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Setting up a surgical complex gallstone service in a non-HPB unit

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ABSTRACT

Objective: Complex gallstone disease is associated with a higher risk of complication during laparoscopic cholecystectomy than biliary colic and simple cholecystitis. It is traditionally managed in a hepatopancreaticobiliary (HPB) unit where there is expertise for common bile duct exploration and repair. We developed a mentorship scheme for a busy upper gastro-intestinal (UGI) unit, with support from a specialist HPB unit to treat complex gallstone disease, to reduce the burden on the HPB unit and enable local treatment of patients.

Material and Methods: Through the creation of a service level agreement, the specialist HPB unit were commissioned to provide mentorship for two surgeons at a large UGI unit with an interest in providing a complex gallstone service to their local population. Eight sessions of mentored operating were supported, with the provision for additional support if complications occurred.

Results: There were 14 patients included in the mentorship phase of the programme from November 2015 to May 2017. Cholecystectomies were performed on patients with previously complex histories, which included: previous cholecystostomy; CBD stones and multiple ERCPs; suspected choledochoduodenal fistula; suspected cholecystoduodenal fistula; suspected Mirrizzi's syndrome; previous significant intra-abdominal operation; and significant medical co-morbidities. There was one post-operative complication requiring a return to theatre, and one minor wound infection associated with the complex gallstone lists.

Conclusion: We demonstrated a method to reduce the burden on specialist HPB unit for the operative management of complex gallstone disease and safely implement such a service at large UGI unit with an interest in providing a complex gallstone service.

Keywords: Complex gallstone disease, laparoscopic cholecystectomy, mentorship, hepatobiliary surgery

INTRODUCTION

Gallstone disease is common, being present in 10-20% of the adult population in Europe and the United States (1). Clinical manifestations of gallstone disease are also common, with 1-2% of adults becoming symptomatic from their gallstones within a year (2). Symptomatic gallstone disease represents a significant healthcare burden with 60.000 cholecystectomies performed in the UK in 2011 (3). However, not all cholecystectomies can be performed as straightforward day-case procedures as there is a considerable spectrum in gallstone disease and variation in the age and comorbidity profile of patients.

The UK population is ageing, and with this brings a patient population with increasing number and severity of comorbidities. Increasing age and co-morbidity can lead to repeated trials of conservative management, with patients developing increasingly complex gallstone disease, with for example: multiple attacks of cholecystitis; CBD stones with multiple ductal instrumentation procedures; gallbladder drainage procedures and gallbladder fistulation. With an increasingly aged and co-morbid population, treatment of gallstone disease carries a higher risk, with age, co-morbidity and multiple episodes of acute cholecystitis being independently associated with bile duct injury (4). Treatment of complex gallstone disease in these patients should therefore only be performed by appropriately trained surgeons.

Bile duct injuries during cholecystectomy have a significant impact on patient survival and quality of life. Patients who experience a bile duct injury during cholecystectomy are three times more likely to die within 10 years after cholecystectomy

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compared to non-injured patients (5). Patient's quality of life is also significantly negatively impacted following bile duct injury, with poorer mental and physical quality of life after major bile duct injury (6). Furthermore, bile duct injury is associated with significant litigation costs, varying from £2.500 to £216.000 in the UK, and $628.138 to $2.891.421 in the USA (6).

The normal pathway for patients with complex gallstone disease is referral to specialist hepatopancreaticobiliary (HPB) unit where there is expertise for common bile duct exploration and repair. The requirement for specialist HPB units to manage complex biliary disease can unnecessarily stretch resources in a system where cancer operations are a time- and resource-dependent priority. In addition to adding considerable operative burden to the HPB unit, it also underutilizes the skills of UGI surgeons in referring centers who also have extensive experience with gallstone disease.

To address these issues, a mentorship scheme was developed for a busy UGI unit, with support from the specialist HPB unit.

MATERIAL and METHODS

A complex gallstone service was set up through a service level agreement with a specialist HPB unit and a large UGI unit with an interest in providing this service to their local population. The HPB unit was commissioned to provide mentorship for two UGI surgeons locally at the UGI unit for eight sessions of mentored operating. The cases for inclusion in the mentorship phase of the programme were identified by the UGI unit as complex gallstone disease requiring operative management from the outpatient clinic environment. Two consultant surgeons at the UGI unit participated in the mentorship phase, acquiring skills to independently undertake complex gallstone operations by the end of the programme.

Requirements for the collaboration:

- HPB unit would provide a surgeon to support operating on complex gallstone disease for up to eight sessions (four days) per annum. This would equate to one day of operating every three months.
- The operating sessions would take place on the local UGI site.
- The patients would be identified by the local Upper GI consultants and remain under their care.
- A provision for emergency service by the HPB unit to support when unexpected complications arose at the local UGI site.
- An expectation that two local UGI surgeons can be signed off by the HPB unit to carry out this work independently after a suitable period of mentorship.

Patients were identified for inclusion on the complex gallstone lists if they fulfilled one of the following criteria:

- History of significant degree of gallbladder inflammation, such as multiple episodes of acute cholecystitis resulting in fistulation to adjacent organs or requiring intervention (cholecystostomy)
- Multiple ERCPs
- ERCP with incomplete ductal clearance

Patients were excluded if they had obvious Mirizzi's syndrome grade II-IV requiring biliary reconstruction (7).

Prior to each operating list, the UGI surgeons liaised with the HPB surgeons regarding case selection. On the day of surgery, an extended pre-operative briefing was performed with the UGI surgeon, HPB surgeon and theatre team, reviewing all investigations and discussion of operative strategy.

RESULTS

There were 14 patients identified with complex gallstone disease for inclusion in the mentorship phase of the programme from November 2015 to May 2017 (Table 1). These included eight females and six males, with a median age of 67 years (range 28-77 years). There were a range of indications for inclusion into the complex gallstone disease operating list, including: previous cholecystostomy (six cases); CBD stones and multiple ERCPs (six cases); suspected choledochoduodenal fistula (one case); suspected cholecystoduodenal fistula (one case); suspected Mirrizzi's syndrome (one case); previous significant intra-abdominal operation (four cases); and significant medical co-morbidities (six cases).

The median time from referral to operation was 18 months; however, in one case, the patient had waited 73 months for operative management by an appropriately qualified team (see case 1).

Nine operating sessions (over three operating lists) were mentored by two HPB surgeons during the collaboration. A range of procedures were undertaken, including: open cholecystectomy with CBD exploration (six cases); laparoscopic cholecystectomy (five cases); laparoscopic subtotal cholecystectomy (1); laparoscopic converted to open cholecystectomy and repair of choledochoduodenal fistula (one case); and laparoscopic converted to open cholecystectomy (one case). The indication for each patient, and operation performed are displayed in Table 1.

Post-operatively, one patient returned to the theatre with a bile leak from the gallbladder bed and a small bleed from a peripheral branch of middle hepatic vein in liver bed following open cholecystectomy and CBD exploration. With the support of the HPB unit consultant the patient underwent an emergency laparotomy for control of bile leak and bleeding and placement of T-tube. The patient was subsequently discharged from hospital without further complication. One further patient had a superficial wound infection following open cholecystectomy with

Table 1. Operation performed with respective indications for each patient

Case No.	Operation	Indication
1	Laparoscopic converted to open cholecystectomy	Acute cholecystitis complicated by liver abscess requiring percutaneous cholecystostomy, and drainage of liver abscesses. Previous gastric bypass.
2	Laparoscopic cholecystectomy	Gallbladder perforation and cholecystostomy.
3	Open cholecystectomy with CBD exploration and T-tube insertion	Cholangitis secondary to CBD stones. ERCP not possible due to previous subtotal gastrectomy (via rooftop incision). Previous PTCs. Alcohol-related cirrhosis.
4	Laparoscopic cholecystectomy	Recurrent gallbladder empyema and cholecystitis requiring cholecystostomy.
5	Laparoscopic converted to open cholecystectomy and repair of choledochoduodenal fistula	Emphysematous cholecystitis x 2 requiring cholecystostomy with choledochoduodenal fistula, suspicious calculi in CBD.
6	Laparoscopic cholecystectomy	40-year history of pain. Choledocystoduodenal fistula, previous abandoned lap chole by another surgeon.
7	Laparoscopic cholecystectomy	History of acute cholecystitis and gallbladder perforation requiring cholecystostomy. Previous laparotomy for suspected oesophageal perforation.
8	Open cholecystectomy with CBD exploration	5X ERCPs, impacted stones in CBD, CBD stone not amenable to ERCP removal.
9	Open cholecystectomy with CBD exploration	Pancreatitis. Known CBD stones, 3X ERCPs (duct presumed clear, normal LFTs).
10	Laparoscopic subtotal cholecystectomy	Empyema with cholecystostomy.
11	Open cholecystectomy with CBD exploration	Impacted CBD stone not amenable to ERCP removal (4X ERCP), stent in situ, previous PTC. History of acute cholecystitis.
12	Laparoscopic cholecystectomy	ERCP for CBD stone Possible Mirrizzi's on EUS.
13	Open cholecystectomy with CBD exploration	Gallstone pancreatitis. CBD stone not amenable to 2X ERCP removal. Biliary stent in situ. Cholecystitis, associated with portal vein thrombosis. Previous 2 laparotomies.
14	Open cholecystectomy with CBD exploration	12X ERCPs with incomplete ductal clearance and stent in situ.

CBD exploration and T-tube insertion and this was managed conservatively with antibiotics.

DISCUSSION

Developing local expertise in the operative management of complex gallstone disease though a mentorship-based service level agreement with a specialist HPB unit and a UGI unit is a pragmatic approach to improving patient care and NHS efficiency. We demonstrated that complex gallstone disease can be safely treated in non-HPB units through the creation of a mentorship scheme using a service level agreement with defined and achievable objectives. This is a financially viable option for the UGI and HPB units both for the mentoring phase, and in the future treatment of patients with complex gallstone disease. Not only does it increase the range of biliary procedures that can be delivered locally, but it also reduces the clinical burden of complex gallstone disease on specialist HPB units. This enables HPB units to concentrate more time and resources into cancer care, which is a top priority of the '*The NHS Five Year Forward View*', especially as cancer waiting time standards have not been met for several years (8). Furthermore, developing this service will in turn reduce waiting times in local centers for operative management of complex gallstone disease, and enable the delivery of local treatment for patients, a key NHS target.

Laparoscopic cholecystectomy is a potentially high-risk operation, with devastating outcomes in the presence of severe complication. Multiple episodes of acute cholecystitis, gallbladder drainage procedures, and bile duct instrumentation have been shown to increase the length of operation for laparoscopic cholecystectomy, conversion rate to open surgery and complication profile (9). Furthermore, the occurrence of extreme vasculobiliary injuries have been identified as being related to severe inflammation and fundus-first cholecystectomy (10). The recent '*Tokyo Guidelines 2018 Surgical Management of Acute Cholecystitis*' describes safe steps in laparoscopic cholecystectomy for acute cholecystitis through expert review and Delphi process. They recognize the potential difficulty of laparoscopic cholecystectomy in the setting of acute cholecystitis and describe strategies to prevent vasculobiliary injury and complica-

tions (11). Previously, Grade III (severe) acute cholecystitis was a contraindication to laparoscopic cholecystectomy in the acute setting, unless a gallbladder drainage procedure had been performed. However, in the 2018 guidelines it is propose[d] that '*some Grade III acute cholecystitis can be treated by laparoscopic cholecystectomy when performed at advanced centers with specialized surgeons experienced in this procedure and for patients that satisfy certain strict criteria related to favorable organ system failure and ASA score less than or equal to 2*' (12). This emphasizes the importance of a mentored programme whilst competence is acquired for the treatment of Grade III cases.

Complex gallstone disease represents a significant healthcare burden to the NHS. Bile duct injuries have significant impact on patient's quality of life and financial penalty through litigation to organisations. Furthermore, general surgeons have the highest risk of litigation following laparoscopic cholecystectomy compared to all other general surgery procedures in the UK (13). Treatment of complex gallstone disease is therefore a high-risk operation that should only be undertaken by appropriately trained surgeons.

This model for mentored local expertise development can be translated to other conditions with considerable waiting list with patients currently being referred to specialist centers for treatment. For example, in our unit, this model is now being used to develop laparoscopic day-case anti-reflux surgery in referring hospitals, sharing and developing expertise for local populations. This represents an innovation in service delivery that can be utilized for many different conditions.

CONCLUSION

Using a service level agreement with a specialized HPB unit, with appropriate mentorship, a complex gallstone service can be safely developed in referring hospitals, relieving operative burden from specialized HPB units.

Ethics Committee Approval: The current work was accessed by Medical Research Council (MRC) and Health Research Authority (HRA) tool (http://www.hra-decisiontools.org.uk/research/question1.html) and was deemed not to be clinical research but instead classified as a clinical audit of outcomes. I can confirm that the current work was registered and approved as an audit at University Hospitals Birmingham NHS Foundation Trust by the Governance/ Ethical committee (CARMS Ref. No: 16827).

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ORİJİNAL ÇALIŞMA-ÖZET
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HPB birimi olmayan bir ünitede kompleks safra kesesi taşı cerrahisi servisi kurmak

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ÖZET

Giriş ve Amaç: Kompleks safra kesesi taşı hastalığı, biliyer kolik ve basit kolesistite kıyasla laparoskopik kolesistektomi esnasında daha yüksek riske sahiptir. Genellikle, müşterek safra kanalı eksplorasyonu ve onarımında uzman hepatopankreatikobiliyer (HPB) cerrahi ünitelerinde tedavi edilir. Kompleks safra kesesi taşı hastalığını tedavi etmek, HPB ünitesinin üzerindeki yükü azaltmak ve hastaların lokal tedavi alabilmelerini sağlamak amacıyla uzman bir HPB ünitesinden destek alarak yoğun üst gastro-intestinal (UGI) ünitesi için bir mentorluk programı oluşturduk.

Gereç ve Yöntem: Servis seviyesinde bir anlaşmanın yapılmasıyla birlikte uzman HPB ünitesi, büyük bir UGI ünitesinden iki cerraha kendi hastalarına kompleks safra kesesi taşı hizmeti verebilmeleri amacıyla mentorlük görevi verildi. Mentor denetiminde sekiz cerrahi seans yapıldı ve komplikasyon oluşması durumunda ek destek sağlandı.

Bulgular: Kasım 2015-Mayıs 2017 arasında programın mentorluk safhasında toplam 14 hasta dahil edildi. Önceden kompleks öyküleri bulunan hastalara kolesistektomi uygulandı. Bu kompleks öyküler arasında önceden geçirilmiş kolesistektomi, müşterek safra kanalı taşları ve çoklu ERCP, şüpheli koledokoduodenal fistül, şüpheli kolesistoduodenal fistül, şüpheli Mirrizzi sendromu, önceden geçirilmiş ciddi intra-abdominal cerrahi ve ciddi tıbbi komorbiditeler vardı. Bir hastada, ameliyathaneye dönmeyi gerektiren post-operatif bir komplikasyon oluşurken bir hastada da kompleks safra kesesi taşları ile ilişkili minör yara enfeksiyonu görüldü.

Sonuç: Biz bu çalışmamızda, kompleks safra kesesi taşı hastalığının cerrahi yönetimi açısından uzman HPB ünitesindeki yükü azaltmak adına bir metot geliştirdik ve kompleks safra taşı cerrahisi servisini büyük bir UGI ünitesinde güvenle yürüttük.

Anahtar Kelimeler: Kompleks safra kesesi taşı hastalığı, laparoskopik kolesistektomi, mentorluk, hepatobiliyer cerrahi

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