

# Comparison of Operative Ultrasonography and Radiography in Screening of the Common Bile Duct for Calculi

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We report a 4-year experience of operative ultrasonography in 449 patients who underwent cholecystectomy for biliary lithiasis. Intraoperative ultrasonography and intraoperative cholangiography were performed in all of these patients and compared with the operative findings. The diagnostic accuracy of sonography was 97.5% and that of cholangiography was 94.4% in the patient group as a whole. The predictive value of a positive sonogram in this group was 96.4%, while that of a positive cholangiogram was lower at 86.9%. In 148 patients who underwent surgical exploration of the common duct, sonography appeared to have more accurately predicted presence or absence of stones (92.5%) than did cholangiography (79.8%). Use of these intraoperative screening tests together led to a positive common duct exploration in 76.6% of the 148 patients, which is higher than our previous experience in which common duct exploration was performed on the basis of clinical criteria. In 7% of the 301 cholecystectomized patients, unpredicted stones were detected at operative sonography and cholangiography. If the common duct exploration were to be performed based solely on the outcome of the sonogram, the rate of positive exploration could be 97%. Overall morbidity in this series was 9%, and retained stones following duct exploration were encountered in 1 patient. The overall mortality rate of the entire patient group was 0.9%. Operative ultrasonography of the biliary tract as a screening procedure is, in experienced hands, a reliable method and substitute for operative cholangiography.

The best results of surgical therapy for biliary lithiasis are strongly related to a rational approach to exploration of the common bile duct (CBD) for stones. On one hand, 3-7% of patients undergoing cholecystectomy, without duct exploration, may harbor undetected stones in the duct [1-3]. On the other hand, exploration of CBD based on the classical absolute and relative clinical indications may result in negative explorations in up to 45% of patients [4]. In either case, there is increased morbidity and mortality, leading to increases in health service costs. To achieve optimal therapeutic effects in the surgical treatment of biliary stones, it is necessary to have an intraoperative means of detecting CBD disease that is simple, safe, rapid, and reliable. The routine use of operative cholangiography for such screening purposes is still debatable. A high percentage of false-positive examinations can be encountered with this method [1, 3, 5], leading to a high incidence of negative duct explorations and offsetting its advantages in detecting unanticipated conditions in the duct.

Many previous reports [1, 6-12] have supported routine operative cholangiography for such purposes. Some authors have suggested, however, that cholangiography may not be cost-effective as a screening procedure except when CBD disease is clinically suspected [12-16]. The rapid progress in ultrasound imaging technology and the development of mobile, B-mode scanners and ultrasound transducers providing highquality images have suggested that intraoperative sonography may be feasible and cost-effective for routine screening of the biliary tract during cholecystectomy. To gain general acceptance, such a method must fulfill certain criteria [2, 17]: first, the method should be easy to perform; second, it should be capable of confirming or excluding anticipated disease states and of demonstrating unanticipated lesions; third, it should identify anatomic relations of the duct; and fourth, it should be generally available, relatively noninvasive, and cost-effective.

The present study was undertaken to assess the value of operative ultrasonography, in comparison to operative cholangiography, as a screening tool for common duct stones in patients undergoing cholecystectomy. We evaluated both methods with respect to the above-mentioned criteria.

## **Material and Methods**

From April, 1982, to May, 1986, a total of 615 patients underwent cholecystectomy for biliary lithiasis. Operative sonography and cholangiography were both performed in 449 patients. Only 1 or no studies were performed in 166 patients, owing to technical problems or equipment availability. Ultrasound examination was always performed prior to cholangiography. The final decision as to a positive or negative outcome of the sonographic examination was made by the surgeon before the results of cholangiography were known. If one of the examinations proved to be positive, CBD exploration was always performed. Patients in whom both tests were negative and without other clinical signs of disease were assumed to have no stones and classified as true-negative. Patient data were collected according to protocol and entered into a computer.

In the first stage of this study, the operative ultrasound examinations were performed by 2 expert individuals. Subse-

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quently, all members of the surgical staff who were performing biliary surgery were trained to perform these examinations. All patients who underwent CBD exploration underwent completion choledochoscopy at the end of the procedure, and placement of a T-tube in the CBD. On the seventh postoperative day, T-tube cholangiograms were performed in this group of patients to assess the final appearance of the CBD. All patients in the study remain in follow-up in the out-patient clinic.

#### Equipment

The usefulness of operative sonography of the extrahepatic biliary ducts requires that the scanner be compact, mobile, and easy to operate. It is necessary to cover the keyboard with a sterile transparent plastic sheet to permit the surgeon access to the keyboard. High-quality real-time, B-mode images are essential, and the system should provide for use of either mechanical sector or linear-array transducers. It is also very useful to have a means of recording the imagings for subsequent review.

In this study, a Philips SDR-1500 scanner, with a 7.5-MHz focused, mechanical sector scanning transducer, was used for operative sonography of the bile ducts (Fig. 1). The techniques for using this equipment have been discussed in detail [2, 17]. Operative cholangiography was performed under fluoroscopy and it was possible to record and store up to 25 frames of each examination for further review and documentation.

## Procedures

The technique of biliary operative sonography has been reported in detail [2, 17, 18]. The main points are:

1. A clean, nonsterile transducer is placed in a sterile plastic sleeve with methyl cellulose gel on the tip to provide adequate acoustic contact.

2. Examination of the CBD is performed after removal of the gallbladder and ligation of the cystic duct, although an adequate stump of the cystic duct is left to permit cannulation for cholangiography.

3. The duodenum is mobilized using Kocher's maneuver and reflected anteromedially.

4. The transducer is placed, under direct vision, on the anteromedial aspect of the CBD without compressing the CBD.

5. The space between the transducer and the CBD is filled with saline to achieve adequate acoustic contact.

6. Screening maneuvers include an examination along the length of the duct, with axial rotation of the transducer as it approached the distal part of the CBD.

7. The proximal CBD is examined first, and then the pancreatic portion and papilla are visualized in sequence. The prepapillary region is examined as an enlarged image, using the  $2 \times$ zoom function of the scanner.

8. The internal diameter of the duct is always measured sonographically.

9. Cholangiography is performed after cannulation of the cystic duct. Thirty percent Conray contrast material is injected under fluoroscopy.

## Results

Of the 449 patients who underwent both operative sonography and cholangiography, 148 underwent common bile duct explo-



Fig. 1. The Philips SDR-1500 mobile, real-time, B-mode ultrasound scanner and the small parts 7.5-MHz transducer.

ration. Data on age and sex distributions are presented in Fig. 2 for the patients who underwent cholecystectomy only (n = 301) and in Fig. 3 for the patients who underwent cholecystectomy and CBD exploration (n = 148). Table 1 summarizes associated clinical findings and operative procedures in the 449 patients who entered the study.

The use of operative diagnostic procedures resulted in a relatively high percentage (75.7%) of positive surgical explorations of the CBD. It should be stressed, however, that 23 (7%) of the 301 patients who underwent cholecystectomy alone were found, during operation, to have stones detected by sonography or cholangiography. Figures 4-8 demonstrate different sonographic findings found at operation. Use of 2 and sometimes 3 diagnostic procedures (if completion choledochoscopy was performed) did not appear to increase morbidity or mortality or lengthen the operation unduly. The average duration of surgery, including these procedures, for cholecystectomy alone was 55 minutes and for cholecystectomy plus CBD exploration, 1 hour and 35 minutes. Overall morbidity was 7% in the cholecystectomy group and 12.7% in the group that underwent cholecystectomy and CBD exploration. The main complications in both groups, the cholecystectomy group and CBD exploration group, were, respectively: pulmonary, 2.6% and 6.0%, and wound infection, 2.3% and 3.3%. The operative mortality rate in the cholecystectomy group was 0.2% and, in the group undergoing CBD exploration, there was no mortality. The overall mortality rate of the 615 patients who underwent biliary surgery for gallstones in the study period was 0.9%.

Tables 2 and 3 provide a comparison of the value of operative sonography and cholangiography for routine evaluation of the common bile duct during cholecystectomy. Table 2 compares use of the 2 procedures in the 449 patients as a whole, while Table 3 compares them in the 148 patients found by 1 procedure or both to have stones in the CBD.



Fig. 2. Age and sex distribution in the cholecystectomy group (n = 301).

# Discussion

The decision to explore the common bile duct surgically can be difficult. Since the late 1970's [19, 20], operative sonography has been under evaluation as a simple, reliable, and noninvasive tool to facilitate this operative decision. Preliminary observations have indicated that this modality may be helpful [21, 22] and that operative sonography and cholangiography may be equally accurate in predicting conditions that require duct exploration [22, 23]. Sigel et al. [24] have stated that operative diagnosis of common bile duct stones [24]. Our preliminary experience from a prospective comparative study, previously reported, confirms this impression, as do the data from the present study.

Operative sonography and cholangiography each have distinct advantages and disadvantages. Tables 2 and 3 summarize the comparison of the 2 methods in detecting gallstones in the CBD. Table 4 compares a number of other technical advantages offered by 1 or both modalities.

Both procedures are easy to perform and interpret. Sonography can be performed adequately with the exposure offered by the usual right subcostal incision. Cannulation of the cystic duct for cholangiography can be difficult, and it is impossible in 5%



AGE

Fig. 3. Age and sex distribution in the common bile duct exploration group (n = 148).

 Table 1. Comparison of operative ultrasonography and contrast radiography.

Total no. of patients	449
Male	119
Female	330
Average age (yr)	54.3
Cholecystectomy	301
Cholecystectomy + CBD exploration	146
CBD exploration	2
Papilloplasty	5
Choledocho-duodenostomy	9
Roux-en-Y choledochojejunostomy	1
Positive CBD exploration	112 (75.7%)
Negative CBD exploration	36 (24.3%)
Icterus	34
Cholecystitis	27
Cholangitis	8
Unpredicted stones	23 (7%)
Retained stones	1 (0.7%)

CBD = common bile duct.

of patients. Surgeons do not usually have difficulty in interpreting cholangiograms, whereas interpretation of real-time sonographic images requires a greater degree of experience. We will comment below on the learning period required for sonography.

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Fig. 4. A common bile duct of 0.7-mm internal diameter. The portal vein is in the left lower corner of the view field. Notice the length of the duct in view (5 cm).

**Fig. 5.** A tumor of the common bile duct (CBD) occluding the duct over a distance of 2.5 cm (*between asterisk*). Notice the proximal CBD of 1-cm diameter and thickened anterior wall of the CBD. In the right upper corner, the diameter of the distal CBD is 4 mm. No tumor invasion of the portal vein and intrahepatic ducts was confirmed at pathological examination.

Fig. 6. A common bile duct of 9-mm internal diameter with 2 small stones, both causing an evident acoustic shadow.

Fig. 7. A distal common bile duct of 6-mm internal diameter with 2 small stones of 3- and 4-mm diameter. One of them is located just proximal to the papilla.

Fig. 8. A distal common bile duct prepapillary region. A duct of 7-mm internal diameter with a stone of 4 mm located at the papillary orifice (to the right of the stone).

The main purpose of these operative diagnostic procedures, in the setting of verified or suspected cholelithiasis, is to detect common bile duct disease that would not otherwise be suspected. Consideration of data gathered in the present large series of patients and in the patients followed by Sigel et al. [24] lead to the conclusion that both methods are reliable, but operative sonography in experienced hands is more accurate. Both studies, using similar methods of comparison and analysis of these imaging procedures, offer a similar conclusion. It should be noted, however, that the prevalence of common duct stones, as assessed by both sonography and cholangiography, was lower (12–13%) in the patients evaluated by Sigel et al. [24]

 
 Table 2. Comparison of operative ultrasonography and cholangiography in the whole population examined.

	Ultrasonography $(n = 449)$	Cholangiography $(n = 449)$
True-negative	333	311
True-positive	104	93
False-negative	7	15
False-positive	4	14
Technically		
unsatisfactory	1	16
Sensitivity (%)	93.7	86.1
Specificity (%)	98.8	95.6
Accuracy (%)	97.5	94.4
Predictive value of a		
negative test (%)	97.9	95.3
Predictive value of a		
positive test (%)	96.3	86.9
Prevalence (%)	24.7	24.1

 
 Table 3. Comparison of operative ultrasonography and cholangiography in patients who underwent common bile duct exploration.

	Ultrasonography $(n = 148)$	Cholangiography $(n = 148)$
True-negative	32	22
True-positive	104	93
False-negative	7	15
False-positive	4	14
Technically		
unsatisfactory	1	4
Sensitivity (%)	93.7	86.1
Specificity (%)	88.8	61.1
Accuracy (%)	92.5	79.8
Predictive value of a		
negative test (%)	82.0	59.4
Predictive value of a		
positive test (%)	96.4	86.9
Prevalence (%)	75.5	75.0

than in the present series (24.7%). Biases in the study population can alter estimates of diagnostic accuracy. Nevertheless, in the group evaluated by Sigel et al. [24], the accuracy of operative sonography for detecting CBD stones was 98% and the cholangiography 94%, as compared to 97.5% and 94.4%, respectively, in our experience.

In the current series, the difference in accuracy between the 2 methods is significant both in the group as a whole and in patients who underwent exploration of the common bile duct. This was particularly true in regard to the predictive value of a positive test (Tables 2 and 3). In practical terms, the data suggest that the rate of radiographically indicated, but negative CBD explorations, could be reduced from over 10% to 2.7% if the decision for exploration of the CBD was based on sonography rather than cholangiography. In the patients for whom CBD exploration was performed (Table 3), sonography was significantly more accurate (92.5%) in predicting results of the exploration than was cholangiography (79.8%).

Both methods provide information concerning the number and location of stones in the bile duct (Fig. 6). When using a linear-array transducer, intrahepatic stones may be identified more accurately by cholangiography [25]. Sonography cannot provide a single picture of the common bile duct as does

 Table 4. Comparison of operative ultrasonography and operative cholangiography.

	Operative ultrasonography	Operative cholangiography
Repeatability	Good	Limited
Time required	5–7 min	10–15 min
Learning period	Long	Short
Cost of single examination	Low	High
Visualization of bile	Not possible	Possible
Detection of intrahepatic stones	Limited	Good
Potential for further improvement	High	Low
Detection of disease of the papilla	Good	Good

cholangiography. The image of the duct depends on a composite of several real-time images of 2–6-cm segments of the duct (Fig. 4) and the intrahepatic ducts may be difficult to visualize. Sonography, however, provides additional information concerning thickness of the duct wall, internal diameter of the duct, extraductal disease, and it provides detailed information concerning the papilla. The pancreatic head and associated blood vessels can be visualized by ultrasound (Figs. 5, 7, 8). Sonography also may localize the common bile duct and other key structures when they are obscured by tumor or an inflammatory mass [22, 24]. The main advantage of sonography is that it is completely noninvasive and uses no ionizing radiation or contrast material.

In addition, it is important to analyze costs of any diagnostic or therapeutic procedure (such as ERCP, PTC, CT, HIDAscans) that are used preoperatively to detect biliary disease. Factors in assessing cost include: (a) the cost of the procedure itself; (b) the charge in operative management due to a falsenegative or false-positive result; (c) the consequences of leaving retained stones untreated; and (d) the overall cost of negative common duct exploration, which leads to an increase in morbidity and prolonged hospital stay (an increase averaging 3 days in the current series). The final evaluation of the cost-effectiveness is strictly dependent on local situations, levels of hospital cost, physician fees, and cost of equipment. Based on the local situation in The Netherlands and in our institution, we have calculated [26] that the potential savings resulting from use of operative sonography as a routine diagnostic procedure in the current series of patients would allow the purchase of 2 ultrasound scanners such as those used in the current series. Routine cholangiography also appears to be cost-effective, but marginally so. The conclusion is that routine use of an operative diagnostic procedure, such as operative sonography, has a positive cost-benefit result, as effective surgical therapy with a limited complication rate always has.

A few points should be stressed regarding technical aspects of both diagnostic procedures (Table 4). First, ultrasonography may be repeated at any stage of the operation and can produce multiple images in real-time. In addition, the time necessary to complete a sonogram is shorter than that for cholangiography, which requires cannulation of the cystic duct. Finally, the simplicity of operating the modern ultrasound scanner eliminates much of the need for additional technical personnel.

One difficulty that has prevented general acceptance of operative sonography is the more complex image that it produces. Much more information is contained in the sonographic image than in cholangiographic pictures. The surgeon will, therefore, require a longer learning period before accurate interpretation is possible. This learning interval can, however, be shortened by several measures. First, equipment must be adequate, with a transducer probe that provides an image of a long segment of duct in 1 image, at least 5 cm. Such an image can resemble the cholangiographic pictures with which the surgeon may be more familiar. Second, correct technique of examination and standardization of the sonographic procedures must be learned. Third, ultrasonography should be performed routinely to avoid the known problems of occasional ultrasonography. Fourth, a teaching program should be provided for training in ultrasonography, similar to programs in centers with a large experience in endoscopic procedures. Finally, audiovisual aids to training in operative ultrasonography can be helpful. In order to perform operative ultrasonography reliably, it is enough to perform from 5 to 10 examinations under the guidance of a more experienced sonographer, and to perform another 20 examinations in this self-teaching period.

Cholangiography, particularly when performed under fluoroscopic control, enables observation of the passage of radiopaque contrast through the papilla into the duodenum. In our experience, it is also possible to demonstrate sonographically passage of fluid (saline or microbubbles ultrasound contrast) into the duodenum and to observe motility of the distal common bile duct, papilla, and peristalsis of the duodenum. The passage of fluid into the duodenum is clearly visualized using the  $2 \times$ magnification capability of the sonographic system. It is debatable whether all such information is essential, if there is no dilatation of the CBD, increased ductal thickness, or other indications of papillary disease. Nevertheless, the equipment used for operative sonographic evaluation has a resolution of 1 mm, enabling recognition of minute disease signs (Figs. 7, 8).

The sonography equipment used in the present series of patients has a limited capacity for detection of intrahepatic stones, particularly those localized deep in the liver. Other investigators have found that linear-array transducers for sonography seem more reliable for detecting intrahepatic stones, but such transducers may be less reliable for screening the common duct (Pera, C., personal communication). Intrahepatic lithiasis is rare, however, in Western countries and it is our opinion that screening ultrasonography for this condition is of secondary importance. Operative ultrasonography is very useful in detection of papillary disease. In contrast to cholangiography, operative sonography may demonstrate not only stones or other etiologies of occlusion of the distal common bile duct or papilla, but it can reveal the size and extent of extrinsic tumors and the relations of the common duct to surrounding structures such as the portal or mesenteric veins or the cava (Figs. 5, 7). The presence of diseased lymph nodes can also be confirmed. In our experience with 58 patients having papillary or prepapillary disease state, the accuracy of operative sonography in identifying stone or tumor was high: there were 2 false-negative and 2 false-positive findings in this group. Operative ultrasonography is, therefore, a reliable tool for evaluating the pathological conditions in this region.

Finally, operative ultrasonography has a significant potential for further improvements. The development of more compact scanners, smaller electronic transducers, and improvements in image quality and equipment designed specifically for operative imaging of the biliary tract suggest that this modality will become even more reliable and easier to apply. Similar improvements in cholangiographic techniques are not expected at the present time.

In conclusion, operative ultrasonography as a screening procedure during biliary tract surgery appears to offer several advantages. It is highly reliable in detecting and localizing disease conditions of the common bile duct, provides useful information regarding the anatomy of the duct and its surroundings, and has a potential for wide application. It can be cost-effective and, with proper training and equipment, is easy to perform and interpret. The current experience suggests that this method can become an effective substitute for cholangiography as a screening procedure for common duct stones during cholecystectomy and may be very helpful when associated pathological conditions in the biliary tract are suspected. We hope our experience will soon be confirmed by other studies evaluating the merits and limitations of this intraoperative diagnostic procedure.

## Résumé

Au cours d'une période de 4 ans l'échographie opératoire des voies biliaires a été employée chez 449 malades qui ont subi une cholécystectomie pour lithiase biliaire et chez qui a été pratiquée ensuite une exploration cholangiographique. L'efficacité diagnostique des deux méthodes a été identique (97.5% pour l'échographie, 94.4% pour la cholangiographie). En ce qui concerne la valeur prédictive des deux explorations les taux furent respectivement de 96.4% et de 86.9%. Chez les opérés qui furent soumis à une exploration de la voie biliaire principale (148 patients) une différence significative se manifesta dans la fiabilité (92,5% contre 79.8%). Chez 7% des malades cholécystectomisés furent découverts des calculs insoupçonnés. Le taux d'exploration positive de la voie biliaire principale fut de 76.6%, taux plus élevé que celui observé lorsque l'exploration avait été basée sur de seuls critères cliniques. Si l'exploration de la voie biliaire avait reposé seulement sur les seules données de l'échographie le taux d'exploration positive aurait pu être de 97%. Dans cette série le taux de morbidité fut de 9%, celui de la mortalité de 0.9%. Un calcul résiduel fut observé chez un seul malade. On peut conclure de ces faits que l'échographie opératoire exercée par des mains expérimentées est une méthode sûre et un substitut valable de la cholangiographie opératoire.

## Resumen

Se presenta la experiencia de 4 años con ultrasonografía operatoria del tracto biliar en 449 pacientes sometidos a colecistectomía por litiasis biliar en quienes se realizó tanto la ultrasonografía operatoria como la colangiografía. Los resultados numéricos son presentados con las cifras de la ultrasonografía primero, seguidas de la colangiografía. La eficacia diagnóstica de los dos procedimientos en la totalidad de la población examinada fue similar (97.5% versus 94.4%); se observaron diferencias en el valor de predicción de la prueba positiva, 96.3% versus 86.9%. También se observó una diferencia significativa en la certeza (92.5% versus 79.8%) en el grupo de pacientes que recibieron exploración del colédoco (148 pacientes). Se detectaron cálculos no sospechados en 7% de los pacientes colecistectomizados. La tasa de exploración positiva del colédoco fue de 76.6%, la cual es significativamente mayor que la de nuestra experiencia previa cuando la decisión para realizar exploración del colédoco se hacía exclusivamente con base en criterios clínicos. Si la decisión de explorar el colédoco se hiciese con base exclusivamente en el resultado del examen por ultrasonido, la tasa de exploración positiva podría ser de 97%. La morbilidad global en esta serie fue de 9%, y se encontraron cálculos residuales en 1 de los pacientes. La mortalidad global incluyendo el grupo con exploración del colédoco fue de 0.9%. La ultrasonografía operatoria del tracto biliar como procedimiento de tamizaje en manos experimentadas es un método confiable y un sustituto viable de la colangiografía operatoria.

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