up patients with the thought that the biliary fistula will heal by itself in 5 patients. Mortality was not observed in any of the examined files.

Conclusion: The issues where physicians were most frequently found to be faulty were failure to obtain written patient consent, late recognition of injury and late transfer of the patient.

Key Words: Biliary injury, complication, malpractice

INTRODUCTION

Bile duct injuries following laparoscopic cholecystectomy is encountered approximately once in every 200 cases. This rate is twice as high as the rate in open cholecystectomy (1). Bile duct injuries may have troublesome consequences such as elongated hospital stay, economic burden, morbidity, and mortality, as well as exposure of surgeons to penalties and remedial actions. There has been a 40-120% increase in such legal actions in Turkey (2, 3). Western publications are more related to remedial actions, while in our country publications are mainly related to forensic medicine, and decisions of chamber of physicians or Courts (3-6). The publications focused on the results of remedial or criminal actions, rather than expert opinion and the parameters that are taken into account by an expert in making the decision. The aim of this study was to evaluate the parameters that were considered by Forensic Medicine in bile duct injury as well as the issues that the physicians were found to be faulty.

MATERIAL AND METHODS

Twenty-one patient files that were referred to İstanbul Forensic Medicine Institute with request of expert opinion due to bile duct injuries between 2008-2012 were examined retrospectively.

Patient's age, gender, diagnosis, written patient consent, type of first surgery, surgical complications, timing of complication diagnosis within the scope of complication management, patient's referral timing, troubleshooting procedures and mortality rate were assessed along with expert decisions.

Statistical Analysis

The rates and distributions in this case series were indicated as percentages and frequencies.

RESULTS

The physicians were found to be faulty in all the cases that were examined. The reason for physician fault was failure to show the necessary professional care and attention in one (4.7%) file, whereas the

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Received: 16.04.2014

Accepted: 28.06.2014

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reason in 20 cases (95.3%) was causing late intervention and preventing effective treatment due to late recognition of the complication and failure to refer the patient to a center where complex bile duct surgery was performed in time. The reason for late referral was delays related to pending test results in 12 patients. Four of these patients had received magnetic resonance cholangiopancreatography (MRCP), 3 endoscopic retrograde cholangiopancreatography (ERCP) and 5 ERCP following MRCP. Furthermore, all patients had received abdominal ultrasound. Three patients were observed due to vague signs, and it was thought that the biliary fistula would heal by itself in five patients. Thirteen of the patients were female (61.9%), 8 were male (30.1%) and their mean age was 43.3. The patient consent form was a standard form that was prepared for all the cases. None of them had a written consent. Nineteen of the patients (90.4%) had been operated on due to cholelithiasis, while 2 were operated on for a mass in the head of the pancreas (9.5%). Fifteen out of 19 patients (78.9%) with cholelithiasis received laparoscopic cholecystectomy, 4 (21.1%) of them underwent open cholecystectomy, and a Whipple's procedure was performed in 2 patients with a mass in the head of the pancreas. The complications that developed were as follows: biliary fistula due to bile duct injury in nine patients (42.8%), biliary fistula due to a leak in the hepaticojejunostomy anastomosis following Whipple procedure in two patients (9.5%), intervention-related stricture in the bile ducts in one patient (4.7%), full obstruction of the bile ducts in 6 patients (28.5%), a cystic duct fistula in one patient (4.7%) due to a retained stone in the common bile duct, and duodenum perforation in two patients (9.5%). The diagnosis was made during the operation in one patient (4.7%), and in the post-operative period in twenty patients (95.3%). The time for post-operative diagnosis was in the range of 3-6 days. All the patients were referred to a tertiary healthcare institution following diagnosis. As for the referral durations, it was one day for the patient for whom the injury was identified at the time of the operation, and between 4-10 days for the patients for whom it was identified in the post-operative period. In the center they were referred to, 6 patients (28.5%) received bilioenteric anastomosis, 5 patients (23.8%) underwent repair via a T-tube, 2 patients (9.5%) had tube duodenostomy, 2 patients (9.5%) required sphincterotomy and stent placement with ERCP, 2 patients (9.5%) had drainage and stent placement via percutaneous transhepatic cholangiography (PTC) and 4 patients (19%) underwent nasobiliary drainage with ERCP. There was no mortality within the group due to the interventions performed.

DISCUSSION

Surgical interventions pose certain risks by their very nature. The risks that occur are accepted as complications if the physician has demonstrated the due attention and care acting within the rules of the science of medicine; otherwise, they are assessed as a faulty practice in medicine (malpractice). In the forensic medicine institutions, 4 parameters are taken into account as essential parameters for the assessment of bile duct injuries. The absence of even one of them may lead to a decision on malpractice. These are as follows: informing the patient about potential complications and receiving their written consent, noticing the complication in time as it occurs, performing the required medical interventions when recog-

nized in time, referring the patient to a center where complex bile duct surgery is performed if the required interventions cannot be conducted at that hospital.

In all of the 21 cases examined in our study, informed consent was received from the patient. However, these consents were received by having them sign a standard form that was prepared. In judicial investigations, the bile duct surgeries are categorized as risky surgeries and informed consent from the patients about complications that may develop is required. The absence of a written consent is deemed to be a crime (7). In the study by Reuver et al. (8), informed consent had been received from 23% of the patients. The fact that cholecystectomy surgeries are performed very often and the rate of complications is relatively low often causes the physicians to skip that step. However, this fact alone causes the physician to be deemed faulty to a certain extent.

It is important to recognize any complications that develop early, and to perform the intervention in a timely manner. Late diagnosis would result in severe morbidity, not to say, mortality, long durations of hospital stay and increase in patient unjust treatment (9). The immediate recognition of the complication and performance of the required intervention at this phase would bring about the best result. In our study, one patient was diagnosed at the time of the operation (4.7%). The period for diagnosis in the post-operative phase was in the range of 3-6 days. All the patients who were diagnosed had been referred. It is reported in the western literature that the recognition of bile duct injuries at the time of operation is between 14-27% and the rate at which the revision surgery is performed at the center where the initial surgery was performed is between 35-45% (1, 4, 8, 10, 11). The reason why the rate for immediate diagnosis and revision surgery at the center where the initial surgery was performed was low in our study could be that the equipment that would enable diagnosis at the time of operation was not present and training on bile duct surgery was insufficient.

It is important in terms of judicial investigations that the patient is referred to a center experienced in such interventions as soon as a complication is diagnosed. Proper referral in the early stage reduces the treatment time and diminishes unjust treatment of the patient (12). Considering that prolonged hospital stay would also increase the economic loss of the patient, the penalty to be imposed on physicians as part of remedial action would also rise. In our study, all the patients were referred and the referral durations were in the range of 4-10 days. The delegation of experts found the physician faulty since the diagnosis was made late in 20 out of 21 cases and the patient was referred late, which enhanced the unjust treatment of the patient. In the western literature, the patient referral rates are reported as between 46-55% and the rates at which physicians are deemed faulty between 30.6-86% (8, 12). In the study by Yaycı et al. (5), 24 non-traumatic general surgery cases were investigated and the rates at which the physicians were deemed faulty was identified to be 62%. This rate was found 100% in our study for bile duct injuries. The reason why the rate of referral in our study was high could be that the number of physicians experienced in bile duct surgery was low, and the hospitals had some technical deficiencies. The differences between the rates at which the physicians were found faulty could have

stemmed from the differences in perspectives of the delegation of experts since no standard assessment method exists in relation to this matter.

CONCLUSION

The forensic medicine institution takes the following parameters into account while assessing cases: presence of a written patient consent, recognition of the complication in time, performance of the intervention in time and referral of the patient in the appropriate time frame. The physicians are deemed faulty most often due to the fact that they did not receive an informed patient consent, recognized the complication late or were late in referring the patient.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Istanbul Forensic Medicine Institution.

Informed Consent: No informed consent was required for this retrospective study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - M.A.K., A.F.A.; Design - M.A.K.; Supervision - A.F.A.; Funding - M.A.F., O.K.; Materials - M.A.K.; Data Collection and/or Processing - M.A.K.; Analysis and/or Interpretation - A.F.A., F.E.; Literature Review - O.K.; Writer - O.K., A.F.A.; Critical Review - M.A.K., A.F.A.

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

Financial Disclosure: The authors declared that this study has received no financial support.

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