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SURGICAL ENDOSCOPY
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A prospective single-blinded controlled study comparing laparoscopic ultrasound of the common bile duct with operative cholangiography

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Abstract
Background: Ultrasound examination of the bile duct during cholecystectomy compares well with operative cholangiography. Studies so for have not been blinded, nor has the stone content been validated immediately. We have, therefore, carried out a blinded comparison of laparoscopic ultrasound with fluoroscopic operative cholangiography.
Methods: This study included 135 patients (average age, 53 years) undergoing laparoscopic cholecystectomy with or without bile duct exploration. Laparoscopic ultrasound examination was performed by an experienced surgeon blinded to the patient's clinical condition. This was followed by an operative cholangiogram. Bile ducts were explored if stones were seen, and the patients were followed up.
Results: Laparoscopic ultrasound identified the bile ducts satisfactorily in 131 cases and operative cholangiography in 121 cases. Duct stones were present in 49 cases. They were correctly identified by ultrasound in 47 cases and by cholangiography in 42 cases. There was one false positive cholangiographic examination. The sensitivity was 96% for ultrasound and 86% for cholangiography. The specificities were 100% and 99%, respectively.
Conclusion: Laparoscopic ultrasound examination of the bile duct is superior to operative cholangiography and could replace it.

Key words: Laparoscopic cholecystectomy — Ultrasound cholangiography

Controversy surrounds the subject of bile duct imaging during laparoscopic biliary surgery. There are two objectives: to define the anatomy of the biliary tract with a view to preventing bile duct injury, and to establish the presence or absence of stones in the bile ducts. Operative cholangiography has been the standard imaging technique. It gives very clear images of the biliary tree, probably helps to prevent injury to the ducts [5, 6], and possibly reduces the magnitude of any biliary injury. In up to 17% of attempts, it fails [1, 3, 4, 8–12]. It also is time consuming and exposes the patient and theater personnel to radiation. Interest in laparoscopic ultrasound as an alternative has been increasing. The anatomy of the bile ducts can be demonstrated, and it has been shown to be of potential use in detecting bile duct injury [2].

The presence or absence of stones in the bile ducts can be determined to some extent by using preoperative clinical criteria or screening [14], but these do not reach 100% accuracy. Operative cholangiography has been compared in a number of studies with laparoscopic ultrasound scanning and found to be equivalent or better, although the number of bile duct stones in these studies usually has been small [1, 3, 4, 8–12].

If laparoscopic bile duct exploration is to be used, accurate intraoperative imaging of the bile duct is mandatory. During laparoscopic ultrasonography, knowledge of the patient's clinical condition, particularly with regard to the likelihood or otherwise of bile duct stones, might prejudice the interpretation of the image. This has not been considered in previous studies. For this reason, we undertook a study in which the surgeon who performed the laparoscopic ultrasound examination knew no details of the patient's clinical condition. In addition, any positive biliary imaging resulted in immediate duct exploration so that the results of the imaging could be validated immediately, at least as far as positive results were concerned. Most previous studies have relied on postoperative removal of duct stones. In the interval, stones could enter or leave the bile duct spontaneously.

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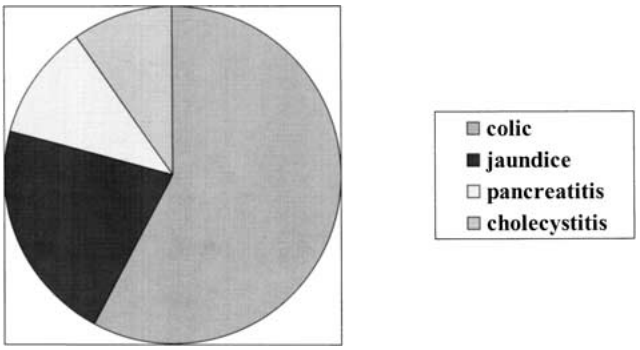

Fig. 1. Clinical presentation.

Methods

This study included 135 patients (104 women and 31 men) undergoing laparoscopic cholecystectomy with or without bile duct exploration. The average age of patients was 53 years. Their clinical presentation is shown in Fig. 1.

All the patients underwent transabdominal ultrasound and biochemical liver function tests during the week before surgery. Laparoscopic cholecystectomy was undertaken using four ports: one umbilical, one epigastric, and two right subcostal ports. A wide dissection of Calot's triangle was undertaken to identify the cystic duct and artery as well as common bile duct if visible at this stage. A surgeon experienced in laparoscopic ultrasound examination (80 examinations under supervision) but ignorant of the patient's clinical condition then entered the operating room and conducted the investigation.

The right upper quadrant of the abdomen was flooded with saline, and a 7.5-MHz Aloka linear ultrasound probe (Key Med, Southend, UK) inserted via the epigastric port. The bile duct was identified and scanned in one plane only. The scan was judged to be successful only if the common hepatic duct from its junction with the intrahepatic ducts downward and the common bile duct down to the duodenum were visualized. The diameter of the duct was measured at the widest point. The size and number of any stones were noted. The details of the examination were recorded.

The operating surgeon, either a consultant or trainee under supervision, then performed an operative cholangiogram. A Reddick cholangiogram cannula was used (Storz, UK), and the images were viewed fluoroscopically. The examination was regarded as satisfactory only if the intrahepatic, common hepatic, and common bile ducts were adequately identified. In addition, in the absence of stones, the intraduodenal segment had to be seen together with free flow of contrast into the duodenum. This is not always seen in the presence of stones, and in such circumstances was not a requirement for a successful cholangiogram. The size and number of any stones were recorded. If either of the investigations showed stones in the bile duct this was explored laparoscopically and the findings recorded. If the results of the two imaging investigations were negative, the bile duct was regarded as free of stones. Patients were followed postoperatively after 6 months by telephone contact. This study protocol was approved by the Ethical Committee of the North Bristol NHS Trust.

Results

The bile ducts were explored on the basis of the intraoperative investigations in 50 cases, and stones were retrieved in 49 of the cases. Laparoscopic ultrasound succeeded in identifying the bile ducts according to the defined criteria in 132 of the 135 cases. Two examinations failed completely, and one examination failed because only part of the biliary tree was seen. The mean common bile duct diameter measured laparoscopically was 8.1 mm, as compared with a mean 6.0 mm for the preoperative study (Fig. 2). The results of the intraoperative laparoscopic ultrasound measurement are shown in Fig. 3 according to the presence or otherwise of ductal stones. Bile duct stones were correctly identified in 47 of the 49 cases with bile duct stones. No stones were falsely demonstrated in the remaining 86 cases. The average stone size was 7.5 mm.

Operative cholangiography succeeded in identifying the biliary tree satisfactorily in 121 cases, a significant reduction as compared with ultrasound ($p = 0.012$, chi-square test). In eight cases, cannulation of the cystic duct failed, and in five cases, the anatomic demonstration was incomplete. In one case the x-ray equipment failed. The failures were equally distributed between cases with and those without stones. Stones in the ducts were correctly identified in 42 of the 49 cases by cholangiography, but there was one false-positive demonstration of a bile duct stone. The statistical results are shown in Table 1. Both ultrasound and cholangiography underestimated the number of stones in the bile duct in one-fifth of the cases.

Discussion

In this study, laparoscopic ultrasound succeeded in fulfilling the two criteria laid down at the outset. It satisfactorily demonstrated the biliary tree better than intraoperative cholangiography, and proved to be more sensitive and specific in the diagnosis of bile duct stones. Both studies underestimated the number of stones. This result has practical importance. It is not sufficient to remove only the stones seen on the intraoperative ultrasound or cholangiogram. A duct cannot be judged clear after exploration until it has been separately assessed, and for this purpose, choledochoscopy probably is the best method [7, 13]. Measurement of the bile duct diameter was only a rough guide to the stone content. In the middle range (6–10 mm) there was a large overlap between ducts with and those without stones. Of the ducts 10 mm or more in diameter 85% contained stones.

This study has two advantages over others so far. First the ultrasonographer was blinded. Second, the exact status of the bile duct in terms of its stone content was established at the same time. Clearly, a negative result for both techniques may have produced an undiagnosed false-negative result. Patients in 88% of the cases have been followed up beyond 6 months and maximally up to 6 years postoperatively. No missed stones have become evident. This study produced an unusually high failure rate for operative cholangiography, significantly lower than our previously published 94% success rate, but such low success rates have been seen before [4]. This is likely the result of the disease state in the patients. In the face of a difficult cannulation, the knowledge that the ultrasound examination had been completed may have caused the attempt to be abandoned earlier than would otherwise have been the case. In our previous study, the sensitivity and specificity for cholangiography still fell below that for ultrasound in the current study.

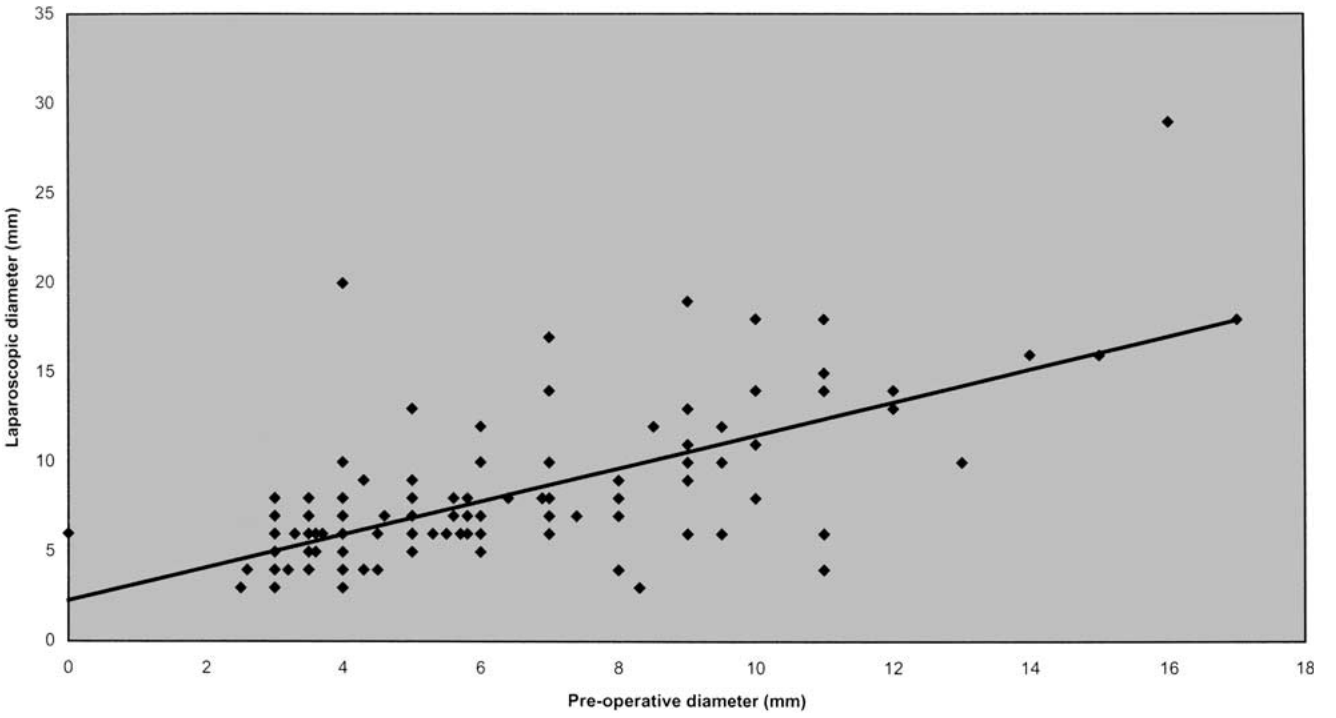

Fig. 2. A comparison of preoperative and laparoscopic ultrasound common bile duct.

Table 1. Results of laparoscopic ultrasound and operative cholangiography

	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Laparoscopic ultrasound	96	100	100	98
Operative cholangiography	86	99	98	92

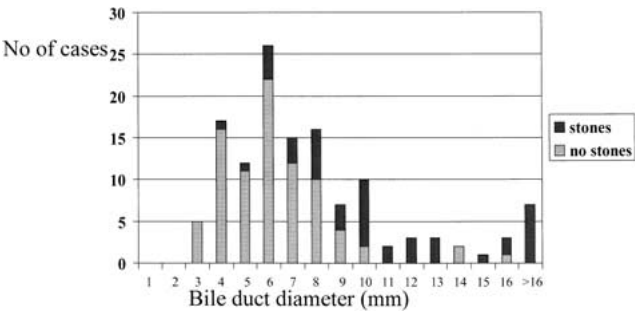

Fig. 3. Bile duct diameter: laparoscopic ultrasound.

The demonstration of the bile ducts by ultrasound in this study was satisfactory. It remains to be seen whether ultrasound can detect injury to the duct in clinical practice. The study of Birth et al. [2] was very successful in this respect, but the injuries were deliberately created in pigs, and there was no control group. The observers would therefore be looking for injuries. Biffl et al. [1] noted a significant reduction in biliary injury when routine ultrasound followed by cholangiography was used but there was no suggestion that the ultrasound examination identified any injury.

In our study, two of the three laparoscopic failures were associated with failure of the cholangiogram also. We were therefore unable to observe any benefit from the use of both together.

Laparoscopic ultrasound has given a superior diagnostic performance in this and most previous studies. Considering the additional benefits of time saved and lack of radiation, it could reasonably replace operative cholangiography.

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