Cost effectiveness of intraoperative laparoscopic ultrasound for suspected choledocholithiasis; outcomes from a specialist benign upper gastrointestinal unit

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ABSTRACT

Introduction Common bile duct stones are present in 10% of patients with symptomatic gallstones. One-third of UK patients undergoing cholecystectomy will have preoperative ductal imaging, commonly with magnetic resonance cholangiopancreatography. Intraoperative laparoscopic ultrasound is a valid alternative but is not widely used. The primary aim of this study was to assess cost effectiveness of laparoscopic ultrasound compared with magnetic resonance cholangiopancreatography.

Materials and methods A prospective database of all patients undergoing laparoscopic cholecystectomy between 2015 and 2018 at a district general hospital was assessed. Inclusion criteria were all patients, emergency and elective, with symptomatic gallstones and suspicion of common bile duct stones (derangement of liver function tests with or without dilated common bile duct on preoperative ultrasound, or history of pancreatitis). Patients with known common bile duct stones (magnetic resonance cholangiopancreatography or failed endoscopic retrograde cholangiogram) were excluded. Ninety-day morbidity data were also collected.

Results A total of 420 (334 elective and 86 emergency) patients were suspected to have common bile duct stones and were included in the study. The cost of a laparoscopic ultrasound was £183 per use. The cost of using the magnetic resonance cholangiopancreatography unit was £365 per use. Ten postoperative magnetic resonance cholangiopancreatographies were performed for inconclusive intraoperative imaging. The estimated cost saving was £74,650. Some 128 patients had common bile duct stones detected intraoperatively and treated. There was a false positive rate of 4.7%, and the false negative rate at 90 days was 0.7%. laparoscopic ultrasound use saved 129 bed days for emergency patients and 240 magnetic resonance cholangiopancreatography hours of magnetic resonance imaging.

Conclusion The use of laparoscopic ultrasound during laparoscopic cholecystectomy for the detection of common bile duct stone is safe, accurate and cost effective. Equipment and maintenance costs are quickly offset and hospital bed days can be saved with its use.

KEYWORDS

Laparoscopic ultrasound – Cost – Cholecystectomy, laparoscopic – Gallstones – Choledocholithiasis

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Introduction

Common bile duct stones are reported to be present in approximately 10% of patients with symptomatic gallbladder stones.¹ Untreated, these stones can lead to recurrent symptoms, pancreatitis and cholangitis, and the recommendation is therefore to treat.² There are currently no clear guidelines on best practice for the management of possible common bile duct stones. Currently, one-third of the 66,000 patients undergoing cholecystectomy annually in the UK will have ductal imaging preoperatively, commonly with magnetic resonance cholangiopancreatography (MRCP), most of which are normal.^{1,5} The Sunflower Trial (currently underway at the time of writing this paper)

may provide guidance on more focused use of preoperative MRCP.

Intraoperative laparoscopic ultrasound at the time of cholecystectomy is a valid imaging modality, but not as widely used to screen for common bile duct stones.^{1,5} It can provide an efficient assessment of the common bile duct and thus can be used as an alternative to MRCP.⁴ However, the cost of purchasing equipment and training is perceived to be a barrier.

We investigated the objective benefits of an intraoperative laparoscopic ultrasound service. The primary aim of this study was to assess the cost effectiveness of laparoscopic ultrasound to justify the purchase of the equipment. The

measure of cost effectiveness was reduced use of MRCP. The secondary outcome measures were to determine laparoscopic ultrasound safety and quality expressed in terms of sensitivity and specificity and an estimate of hospital bed days saved.

Materials and methods

Analysis was performed using a prospective database maintained within our specialist benign upper gastrointestinal unit. This contained all patients who underwent laparoscopic cholecystectomy with laparoscopic ultrasound at a single district general hospital between January 2015 and November 2018. These operations were performed by five consultant surgeons who were experienced at using laparoscopic ultrasound and had all completed a laparoscopic ultrasound accreditation course.⁵ All patients with symptomatic gallstones who were suspected to have common bile duct stones and would have traditionally undergone preoperative MRCP (as agreed by at least two consultants), but instead received laparoscopic ultrasound, were included in the study. Inclusion criteria were common bile duct stones suggested preoperatively by transabdominal ultrasound, history of pancreatitis or cholangitis, dilated common bile duct preoperatively on transabdominal ultrasound ($\geq 25\%$ adjusted for age greater than 5mm +1mm for every decade of life over 50 years) and/or any derangement in any liver function test at the time of surgery or in the 12 months before surgery (unexplained by non-alcoholic steatohepatitis, Gilbert's syndrome or medication). We included both sexes, all ages and elective and emergency patients in the study. Patients with known common bile duct stones preoperatively demonstrated by previous MRCP, failed endoscopic retrograde cholangiogram (ERCP), tubogram via cholecystostomy or endoscopic ultrasound were excluded. If there was uncertainty about laparoscopic ultrasound interpretation during surgery then an intraoperative x-ray cholangiogram was also performed. If there was still uncertainty, a postoperative MRCP was performed.

A prospective database was used to identify patient outcomes and morbidity data. Literature is available on cost per MRCP and time to perform each scan.^{4,6,7} These figures were used to calculate the resource savings over a four-year period in a district general hospital.

Results

1273 LCs were performed during the study period, and 420 patients were suspected to have common bile duct stones using the above criteria, and therefore included in the study. Table 1 gives a list of indications recorded for laparoscopic cholecystectomy; 261 patients were female and 159 male. Age at the time of surgery ranged from 15 years to 90 years, median age was 56 years. Of the total, 334 cases were elective and 86 were emergency.

Our hospital purchased one BK Medical ultrasound machine (FlexFocus 500) and five ultrasound probes (Model 8836) at a cost of £70,000 (year of purchase 2015).

Our upper gastrointestinal unit purchased five probes as there was a requirement from our infection control department that each probe must be formally sterilised after each use. This meant that five probes were required to run a continuous service. An estimation of £5,000 was given to the cost of providing this sterilisation service over the study period, which is performed by our theatre sterilisation department using gas plasma sterilisation. The total cost for purchase and maintenance was therefore £75,000.

Fifty-two intraoperative x-ray cholangiograms were required in addition to laparoscopic ultrasound due to equivocal interpretation of the common bile duct at the time of surgery (12.4%), which were estimated to be of negligible cost. Ten postoperative MRCPs were required for inconclusive intraoperative imaging with both laparoscopic ultrasound and x-ray cholangiogram at time of surgery (2.4%).

The calculated cost of laparoscopic ultrasound was £178.57 per use (£75,000/420). Using routine laparoscopic ultrasound and limited support of x-ray cholangiogram meant that 410 MRCPs were not required; The MRCP unit cost is estimated at £365.⁷ An MRCP cost saving of £149,650 ($410 \times £365$) was calculated. When offset against cost of laparoscopic ultrasound equipment purchase and maintenance (£75,000), this represents an overall cost saving of £74,650 (£149,650 – £75,000).

Some 128 patients had common bile duct stones detected intraoperatively, which were treated with either intraoperative laparoscopic common bile duct exploration (LCBDE) or postoperative ERCP. In six cases, no stones were found, so false positive treatments occurred in 4.7% of the patients. A total of 292 patients were reassured that the common bile duct was normal intraoperatively, and 2 patients represented with missed common bile duct stones requiring ERCP within 90 days (a false negative outcome of 0.7%). Median time for intraoperative laparoscopic ultrasound in our study was five minutes, which is supported in the literature.⁶ In our hospital, median time of inpatient wait for MRCP and report is 36 hours. For the emergency cases in our study (86 patients), this represents 129 inpatient bed days saved. For elective patients, 334 outpatient MRCP appointments were avoided and overall an estimated 240 hours of magnetic resonance imaging time saved.

Table 1 Patients who underwent laparoscopic cholecystectomy for each nationally recognised indication

Indication for laparoscopic cholecystectomy	Patients (n)
Obstructive jaundice	7
Biliary colic (with deranged liver function tests)	117
Cholecystitis (with deranged liver function tests)	197
Cholangitis	20
Gallstone pancreatitis	79

Discussion

Current national guidance recommends preoperative imaging predominantly with MRCP when stones have not been detected on transabdominal ultrasound but the common bile duct is dilated on ultrasound and/or there is presence of deranged liver function tests.⁸ If common bile duct stones are identified on MRCP, it is suggested that these patients undergo either preoperative ERCP or LCBDDE at the time of laparoscopic cholecystectomy.⁹ The evidence for this treatment is strong, as untreated common bile duct stones can cause serious complications such as pancreatitis, cholangitis, pain and jaundice.¹⁰ However the majority of preoperative MRCPs are negative for common bile duct stones, suggesting that the investigation is overused. MRCP is usually performed weeks or months before laparoscopic cholecystectomy, so information obtained from these images is historical at the time of surgery. This probably explains why MRCP has a positive predictive value of 89%, as some common bile duct stones pass spontaneously before intervention.^{11,12}

The Sunflower Trial data may demonstrate that less use of preoperative MRCP is safe for low and moderate suspicion of patients with common bile duct stones, although at five minutes median scan time for laparoscopic ultrasound, all suspected patients can be screened with little burden. Previous studies have shown that laparoscopic ultrasound is safe, quick to perform, accurate and cost effective.^{6,15} This study adds further weight to these findings. Performance of laparoscopic ultrasound at identifying common bile duct stones is comparable with MRCP, with a sensitivity and specificity of 95% and 100% respectively.^{14,15} Our study found similar outcomes: specificity 95.3% and sensitivity 99.3%. We propose that the current practice of the excessive use of preoperative MRCP is not required and, in trained hands, performing laparoscopic ultrasound at time of laparoscopic cholecystectomy can largely negate the need for MRCP. Although there is an initial learning curve for laparoscopic ultrasound, Machi *et al* estimate that this requires a surgeon to perform 30–40 examinations to achieve technical competence.¹³ It is important to emphasise that laparoscopic ultrasound is a competency related skill and an approved training course and mentorship is advised.

Equipment for laparoscopic ultrasound is expensive, but with each use the cost per case reduces; the tipping point for cost neutrality in our study was 100 cases. This makes the business case for purchase fairly straightforward. Other significant savings relate to emergency treatment and reduced occupancy of emergency beds while patients wait for inpatient MRCP.

Our study was based on using gas plasma to formally sterilise probes between each patient use. The current UK practice on laparoscopic probe decontamination between patients is split. Many units that offer this service have a policy of Tristel™ wiping and use of probe sheaths between patients, which would reduce the number of ultrasound probes required to set up the service, reducing initial outlay costs.

Conclusion

Our results show that the use of laparoscopic ultrasound during laparoscopic cholecystectomy largely negates MRCP use. Cost savings quickly offset initial equipment and maintenance costs. The use of laparoscopic ultrasound moves away from the concept of risk stratifying patients into low or high risk of common bile duct stones and selectively investigating patients. Instead, it adopts a more blanket approach to screening all patients with any recognised risk factors for the presence of common bile duct stones, as it is quick and accurate.

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