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Bile leak management in post laparoscopic cholecystectomy patients

Kalpita Patra and Sibaram Mahapatra

Abstract
Bile leaks post laparoscopic cholecystectomy is an infrequent but quite feared complication for surgeons. Surgery was previously regarded as the gold standard approach to these cases but with advent of newer modalities of biliary endoscopic treatment, there has been a wide shift in general approach to manage this dreaded complication. In this study we evaluated the best modality of treatment for managing post laparoscopic cholecystectomy bile leak by endoscopic biliary procedures, percutaneous biliary drainage and open surgical treatment wherever applicable. We got most patients sufficed with endoscopic sphincterotomy with or without stenting or percutaneous drainage or by conservative management. The endoscopic method was effective and successful in managing most of the cases with post laparoscopic cholecystectomy bile leak. Endoscopic treatment can easily substitute surgery in all cases of simple bile leak however complex bile leaks should be managed following a protocol combining endoscopic and surgical methods.

Keywords: Cholecystectomy, Bile leak, laparoscopic

Introduction
Cholecystectomy is one of the most frequent and common surgeries undertaken by surgeons all over the world. Laparoscopic cholecystectomy was first performed in 1980 and has managed to retain its place as the gold standard treatment of choice in the management of gallstones over these past few decades. Bile leak after laparoscopic cholecystectomy is uncommon but can occur in 0.3–2.7% of patients [1-3]. Lack of surgical experience has increased correlation with laparoscopic bile duct injuries with around 97% accountable to misidentification of biliary structures and lack of skill and training accounts for around 3%. Bile leak is defined as the persistent leakage of bile from the biliary tree**.** When both laparoscopic cholecystectomy and minimally invasive techniques were in their early days, most bile leaks were managed conservatively and observed for improvement: if the patient did not improve clinically or by imaging studies, a laparotomy was often performed as a gold standard. But this was associated with a higher rate of morbidity. However, with the newer advent of improved radiological percutaneous drainage, therapeutic endoscopic retrograde cholangiography (ERC) [5-7] and appropriate training of standard laparoscopic techniques including suturing, it is now clear that bile leaks could be effectively managed in a minimally invasive method, significantly reducing morbidity and mortality [8-9]. The mainpurpose of this study is to compare patient outcome following new management protocol and managing patient on a case to case basis either conservatively or by open surgical method and not following a definitive management protocol and comparing it to the patients treated with endoscopic modalities which followed the management protocol and to determine the impact of a structured minimally invasive approach to the management of bile leaks.

Material and methods
Patients who presented with symptoms of bile leak post cholecystectomy were included in this study. After routine investigations such as liver function tests, USG abdomen, CT scan, MRCP were done to establish a diagnosis of positive bile leakage then the patients were divided into two distinct groups.

Group A and Group B.
A strategised and minimally invasive protocol with a clear stepwise approach for the management of bile leaks was followed for one group of patients (n=14) {Group B}and for the other group (n=10) [Group A] a case by case treatment was done without following the management protocol for bile duct injuries.

Management protocol for bile duct injuries
If a drain was left *in situ* at the initial procedure and continued to drain bile, this is left. If not, then an ultrasound scan (USG) is performed and any collection identified drained percutaneously under USG guidance.

Data analysis
Data were not normally distributed and results are expressed as raw numbers (%) or median values (range). A *P*-value < 0.05 was considered to be significant.

Results
All patients initially had a standard 4-port procedure performed mainly by consultant surgeons. More emergency cholecystectomies were performed and the median operative time was significantly less in the latter group. On table, cholangiography was not routinely undertaken and was unremarkable in the 3 patients in which it was performed. Three procedures required conversion in the GROUP A; the anatomy of the biliary tree was unclear in one patient and in two others there were dense adhesions in the right upper quadrant (RUQ). Subsequently, two procedures required conversion; due to bleeding from the cystic artery in one and the presence of an inflammatory phlegmon around the gall-bladder in the other. Pre-operative demographics, indications for surgery and operative details are shown in table 1.

Table 1: Patient demographics, indications for surgery and operative details

	Conservative or open Group **A (*n* = 10)**	**Minimally invasive protocol** Group **B (*n* = 14)**	***P*-value**
Patient age (years)	51 (25–70)	63 (28–73)	0.26
Sex (male/female)	5/5	6/8	1.00
Indication for surgery			0.70
Biliary colic/chronic cholecystitis	4 (40)	8 (57)	
Acute cholecystitis	5 (50)	3 (22)	
Empyema	0	1(7)	
Previous obstructive jaundice	1 (10)	1 (7)	
Pancreatitis	0	1(7)	
Pre-operative ERCP ± stone removal	5 (50)	2 (14)	0.09
ASA grade			0.13
I	4(40)	8 (57)	
II	4 (40)	4 (29)	
III	2 (20)	2 (14)	
Elective/emergency surgery	10/0 (100/0)	9/5 (64/36)	0.05
Duration procedure (min)	150 (105–210)	95 (25–135)	< 0.01
Operative findings			0.81
Quiescent GB	6 (60)	9 (64)	
Inflamed GB	4 (40)	4 (29)	
Gangrenous GB	0	1(7)	
OTC	2 (20)	1 (7)	0.55
Conversion to open procedure	3 (30)	2 (14)	0.61
Postoperative drain	10 (100)	11 (79)	0.24

The therapeutic procedures performed are summarised in table 2. In GROUP A, conservative management in 4 (40%) individuals was sufficient, the remaining 6 (60%) required operative intervention. The indications for surgery were biliary peritonitis following early drain removal in two, persistent drainage of bile (3, 5 and 8 days) in three and the development of a large subphrenic collection in association with a persistent bile leak (20 days) in a septic patient on ITU. All six individuals underwent a laparotomy with on-table cholangiography routinely performed. The site of the leak was an inadequately secured cystic duct (n = 2), a hole just proximal to clips/ligation of the cystic duct (n = 2) or a hole at the junction of the cystic duct and common bile duct (CBD; n = 2). In each case, the site of the leak was sutured and a thorough washout/drainage performed. CBD stones were only identified in one individual who went on to have exploration of the CBD and stone removal with insertion of a T-tube. A postoperative T-tube cholangiogram was unremarkable and this was removed 12 days after insertion.

Table 2: Management of bile leaks before and after the introduction of a minimally invasive protocol

	No protocol Group **A (*n* = 10)**	**Minimally invasive protocol Group B (*n* = 14)**	***P*-value**
Percutaneous USS-guided aspiration/drainage	3 (30)	4 (29)	1.00
ERCP	2 (20)	11 (79)	0.01
Stone extracted	0	4(29)	
Endoscopic sphincterotomy	0	4(29)	
Stent insertion	1 (10)	10 (72)	
Laparoscopy	0	5(36)	0.05
Laparotomy	6 (60)	0 (0)	< 0.01

Discussion

Laparoscopic cholecystectomy is currently the procedure of choice for symptomatic gallstones. It has evolved from an innovative, but time-consuming, novelty to a routine day-case procedure over the last 20 years [10]. Similarly, the management of bile leaks following this procedure has changed. However, the fundamental principles underpinning this have not, *i.e*. successful drainage of a bile leak is critical. If drainage is inadequate, sepsis and biliary peritonitis develop and this remains a clear indication for surgical intervention. This study documents the changes in technique that have occurred in a specialist unit over the last 10 years and advocates a minimally invasive structured management protocol to treat patients with bile leaks.

Thus, a common indication for surgical intervention was persistence of the bile leak. In comparison, following introduction of the minimally invasive protocol, this was the main indication for ERC and stenting but was not an indication for surgical intervention. In all but one patient (who developed peritonitis post drain removal), this allowed rapid resolution of the bile leak. ERC and stenting also plays an important role as an adjunct to laparoscopy and washout in patients with biliary peritonitis, helping to reduce or eliminate postoperative bile leakage thus accelerating recovery. However, although the use of ERC has undoubtedly been a major advance, it does have potential drawbacks. The plastic stents inserted into the CBD need removal after 6 weeks, exposing the patient to a second ERC and hospital visit. This explains the longer follow-up for those following the minimally invasive protocol. Furthermore, although there were no ERC-related complications in this study, these are always a concern and can, rarely, be life-threatening.

The second major change advocated by the protocol is the use of laparoscopy rather than laparotomy in the management of patients requiring surgical intervention. Successful ERC and stenting has been accompanied by a shift in the indications for surgery, with biliary peritonitis (5/5) rather than failure of conservative management being the main indication in the protocol era. Interestingly, in both groups, the placement of a drain following laparoscopic cholecystectomy did not prevent the development of biliary peritonitis in a minority of individuals (3/24) presumably either because it became blocked or was removed prematurely. The role of surgical intervention in both groups is primarily to wash out bile from the peritoneal cavity and establish adequate external drainage in order to prevent reaccumulation. If the site of the bile leak can be identified, then an attempt is made to repair this. This was identified in all 6 patients who underwent laparotomy compared to only 2/5 individuals managed laparoscopically. Some authors have been able to identify the majority of bile leaks laparoscopically, advocating the magnification provided by the laparoscope as an important aide [9]. However, in our series, 3/5 patients had an ERC and stent before laparoscopy, significantly reducing the leak at the time of surgery. This potentially explains the lower number of leaks identified compared to either laparotomy at our centre or laparoscopy elsewhere. In addition, the anatomical pattern of bile leaks identified varied, with leaks coming from the cystic duct stump itself or its junction with the CBD in those undergoing laparotomy compared with leaks from ducts of Luschka in the laparoscopic group. Once again, the use of ERC and stenting in the latter group may explain this as leaks from the cystic duct stump were effectively sealed in 4 patients without the need for surgical intervention.

Conclusion

Overall morbidity, mortality and hospital stay post laparoscopic cholecystectomy were similar both before and after introduction of a minimally invasive management protocol. It is not surprising that these were similar in view of the relatively small numbers and the pathophysiology of bile leaks (*i.e*. patients with biliary peritonitis often take several days to get better from the 'peritonitis' irrespective of the operative technique). However, anecdotally and bearing in mind that our patients have increasingly high expectations, we feel that the minimally invasive approach is preferable. This minor, but significant, change in the management of bile leaks and saving a laparotomy has a major impact on the patient's perception of the significance of the complication. Furthermore, longer-term problems such as intra-abdominal adhesions and incisional hernias may be reduced.

In our experience, a structured stepwise approach to the management of uncommon complications such as bile leaks is advantageous. In order to run such a protocol there must be the resources and skills available to provide ERC and advanced laparoscopic surgery, 7 days a week. If this is not available, as we have shown, it is perfectly possible, although not preferable, to manage these patients using conventional techniques. Alternatively, they can be transferred to centres where minimally invasive expertise is routinely available. Bile leak remains an unusual problem in our practice. Thus it has taken over 10 years to accumulate the relatively small series. Nonetheless, this study provides a useful analysis of the historical and current management of bile leaks.

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