Predictors of success of conventional ERCP for bile duct stones and need for single-operator cholangioscopy

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ABSTRACT

Background and study aims The characteristics of difficult stones requiring cholangioscopy-assisted lithotripsy are poorly defined. We sought to determine clinician perception of these characteristics and decision-making in biliary endoscopy.

Methods One hundred twenty-four delegates attending an online course were invited to assess 20 clinical stone cases. Each image was graded on a 4-point Likert for: grading of stone difficulty, confidence of clearance with conventional endoscopic retrograde cholangiopancreatography (ERCP) methods, likelihood of needing cholangioscopy-assisted lithotripsy, and confidence of clearance with one session of lithotripsy. An independent reviewer rated each case on largest stone size, stone number, presence of stricture distal to stone, size of stone relative to distal duct size, and acute common bile duct (CBD) angulation <135°. Multilevel (mixed) statistical methods with a two-level model were utilized with multilevel ordinal logistic regression.

Results Stone size and location, stricture and stone diameter:duct ratio impacted perceived procedural difficulty $P < 0.01$). Stone:duct ratio (< 50% odds ratio [OR] 0.22, $P < 0.001$), stricture (OR 7.26, $P < 0.001$) and stone location impacted confidence of clearance with conventional ERCP. Intrahepatic and cystic duct stones were least likely to engender confidence ($P < 0.01$). The same factors plus CBD angulation < 135° predicted cholangioscopy requirement ($P < 0.01$). Stone number did not influence procedure difficulty or cholangioscopy requirement. Strictures (OR 0.29, $P < 0.001$) and location, especially intrahepatic (OR 0.42, $P < 0.001$) impaired confidence in clearance with one cholangioscopy session.

Conclusions Ductal anatomy, the presence of a stricture distal to a stone, cystic and intrahepatic stones and stones larger than the distal duct are considered by endoscopists to be significant predictors of requiring cholangioscopy-assisted lithotripsy.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the primary treatment method used to clear common bile duct (CBD) stones and > 50% of ERCPs are performed for this indication [1]. Conventional ERCP techniques including sphincterotomy and basket or balloon extraction are successful in the treatment of 85% to 95% of stones [2]. Certain anatomical characteristics are reported to be associated with failed stone clearance, including large stone size (> 15 mm), multiple stones,

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stone size greater than the diameter of the distal bile duct, stones located in the intrahepatic/cystic ducts, and a stricture distal to a stone [2, 3]. The evidence specifically characterizing the features of difficult stones is limited, with reports focusing on a small number of these features at a time rather than analyzing the full range of features together [4, 5, 6, 7].

Cholangioscopy-assisted lithotripsy allows direct visualization of bile duct stones and subsequent stone fragmentation with laser lithotripsy or electrohydraulic lithotripsy (EHL) to achieve stone clearance. It has been shown to be safe and effective in the context of difficult CBD stones, with rates of stone clearance of 77% to 80% in a single session and overall successful stone fragmentation of 91% [8, 9].

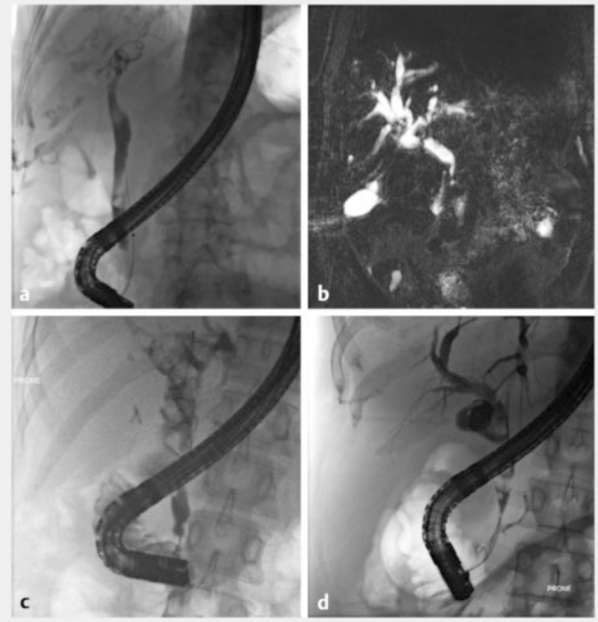
Current European guidelines recommend the initial use of conventional ERCP techniques including endoscopic papillary large-balloon dilatation (EPLBD) before consideration of mechanical lithotripsy or cholangioscopy-assisted lithotripsy in patients with "difficult stones" [3]. While some centers may be able to offer cholangioscopy at index ERCP, most are not and this may result in patients undergoing conventional ERCP with limited chance of stone clearance, only to require repeat procedures with cholangioscopy. Indeed, National Health Service (NHS) data in the UK suggest that 52.7% of ERCPs for stones are repeat procedures, with 11,322 patients undergoing more than one ERCP for stones between 2015 and 2017 [10]. Further characterization of features that predict a low likelihood of success with conventional ERCP could improve pre-endoscopic evaluation of patients with difficult CBD stones, to allow earlier use of advanced ERCP techniques at index ERCP. This could reduce the risks encountered through multiple procedures while also leading to significant cost savings for healthcare services [11]. It might also allow triage of patients to specialist centers as necessary and improve the patient journey.

The aim of this study was to determine the anatomical features that endoscopists perceive are characteristic of difficult CBD stone disease, predict the likelihood of success with conventional ERCP, the need for cholangioscopy-assisted lithotripsy, and the likely success of this approach. In doing so we wished to identify the imaging characteristics which predict procedural difficulty and so allow stratified clinical decision making.

Methods

All delegates attending a special-interest cholangioscopy meeting were invited to participate. The 4.5-hour meeting was online, free to attend, and streamed live involving a mixture of short lectures, pre-recorded cases, and facilitated live discussion. The survey was conducted during a break between sessions.

Delegates were asked to examine a series of 20 anonymized magnetic resonance cholangiopancreatography (MRCP) or ERCP fluoroscopy images featuring biliary stones, pre-selected to clearly demonstrate a well-recognized pattern of stone disease. These included stones in the extrahepatic bile duct, intrahepatic ducts, and cystic duct (Mirizzi's syndrome) of varying size, number, and location, and stones associated with anatomic variants (eg distal bile duct stricture). An example of some of the images can be seen in ▶ **Fig. 1**. For each image, delegates were asked to answer four questions rated on a Likert scale (in total 80 questions):



▶ **Fig. 1** An example of cases from the survey. a Small stones. b Intrahepatic stones. c Multiple large stones in a dilated duct. d Stones above a stricture.

1. Grade of difficulty: 1 (straightforward), 2 (quite difficult), 3 (very difficult), 4 (not possible with conventional ERCP Conventional ERCP defined as any methods short of cholangioscopy – i. e. sphincterotomy, sphincteroplasty and balloon/basket extraction.
2. Confidence of clearance at conventional ERCP: 1 (extremely unconfident), 2 (unconfident), 3 (neither confident nor unconfident), 4 (confident) to 5 (extremely confident).
3. Likelihood of needing single-operator cholangioscopy for definitive clearance: 1 (extremely unconfident), 2 (unconfident), 3 (neither confident nor unconfident), 4 (confident) to 5 (extremely confident).
4. Confidence of clearance with one session of cholangioscopy-assisted lithotripsy: 1 (extremely unconfident), 2 (unconfident), 3 (neither confident nor unconfident), 4 (confident) to 5 (extremely confident).

The images were separately submitted to an independent reviewer (AS) who rated each of the cases on the presence or absence of clinical features previously identified in the literature as having an influence on procedure difficulty [3], specifically:

- Number of stones (1, 2–3, > 3)
- Stone size (< 10 mm, 10–15 mm, > 15 mm)
- Size of stone relative to distal duct (stone) < 50%, 50%-100% or > 100% of the diameter of the distal CBD

▶ **Table 1** Demographics of course attendees and survey respondents.

Course attendees			**Survey respondents**		
Europe		**93%**	**Specialty**		
UK	72	58%	Gastroenterologists	46	87%
France	8	6%	Surgeons	6	11%
Germany	5	4%	Not disclosed	1	2%
Poland	5	4%	**Location**		
Hungary	4	3%	UK	43	81%
Ireland	3	2%	Germany	2	4%
Spain	3	2%	Slovakia	2	4%
Czech	2	2%	Hungary	2	4%
Denmark	2	2%	Greece	1	2%
Finland	2	2%	Poland	1	2%
Italy	2	2%	Italy	1	2%
Slovenia	2	2%	South Africa	1	2%
Sweden	2	2%	**ERCP experience**		
Belgium	1	1%	Independent	43	81%
Greece	1	1%	In training	4	8%
Netherlands	1	1%	Not disclosed	6	11%
Middle East and Africa		**7%**	**Cholangioscopic experience**		
South Africa	5	4%	Minimal (0–20)	37	70%
Egypt	1	1%	Moderate (21–50)	4	8%
Israel	1	1%	High (51–150)	2	4%
Kenya	1	1%	Very high (> 150)	3	6%
Zimbabwe	1	1%	Not disclosed	7	13%

- Stone location (extrahepatic duct, intrahepatic ducts, cystic duct or a combination)
- Presence of a stricture below the stone
- Acute distal CBD angulation (≤ 135°)

Statistical methods

Multilevel (mixed) statistical methods were used. A two-level model was utilized and analyses were performed using multilevel ordinal logistic regression.

For each outcome, the analysis was performed in two stages. First, the association between each factor and each outcome was assessed separately in a series of univariable analyses. Subsequently, the joint association between variables was examined in a multivariable analysis. To reduce the number of variables in this stage of the analysis, only factors showing some association with the outcome in the univariable analyses ($P \leq 0.2$) were included. A backward selection procedure was used to retain only the statistically significant variables.

Spearman's Rank correlation was used to assess respondents' Likert gradings with clinical outcomes and the Mann-Whitney U test was used to compare differences survey scores in cases that required standard of care (SOC) with cases that did not.

Results

One hundred twenty-four participants attended the online meeting, and all were given the opportunity to answer 80 questions, with 58% from the UK and the remainder from Europe, the Middle East, and Asia. Fifty-three (47%) submitted responses; 46 gastroenterologists (87%), six surgeons (11%), and one (2%) not disclosed. Eighty-one percent of respondents were independent ERCP practitioners and 8% in training. The majority (70%) had minimal cholangioscopic experience (0–20 procedures), four (8%) had moderate experience (21–50), two (4%) had high levels of experience (51–150), and three (6%) had very high levels of experience (> 150). Seven (13%) did not disclose their experience. Not all participants completed all 80 questions and for each question, the median number of respon-

▶ **Table 2** Associations with grading: Data summaries.*

Variable	Category	Straightforward	Quite difficult	Difficult	Not possible
Number of stones	1 stone	76 (18.4%)	87 (21.0%)	214 (51.7%)	37 (8.9%)
	2–3 stones	16 (19.8%)	38 (46.9%)	26 (32.1%)	1 (1.2%)
	> 3 stones	68 (21.4%)	104 (32.7%)	130 (40.9%)	16 (5.0%)
Largest stone	< 10 mm	97 (40.6%)	56 (23.4%)	72 (30.1%)	14 (5.9%)
	10–15 mm	46 (16.4%)	90 (31.6%)	132 (46.3%)	17 (6.0%)
	> 15 mm	17 (5.9%)	83 (28.7%)	166 (57.4%)	23 (8.0%)
Size of stone relative to distal duct	> 100%	10 (3.7%)	83 (30.9%)	164 (61.0%)	12 (4.5%)
	50–100%	51 (17.5%)	71 (24.3%)	141 (48.3%)	29 (9.9%)
	< 50%	99 (39.3%)	75 (29.8%)	65 (25.8%)	13 (5.2%)
Stone location	Cystic duct	12 (14.8%)	18 (22.2%)	47 (58.0%)	4 (4.9%)
	Intrahepatic	6 (7.8%)	12 (15.6%)	43 (55.8%)	16 (20.8%)
	Extrahepatic	77 (23.7%)	93 (28.6%)	143 (44.0%)	12 (3.7%)
	Cystic + intrahepatic	0 (0.0%)	14 (15.7%)	58 (65.2%)	17 (19.1%)
	Intrahepatic + extrahepatic	13 (31.7%)	21 (51.2%)	6 (14.6%)	1 (2.4%)
	All locations	52 (26.0%)	71 (35.5%)	73 (36.5%)	4 (2.0%)
Stricture distal to stone	No	154 (23.8%)	199 (30.8%)	263 (40.7%)	31 (4.8%)
	Yes	6 (3.6%)	30 (18.1%)	107 (64.5%)	23 (13.9%)
CBD angulation	No	160 (20.6%)	219 (28.2%)	346 (44.5%)	52 (6.7%)
	Yes	0 (0.0%)	10 (27.8%)	24 (66.7)	2 (5.6%)

*Figures are number and percentage of responses in each grading category.

dents was 39 (range 36–53). A summary of the participants' can be found in ▶ **Table 1**.

Grading of difficulty

Grading of difficulty was assessed on a 4-point scale from straightforward to not possible. A data summary of the gradings for each category of the independent variable can be seen in ▶ **Table 2**. The figures are the number of respondents with percentages of individual measurements given for each grading category.

Regression analyses were performed to examine if each of the factors was significantly associated with grading. The results of both the univariable and multivariable analyses are summarized in ▶ **Table 3**.

The size of association between each factor and grading is expressed as odds ratios (ORs), which are presented together with corresponding confidence intervals. These give the odds of being in the next highest grading category (e. g. quite difficult compared to straightforward, or not possible relative to difficult) in each category relative to the odds in a baseline category. *P* values indicating the overall significance of each factor (i. e. the difference in grading between all categories) are also shown.

The univariable results suggested that, when each factor was examined individually, only a stricture distal to a stone was statistically significant for procedure difficulty.

The multivariable analysis suggested that larger stone size, size of stone relative to distal CBD size, stone location, and stricture distal to the stone were all considered significant predictors of procedure difficulty ($P < 0.01$). A larger stone size was associated with a greater level of difficulty, while a stone size <50% of the distal CBD represented a four times lower level of difficulty than the > 100% group.

The results for stone location suggested that cystic duct and intrahepatic duct location had the greatest level of difficulty, with the extrahepatic duct the lowest level of difficulty. Having a stricture distal to the stone was associated with a large increase in difficulty. The odds of being in the next highest outcome category were over seven times higher for such stones, compared to the odds without this characteristic.

Confidence of success with conventional ERCP

The statistical associations between each factor and confidence of success were examined, both in univariable analyses and jointly in a multivariable analysis. The results are summarized in ▶ **Table 4**. The size of association between each factor and confidence were summarized by ORs, representing the differ-

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▶ **Table 3** Associations with grading: Regression analysis.

Variable	Category	Univariable		Multivariable	
		Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Stone number	1 stone	1	0.61		
	2–3 stones	0.34 (0.03–4.22)			
	> 3 stones	0.55 (0.11–2.64)			
Largest stone	< 10 mm	1	0.08	1	0.01
	10–15 mm	3.10 (0.62–15.5)		1.87 (0.80–4.32)	
	> 15 mm	6.35 (1.27–31.7)		3.73 (1.52–9.20)	
Stone size relative to distal duct	> 100%	1	0.05	1	< 0.001
	50%-100%	0.58 (0.12–2.82)		0.27 (0.14–0.54)	
	< 50%	0.14 (0.03–0.71)		0.22 (0.08–0.55)	
Stone location	Cystic	1	0.05	1	< 0.001
	Intrahepatic	3.27 (0.20–52.3)		4.44 (1.24–15.9)	
	Extrahepatic	0.39 (0.04–3.70)		0.29 (0.10–0.84)	
	Cystic + intrahepatic	4.67 (0.29–73.9)		7.81 (2.13–28.6)	
	Intrahepatic + extrahepatic	0.14 (0.00–3.91)		0.41 (0.10–1.63)	
	All locations	0.30 (0.03–3.14)		0.31 (0.12–0.85)	
Stricture distal to stone	No	1	0.02	1	< 0.001
	Yes	6.75 (1.28–35.6)		7.26 (3.67–14.4)	
CBD angulation	No	1	0.53		
	Yes	2.99 (0.10–88.3)			

ence in the odds of being in the next highest outcome category for each group relative to the odds in a baseline group.

Univariable results suggested that stone size relative to duct diameter distal to stone was significantly associated with confidence at achieving clearance using conventional ERCP techniques. Multivariable analysis suggested that stone size relative to duct diameter distal to stone, stone location, and stricture distal to the stone were statistically significant.

A larger stone size relative to distal duct was associated with a lower level of confidence with conventional methods while a smaller stone relative to duct size was associated with a greater level of confidence. The odds of being in the next highest confidence category were over four times higher for stone size < 50% of the diameter of the lower duct, compared to the odds for those with a stone size > 100% of the lower duct diameter.

The stone location results suggested that the extrahepatic and all locations groups had the highest confidence in removal, with the lowest being the intrahepatic duct location.

Likelihood of needing cholangioscopy

Regression analyses were performed to examine the association between the variables and the need for a cholangioscopy. The results are summarized in ▶ **Table 5**.

The univariable analyses suggested that the largest stone size and duct size were statistically significant. A larger stone was associated with an increase in perceived need for cholangioscopy, while a stone being smaller relative to duct size was associated with a lower need for cholangioscopy. Number of stones did not directly influence a perceived need for cholangioscopy.

In the multivariable results, after each factor was adjusted for the other factors, duct size, stone location, stricture distal to the stone, and CBD angulation were significant. However, the largest stone was no longer statistically significant. As in the univariable analyses, a smaller stone-to-duct ratio was associated with a reduced perceived requirement for cholangioscopy. The stone location was not significant in the univariable analyses but was significant after adjustments for other factors. The cystic and intrahepatic location had the highest perceived need for cholangioscopy while extrahepatic location was perceived as least likely to require it.

Both a stricture distal to the stone and CBD angulation were perceived as being associated with a greater requirement for cholangioscopy in the multivariable analyses. A distal stricture was associated with a three-fold increase in the odds of being

▶ **Table 4** Associations with confidence of success with conventional methods: Regression analysis.

Variable	Category	Univariable		Multivariable	
		Odds ratio (95% CI)	*P* value	Odds ratio (95% CI)	*P* value
Stone number	1 stone	1	0.45		
	2–3 stones	2.98 (0.30–29.7)			
	> 3 stones	2.26 (0.55–9.250)			
Largest stone	< 10 mm	1	0.08	1	0.06
	10–15 mm	0.30 (0.07–1.45)		0.56 (0.24–1.35)	
	> 15 mm	0.17 (0.04–0.80)		0.34 (0.13–0.87)	
Stone size relative to distal duct	> 100%	1	0.03	1	< 0.001
	50%-100%	1.83 (0.44–7.62)		3.82 (1.92–7.59)	
	< 50%	7.13 (1.62–31.5)		4.80 (1.83–12.6)	
Stone location	Cystic	1	0.05	1	< 0.001
	Intrahepatic	0.62 (0.05–7.33)		0.43 (0.12–1.54)	
	Extrahepatic	2.67 (0.38–18.8)		3.47 (1.20–10.0)	
	Cystic + intrahepatic	0.24 (0.02–2.89)		0.15 (0.04–0.54)	
	Intraheptic + extrahepatic	7.09 (0.34–146)		2.56 (0.63–10.5)	
	All locations	4.42 (0.56–35.0)		4.24 (1.55–11.6)	
Stricture distal to stone	No	1	0.06	1	0.005
	Yes	0.21 (0.04–1.05)		0.19 (0.09–0.37)	
CBD angulation	No	1	0.27		
	Yes	0.18 (0.01–3.91)			

in the next highest category of difficulty, while CBD angulation was associated with a five-fold increase.

Confidence of success with one session of cholangioscopy

The final outcome was the confidence of success of stone clearance with one session of cholangioscopy, which was measured on a 5-point scale from extremely unconfident to extremely confident. Summaries of the regression analysis are shown in ▶ **Table 6**.

The univariable results suggested that only stone location, stricture distal to the stone, and CBD angulation were statistically significant. The multivariable analysis suggested that only stone location and stricture distal to the stone were significant. After adjusting for these two factors, CBD angulation was no longer independently associated with the outcome.

The stone location results suggested that stones in the intrahepatic and extrahepatic duct location had the highest levels of confidence of clearance. Conversely, confidence at achieving stone clearance with a single session of cholangioscopy was lowest with stones in both the cystic duct and intrahepatic ducts.

A stricture distal to the stone was associated with lower levels of confidence. The odds of being in the next highest confidence group were over three times lower for those stones, compared to stones without this characteristic.

Comparison with clinical outcomes

There was a significant correlation between lower confidence scores in regard to clearance with conventional ERCP and cases that did require SOC (r = 0.78, $P < 0.01$). The mean confidence score was significantly lower for cases that went on to require SOC than those that did not at 1.94 (95% confidence interval [CI] = 1.84–2.04) vs 3.55 (95% CI = 3.69–3.41, $P < 0.01$). There was also a strong correlation between the clinicians' rating of the likelihood of requiring SOC and real-world requirement (r = 0.74, $P < 0.01$). The mean score was significantly higher (4.04, 95% CI = 3.93–4.15) in cases that required SOC than those that did not (2.79, 95% CI = 2.65–2.94, $P < 0.01$).

Discussion

This online survey has given useful insights into ERCP practitioner-perceived experience in managing patients with "difficult" bile duct stones. The use of previously described criteria

▶ Table 5 Associations with likelihood of needing cholangioscopy-assisted lithotripsy: Regression analysis.

Variable	Category	Univariable		Multivariable	
		Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Number stones	1 stone	1	0.46		
	2–3 stones	0.65 (0.11–3.88)			
	> 3 stones	0.49 (0.16–4.48)			
Largest stone	< 10 mm	1	0.006		
	10–15 mm	4.00 (1.35–11.9)			
	> 15 mm	5.49 (1.85–16.3)			
Stone size relative to distal duct	> 100%	1	0.005	1	< 0.001
	50%-100%	0.54 (0.19–1.54)		0.48 (0.27–0.84)	
	< 50%	0.17 (0.06–0.50)		0.15 (0.08–0.26)	
Stone location	Cystic	1	0.18	1	< 0.001
	Intrahepatic	0.59 (0.08–4.62)		0.46 (0.17–1.24)	
	Extrahepatic	0.36 (0.07–1.80)		0.13 (0.06–0.29)	
	Cystic + intrahepatic	1.82 (0.23–14.3)		1.32 (0.47–3.71)	
	Intrahepatic + extrahepatic	0.24 (0.02–2.93)		0.61 (0.21–1.82)	
	All locations	0.23 (0.04–1.25)		0.17 (0.08–0.36)	
Stricture distal to stone	No	1	0.18	1	< 0.001
	Yes	2.41 (0.66–8.76)		3.28 (1.89–5.67)	
CBD angulation	No	1	0.2	1	0.002
	Yes	4.75 (0.43–52.2)		5.12 (1.80–14.6)	

for defining difficult stones and multivariable statistical analysis has allowed an understanding that a combination of anatomical factors influence clinician confidence in achieving endoscopic stone clearance. These results might inform both patient consent prior to ERCP and selection of cases likely to need cholangioscopy-assisted lithotripsy.

It is clear that stone size is a predictor of procedure difficulty, with stones > 15 mm having an OR of 3.73 being considered more difficult to treat than stones < 10 mm. However, endoscopist confidence of clearance at conventional ERCP dependent on stone size did not reach statistical significance. Taking these findings into consideration, the presence of a large stone in isolation should not preclude attempts at conventional ERCP with sphincterotomy +/- EPLBD unless other case-specific factors suggest this is likely to fail and thus require cholangioscopy. Stone size only significantly influences success of clearance in the setting of other factors. The number of stones per se was not shown to influence confidence of duct clearance with conventional ERCP or need for cholangioscopy.

The presence of a stricture distal to the stone and a stone size > 100% the diameter of the distal duct are both predictors of procedure difficulty in the multivariable analysis. This is representative of the mechanical challenge in trying to pull a stone through a relatively narrow distal lumen. Unsurprisingly, this is corroborated by endoscopist perceived need for cholangioscopy and visually-directed lithotripsy for stone clearance. Of note, the presence of a stricture alone, duct angulation, and stone location did not meet statistical significance for predicted need for cholangioscopy in the univariable analysis but did on multivariable analysis, underscoring the interplay of several factors that should be considered when planning endoscopic therapy.

The number of stones, largest stone size, and stone size relative to duct size were not predictors of successful clearance in one session of cholangioscopy. This indicates that endoscopists are confident of the efficacy of cholangioscopy-assisted lithotripsy in treating large or numerous stones. Confidence of stone clearance lessens in patients with distal strictures, perhaps due to uncertainty, even with cholangioscopy, of removal of stone fragments through a strictured lower duct. Intrahepatic and cystic duct stones also carried reduced confidence in clearance for the surveyed endoscopists, perhaps due to uncertainty that the stones will be reached with the cholangioscope.

A criticism of our survey is that the respondents were relatively inexperienced in cholangioscopy. Seventy percent had performed < 20 procedures. However, 81% of participants were independent ERCP practitioners (with the remainder in

▶ **Table 6** Associations with confidence of success with one session of cholangioscopy-assisted lithotripsy: Regression analysis.

Variable	Category	Univariable		Multivariable	
		Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Stone number	1 stone	1	0.2		
	2–3 stones	2.96 (0.73–12.0)			
	> 3 stones	0.80 (0.34–1.88)			
Largest stone	< 10 mm	1	0.62		
	10–15 mm	1.27 (0.47–3.46)			
	> 15 mm	0.77 (0.28–2.10)			
Stone size relative to distal duct	> 100%	1	0.27		
	50%-100%	0.75 (0.28–1.98)			
	< 50%	1.72 (0.62–4.77)			
Stone location	Cystic	1	< 0.001	1	< 0.001
	Intrahepatic	0.24 (0.13–0.44)		0.42 (0.23–0.79)	
	Extrahepatic	0.73 (0.46–1.17)		1.03 (0.64–1.67)	
	Cystic + intrahepatic	0.12 (0.07–0.21)		0.11 (0.06–0.20)	
	Intrahepatic + extrahepatic	2.49 (1.15–5.37)		2.56 (1.18–5.55)	
	All locations	0.61 (0.37–0.99)		0.78 (0.47–1.30)	
Stricture distal to stone	No	1	0.02	1	< 0.001
	Yes	0.31 (0.12–0.80)		0.29 (0.21–0.41)	
CBD angulation	No	1	0.04		
	Yes	1.86 (1.02–3.38)			

training or undisclosed), so one can assume that they would have a good understanding of what clinical scenarios result in failed clearance in their own practice and which patients to refer to centers with access to cholangioscopy. In addition, there was a significant difference in the scores given by survey participants in confidence of clearance and likelihood of requiring cholangioscopy. This indicates that overall, the participants' experience of performing cholangioscopy was low and they had a good understanding of cases that require it.

We only used one independent assessor of the anatomical features of the images provided (ie stone size, number, location, and other factors) and, therefore, cannot exclude interobserver variability in the interpretation of imaging features. However, our assessor (AS) is an extremely experienced biliary endoscopist.

This study may inform clinical practice and focus a need on careful imaging review prior to endoscopic intervention in patients with CBD stones. The review into the national performance of CBD stones in England [10] showed a stone clearance rate at index ERCP of 69.8% and that 52.9% of all ERCPs performed were repeat procedures. Many patients underwent in excess of three ERCPs with the associated inherent risks.

Conclusions

These data and the results of our survey indicate that clinicians need to analyse imaging prior to ERCP in patients with biliary stones, and to carefully reflect on the likelihood of definitive stone clearance at index conventional ERCP. This should also be discussed during the patient consent process, when achieving duct decompression (e. g. stenting to relieve obstruction/cholangitis) may carry a different probability to stone clearance. At present, we believe that these distinct outcomes are rarely discussed. We also believe that few endoscopists include an expectation about stone clearance when obtaining informed consenting from patients for ERCP.

Imaging features that indicate a significant likelihood of failed clearance with conventional ERCP (including Mirizzi, intrahepatic stones, distal bile duct strictures or a narrow duct: stone ratio) indicate a need to consider cholangioscopy-assisted lithotripsy at an early stage. When a patient's clinical condition does not preclude it, one might advocate for direct referral to a center with access to cholangioscopy-assisted lithotripsy in patients with multiple "difficult" features. This may lead to a smoother patient pathway, improved patient outcomes, and a need for fewer repeat endoscopic interventions.

Conflict of Interest

George Webster has received honoraria for teaching and participation on advisory boards for Boston Scientific, Pentax Medical, Olympus Medical and Cook Medical. Amrita Sethi is a consultant for Boston Scientific, Interscope, Medtronic, Olympus. Amrita Sethi has received research support from Boston Scientific and Fujifilm. The remaining authors have no conflict of interest to declare.

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