Original Article

Predictors of failure of endoscopic retrograde cholangiography in clearing bile duct stone on the initial procedure

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Abstract

Background/Aims: The aim of this study is to predict cases where the clearance of the biliary system from stones at the initial endoscopic retrograde cholangiopancreatography (ERCP) might be of value for better risk-stratifying patients. We attempted to identify factors that are associated with a higher failure rate of clearing the biliary system on the index ERCP.

Patients and Methods: This is a retrospective study from January 2008 to January 2015. All patients with bile duct stones confirmed on ERCP were included in this study. Patients who had prior attempts of bile duct stone extraction were excluded.

Results: A total of 554 ERCPs were performed to extract biliary duct stones from 426 patients. The mean age was 46.3 years and 41.7% were males. The group where the index ERCP did not clear the biliary system tended to be older (50.4 vs. 45.2 years, $P = 0.03$). On multivariate analysis, the presence of fever (OR 4.64; 95% CI, 1.66–12.79), a larger number of filling defects (OR 1.34; 95% CI, 1.13–1.93), presence of a stricture distal to a stone (OR 4.63; 95% CI, 1.36–15.78), the use of an extraction basket (OR 3.23; 95% CI, 1.56–6.74), and/or mechanical lithotripsy (OR 3.05; 95% CI, 1.10–8.49) were all associated with a lower odds of clearing the biliary system. The use of an extraction balloon was associated with the success of clearing the biliary system (99.7% vs. 77.4%, $P < 0.01$) and a lower odds of failing (OR 0.01; 95% CI, 0.00–0.08) on multivariate analysis.

Conclusion: A few of the characteristics that are found on cholangiography at the index ERCP could be used to identify patients that might require more than one ERCP to clear the biliary system from stones.

Keywords: Biliary stones, biliary system, endoscopy, endoscopic retrograde cholangiopancreatography, stricture

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INTRODUCTION

A common indication for performing an endoscopic retrograde cholangiopancreatography (ERCP) is the removal of biliary stones. Although the majority of cases are usually amendable to clearance of the biliary system during a single session, there remains a portion where

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repeated procedures are required either due to factors pertaining to the anatomy of the biliary system[1] or the stones themselves[2] (e.g., size and number). Attempting to identify cases, where the clearance of bile duct stones through ERCP would be challenging during the index ERCP, might be of benefit in allocating better resources in the following sessions and even a more informative discussion with the patients that more than one session might be required to achieve clearance of the biliary system. Furthermore, identifying factors that might predict cases where biliary system clearance would be challenging might give the health-care provider an opportunity to possibly pursue other lines of management, for example, those who still have intact gallbladders might favor the referral of patients to laparoscopic cholecystectomy combined with intraoperative bile duct clearance.

In this study, we aim to identify factors that are associated with the failure of clearing the biliary system from stones during the index ERCP.

PATIENTS AND METHODS

This is a retrospective study conducted at a tertiary care university hospital from January 2008 to January 2015. All patients with bile duct stones confirmed on ERCP after successful biliary cannulation were included in this study. For patients who had prior attempts of bile duct stone extraction by ERCP (either before the study period or attempted at an outside institution), or extracorporeal shock wave lithotripsy, were excluded from this study.

The presence of bile duct stones was confirmed by finding a filling defect on cholangiographic images or a visible extracted stone seen on endoscopic view during the use of an extraction balloon or basket. Data were retrieved from hospital charts including demographic information, such as age, sex, prior abdominal surgery, and prior cholecystectomy, and also whether the patient presented with abdominal pain, jaundice, or fever indicating cholangitis and if a stone was seen on an ultrasound prior to the ERCP. Endoscopic findings including the timing of the procedure (morning, afternoon, or after hours), presence of a periampullary diverticulum, the presence of an impacted ampullary stone, the instruments used during the ERCP (extraction balloon and/or basket, and/or mechanical lithotripsy) or the use of endoscopic papillary large balloon dilatation (EPLBD) as well as the findings on cholangiography (common bile duct [CBD] size, CBD stone size, number of filling defects, the presence of a biliary stricture, the presence of angulation in the biliary system, or Mirrizi syndrome) were extracted from endoscopy reports.

Two therapeutic gastroenterologists (ME, ST) reviewed all fluoroscopic images independently. The diameter of the bile duct and the maximum transverse diameter of the stone were measured after correction for the magnification using the known diameter of the duodenoscope and its apparent diameter on the radiographic image.

Angulation of distal CBD was measured using the sharpest angle along CBD from 1 cm below the bifurcation into the hepatic ducts to 1 cm above the papilla with a cutoff angle of <135°[3,4] [Figure 1a and b].

The use of EPLBD and mechanical lithotripsy and the extraction methods were at the discretion of the endoscopist. Although cholangioscopy has been available in our unit since 2012 and we mainly used electrohydraulic lithotripsy for the management of difficult-to-treat CBD stones, we did not include cases where this technology was used. We did not include cases with complex prior surgeries that might make reaching the papilla challenging (e.g., Bilroth II, Roux-en-Y gastric bypass, etc).

Successful bile duct clearance was defined as having no filling defect on the final cholangiogram recorded for the procedure. When the index ERCP could not achieve clearance of the biliary system, the number of subsequent procedures was recorded.

Statistical analysis

Descriptive statistics were computed for continuous variables, including means, standard deviations, minimum, and maximum values, as well as 95% confidence intervals (CIs) and frequencies for categorical variables.

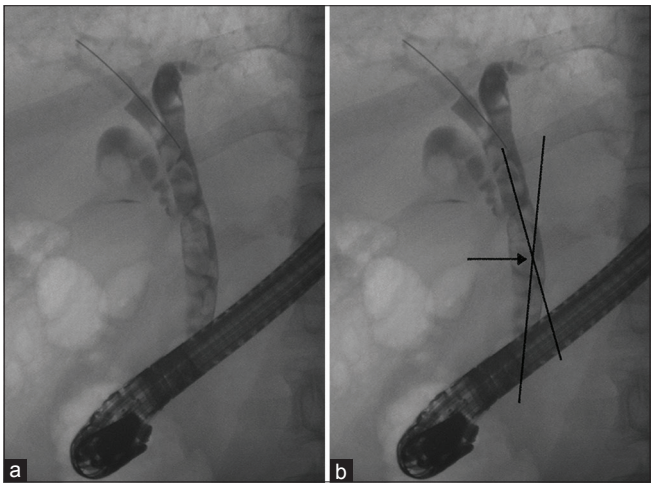

Figure 1: (a) Cholangiogram demonstrating multiple filling defects throughout the length of the biliary system and (b) method of calculating the angulations; the sharpest angle along the common bile duct by drawing a line 1 cm below the bifurcation to 1 cm above the papilla

If hypothesis testing was used, the Pearson's Chi-squared *t*-test and, where appropriate, the Fisher's exact tests were used.[5] A one-way analysis of variance to test for differences among groups when comparing more than one group was performed when appropriate. Univariate and multivariate logistical regression analyses, odds ratio (OR), and 95% CIs were performed. A backward selection method was used to determine the variables to be included in the final model. The goodness of fit for the multivariable model was based on the Akaike information criteria (AIC).

A sample-size calculation was performed to detect a 20% difference in the success of clearing the biliary system with a power of 80% and type I error of 5%; a sample size of 390 patients was required.[6]

R Studio[7] was used for analysis using the R statistical language.[8] A statistical significance threshold of $P = 0.05$ was adopted. No attempt at imputation was made for missing data.

RESULTS

A total of 554 ERCPs were performed to extract biliary duct stones from 426 patients [Figure 2]. The mean age was 46.3 ± 19 years and 41.7% were males. The demographic, clinical, and endoscopic findings are demonstrated in Table 1.

On cholangiography, the mean diameter of the bile duct was 9 ± 4 mm. The number of stones ranged from one to five stones and the stone diameter ranged from 5 to 30 mm. Bile duct clearance was achieved on the index ERCP in 344 patients (80.8%), the remaining patients underwent up to seven additional attempts.

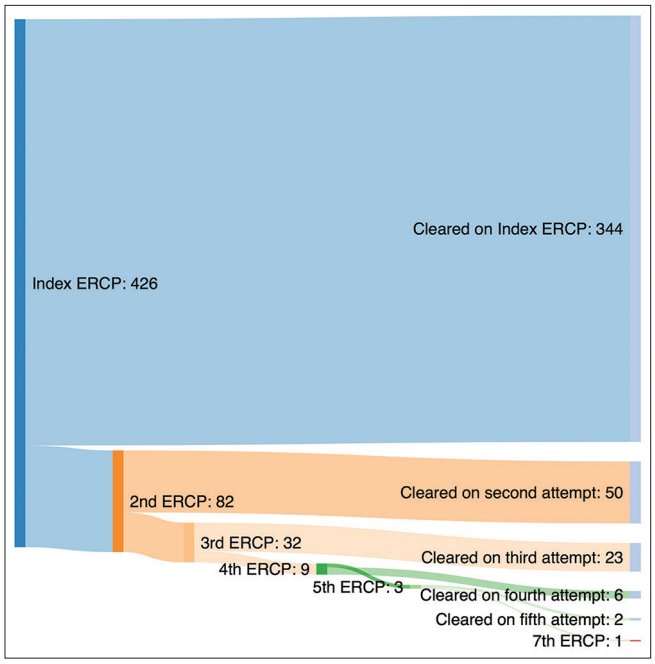

Figure 2: A Sankey diagram showing the flow of endoscopic retrograde cholangiopancreatographies and those who achieved biliary clearance after each sequential procedure

Patient related characteristics

Those, where biliary system clearance was not possible on the index ERCP, tended to be older in age (50.4 vs. 45.2 years, $P = 0.03$) and presented with fever (15.1% vs. 6.0%, $P < 0.01$).

On univariate and multivariate analysis, the only characteristic associated with increased odds of failing to clearing the biliary system on the index ERCP was the presentation with fever (OR 2.77; 95% CI, 1.32–5.70 and OR 4.64; 95% CI, 1.66–12.79, respectively). None of the other characteristics were associated with an increased risk of failing to clear the biliary system on the index ERCP [Tables 1-3].

Findings on ERCP

There was a higher rate in failing to clear the biliary system when there was an impacted stone (17.2% vs. 6.3%, $P < 0.01$; OR 3.09; 95% CI, 1.52–6.18) but was not significant on multivariate analysis (OR 1.34; 95% CI, 0.47–3.61).

Also, although there was a higher rate of failure to clear a CBD with a size larger than 15 mm on the index ERCP (72.0% vs. 52.0%, $P < 0.01$) that was also found on univariate analysis (OR 2.38; 95% CI, 1.46–3.99), this risk factor was not significant on multivariate analysis as it was not a predictor when optimizing the model using the AIC criterion during the backward selection method.

A larger mean number of filling defects (1.8 vs. 2.6 stones, $P < 0.01$) was associated with decreased odds of clearing the biliary system on univariate analysis (OR 1.63; 95% CI, 1.32–2.02) and multivariate analysis (OR 1.34; 95% CI, 1.13–1.93), which was also the case when a stricture was found distal to the stone (12.1% vs. 3.8%, $P < 0.01$), univariate analysis (OR 3.53; 95% CI, 1.30–9.34), and multivariate analysis (OR 4.63; 95% CI, 1.36–15.78).

The biliary system could not be cleared on the index ERCP where an endoscopist used an extraction basket (49.5% vs. 24.3%, $P < 0.01$), which was persistent on univariate and multivariate analysis (OR 3.04; 95% CI, 1.89–4.92 and OR 3.23; 95% CI, 1.56–6.74, respectively). A similar finding when mechanical lithotripsy was used (22.6% vs. 4.2%, $P < 0.01$) and on univariate analysis (OR 6.65; 95% CI, 3.25–13.97), which persisted with multivariate analysis (OR 3.05; 95% CI, 1.10–8.49).

Table 1: The demographic, clinical and endoscopic findings in 426 patients

Variable	Successful clearance	Unsuccessful clearance	*P*	Total Percentage or mean, SD
Age (years)	45.2 years	50.4 years	0.03*	46.3 years
Male	41.7%	46.2%	0.44	42.7%
Prior cholecystectomy	16.1%	15.8%	0.96	16.1%
Prior abdominal surgery	75%	66.7%	0.77	73.3%
Jaundice	33.4%	41.9%	0.12	35.2%
Fever	6.0%	15.1%	<0.01*	8.0%
Abdominal pain	27.3%	25.8%	0.77	26.9%
CBD stone seen on ultrasound	38.4%	43.6%	0.55	39.4%
Timing of ERCP				
Morning	53.5%	54.8%	0.42	53.8%
Afternoon	42.9%	38.7%		42.0%
Afterhours	3.6%	6.5%		4.2%
Experience of the endoscopist is more than 5 years	64.9%	72.0%	0.19	66.4%
Periampullary diverticulum	2.1%	5.4%	0.09	2.8%
Impacted stone	6.3%	17.2%	<0.01*	8.7%
CBD size more than 15 mm	52.0%	72.0%	<0.01*	56.3%
CBD stone size more than 15 mm	9.3%	10.8%	0.68	9.6%
Number of filling defects	1.8	2.6	<0.01*	2.0
Presence of a stricture	3.8%	12.1%	<0.01*	5.4%
Presence of an angulation	12.4%	11.3%	0.82	12.1%
Mirrizi Syndrome	1.5%	3.2%	0.28	1.9%
EPLBD	6.6%	11.8%	0.10	7.7%
The use of an extraction balloon	99.7%	77.4%	<0.01*	94.8%
The use of an extraction basket	24.3%	49.5%	<0.01*	29.8%
The use of mechanical lithotripsy	4.2%	22.6%	<0.01*	8.2%

CBD; Common bile duct, CI; Confidence interval, ERCP: Endoscopic retrograde cholangiopancreatography, EPLBD; Endoscopic papillary large balloon dilatation, OR; Odds ratio. *Statistically significant

While the use of an extraction balloon was associated with the success of clearing the biliary system from stones (99.7% vs. 77.4%, $P < 0.01$) and a lower odds of failing to clear the biliary system at the index ERCP univariate analysis (OR 0.01; 95% CI, 0.0–0.05) and multivariate analysis (OR 0.01; 95% CI, 0.00–0.08).

None of the other characteristics were associated with an increased risk of failing to clear the biliary system on the index ERCP [Tables 2-3].

Table 2: Univariate analysis of factors associated with the decreased clearance of the biliary system from stones

Variable	OR	95% CI
Age	1.01	1.00 to 1.03
Male	1.20	0.75 to 1.90
Prior cholecystectomy	0.97	0.34 to 2.44
Prior gastroentestinal surgery	0.67	0.04 to 17.41
CBD size more than 15 mm	2.38	1.46 to 3.99
CBD stone seen on ultrasound	1.24	0.60 to2.51
Jaundice	1.44	0.90 to 2.31
Fever	2.77	1.32 to 5.70
Abdominal pain	0.92	0.54 to 1.54
Timing of ERCP		
Morning	Comparator	Comparator
Afternoon	0.88	0.54 to 1.42
On call	1.75	0.58 to 4.73
Experience of the endoscopist is more than 5 years	1.40	0.85 to 2.35
Ampullary diverticulosis	2.65	0.77 to 8.49
EPLBD	1.90	0.85 to 3.99
Impacted stone	3.09	1.52 to 6.18
CBD stone size more than 15 mm	1.17	0.53 to 2.42
Number of filling defects	1.63	1.32 to 2.02
Presence of a stricture	3.53	1.30 to 9.34
Presence of an angulation	0.90	0.35 to 2.05
Mirrizi Syndrome	2.19	0.44 to 9.08
The use of an extraction balloon	0.01	0.0 to 0.05
The use of an extraction basket	3.04	1.89 to 4.92
The use of mechanical lithotripsy	6.65	3.25 to 13.97

CBD; Common bile duct, CI; Confidence interval, ERCP: Endoscopic retrograde cholangiopancreatography, EPLBD; Endoscopic papillary large balloon dilatation, OR; Odds ratio

DISCUSSION

Although the clearance of the biliary system of stones is achieved in the majority of cases, some cases require repeated procedures and in very few cases long-term stenting.[9,10] Repeated ERCPs are required in this setting[11,12] and the mean number of ERCPs can reach 2.5 procedures.[12] The identification of these difficult cases has been attempted prior to ERCP using different modalities including endoscopic ultrasound[13] with the intent of optimizing the setup of the procedure, for example, the use of cholangioscopy.[14] Other advantages of predicting these cases might be for having a more informative discussion with the patient about the need for repeated procedures or the referral of these cases to more experienced centers.

A number of the factors that have been evaluated in this study may not lend themselves to the endoscopist before the index procedure (e.g., anatomical and stone-related characteristics) and thus might not change the endoscopists' attitude in trying to remove the stone based on

Table 3: Multivariate analysis of factors associated with the decreased clearance of the biliary system from stones

Variable	OR	95% CI
Fever	4.64	1.66 to 12.79
Impacted stone	1.34	0.47 to 3.61
Number of filling defects	1.47	1.13 to 1.93
Presence of a stricture	4.63	1.36 to 15.78
Presence of an angulation	0.65	0.21 to 1.75
The use of an extraction balloon	0.01	0.00 to 0.08
The use of an extraction basket	3.23	1.56 to 6.74
The use of mechanical lithotripsy	3.05	1.10 to 8.49

his/her comfort level and availability of various therapeutic techniques. Furthermore, the success of a device (basket vs. balloon) might be influenced by the sequence in which they were used and might be compounded by whether or not they were used in combination, which even makes any definite conclusion difficult. But we believe the value of this study stems from the insight that it might lend to the endoscopist after the index procedure on what the next line of action should be.

The duct clearance rate on the index ERCP in our study was 80.8%, that resembles the rates reported by other groups where the duct clearance at the index ERCP ranged from 72.5% to 79.1%.[12,15]

The higher clearance rate reported in the study by Brown *et al.*[12] might be related to the fact that they accounted for the use of cholangioscopy as a technique in their study while we excluded those who had cholangioscopy. In addition, the study population in those two trials included a more heterogeneous population, which had included patients who underwent a prior ERCP and attempted stone clearance but had failed. It is not clear whether the inclusion of such a population would increase the clearance rate at the first ERCP accounted for in those studies, as they would be in fact including patients who had two ERCPs prior to achieving biliary clearance. In our study, the majority of cases (92.5%) had achieved biliary clearance by the second ERCP.

It was interesting to find that the presence of cholangitis was associated with an increased rate of failure in clearing the biliary system on the index ERCP. We believe that such an association might be a marker that the aim of the index ERCP was to achieve biliary drainage and control of the source of infection with the least possible intervention, given the ongoing sepsis with clearing of the biliary system of stones being deferred to when the patient would be free of sepsis. Unfortunately, we could not clarify this assumption as we could not retrieve documentation that clearly stated that intent, nor did we have variables that would enable us to stratify cases by the severity of cholangitis.

Although successful stone clearance rates were reported to be lower in individuals with periampullary diverticula compared to those without (83.53 vs. 94.31%, $P = 0.005$),[16] we did not find such an association but our study was not powered to detect such a difference. Of note, in a large study by Christoforidis *et al.*,[17] they did not find an effect of periampullary diverticula on the success of stone extracting on multivariate analysis, which is in keeping with our study.

Although stone characteristics like the number or size and relation to the CBD diameter were not found to be associated with the stone clearance rates in studies,[12] this is in contrast to others[11,15,17,18] where larger stones ($\geq 17.7 \pm 6$ mm) were found to require a combination of advanced ERCP techniques to achieve duct clearance.[12] In our study, we did not find an association between stone size and the failure to clear the biliary system on the index ERCP; again, this could be due to the fact that only a small proportion had large CBD stones in our cohort (9.6% had a stone larger than 15 mm) as well as the fact that endoscopists could have utilized advanced endoscopic techniques to clear these stones during the index ERCP. The presence of a stricture below a stone is an intuitive cause for increased difficulty in extracting a stone, which was the case in our study and is consistent with the literature[18] where a stemware-shaped CBD was associated with a bile duct clearance rate on the index procedure of only 41.2%; even in those with stones less than 1 cm in size, the clearance rate on the index procedure was only 62.5% while the overall procedure-related adverse events were relatively high, that is, 14.7%.[11] In addition, the presence of an angulation in the distal CBD has been thought to be a cause of decreased clearing rates of the biliary system[4] but was not the case in our cohort. Furthermore, we found that the larger the number of filling defects, the higher the odds of not being able to achieve biliary clearance on the initial ERCP; this is once again an intuitive finding and whether this is an effect of the anticipated prolonged time of the procedure and the planned multi-procedure approach by the endoscopist or a true difficulty, remains to be clarified.

The use of EPLBD is a highly successful method in the management of bile duct stones and has shown to achieve a clearance rate up to 89.7% on index ERCP[12] and has also been shown to have a higher rate for the removal of CBD stones during the index ERCP compared to endoscopic sphincterotomy (86.9% vs. 71.4%, $P = 0.01$).[19] In this study, only a small proportion of cases had an EPLBD performed and there was no difference in the clearance rate when it was used; whether this is related to the small proportion or to factors related to the procedure itself is unclear. Although it is a common practice in our unit

that when EPLBD is performed it is usually more than a minute, we could not account for that data as it was rarely documented.

We believe that the association of a higher rate of failure of clearing the biliary system when a mechanical lithotripter and/or extraction basket was used is in reality a confounder and marker for a more difficult procedure rather than a cause *per se,* as these techniques are not usually resorted to unless the more conventional balloon extraction method is used, which also explains the high success rate of the latter.

Interestingly, there was no effect of the experience of the endoscopist or the timing of the procedure on the success of clearing the biliary system, although the study was not powered to detect such differences.

There are limitations to our study including the retrospective nature of the analysis, and inclusion criteria used which might have underestimated the true number of patients treated in our unit with difficult stones as these are referred to us more commonly as opposed to managing cases without prior ERCP attempts. In addition, the relatively small number of ERCPs included in the study reflects the nature of the center of dealing with advanced ERCP cases and endoscopic ultrasound for oncology cases rather than bile duct stones. Furthermore, there might be confounders not accounted for like procedure time and the effect of patient comorbidities that might affect the decision on the termination of the procedure and deferring clearance of the ducts to a following session. Furthermore, we did not have the number of extraction attempts during the procedure. We did not compare the difference when using different extraction accessories which the study design was not appropriate for, although it does not appear to affect the success rate when stones are less than 11 mm in size.[20] Also, owing to the retrospective nature of the study, we could not devise a unified management algorithm by which patients with biliary stones would by managed; as such, this factor also might introduce biases of unclear magnitude or effect direction, but even then these do reflect "real world" occurrences.

Nonetheless, the strengths of this study are that the data generated were derived from the cholangiographic images obtained during ERCP which increases the precision of the reported measurements rather than relying on the estimates in endoscopy reports as well as the variety of variables that were included in the modeling which is not a common feature in studies where the usual focus is on a single variable and its effect on the clearance rate of the biliary system.

CONCLUSION

In conclusion, a few factors such as the number of filling defects and the presence of a stricture in the CBD were associated with a decreased rate of clearance of the biliary system from stones in a single ERCP session. These findings could be confirmed by other cohorts and if replicated would be of value in establishing a risk stratification system that could eventually result in better patient care.

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Conflict of interest

There is no conflict of interest.

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