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Prospective randomized comparison of laparoscopic ultrasonography using a flexible-tip ultrasound probe and intraoperative dynamic cholangiography during laparoscopic cholecystectomy

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Abstract
Background: We performed a prospective randomized comparison of laparoscopic intraoperative ultrasonography (LIOU) and dynamic intraoperative cholangiography (IOC) during laparoscopic cholecystectomy (LC).
Methods: LIOU and IOC were attempted in 518 consecutive patients scheduled for laparoscopic cholecystectomy. The order in which the diagnostic procedures were performed was randomly assigned.
Results: LIOU failed in two patients (0.4%), and there were 41 (7.9%) failed IOC. The common bile duct (CBD) was visualized reliably with both methods. Our patients showed sensitivities of 83.3% and 100% and specificities of 100% and 98.9%, with an overall accuracy of 99.2% and 98.9% for LIOU as compared to IOC for identifying unsuspected common bile duct stones. The time necessary for the examination was significantly shorter in LIOU than in IOC (7 versus 16 min).
Conclusion: LIOU performed by experienced surgeons is a good and effective method to assess the CBD, including the neighboring structures of hepatoduodenal ligament. Using powerful, flexible-tip ultrasound probes, CBD exploration can be done in a longitudinal fashion, which is necessary for good anatomical clarity. A lack of adverse effects, shorter examination times, and lower costs are some of the advantages of this method. The most important advantage is the possibility of unlimited repetition, especially if there is difficulty identifying anatomic structures. In addition, there are some indications that LIOU has the potential to recognize major iatrogenic bile duct injuries.

Key words: Laparoscopic intraoperative ultrasound — Ultrasonography — Intraoperative cholangiography — Flexible-tip ultrasound probe — Extrahepatic bile ducts — Common bile duct — Laparoscopic cholecystectomy

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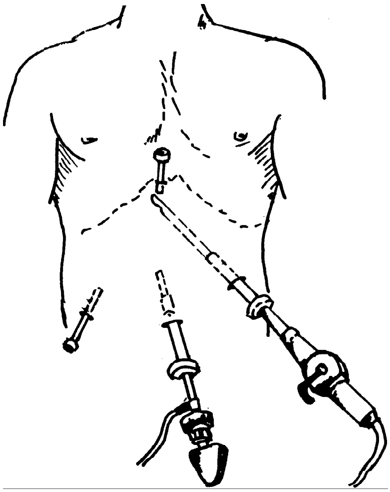
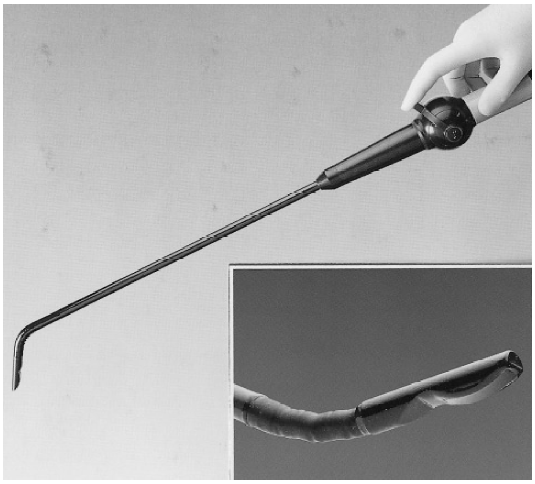
As surgeons have gained greater experience and familiarity with laparoscopic techniques, more challenging cases such as acute cholecystitis with empyema or shrunken gallbladder have been performed laparoscopically. In these situations, the surgeon is handicapped by the loss of tactile sensation and the two-dimensional presentation of the operative field, which makes it difficult to identify anatomical structures. So there has been a search for intraoperative diagnostical tools that can compensate for these restrictions. Previous examinations using laparoscopic intraoperative ultrasonography (LIOU) have shown promising results; however, the examinations were done mostly with ultrasound probes, that were not ideally suited for this purpose [16, 33]. A number of examination techniques have been described but no standards were given for probe positioning, trocar placement, or ultrasound frequency. When rigid ultrasound probes are used, whole extrahepatic bile ducts can only be screened in a transverse fashion. Only partial longitudinal visualizations are possible [2, 13, 22, 33, 34]. However, a new generation of ultrasound probes with flexible tips has shown the potential to surmount these shortcomings and allow visualization of the biliary system, including all of the anatomical structures of the hepatoduodenal ligament, in a longitudinal fashion [14, 15, 17, 31]. At the same time, these probes also give the surgeon the opportunity to visualize major iatrogenic bile duct lesions [3].

Until now there has been no prospective randomized study comparing LIOU and intraoperative cholangiography (IOC). Since April 1994, we have routinely performed intraoperative ultrasonography during laparoscopic cholecystectomy. Before starting the study, we examined 108 patients to learn the technique, improve our skills, and generally become comfortable with this diagnostic tool. This report deals with the results of laparoscopic ultrasonography in a prospective randomized comparison with intraoperative dynamic cholangiography in 518 consecutive patients during laparoscopic cholecystectomy.

Materials and methods

In the period from June 1994 until April 1996, 518 consecutive patients scheduled for elective laparoscopic cholecystectomy were enrolled in this





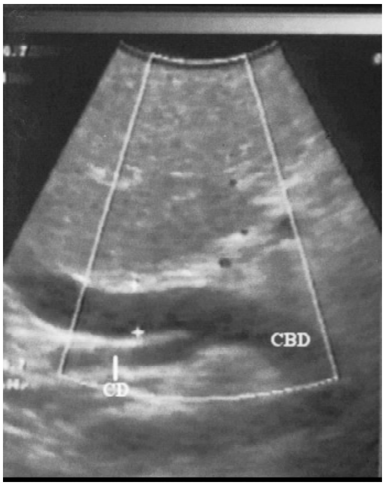


Fig. 1. (left) Positioning of trocars and insertion of ultrasound probe.

Fig. 2. (center) Flexible-tip ultrasound probe for laparoscopic application.

Fig. 3. (right) Intraligamental part of CBD and insertion of cystic duct; measurement of CBD- diameter using the inward-outward technique.

study. The average age of the 391 women and 127 men was 51.7 years (range, 15–88). Twenty-six patients who were converted to the open procedure prior to visualization of the biliary tree by either imaging method were excluded from the study.

Preoperatively, all patients underwent transcutaneous abdominal ultrasonography with CBD measurement, as well as liver function tests. In all patients whose clinical parameters suggested choledocholithiasis, or who had elevated function tests and/or a sonographical CBD diameter of > 6 mm, a preoperative endoscopic retrograde cholangiopancreaticography (ERCP) was arranged.

Placement of equipment and trocars and laparoscopic cholecystectomy were performed in a standard fashion (Fig. 1).

In order to avoid influencing interpretations, the order in which the diagnostic procedures were performed was randomly assigned. Thus, laparoscopic ultrasound was performed prior to any dissection in one group and directly after the IOC in the other group.

To perform the radiological imaging, a flexible plastic catheter was used for cannulation of the cystic duct, and the cholangiography was performed under direct radiological vision by hand injection of a 1:1 solution of radiological contrast (Conray 60; Mallinckrodt Medical GmbH, Hennef-Sieg, Germany) and saline solution.

All ultrasonographical examinations were performed with a 9.5-mm ultrasound transducer (type 8555; B&K Medical A/S, Naerum, Denmark). The ultrasound probe has a mobile tip with a 60° convex array that can be moved 90° up and down by operating a lever on the probe handle (Fig. 2). The scanner is equipped with a B&K Medical ultrasound unit 3535. The ultrasound frequency can be changed (5, 6.5, 7.5 MHz), but for these examinations the 7.5-MHz setting was used in the majority of the cases. The application of color-flow imaging allows the surgeon to differentiate blood vessels and biliary structures.

Introduction of the ultrasound probe into the abdominal cavity was done primarily via the left lateral port or after changing the optic via the umbilical port (Fig. 1). Following diagnostic laparoscopy, the tip of the transducer was placed on the liver surface directly over the porta hepatis. For optimal application, moving the tip down 20°–30° was often helpful. By performing a slow screening of the liver tissue via slight lateral movement of the transducer, the hepatic duct could be located and followed to its division. Differentiation of the central intrahepatic and extrahepatic bile ducts from the blood vessels was done by routinely using the color-flow imaging.

The hepatic duct, cystic duct, and common bile duct were scanned in longitudinal sections by slow withdrawal of the transducer toward the examiner with simultaneous slightly rotation, while keeping the duct continuously in view (Fig. 3). By pulling the gallbladder in a caudal direction with a forceps, the liver edge was moved down and used as an acoustic window for a long section. The medial and more distal parts of the common bile duct were scanned by placing the transducer on the hepatoduodenal ligament or dipping the tip into a simple saline solution, which creates the acoustic coupling and placing the transducer directly upon the bile duct. To screen the intrapancreatic part of the CBD, the transducer was placed on the upper duodenal edge, and the tip was moved down carefully in a dorsal direction until the corresponding part was visualized.

Measurement of the common bile duct by ultrasound was performed three times—at the level directly below the hepatic bifurcation, at the level were the cystic duct entered the common hepatic duct (or at the middle of the CBD if the cystic duct could not be visualized), and in the preampullary section. In each patient, the greatest of these three values was compared with the greatest diameter as determined by IOC. Sonographic measurement of the duct diameter, using the inward–outward method, was easily done at the frozen ultrasound screen. For cholangiography, the diameters were determined on the radiographs after surgery. To determine magnification on the cholangiogram, the plastic catheter used for cannulation of the cystic duct with a diameter of 5 Ch was used as a reference point.

Time to perform the ultrasound examination was measured from insertion of the transducer until removal, whereas time to perform the cholangiography was measured from incision of the cystic duct until removal of the catheter.

Statistical analysis was performed using the Mann-Whitney test.

Results

LIOU was performed in 516 of our 518 patients (99.6%). In one case, marked adhesions in the upper right abdomen prevented correct positioning of the ultrasound probe, and there was one defective probe that prevented examination of the duct. IOC was successfully performed in 477 cases (92.1%). The following reasons accounted for the 41 failed IOC: unsuccessful cannulation of a very thin cystic duct, 25 cases; short cystic duct, four cases; cystic duct transection, one case; cystic duct perforation, one case; allergy to iodine, four cases; thyroid hyperfunction, six cases.

Results of scanning the several parts of the biliary tree with ultrasonography and IOC are listed in Table 1. Although the feasibility of each method tended to vary, there were no differences in visualizing the extrahepatic bile ducts, with the exception of the cystic duct and preampullary section of CBD. In 31 cases, insertion of the cystic duct into the common bile duct could not be judged exactly by cholangiography due to overlapping structures.

In 42 patients (8.1%), a preoperative ERCP was ar-

Table 1. Feasibility and visualization of extrahepatic bile ducts using LIOU and IOC

	LIOU	IOC
Feasibility	516 (99.6%)	477 (92.1%)
Visualization	% related to 516/518	% related to 477/518
Hepatic duct	502 (97.3/96.6%)	462 (96.9/89.2%)
bifurcation in part	8 (1.6/1.6%)	10 (2.1/1.9%)
Hepatic duct	511 (99.0/98.6%)	467 (97.9/90.2%)
in part	5 (1.0/1.4%)	9 (1.9/1.7%)
Cystic duct		459 (96.2/88.6%)
before closure ($n = 259$)	101 (39%)	
after closure ($n = 257$)	83 (32.3%)	
insertion of cystic duct	163 (31.6/31.5%)	446 (93.5/86.1%)
CBD:		
intraligamental	513 (99.4/99.0%)	472 (99.0/91.1%)
preampullary	439 (85.1/84.7%)	475 (99.6/91.7%)

ranged because there was a suspicion of choledocholithiasis based on patient history, elevated liver function tests, or dilated bile ducts seen on transcutaneous ultrasonography. The procedure was successful in 41 of these cases. In 25 patients, the diagnosis was confirmed and after papillotomy stones were removed. Twenty-three of these 25 patients had clear, nondilated CBD on intraoperative cholangiographical and sonographical exploration (Fig. 4). In two patients with preoperative papillotomy, including stone removal, retained stones were found intraoperatively but no therapeutic interventions were performed. Postoperative liver function tests in these two patients were normal; thus, we believe the stones passed the ampulla spontaneously. No calculi were found intraoperatively in the patient who had unsuccessful preoperative ERCP.

Intraoperatively, stones were found in 24 patients; in 22 of these patients (4.3%), the stones were unsuspected (Fig. 5). Calculi were demonstrated cholangiographically in 23 instances, and IOC was not performed in one patient (Table 2). At the same time, there were five false positive results (confirmed by transcystic choledochoscopy or intraoperative ERCP).

LIOU demonstrated stones in 20 patients, but in four cases with poor visualization of distal CBD small preampullary calculi could not be identified. There were no false positive results in the ultrasonography group. Therapy of the choledocholithiasis was as follows: intraoperative ERCP with stone removal, 16 cases; laparoscopic transcystic CBD exploration, three cases; conversion and open choledochotomy, two cases; postoperative ERCP, one case; postoperative observation, two cases.

Sixteen of 24 patients with stones (thus, three of the four with sonographically unidentified calculi) had a slightly dilated CBD (7–10-mm diameter) that had not been recognized by preoperative ultrasound (Fig. 5). The mean CBD diameter in patients with common bile duct stones was 7.4 mm (range, 3.8–10 mm), whereas the mean CBD diameter in patients without common bile duct pathology was 3.7 mm (range, 1.2–8.2 mm). The difference was significant ($p < 0.001$) (Fig. 4). Correlation of maximal CBD diameter measured by LIOU and IOC is also demonstrated in Fig. 4.

In 257 patients who had IOC prior to LIOU, the possibility of locating hemoclips was tested by ultrasound. Reproducible visualization of the hemoclips succeeded in 213 cases (82.9%). There were no sonographical indications for major alterations of the hepatic or common bile duct, such as partial or complete occlusion caused by hemoclips; these findings were confirmed by the postoperative course.

Using color-flow imaging, the portal vein and the hepatic artery was displayed by ultrasonography in all 516 patients. In 49 patients (9.5%), the cystic artery was visualized over a long distance, including its relation to the cystic duct, but in 104 patients (20.2%), only parts could be seen. Thirty-seven relevant anatomical variations of blood vessels were found using LIOU (ventral crossing of hepatic artery, impressions of CBD by right hepatic artery, accessory liver arteries).

On average, sonographical exploration takes 7 min (range, 3–25 min), which is significantly less than the 16 min (range, 5–45 min) required for performing cholangiography ($p < 0.001$).

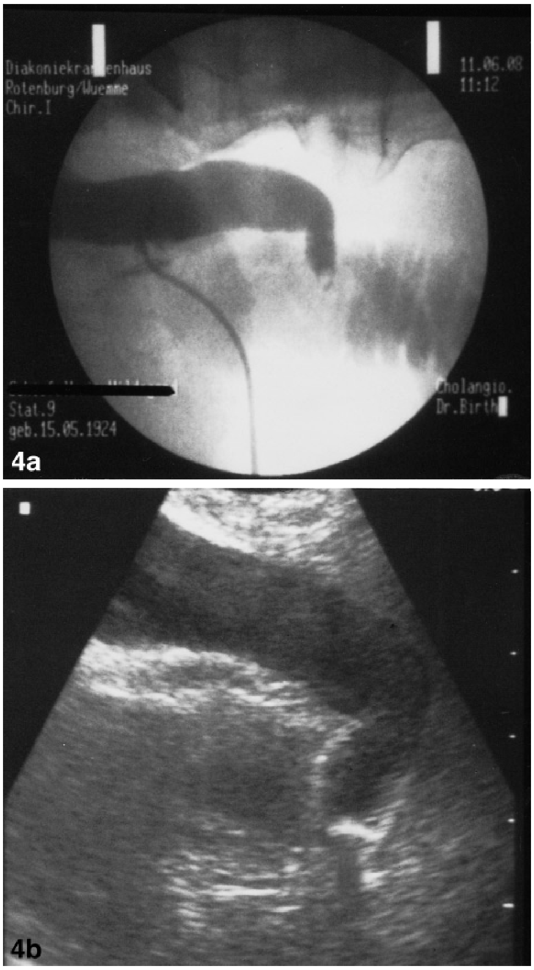
Discussion

In complicated cases, the well-known limitations of laparoscopic techniques may create problems, so that intraoperative radiological evaluation of biliary tree becomes advisable for confirmation of the anatomy.

A decisive disadvantage of IOC, however, is that it can be performed only once at a definite point in time during the surgical procedure. For the surgeon performing a retrograde removal of the gallbladder, the cholangiogram can be helpful to establish anatomical orientation early on during surgery. On the other hand, it cannot guarantee the absence of an iatrogenic bile duct lesion at the end of cholecystectomy [1]. If cholangiography is used to document undamaged status of the biliary tree, the gallbladder would have to be removed using an antegrade technique, and IOC would have to be performed at the end of the procedure. Thus, throughout the dissection, there is no radiological evaluation of the bile ducts, and iatrogenic lesions cannot be avoided through knowledge of the anatomy. Status can only be verified radiologically at the end of the operation. That is why the use of routine cholangiography and its role in decreasing the incidence and severity of bile duct injuries is still under debate. At present, most surgeons do not use routine cholangiography during LC [19, 20, 35, 39].

Additionally, many reports have shown inaccurate results from IOC, including false positive calculi in $\leqslant$ 16% of the cases, followed by unnecessary conversions or common bile duct explorations [19, 24, 39]. Other restrictions of IOC include the high failure rate during minimally invasive procedures (75–98%), as well as patient exposure to x-rays and additional expenditure of time and money [23, 24, 32]. At the same time, in spite of routinely using IOC, surgeons frequently fail to recognize bile duct injuries because of misinterpretation [5].

In the search for a possible alternative, laparoscopic ultrasonography, which was first described by Yamakawa et al. in 1958, was rediscovered [40]. However, technical limitations of the ultrasound equipment (A-mode), as well as a lack of laparoscopic indications in abdominal surgery, slowed further development. After the development of B-



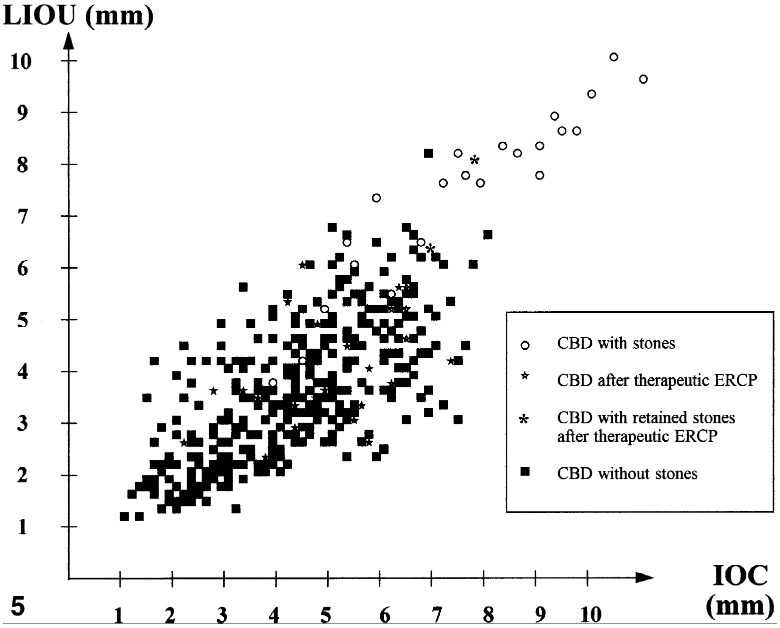


Fig. 4. Dilated CBD with a preampullary stone visualized by LIOU **(a)** and IOC **(b).**

Fig. 5. CBD diameters measured by LIOU and IOC.

Table 2. Accuracy of LIOU and IOC in visualizing unsuspected CBD stones

CBD stones (n = 24)	LIOU (516 patients)	IOC (477 patients)
True positive	20	23[a]
True negative	496	454
False positive	—	5
False negative	4	— (1)[a]
Sensitivity (%)	83.3	100 (95.8)[a]
Specificity (%)	100	98.9
Positive predictive value (%)	100	82.1
Negative predictive value (%)	99.2	100 (99.8)[a]
Accuracy (%)	99.2	98.9 (98.7)[a]

[a] IOC failed in one patient, who had a stone visualized with LIOU.

mode probes, which can be brought into place laparoscopically, the technique was used first for the diagnosis of pancreatic and liver tumors and for ultrasound-guided ethanol injection in the treatment of hepatocellular carcinomas [7, 12, 26].

The use of flexible-tip ultrasound probes for those purposes was reported in 1984 [27]. In 1991, Jakimowicz, Röthlin et al., and Yamashita et al. were the first to report the intraoperative use of ultrasonography for exploration of the biliary tree during LC [13, 33, 42]. At the beginning, most of the examiners used rigid probes, which only allowed visualization of the CBD in a transverse direction or partial visualization in a longitudinal fashion [13, 22, 33, 34].

The mobile-tip ultrasound probe used in this study allows for an improved transducer position, so that the whole hepatic and common bile duct can be demonstrated in a longitudinal fashion [4, 14–17, 31]. Jakimowicz has documented a number of improvements, including fewer failures and the ability to visualize longer segments of the bile duct in one section, as a result of increasing experience with the flexible versus the rigid probe [14, 15]. Flexible ultrasound probes can also improve the detection of anatomical variations [32].

We were able to show the hepatic duct sonographically, including its division and the intraligamental part of the common bile duct, in 98% of cases. The intrapancreatic section was visualized sonographically in 84.7% of cases, and the ampulla was identified in 24.2% of cases, whereas by IOC the intrapancreatic part was always shown in good contrast (Table 1). The results are consistent with previous reports showing sonographic visualization of the intraligamental section of 97–100% and of the intrapancreatic part of 83–100% [2, 16, 28–30, 41]. Thus, ultrasonography proved to be equal to cholangiography in screening the suprapancreatic part of the extrahepatic bile ducts, whereas IOC seems to be superior in visualizing the preampullary

Table 3. Results of LIOU and IOC in visualizing CBD stones

Author	no.	Stones	LIOU Sensitivity (%)	LIOU Specificity (%)	LIOU Accuracy (%)	IOC Sensitivity (%)	IOC Specificity (%)	IOC Accuracy (%)
Barteau (1995)	236	?	82.6	97.2	?	95.6	98.9	?
Castro (1995)	50	8	89	100	98	89	93	92
Goletti (1994)	30	4	100	100	100	75	100	96.6
Greig (1994)	54	7	71	95	93	83	96	94
Orda (1994)	117/57	12	91.6	98	96.6	100	86.9	89.4
Pietrabissa (1995)	73	4	100	100	100	100	98.5	98.6
Röthlin (1996)								
Rigid probe	100	4	100	98	98	75	99	98
Flexible probe	100	11	91	100	99	64	100	96
Stiegman (1995)	209	19	89	100	99	52.6	100	96.5 (95.5)[a]
Our results	518	24	83.3	100	99.2	100 (95.8)[a]	98.9	98.9 (98.7)[a]

[a] Indices take into account failed IOC in patients who had stones.

section. But when we consider relative feasibility and review the overall numbers and results, with 91% radiological visualization in our patients, the difference between these modalities becomes much less distinct.

Critics refer to this aspect of intraoperative bile duct ultrasonography as its ''Achilles' heel'' and point to the frequent pre- and intrapapillary locations of calculi. Correspondingly, all four ultrasonographically unidentifiable stones in our patients were located in the preampullary area. After their radiological detection, it was possible to demonstrate three of these stones using ultrasound after filling the stomach and duodenum with ~400 ml saline solution through an NG tube and screening transduodenally. However, this method is time-consuming and probably only justified when there is a suspicion of choledocholithiasis, i.e., a dilated common bile duct with no sonographic proof of stones.

In our patients, we found sensitivities of 83.3% and 100% and specificities of 100% and 98.9%, with an overall accuracy of 99.2% and 98.9% for LIOU as compared to IOC for identifying unsuspected common bile duct stones (Table 2). Similar results have been reported by other authors, who found no decisive differences between the two methods (Table 3) [2, 6, 9–11, 14, 21, 28, 30, 32, 34]. The small number of stones explains the relatively large differences in the indices. Although cholangiography should be the preferred method for proof of preampullary stones and for judgment of papillary function, in the suprapancreatic section of CBD ultrasonography seems to be superior when small calculi and bile duct debris are in question [32]. At the same time, two-thirds of our patients with common bile duct stones had a CBD diameter of $\geqslant$ 7 mm, and the median CBD diameter was significantly higher than in patients without CBD pathology. Other groups' experience has been similar [14, 30]. For detection of intrahepatic biliary stones, intraoperative ultrasound is the method of choice. It can accurately localize intrahepatic calculi, demonstrate the spatial relation between the stones and critical intrahepatic structures, and directly orient lithotomy instruments to approach the stones [18, 37].

Sonographic explorations of the cystic duct in our patients were successful in ~33% of cases—far fewer than in other reports (30–95%) [29, 30, 32, 34, 41]. There was no adequate demonstration in patients with a small and/or very curved cystic duct. Although cholangiography is clearly superior in evaluation of the cystic duct, this apparent advantage is actually more theoretical. To perform a cholangiogram, the cystic duct has to be extensively dissected; therefore, subsequent radiological evaluation of this area is not really helpful in guiding the dissection of Calot's triangle. Furthermore, due to catheter perforations, transection of the cystic duct, or shortness of the cystic duct, the safe closure of the cystic stump can be hampered by the IOC itself. According to Glättli et al., the technically simpler and safer means of contrasting the bile ducts by laparoscopic cholecystocholangiography yields significantly poorer results; thus, it cannot be regarded as an alternative to transcystic cholangiography [8].

Via color Doppler application, which provides easier identification, the portal vein and right hepatic artery, including 37 relevant anatomical variations, could be visualized reliably. Partial identification of the cystic artery was possible in a third of the cases. However, an exact anatomic assessment of the artery in Calot's triangle is hard to perform. It cannot be judged with certainty to what extent other authors—e.g., Yamamoto et al., who identified the cystic artery in all five examined cases; Othani et al., who reported 53% successful images; or Röthlin et al., who demonstrated this vessel regularly using color-flow imaging—view this technique as relevant for intraoperative decision making [29, 32, 41].

LIOU provided reproducible measurements of the CBD diameter. A respiratory variation of extrahepatic bile duct diameter during transcutaneous ultrasonography has been described, but we did not see any differences in dependence on respiration during the laparoscopic examination [36]. Cholangiographical measurement is prone to systematic errors, including blurred contours of CBD on radiograph and the necessity for an object of reference (i.e., a catheter), which generally does not lie in the same plane as the whole CBD. Additionally, duct dilatation as a result of pressure from the injection of contrast medium seems to lead to slightly thicker measurements (Fig. 4). Once we take all these influences into account, the diameters were often comparable, but in some cases relevant deviations were noticed (Fig. 4).

Although neither the LIOU nor the IOC caused any complications in our patients (with the exception of one perforation of cystic duct with IOC, where safe closure was accomplished without any difficulty) most authors clearly favor ultrasonography. To perform an IOC, the surgeon must cut a duct, which is not necessary for LIOU. All authors agree that the LIOU is noninvasive and has no adverse effects [2, 9, 15–17, 22, 32, 34, 41]. On the other hand, bile duct lesions resulted from the cholangiography itself have also been reported [25, 35, 38].

Ultrasonography required significantly less time to perform than cholangiography (7 versus 16 min, $p < 0.001$). This finding is confirmed by all studies that have compared the two methods [2, 22, 30, 32, 34]. In terms of current costs (IOC requires catheter, contrast medium, x-ray film), ultrasonography is definitely more efficient. On the other hand, we had two cost-intensive repairs of the ultrasound probe due to damage of the isolation coat and the transducer. A precise prospective evaluation of cost factors is ongoing presently and will be the subject of another report.

Because ‘‘selective therapeutical splitting’’ (i.e., preoperative ERCP in all patients suspected for CBD calculi, followed by laparoscopic cholecystectomy without routine IOC) currently seems to promise the best results for treating choledochocholecystolithiasis, in our opinion intraoperative proof for bile duct caculi is not the main indication for laparoscopic ultrasonography. The decisive advantage of this method is that it can be performed at any time during surgery, so that all anatomic structures of the hepatoduodenal ligament can be examined repeatedly, especially in cases where the anatomy is difficult to interpret. LIOU also permits the identification of blood vessels. Anatomical variations of these structures, which occurred in ≤50% of cases, can be identified and considered for surgery [32]. LIOU can be helpful in diagnosing gallbladder polyps and abnormally thickened walls, and it also frequently reveals clinically relevant incidental findings [21, 30]. It should be stressed that there is a clear learning curve [15, 30] and that LIOU does not always prove effective for demonstrating biliary variations [2, 30]. There is no question that at the present time IOC remains the preferred method for any intraoperative suspicion of bile duct lesions. But LIOU has the potential to reliably demonstrate major bile duct injuries that involve clips across the duct [3]. Because almost all iatrogenic lesions during laparoscopic cholecystectomy are located in the suprapancreatic section, which can be screened with certainty, deficits in the sonographical evaluation of the prepapillary area are almost negligible from this point of view [35].

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