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Prospective comparison of endoscopic ultrasonography and endoscopic retrograde cholangiopancreatography in the detection of bile duct stones

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Background Conventional ultrasonography is used widely in the investigation of gallstone disease but is limited in the detection of bile duct stones due to poor visualization of the distal bile duct. Endoscopic retrograde cholangiopancreatography (ERCP) is currently the investigation of choice for suspected choledocholithiasis, but is not without morbidity. Endoscopic ultrasonography clearly visualizes the entire extrahepatic biliary tree and avoids the need for ERCP in many patients.

Methods Some 50 patients with suspected duct stones underwent endoscopic ultrasonography followed by ERCP. All cholangiograms were performed or interpreted by a second doctor blinded to the results of endoscopic ultrasonography.

Results Both tests were successful in 46 patients; both tests failed in two patients and ERCP alone failed in a further two. Duct stones were confirmed in 24 patients. Sensitivity (95 per cent confidence interval (c.i.)) of ERCP and endoscopic ultrasonography in identifying these stones was 79 (58–93) per cent and 88 (68–97) per cent respectively; specificity (95 per cent c.i.) was 92 (75–99) per cent and 96 (80–100) per cent.

Conclusion Endoscopic ultrasonography accurately identifies bile duct stones. It is recommended in all patients with a risk of duct stones but especially in those with a history of ERCP-induced pancreatitis, when other pathology is suspected, when ERCP has failed, when bile duct abnormalities are suspected during pregnancy and in patients with acute pancreatitis.

Endoscopic retrograde cholangiopancreatography (ERCP) is generally regarded as the 'gold standard' for the preoperative recognition of bile duct stones before laparoscopic cholecystectomy. Complications may occur, however, and a significant proportion of investigations are negative, even when applied to patients thought to be at high risk of harbouring bile duct calculi[1–4].

Although conventional ultrasonography is a useful first-line investigation for gallstone disease, it is limited in the investigation of bile duct stones, as visualization of the distal common bile duct (CBD) may be difficult and small stones in a non-dilated duct are easily missed[5,6].

Endoscopic ultrasonography can clearly visualize the entire extrahepatic biliary tree[6] and may be associated with less procedure-related morbidity than ERCP[7]. Despite increasing recognition of its role in the assessment of oesophageal disease, endoscopic ultrasonography has yet to be properly evaluated in the investigation of biliary disease.

If endoscopic ultrasonography could be shown to be sensitive and specific in the detection of bile duct stones, ERCP and its associated morbidity would be avoided in patients without bile duct stones. A prospective study was undertaken to ascertain the accuracy of endoscopic ultrasonography compared with ERCP in the investigation of suspected bile duct stones in patients awaiting laparoscopic cholecystectomy.

Patients and methods

Fifty patients with proven symptomatic gallstone disease and potential bile duct stones were studied. The criteria for suspected duct stones were any of the following features: dilated (greater than 7 mm) bile duct on abdominal ultrasonography, clinical jaundice, gallstone pancreatitis or deranged liver function.

Endoscopic ultrasonography was performed using the Olympus GF-UM 20 radial scanning echoendoscope (Olympus Optical, Tokyo, Japan). Anaesthetic throat spray and intravenous midazolam sedation were used with the patient in the left lateral position. The scope was introduced under endoscopic vision into the second part of the duodenum and scanning commenced at a frequency of 7·5 MHz, adjacent to the ampulla of Vater which is seen as a hypoechoic and well demarcated nodule (*Fig. 1*). The

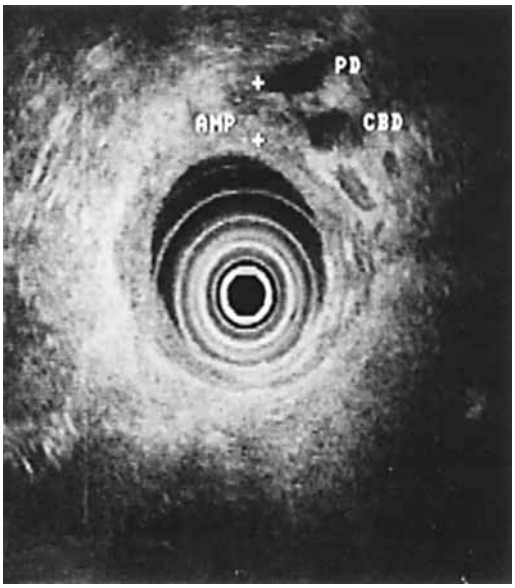

Fig. 1 Ampulla (AMP, between crosses) and lower end of common bile duct (CBD) and pancreatic duct (PD)

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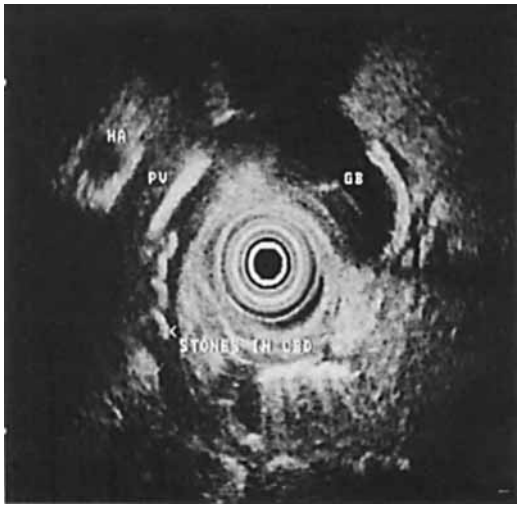

Fig. 2 Stones in common bile duct (CBD) seen as hyperechoic structures casting an acoustic shadow. HA, hepatic artery; PV, portal vein; GB, gallbladder

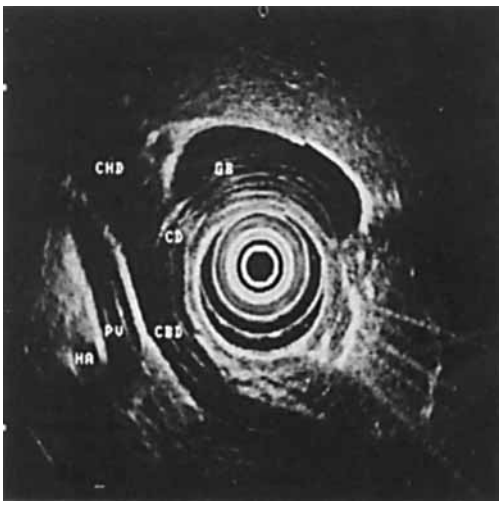

Fig. 3 Extrahepatic biliary tree and adjacent structures. CHD, common hepatic duct; CBD, common bile duct; CD, cystic duct; GB, gallbladder; HA, hepatic artery; PV, portal vein

CBD was identified and the presence or absence of stones noted. Stones were recognized by their hyperechoic image and the acoustic shadow commonly produced (*Fig. 2*). The common hepatic duct, right and left hepatic ducts, cystic duct and gallbladder were routinely sought and imaged (*Fig. 3*). The presence or absence of other pathology including lymphadenopathy was noted. Each procedure was videotaped for later reference.

ERCP was performed either immediately after endoscopic ultrasonography under the same sedation, or within the following 24 h. All cholangiograms were performed or interpreted by a second clinician blinded to the results of ultrasonography. Once the cholangiographic findings had been declared, however, the ultrasonographic results were revealed, allowing further intervention to be performed as necessary before withdrawal of the scope.

If either test suggested the presence of stones, endoscopic sphincterotomy was performed followed by attempted balloon extraction of the suspected stones and further completion cholangiography. Stones were retrieved during open cholecystectomy in one patient in whom ERCP failed.

The results of the two procedures were compared with the final diagnosis. In this way the two tests were compared individually with a 'gold standard' of retrieval of stones, either by endoscopic sphincterotomy or open operation. It is important to note, however, that when stones were not identified by ERCP or endoscopic ultrasonography, a presumptive diagnosis of no ductal stones was made. It was considered ethically unacceptable to perform sphincterotomy and balloon trawling of the bile duct to confirm the absence of stones. A final diagnosis (i.e. retrieval of stones or presumptive diagnosis of no stones) was reached in all 50 patients, and the diagnostic accuracies of endoscopic ultrasonography and ERCP are reported with respect to the total study population, including technical failures.

Results

Fifty patients (34 women) of median age 63 (range 17–83) years were suspected of having bile duct stones. Indications for endoscopic ultrasonography and ERCP are shown in *Tables 1* and *2*.

Both investigations were unsuccessful in one patient owing to intolerance of the procedures and in a second patient because of recurrent cardiac arrhythmias. At cholecystectomy one of these two patients was found to have choledocholithiasis. ERCP was not possible at the first attempt in a further two patients because of inability to cannulate the CBD. In one of these patients, endoscopic ultrasonography indicated the presence of stones; repeat ERCP was attempted successfully, and stones were retrieved by sphincterotomy. In the second patient, endoscopic ultrasonography indicated no stones; the patient was presumed to have no stones and subsequently underwent laparoscopic cholecystectomy with no subsequent symptoms suggestive of retained stones. Both investigations were performed successfully in the remaining 46 patients.

Although it is not possible to validate the presumption that when both tests were negative there were definitely no stones present, no patient categorized as such presented subsequently, either before or after laparoscopic cholecystectomy, with symptoms suggestive of retained stones (follow-up 6–13 months).

CBD stones were retrieved in 24 patients (23 after sphincterotomy and one at open cholecystectomy). ERCP identified stones in 19 and endoscopic ultrasonography in 21 of these patients, giving a sensitivity (95 per cent

Table 1 Indications for endoscopic ultrasonography and endoscopic retrograde cholangiopancreatography

	No. of patients
Abnormal liver function test results	23
Jaundice	15
Dilated common bile duct	21
Pancreatitis	12

Table 2 Number of criteria fulfilled for suspicion of bile duct stones

No. of criteria	No. of patients
1	27
2	13
3	8
4	2

Table 3 Comparison between endoscopic retrograde cholangiopancreatography and presumptive final diagnosis in the detection of bile duct stones (based on 'intention to treat' results)

	Final (confirmed) diagnosis of CBD stones	Final (presumptive) diagnosis of no CBD stones
ERCP diagnosed CBD stones	19	2
ERCP diagnosed no CBD stones	5	24

CBD, common bile duct; ERCP, endoscopic retrograde cholangiopancreatography

Table 4 Comparison between endoscopic ultrasonography and presumptive final diagnosis in the detection of bile duct stones (based on 'intention to treat' results)

	Final (confirmed) diagnosis of CBD stones	Final (presumptive) diagnosis of no CBD stones
Endoscopic ultrasonography diagnosed CBD stones	21	1
Endoscopic ultrasonography diagnosed no CBD stones	3	25

CBD, common bile duct

confidence interval (c.i.)) of 79 (58–93) per cent and 88 (68–97) per cent respectively. Stones were indicated by ERCP in two patients and by endoscopic ultrasonography in one patient in whom no stones were found, giving a specificity (95 per cent c.i.) of 92 (75–99) per cent and 96 (80–100) per cent respectively (*Tables 3* and *4*).

Two patients, one of whom had also undergone endoscopic sphincterotomy, developed pancreatitis (abdominal pain and amylase level greater than three times normal), which was presumed to be due to ERCP. No complications were observed that could reasonably be attributed to endoscopic ultrasonography.

Discussion

ERCP is a well established technique, used widely in the investigation of pancreatic and biliary disease. In the era of open cholecystectomy, suspected choledocholithiasis was usually assessed by intraoperative cholangiography[8], but since the advent of laparoscopic cholecystectomy the number of ERCPs performed has risen markedly as a means of identifying and removing bile duct stones before operation[8,9]. Intraoperative cholangiography is not performed routinely in many centres on the basis that laparoscopic exploration of the bile duct is perceived to be a difficult procedure[10]. The criteria for performing preoperative cholangiography to detect bile duct stones are set to minimize the risk of failing to identify the 3–35 per cent of patients with choledocholithiasis[11]. Despite attempts to refine these criteria[3,12,13], a high rate of negative ERCPs is often described (49–75 per cent)[2,4,10,14]. The procedure is not without complications: approximately 2 per cent of patients develop pancreatitis which may be life threatening[1,3,4,15].

With a significant likelihood of a negative result, a less invasive investigation that carries a lower risk of complications is needed. Endoscopic ultrasonography effectively visualizes the entire extrahepatic tree and accurately determines the presence or absence of bile duct stones[6,16]. Technical failure, due to inability to achieve biliary cannulation, is avoided. The lack of ductal cannulation makes endoscopic ultrasonography particularly attractive in the exclusion of stones in patients with acute pancreatitis, and as no radiological screening is required the technique is valuable in pregnant patients.

Endoscopic ultrasonography is able to visualize microlithiasis, which may be important in the development of acute pancreatitis[17]. The three false-negative results produced by ERCP were all in patients with small stones or microlithiasis in narrow ducts. In patients with symptomatic gallbladder stones who are due to undergo laparoscopic cholecystectomy, this may be unimportant as the source of microlithiasis will be removed, but such positive endoscopic ultrasonographic findings should prompt early surgery to avert the risk of pancreatitis. In addition, endoscopic ultrasonography is able to identify patients who present with acute pancreatitis due to microlithiasis thought to have a normal gallbladder on transcutaneous ultrasonography.

Endoscopic ultrasonographic findings may be difficult to interpret in patients with a previous biliary sphincterotomy when artefact from air within the biliary tree can mask stones. This was the cause of one of the two false-negative results in this study. With further experience this problem has been overcome by filling the duodenum and hence the bile duct with water during endoscopic ultrasonography.

The false-positive result with endoscopic ultrasonography was due to misinterpretation, early in the study, of soft tissue images at the ampulla, now readily recognizable as a normal variant. This can also be a problem with ERCP: one of the two false-positive results resulted from inability to distinguish between a filling defect due to a bulky ampulla and an impacted stone. With endoscopic ultrasonography the characteristic soft tissue echostructure was easily identifiable. The other false-positive result at ERCP was misinterpretation of Mirizzi's syndrome as a stone within the CBD. With endoscopic ultrasonography the stone was apparent within the gallbladder, surrounded by gallbladder wall and indenting the CBD.

Endoscopic ultrasonography is also able to identify other pathology, either within the gallbladder and biliary tree, or involving surrounding structures. Adenomatous polyps, for example, can be mistaken for gallstones on conventional ultrasonography or ERCP but are easily diagnosed on the high-resolution images obtained with endoscopic ultrasonography[15,16]. Early changes of chronic pancreatitis can be seen with endoscopic ultrasonography before they are apparent on ERCP[18–20]. In three patients in this study, changes associated with acute pancreatitis were clearly delineated by endoscopic ultrasonography (free fluid in the lesser sac, heterogeneity of the pancreatic tissue and localized fluid collections). Occasionally, an unexpected periampullary tumour may be the cause of symptoms. Endoscopic ultrasonography can identify the lesion and provide accurate staging in these cases[21,22].

Although endoscopic ultrasonography has the advantages of detecting microlithiasis and other pathology, it has the disadvantage that it cannot be combined with therapeutic manoeuvres. Endoscopic ultrasonography

cannot therefore replace ERCP, implying that the consequence of carrying out routine endoscopic ultrasonography in patients who would otherwise undergo ERCP is that another test would be introduced into the diagnostic pathway.

These findings suggest, however, that routine use of endoscopic ultrasonography may be justified and cost effective. Should stones be identified by endoscopic ultrasonography, in the authors' experience it is simple to proceed immediately to sphincterotomy using a conventional duodenoscope. In this series endoscopic ultrasonography removed the need for ERCP in about half the cases, using widely accepted indications for ERCP. This conclusion is justified despite the relatively wide confidence intervals for the sensitivity and specificity of endoscopic ultrasonography because: (1) these values are as good as those for ERCP; (2) the consequences of missing a patient with CBD stones are identical to those following failed ERCP and the patient can be reinvestigated at a later date if symptoms persist; and (3) the lowest plausible estimate of the specificity of endoscopic ultrasonography (80 per cent) means that unnecessary ERCP can still be avoided in most patients without stones.

Endoscopic ultrasonography is therefore recommended in patients with a low but recognizable risk of bile duct stones, a history of ERCP-induced pancreatitis, when other pathology is suspected, when ERCP has failed, when bile duct abnormalities are suspected during pregnancy and in patients with acute pancreatitis.

Endoscopic ultrasonography can provide significantly more information on the bile duct, ampulla and surrounding structures than cholangiography. Like ERCP, it is a difficult procedure to perfect. Technically it is similar, but interpreting the images requires some practice. The results quoted represent the first 50 patients in whom the technique was attempted, suggesting that an experienced endoscopist, whether radiologist, surgeon or physician, would experience little difficulty in acquiring the necessary skills to use endoscopic ultrasonography for the identification of bile duct stones.

Alternative non-invasive approaches to biliary imaging such as magnetic resonance cholangiography will require prospective comparison against both ERCP and endoscopic ultrasonography in the future. Such comparisons should address both clinical issues and the cost-effectiveness of these approaches.

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