A Prospective Study of Cholecystectomy in District General Hospital Settings with Literature Review.

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Citation

Abstract

Background: Cholecystectomy is a major operation with the potential for serious morbidity and even mortality. Complication rates are varied, with the majority being encountered in the emergency setting. Our aim was to analyse complications following cholecystectomy performed in the emergency and elective setting. Subsequently, with the aid of an extensive literature review, we assess any key factors in predicting complications and make recommendations on optimal management.Methods: Data was collected prospectively over a one-year period during 2004. A data collection tool was designed to be generated at the time of the theatre, completed up until the time of discharge, and at the first follow-up appointment. Literature review involved MEDLINE, EMBASE and Pubmed literature searches performed up until March 2008 to identify original studies, irrespective of language, blinding or publication status, on cholecystectomies and their associated complications.
Results: 442 cholecystectomies were performed in the year 2004; 94.6% were performed laparoscopically, of which 12% were as an emergency. Overall conversion rate was 8.1%, being higher as an emergency as opposed to open (19.3% vs. 3.1%). Bile duct injury was encountered in 0.4% and excessive bleeding in 5%. CBD exploration was carried out in 1%. Overall mortality was 1.5%.Conclusions: There are many factors to take into account when carrying out this commonly performed procedure. Clear identification of anatomy is imperative, and there should be no hesitation in requesting the assistance of a more experienced laparoscopic or upper GI surgeon.

INTRODUCTION

Since the first experimental laparoscopy was performed upon a dog in Berlin in 1901 by Georg Kelling, surgeons have pushed the boundaries in developing the laparoscopic approach to become the gold standard in a variety of procedures. After the first documented laparoscopic cholecystectomy was performed by Erich Mühe in Germany in 1985, following technological developments and advances in surgical technique, the procedure has become one of the most commonly carried out in the United Kingdom, with the majority being carried out laparoscopically. Various studies have been performed in the last two decades to investigate the efficacy of this approach, in helping surgeons more accurately assess whether performing an open or laparoscopic procedure is best under varying circumstances. Regardless of the approach, cholecystectomy is a major undertaking for a patient with substantial risks of major morbidity and even mortality.

AIMS AND METHODS

This prospective study was conducted to obtain our figures concerning various aspects of this commonly performed procedure. Furthermore we conducted an extensive literature review to highlight any areas where we can improve results, and find potential predictors of poor outcome.

We collected data on all cholecystectomy procedures (in both elective and acute setting) carried out during 2004 in the North Tees and Hartlepool NHS trust to evaluate our practices and results. The emphasis was on the complication rates, common bile duct injury rates, conversion rates, critical incidents and mortality. The audit tool was designed to be generated at the time of the theatre, completed up until the time of discharge, and at the first follow-up appointment.

LITERATURE REVIEW

MEDLINE, EMBASE and Pubmed literature searches were performed up until March 2008 to identify original studies, irrespective of language, blinding or publication status, regarding cholecystectomies and their associated complications.

RESULTS

A total of 442 cholecystectomies were performed under 12 consultant surgeons across the trust. Out of these 380 (86%) were elective and the remaining 62 (14%) were emergency procedures (Figure 1). A total of 24 procedures out of 442(5.5%) were scheduled as open procedures; 12 each in elective and emergency group. Reasons for scheduled open procedure included; combination with other procedure (n=8), previous surgery (7), acute cholecystitis (4), empyema (2), emergency laparotomy (2) and gallstone ileus (1). Out of the 418 scheduled for laparoscopic procedure, 50 were emergency and 368 elective (Figure 2).

Figure 1

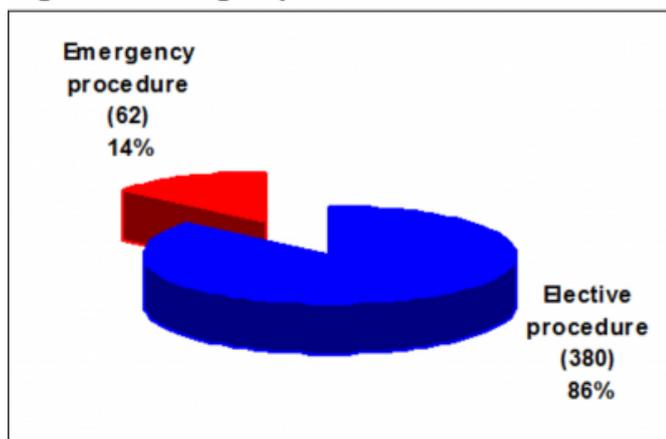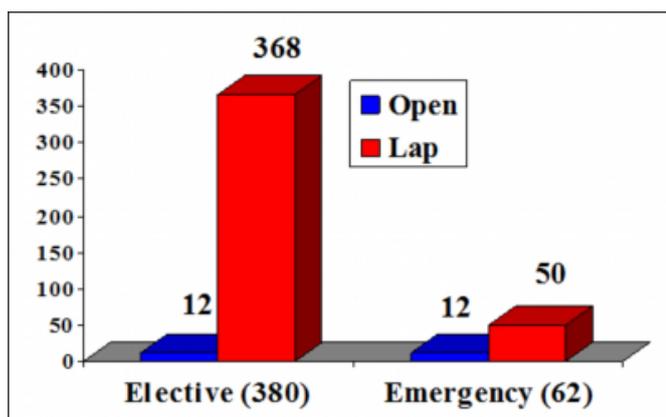Figure 1. Emergency vs Elective distribution

Figure 2

Figure 2. Open vs Laparoscopic distribution

Our overall conversion rate was 8.1% (34 out of 418). The conversion rates for emergency and elective procedures were 19.3% and 3.1%, respectively. In all the conversion cases the consultant was not an Upper GI Surgeon. Intra-abdominal adhesions were encountered in 131 (30%) patients, and 76 (17%) patients had had previous abdominal surgery. There were a total of 25 (6%) injuries recorded as a result of port insertion. Out of these 6 were injuries to liver and 4 were visceral injuries. Drains were used in 164 (37%) procedures. A total of 24 perioperative cholangiograms were carried out and 5 patients (all done open) had common bile duct exploration.

Perioperative complications encountered included bleeding in 21 (5%), minor bile drainage in 4 (0.9%), retained common bile duct stones in 6 (1.3%), pulmonary complications in 4 (0.9%), deep vein thrombosis in 3 (0.6%), and transient hypotension responding to fluid challenge in 1 (0.2%).

We had four major morbidities during the course of this audit. One patient experienced major bleeding from an epigastric port site requiring laparotomy with an eventual satisfactory outcome. The second patient developed a bile leak from the cystic duct stump which presented in the early postoperative phase as biliary peritonitis requiring laparotomy; the patient eventually recovered completely. The third patient had a minor common bile duct injury and required transfer to the regional hepatobiliary unit for conservative treatment. This patient also recovered completely in due course. The fourth patient had a duodenal perforation which needed transfer to the regional specialist upper gastrointestinal unit. This patient developed a retro-colic abscess which necessitated a right hemicolectomy, and subsequently recovered completely with an incisional hernia.

Significantly there were two duodenal injuries; one of these two patients died, whilst the other recovered after a long stay in hospital and transfer to a specialist centre.

On follow-up, 49 patients developed a variety of complications such as non-specific nausea, pain and dyspepsia (30), wound infection (4), diarrhoea (3), small subhepatic collection managed conservatively (2), deranged liver function tests (settled spontaneously) (4), retained stone (2), incidental adenocarcinoma (1), pancreatitis (1), bilateral pleural effusion (1) and port site hernia (1).

A summary of our results is shown in figure 3.

Figure 3

Figure 3. Summary of results

SUMMARY		
Total included in audit	442	
Scheduled for Open Cholecystectomy	24	(5%)
Scheduled for Laparoscopic Cholecystectomy	418	(95%)
Conversions from lap to open procedure	34	(8.1%)
Incidence of Bile Drainage	4	(0.9%)
Bile duct injuries	2	(0.4%)
Exploration CBD	5	(1%)
IR1 (Incident report) form completed for:		
- Serious untoward incidents /Post-op deaths	5	(1%)
- Adverse post-operative events	1	(0.2%)
Complaint via PALS (Patient Advice and Liaison Service)	1	(0.2%)
Mortality	7	(1.5%)

MORTALITY

We lost seven patients in this series during one year. On close inspection of the causes (figure 4), in two cases the cholecystectomy was not the primary reason to operate, and three cases were elective procedures.

Figure 4

Figure 4. Causes of mortality

Cause of Death		Details
1.	Septicaemia and Renal Failure	Combined open gastrectomy for cancer and cholecystectomy, developed biliary collection.
2.	Multi-organ failure and pulmonary embolism	Laparoscopic converted to open procedure. Patient died 10 days post-op.
3.	Myocardial Infarction	Patient presented with acute abdomen, haemo-peritoneum found at laparotomy. Large stone was invading portal vessels. Significant blood loss.
4.	Septicaemia	Patient had ERCP 8 days post lap. cholecystectomy. Developed sepsis from peritoneal collection.
5.	Metastatic malignancy	Previous gastrectomy 4 years prior. Laparoscopic procedure converted to open. Multiple liver metastases found.
6.	Bronchopneumonia, acute cholecystitis, MRSA septicaemia	Admitted with cholangitis, no resolution with medical management. Developed sepsis post-open procedure.
7.	Multi-organ failure	Initially operated on for perforated duodenal ulcer, diseased gallbladder coincidentally found and removed. Patient re-opened for dehisced sutures, second closure also failed.

DISCUSSION

On first impression these results are seen to be acceptable, with our rates of conversion and morbidity in line with current evidence. However, we would have obviously preferred our rates to be lower, in particular that of mortality.

With this in mind we conducted a literature review looking specifically at key factors that may predict outcome, and thus draw conclusions on optimal management.

As with any surgical procedure, in managing a patient throughout the journey of their disease, patient selection is vital. Previous studies have identified male gender, duration of intervention, body weight, duration of operation, the surgeon's experience, conversion to open surgery, ASA score III/IV, body weight and emergency surgery to be associated with a higher incidence of postoperative complications[1].

The decision to convert from a laparoscopic to open procedure can be for a variety of reasons, however is virtually guaranteed to be related to lengthened post-operative recovery and increased morbidity. The overall rate of conversion to open cholecystectomy has been noted to be 1%-22.4%[2-14]. A conversion rate of 13.2%-22.4% has been noted in patients operated upon as an emergency[11-14]. The conversion rates for elective procedures are lower at 1%-7.5%[2-11].

Many studies have highlighted a variety of factors that are related to an increased risk of conversion, and these must be collaborated and analysed as part of a thorough pre-operative assessment, in particular blood tests and imaging, in making the decision as to whether the patient is suitable for laparoscopic procedure. This is as relevant in the acute as well as the elective setting in ensuring the patient receives the most appropriate procedure bearing in mind their clinical condition and co-morbidities.

Ishizaki et al. identified gall bladder thickness and a history of common bile duct stones treated by endoscopic sphincterotomy as predictors of conversion[3]. In their retrospective analysis of 1804 cholecystectomies in Greece, Simopoulos et al. identified male gender, age older than 60 years, previous upper abdominal surgery, diabetes and severity of inflammation to be significantly associated with conversion[11]. Meanwhile no relationship was identified with regards to body mass index, cardiovascular disease, hypertension, or a history of acute cholecystitis or pancreatitis. Of interest, in patients with acute cholecystitis, conversion was found to be associated with a greater white blood cell count, fever, elevated total bilirubin, aspartate transaminase, and alanine transaminase. Furthermore, conversion rate was significantly higher than average at 25.8%, when empyema of the gall bladder was present.

Reasons for conversion are most commonly put down to the inability to define Calot's triangle. Poor anatomy has been cited as the reason for conversion in 19.2% to 74.4% of cases[11,13,15]. Simopoulous et al. observed the other reasons for conversion as bleeding from the cystic artery (n=3 out of 24), common bile duct injury (n=2), cancer of the gall bladder (n=1), polyps of the gall bladder (n=1), cholecystoduodenal fistula (n=6), spilled stone (n=2) and inadequately created pneumoperitoneum (n=9)[11].

In their analysis of 1249 laparoscopic cholecystectomies, Tayeb et al. reported a conversion rate of 7.5% from India[15]. They identified dense adhesions (56.2%), empyema (12.2%), obscure anatomy (19.2%), bile duct stone (6.9 %) and suspicion of bile duct injury (2.7%) as the main reasons for conversion. Furthermore this study identified ultrasonic findings of inflammation and older age (>60 years) to be significant risk factors for conversion. Significantly they did not identify alkaline phosphatase level of >130 IU/L and body mass index >30 as major risk factors.

There are a host of various morbidities related to cholecystectomy, including bile duct injury, bleeding, bowel injury and post-operative pulmonary or thromboembolic events. A morbidity rate of 5% to 30% has been noted previously[2,8,13,16].

The incidence of clinically significant bile leaks varies between 0% and 0.5%[8,14,17-20]. It would be worth emphasising the term "clinically significant" as Dominquez et al. showed asymptomatic subclinical bile leaks in 8% of patients when they performed a PIPIDA (paraisopropyliminodiacetic acid) scan on postoperative day 1, whilst there were no symptomatic leaks identified[20].

Studies have variously shown a figure of 0 to 0.5% for bile duct injury[5-7,14,16-18,21-23]. Others have reported a higher incidence of bile duct injury at 1.4%[24]. It has also been suggested that the incidence of bile duct injury is lower when intraoperative cholangiogram was performed and with increasing surgeon experience. Higher rates of bile duct injury were associated with cholecystitis, older patients and male sex[17,22,23].

The incidence of vascular complications varies between 0.001% and 0.7%[7,19,21,25-27]. Vascular injury usually arises either as a result of initial trocar insertion, or due to difficult dissection of Calot's triangle, where both the portal vein and hepatic artery are at risk. Usal et al. reported injury to the aorta and vena cava in two separate cases (out of 1372) due to trocar insertion, whilst the other case of bleeding was due to portal vein injury during division of adhesions, which eventually resulted in death secondary to liver failure[25]. Singh et al. reported injury to the right external iliac on insertion of the Veress needle[21].

Singh et al. went on to report 9 (0.5%) significant non-biliary injuries in their retrospective analysis of 1748 laparoscopic cholecystectomies. The injuries reported were duodenal perforation (3), diaphragmatic injury (2), small bowel injury (1), right external iliac artery injury (1), portal vein injury (1), and liver laceration (1). Seven of these injuries required conversion. Kwon et al. reported a 0.6% incidence of bowel injury in their retrospective analysis of 1190 consecutive laparoscopic cholecystectomies[24]. All the injuries were dealt with laparoscopically.

Sub-hepatic abscess formation has been reported to occur in around 0.001% of cases[19,27]. These often occur as a result of small bile leaks or dropped gallstones. A recent study on Wistar-Albino rats by Aytekin et al. found that leaked bile and stones cause a significantly higher rate of adhesion formation[28]. Whilst spilled infected stones are seen to be related to increased risk of abscess formation, when they cannot be retrieved, the use of a hyaluronic acid derivative was associated with a significant reduction in the formation of adhesions and subsequent post-operative complications. Further larger studies may lead to its more widespread use in the future.

Wound infection is another complication to bear in mind; however, cases have been significantly reduced in recent times due to meticulous sterilisation procedures, whilst of course having smaller port-site scars from a laparoscopic procedure. In a retrospective study of 3146 laparoscopic cholecystectomies from Poland, infection of the infra-umbilical wound was the most commonly observed complication in 23 patients (0.007%), followed by an umbilical hernia in 14 (0.004%)[5]. Our results reflect similarly, with a wound infection rate of 4 out of the 442 patients (0.009%). Our results do not suggest a benefit to the use of prophylactic antibiotics and this is further reinforced by other studies, such as Wen-tsan Chang et al., who found there was no significant difference in infective complications when 1g of cefazolin was used at time of anaesthesia in elective operations (0.7% with antibiotic, 1.5% without antibiotic p=0.148)[29]. However, this may of course be different in the acute setting.

The mortality rates associated with this operation have been

described in literature to range from 0% to 12%[2,13,16,18,30]. Reasons for mortality included operative injury[18], metastatic gallbladder carcinoma, sepsis and multiple organ failure[14]. If we could take lessons from our experience it would be that the risk of death is significantly higher in the acute setting and when there is a current or previous history of malignant disease.

The final factor that must be considered is the financial cost. Ultimately, the more safe and timely day case procedures that can be performed, the more money is saved. The average cost of a day case laparoscopic cholecystectomy varies between £768 and £1285, whilst for the same procedure as an in-patient it is £1430-£1898[8,10].

With respect to the management of acute cholecystitis, there is increasing evidence to suggest it is more financially economical to remove the gallbladder during this acute phase so as to reduce total hospital stay and avoid the expense of recurrent re-admissions with episodes of biliary colic, along with the development of potential complications such as sepsis, pancreatitis and gallstone ileus.[31-33]

In comparing early (within 24 hours) to delayed (6-8 weeks later), Lai et al. [31] found no significant difference in conversion rate (early 21 per cent versus delayed 24 per cent), postoperative analgesic requirement (1 versus 2 doses) and postoperative complications. There has been much debate over the role of initial conservative treatment followed by interval elective operation, and the impact this has on outcome and the rate of conversion to open procedure. Knight et al.[32] found a delay of 3-4 days following presentation resulted in no significant difference in conversion rate. However, Lo et al. [33] found the delayed group had a tendency toward a higher conversion rate (23% vs. 11%; p = 0.174) and complication rate (29% vs. 13%; p = 0.07), concluding that early operation within 72 hours of admission has both medical and socioeconomic benefits.

CONCLUSIONS

As with any procedure, general and specific complications should be considered. Following our literature review, general factors that may increase operative risk include the male gender, age greater than 60 years and co-morbidity (including diabetes mellitus). Previous upper abdominal surgery is also a significant general risk of any laparoscopic procedure, with the related risk of adhesions and associated trocar injury to visceral or vascular structures.

In the acute setting, one must be particularly wary of the

septic patient with deranged liver function tests. Nevertheless, given the literature findings, operating in the acute setting does not seem to impact on the difficulty of the procedure, provided there are no other pathologies present.

Obviously in the context of any significant complication that results in an obstructed view of Calot's triangle conversion is indicated. However, with respect to poor anatomical identification, an intra-operative cholangiogram is a priceless tool in mapping out the biliary system and ensuring the cystic duct is appropriately ligated. An alternative to this is a pre-operative Magnetic Resonance Cholangiopancreaticography (MRCP).

Our study highlights, as with any procedure, there are surgeon related factors, and those specialising in Upper GI surgery have a lower conversion and complication rate. We would also comment that, in the current climate where trainees receive less exposure to the open procedure, that opinion should be sought from an Upper GI surgeon prior to conversion.

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