

• CLINICAL RESEARCH •

Selection criteria for preoperative endoscopic retrograde cholangiopancreatography before laparoscopic cholecystectomy and endoscopic treatment of bile duct stones: Results of a retrospective, single center study between 1996-2002

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Abstract

AIM: The optimal treatment for bile duct stones (in terms of cost, complications and accuracy) is unclear. The aim of our study was to determine the predictive factors for preoperative endoscopic retrograde cholangiopancreatography (ERCP).

METHODS: Patients undergoing preoperative ERCP (≤ 90 d before laparoscopic cholecystectomy) were evaluated in this retrospective study from the 1st of January 1996 to the 31st of December 2002. The indications for ERCP were elevated serum bilirubin, elevated liver function tests (LFT), dilated bile duct (≥ 8 mm) and/or stone at US examination, coexisting acute pancreatitis and/or acute pancreatitis or jaundice in patient's history. Suspected prognostic factors and the combination of factors were compared to the result of ERCP.

RESULTS: Two hundred and six preoperative ERCPs were performed during the observed period. The rate of successful cannulation for ERC was (97.1%). Bile duct stones were detected in 81 patients (39.3%), and successfully removed in 79 (97.5%). The number of prognostic factors correlated with the presence of bile duct stones. The positive predictive value for one prognostic factor was 1.2%, for two 43%, for three 72.5%, for four or more 91.4%.

CONCLUSION: Based on our data preoperative ERCP is highly recommended in patients with three or more positive factors (high risk patients). In contrast, ERCP is not indicated in patients with zero or one factor (low risk patients). Preoperative ERCP should be offered to patients with two positive factors (moderate risk patients), however the practice should also be based on the local conditions (*e.g.* skill of the endoscopist, other diagnostic tools).

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INTRODUCTION

The rate of coexisting common bile duct stones (CBDS) in patients undergoing cholecystectomy for cholelithiasis is approximately 7-20%^[1-3]. The dramatic shift from conventional to laparoscopic cholecystectomy (LC) in the last 15 years has opened a large debate over the optimal management of patients with CBDS undergoing cholecystectomy^[4,5]. It is generally accepted that bile duct stones should be removed (even if asymptomatic), because they may be associated with severe complications such as pancreatitis and cholangitis. The management of coexisting CBDS may be surgical or endoscopic followed by surgery. Gallbladder preservation has also been suggested, however it has not become universal^[6]. A group of surgeons have recommended laparoscopic management of coexisting CBDS by intraoperative cholangiography or intraoperative ERCP and surgical removal of the stones^[7-9]. However, manipulation of the bile duct during LC is not popular among laparoscopic surgeons. Recent studies suggest that it can be done safely and does not prolong hospitalisation^[10,11], but minimal invasiveness and cost-effectivity remain questionable^[12].

ERCP is the most popular peri-LC bile duct imaging method. It is readily available, safe, highly accurate and has therapeutic potential, even in old patients^[13]. Furthermore ERCP offers the possibility to study bile duct anatomy, identify abnormalities of the bile ducts as well as being useful in the differential diagnosis of questionable lesions (*e.g.* malignancy). The role of new, less invasive imaging techniques (*e.g.* endoscopic ultrasound - EUS, magnetic resonance cholangiopancreatography - MRCP) is less well characterized^[14-16].

Routine preoperative ERCP may not be recommended, due to the low percentage of coexisting cholecysto-choledocholithiasis, a large number of negative investigations, and a small but significant risk of associated morbidity and high additional costs. Postoperative ERCP could reduce the number of unnecessary interventions and the majority of retained stones and postoperative leakages can be treated, although a second operation is required in case of failure. The development of more reliable predictors of CBD stones, based on the patient's clinical, biochemical and ultrasound (US) presentations, could allow a more appropriate use of preoperative ERCP (or EUS, MRCP). However, there is still no consensus as to which particular indicator, or set of indicators should be used, or as to the threshold values of various indicators^[3,17-22].

The aim of this study was to determine a precise and easily applicable clinical, biochemical and US (selection) criteria for patients who should undergo further investigation (preoperative ERCP) prior to LC/surgery.

MATERIALS AND METHODS

Patients who underwent preoperative ERCP from the 1st January 1996 to the 1st January 2003 (≤ 90 d before laparoscopic cholecystectomy) were evaluated in this retrospective study.

The indications for ERCP were one or more of the following: elevated serum bilirubin ($\geq 2 \times$ upper limit of normal - ULN) concentration, elevated liver function tests [LFT, $\geq 1.5 \times$ ULN: either aspartate-aminotransferase (AST), alanine-aminotransferase (ALT), alkaline phosphatase (ALP) or γ -glutamyl transpeptidase (GGT) activities], dilated bile duct (≥ 8 mm) and/or stones at US examination, coexisting acute pancreatitis and/or acute pancreatitis or jaundice in patient's history. The predictive values of age, sex and colic were also investigated. The majority of the ERCPs were performed by two expert endoscopists. Suspected prognostic factors and combination of factors were compared to the results of the ERCP.

Serum bilirubin concentration, AST, ALT, ALP and GGT activities were measured by Olympus AU600 (Olympus Co. Ltd, Shizuoka, Japan) autoanalyser at 37 °C. The enzyme activities were expressed in U/L and serum bilirubin concentration was given in $\mu\text{mol/L}$.

Statistical analysis

Sensitivity, specificity, positive and negative predictive values were calculated for individual factors (compared to all other cases) and for combination of factors. Student *t*-test with separate variance estimates was performed to test the demographic differences. χ^2 test and Fisher exact test were performed to compare between patients with a different number of suggested factors. $P < 0.05$ was considered statistically significant. For the statistical analysis Statistica 6.1 (Statsoft Inc, OK, USA) was used.

RESULTS

A total of 2985 ERCPs and 1248 LCs were performed in the Csolnoky F. Province Hospital between 1st January 1996 and the 31st December 2002. Using our selection criteria (a minimum of one positive factor) preoperative ERCP was performed in 206 patients (16.5%, Table 1). Seventy-seven percent of the patients were women and 23% men. The mean age of women was significantly lower ($P = 0.02$, Table 2). The mean waiting time between ERCP and LC was 17.3 d. Thirty-nine percent of the patients were operated within 3 d, almost 60% within one week.

Table 1 Number of ERCP and/or LC cases per year in the Csolnoky Ferenc Hospital, Veszprém, Hungary

| Year | ERCP | LC | ERCP-LC |
|---------|--------|-------|---------|
| 1996 | 373 | 99 | 15 |
| 1997 | 393 | 164 | 28 |
| 1998 | 375 | 140 | 27 |
| 1999 | 490 | 189 | 33 |
| 2000 | 558 | 183 | 36 |
| 2001 | 378 | 246 | 42 |
| 2002 | 391 | 227 | 25 |
| Total | 2 258 | 1 248 | 206 |
| Average | 423/yr | 178 | 29/yr |

Table 2 Preoperative ERCP, age and gender of patients ($n=206$)

| Gender | <i>n</i> (%) | Mean age |
|--------|--------------|----------|
| Male | 48 (23) | 57.4 |
| Female | 158 (77) | 51.0 |
| Total | 206 (100) | 52.5 |

A successful cannulation was done in 200 patients (97.1%,

Table 3). CBD stones were found in 81 patients (39.3%), the stone/stones were removed endoscopically in 79 cases (97.5%). There was a tendency of increased frequency of CBD stones in men (24/48 = 50.0%) compared to women (57/158 = 36.1%, $P = 0.06$ by Fisher exact test), but CBD stones were equally common in elder (≥ 60 years) and younger (< 60 years) patients (50/128 = 39.1% vs 31/78 = 39.7%).

The results for each individual criterion are shown in Tables 4, 5. With the exception of jaundice or pancreatitis in the patient's history the positive predictive value of each criterion was high (58-72%). Sensitivity and specificity were compared to patients lacking the specific factor.

Table 3 Results of preoperative ERCPs performed prior to LC ($n = 206$)

| ERCP finding | <i>n</i> | % |
|-----------------------------------|----------|------|
| Common bile duct (CBD) stone | 81 | 39.3 |
| Negative | 119 | 57.8 |
| CBD not filled | 6 | 2.9 |
| Successful EST and duct clearance | 79/81 | 97.5 |
| Complication | 3 | 1.5 |
| -bleeding | 1 | 0.5 |
| -pancreatitis | 1 | 0.5 |
| -stone impaction | 1 | 0.5 |

Table 4 Common bile duct stones in cases of different positive prognostic factors (PPF)

| Factor | Number | Stone | Negative | Unsuccessful | % |
|---------------------------------|--------|-------|----------|--------------|----|
| Hyperbilirubinaemia (> 2) | 61 | 44 | 16 | 1 | 72 |
| Elevated ASAT/ALAT ($> 50\%$) | 116 | 74 | 39 | 3 | 64 |
| Elevated GGT/ALP ($> 50\%$) | 134 | 79 | 52 | 3 | 59 |
| Acute pancreatitis (AP) | 26 | 18 | 7 | 1 | 69 |
| AP in the anamnesis | 20 | 4 | 16 | 0 | 20 |
| Jaundice in the anamnesis | 29 | 1 | 26 | 2 | 3 |
| US: CBD ≥ 8 mm | 53 | 38 | 14 | 1 | 71 |
| US: bile duct stone | 7 | 4 | 3 | 0 | 57 |
| Biliary colic | 106 | 62 | 42 | 2 | 58 |

Table 5 Total predictive value of different positive predictive factors (PPF) for common bile duct stone

| Factor | PPV % | NPV % | Sensitivity % | Specificity % |
|---------------------------|-------|-------|---------------|---------------|
| Hyperbilirubinaemia | 73.3 | 73.6 | 54.3 | 86.6 |
| Elevated ASAT/ALAT | 65.4 | 91.9 | 91.3 | 67.2 |
| Elevated GGT/ALP | 60.3 | 97.1 | 97.5 | 56.3 |
| Acute pancreatitis (AP) | 72.0 | 73.5 | 22.2 | 96.2 |
| AP in the anamnesis | 20.0 | 57.2 | 4.9 | 86.5 |
| Jaundice in the anamnesis | 3.7 | 53.7 | 1.2 | 78.2 |
| US: CBD ≥ 8 mm | 73.1 | 70.9 | 46.9 | 88.2 |
| US: bile duct stone | 57.1 | 60.1 | 4.9 | 97.5 |

A more realistic approach was to compare the predictive value in association with other factors. Table 6 demonstrates that the positive predictive value of the investigated factor was high in cases with (at least) two concurrently positive factors. The positive predictive value of two positive markers was 41-55%, again with the exception of pancreatitis or jaundice in the anamnesis.

Table 6 Predictive value of positive predictive factors (PPF) for CBD stones and effect of associated other factors, *n* (%)

| Factor | Alone | One further factor | Two or more further factors |
|---------------------------|----------|--------------------|-----------------------------|
| Hyperbilirubinaemia | 0/3 | 1/5 (20) | 43/53 (81) |
| Elevated ASAT/ALAT | 1/11 (9) | 13/32 (41) | 60/73 (82) |
| Elevated GGT/ALP | 1/24 (4) | 16/35 (46) | 62/75 (83) |
| Acute pancreatitis (AP) | - | 0/3 | 18/23 (78) |
| AP in the anamnesis | 1/12 (8) | 0/3 | 3/5 (60) |
| Jaundice in the anamnesis | 0/27 | 1/2 (50) | - |
| US: CBD \geq 8 mm | 0/7 | 6/11 (55) | 32/35 (91) |
| US: bile duct stone | 0/1 | - | 4/6 (67) |

The association between the number of positive factors and the presence of CBD stones is shown in Tables 7, 8. One factor alone was associated with a very low risk of CBD stone (1.2%). In patients with two, three and four or more positive factors, CBD stones were detected in 43.1%, 72.5% and 91.4% respectively. If we omitted history of jaundice and pancreatitis from the factors the corresponding data were 2.7% (1/41), 1.9% (1/54), 45.6% (23/48) and 82.3% (56/69) for patients with zero, one, two and three or more positive factors.

Table 7 Association between the number of positive predictive factors and ERCP findings (*n* = 206)

| Number of positive factors | Number | Stone | Negative | Unsuccessful | % |
|----------------------------|--------|-------|----------|--------------|------|
| 1 | 84 | 1 | 80 | 3 | 1.2 |
| 2 | 46 | 19 | 25 | 2 | 43.1 |
| 3 | 40 | 29 | 11 | 0 | 72.5 |
| \geq 4 | 36 | 32 | 3 | 1 | 91.4 |

$P < 0.00001$ for the whole group, $P < 0.00001$, between group 1 and groups 2, 3, 4, group 2 and group 4, $P = 0.008$, between groups 2 and 3, $P = 0.035$, between groups 3 and 4.

Table 8 Predictive value of predictive factors according to the number of positive factors

| Number of positive factors | Number | PPV % | NPV % | Sensitivity % | Specificity % |
|----------------------------|--------|-------|-------|---------------|---------------|
| 1 | 84 | 1.2 | - | - | - |
| 2 | 46 | 43.1 | 98.7 | 95.2 | 76.1 |
| 3 | 40 | 72.5 | 84.0 | 59.1 | 90.5 |
| \geq 4 | 36 | 91.4 | 72.0 | 40.2 | 98.4 |

$P < 0.00001$ for the whole group, $P < 0.00001$, between group 1 and groups 2, 3, 4 and group 2 and group 4, $P = 0.008$, between groups 2 and 3, $P = 0.035$, between groups 3 and 4.

DISCUSSION

Although laparoscopic cholecystectomy has become the treatment of choice for cholelithiasis, the treatment of coexisting cholecysto-choledocholithiasis is still controversial^[1,3,8,10,15,17]. The surgical management of CBD stones requires a skilled laparoscopic surgeon and the options of management include conversion to open CBD exploration, intraoperative or postoperative ERC. In contrast, no single non-invasive method is sensitive and/or specific enough to predict the presence of CBD stones. Individual findings are less important than the overall clinical presentation.

A number of methods have been used for the diagnosis of CBDS, including new and improved radiological techniques. However some of them are invasive, more expensive and require special equipment. A major advantage of ERCP is that it could

also offer a therapeutic possibility. Approximately 90-95% of CBDS could be managed endoscopically^[1,23], but it is expensive, technically demanding and is associated with small but significant morbidity.

The question is whether preoperative ERCP should be routinely indicated or whether it should be kept for selected cases only. Most of the studies concluded that routine preoperative ERCP was not indicated^[1,20,24]. One of the earliest studies is the well-known study from Neuhaus *et al.*^[24]. They performed routine preoperative ERCP in 288 prospective patients prior to LC. The rate of successful cannulation was 91.7%, and normal anatomy was found in 86%. CBDS were proved in 29 patients (11%), the stone was asymptomatic in 9 patients. Endoscopic sphincterotomy was performed in all cases and the stones were extracted in all but three patients. One additional patient was operated due to complications. In concordance with the reported rate of 6-13.2% in other studies^[1,14,20], coexisting cholecysto-choledocholithiasis was found in 6.5% of our LC patients (81 cases by preoperative ERCP).

The aim of this and previous studies was to determine a precise and easily applicable selection of clinical, biochemical and US criteria, which would enable the identification of patients with low risk of CBD stones (without the necessity for invasive procedures), and with higher risk of CBD stones who should undergo further preoperative investigation. The selection of patients was difficult. CBD stones were more common in patients with symptoms (e.g. jaundice, cholangitis, pancreatitis) and laboratory alterations including elevated serum bilirubin and liver function test. However, 8-10% of gallstone patients might have asymptomatic ductal stones^[3,25,26].

The positive predictive value of laboratory data for CBD stones was found to be 60-87% in various studies^[26,27]. In our study it was 57.1-73.3% in univariate analysis. However in most of the cases they were not individual parameters. In concordance with previous studies we could not identify jaundice and pancreatitis in the anamnesis as a predictor variable.

Traditional abdominal US is a valuable diagnostic tool. Although it is less sensitive (20-30%) in the detection of ductal gallstones, it provides important additional information about the degree of dilation of the bile ducts. The sensitivity of iv. cholangiography is also relatively low, moreover, it is associated with a severe risk of side effects. However, due to new non-ionic radiocontrast agents and radiological techniques, more and more research groups have started to routinely apply this technique again with improving results^[3]. Laparoscopic intraoperative cholangiography is a useful and reliable method, although its indication remains debated^[10,28]. The sensitivity of traditional CT is similar to that of US, but 3D helical techniques could offer an accuracy comparable to that of MRCP^[29]. MRCP and endoscopic US could approach the diagnostic value of ERCP^[14,15,30].

None of the aforementioned and analyzed factors is fit for the prediction of bile duct stones with sufficient certainty by itself. A combination of the prognostic factors is routinely applied. Several authors have constructed complicated scoring systems^[16,23,27]. However, most of these systems require highly specific and sophisticated softwares, and no universally accepted system exists. More practical is the use of suggested clinical scores based on routine clinical data (jaundice, pancreatitis, liver function tests, ductal dilation and/or stones in the choledochus on US) in everyday practice^[17,20]. Some authors also included the presence of small gallstones, old age and gender.

In concordance with our study, in the different studies based on large patient populations, CBDS/ductal stones or other pathologic deviations were found in 40-60% of ERCP cases performed on selected/restricted indications^[1,16,18,20]. Based on the prognostic factors, patients were usually divided into low,

medium and high-risk CBD stone groups.

Peter Cotton^[31] has presented his guidelines in the American Journal of Surgery. In his opinion the main constituents of the indications of preoperative ERCP were the following: positive predictive factors for CBD stones, the expertise of the endoscopist, and the pressure for laparoscopic intervention as opposed to open surgery. In concordance with our suggestion, he identified low, medium and high-risk patients for CBD stones based on the anamnesis, liver function tests, and ductal dilation on US. According to his conclusions, preoperative ERCP was not indicated for low-risk patients, while it must absolutely be performed in the high-risk group. As for the medium risk group, seemingly paradoxically, preoperative ERCP was only indicated, if the local endoscopist was mediocre. With an experienced endoscopist, preoperative intervention should be avoided, ERCP is to be performed only after the surgery, if the need arises.

Rieger *et al.*^[26] found CBD stones in 56 patients (53%) of the 106 ERCP performed in combination with 1140 LC. More than two-fold elevation in any liver function test, multiple abnormal laboratory tests, stones in the biliary tract on US, a more than 7 mm, dilated ductus choledochus were taken as positive predicting factors for preoperative ERCP. The multicenter study of Welbourn *et al.*^[32] in England also aimed to identify the exact indications of selective preoperative ERCP. The retrospective analysis of 306 preoperative ERC and 1396 LC showed that the predictive value of jaundice was 75%, that of pancreatitis 56%, while the predictive value of pathologic US or liver function tests was 48 %. In a prospective study of Sarli *et al.*^[3], 74 symptom-free, CBD stone patient data were evaluated. Positive US, biliary colic, elevated serum aminotransferase and alkaline phosphatase levels and the presence of multiple, smaller stones were associated with a higher risk, while acute cholecystitis and non-specific upper gastrointestinal complaints were associated with a lower risk. In our study jaundice, elevated LFTs and dilated choledochus or stones in the bile duct on US examination gave a similarly high positive predictive value in univariate analysis for bile duct stones.

In our opinion, the major shortcoming of the above studies is that they analyzed the effects of different predictive factors separately, which in accordance with our own findings, could easily result in misleading conclusions. Santucci *et al.*^[33] and Geron *et al.*^[7] came to the same conclusion, emphasizing the importance of the co-existence of several pathologic markers at the same time. Furthermore, the American Society for Gastrointestinal Endoscopy (ASGE) in its guideline^[29] favors the establishment of the aforementioned risk categories based on "simple clinical" data, such as clinical picture, laboratory findings and US. Interestingly, it recommends intraoperative (during the laparoscopic cholecystectomy) cholangiography to be performed even in low-risk/negative patients, followed by laparoscopic or endoscopic postoperative intervention, if required. In the medium-risk group endosonography or MRCP is recommended as the method of choice or, if these are not available, ERCP. According to the guideline, ERCP should be the first (therapeutic) intervention for high-risk patients.

In Hungary, ERCP is performed on a relatively high level and is generally available. Among the new imaging techniques, the availability of MRCP and endosonography is still limited. At the same time, due to financing reasons, ERCP turns out to be more cost-effective. The accessibility of intraoperative laparoscopic imaging techniques is also limited.

In summary, based on the literature and our own results, the following guideline can be established about the indications of preoperative ERCP.

The possibility of CBD stones should be considered after the evaluation of clinical, laboratory and US findings. Zero or one positive predictive factor indicates low risk, while the risk is high if three or more factors are present. Two positive

predictive factors suggest medium risk. In the low risk group preoperative ERCP is not recommended, LC is advisable without restrictions. In the high risk group the indication of preoperative ERCP is unambiguous. In the medium-risk population, preoperative ERCP is generally indicated. If available, MRCP can be a good alternative. In case of a highly qualified endoscopist, ERCP should be postponed until the surgery can be considered.

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