"Is percutaneous extraction of gallstones safe and effective in high-risk patients? Evidence from a systematic review"

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ABSTRACT

Gallstone disease in high-risk patients presents a management dilemma as cholecystectomy is often not performed due to their co-morbidities. Alternatively, such patients can be managed by percutaneous removal of gallstones. To date, there is paucity of high-quality evidence addressing the safety and efficacy of percutaneous cholecystolithotomy in high-risk patients.

We aimed to conduct a systematic review on the feasibility of percutaneous gallstone removal in high-risk patients.

Methods: A literature review was conducted using the Cochrane review and preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines without setting the time limits to assess the outcomes of percutaneous gallstone removal in high-risk patients.

Results: Twelve studies were identified. A total of 435 patients underwent percutaneous gallstone removal. Success rate was 91%. Overall complications (including minor and major) were 28%. The mean length of stay was 7 days (range, 1–80). Procedure related mortality was 0.7%. The recurrence rate was 7%.

Conclusion: Percutaneous cholecystolithotomy is a safe and effective technique. Although, it cannot substitute the current standard treatment for gallstones i.e., laparoscopic cholecystectomy. However, it may be considered for the patients who cannot undergo laparoscopic cholecystectomy due to their comorbid conditions.

Introduction

Laparoscopic cholecystectomy remains the gold standard treatment for gallstone disease.[1] However, it may not always be possible to operate if the patients have significant co-morbidities which makes them high risk for morbidity and mortality after surgical intervention, in some series, reaching up to 47% and 16% respectively.[2] It can be explained as the stress response and physiological reserves are often suboptimal and diminished in critically ill patients.[3] Percutaneous cholecystostomy provides the short-term solution to drain the gall bladder in acute settings.[1] As the gallstones are still in-situ, these patients frequently suffer, either from complications of cholecystostomy tube like dislodgement, kinking and blockage or from recurrent attacks of cholecystitis, in some series reaching up to 24%. This greatly affects the quality of life of these patients.[4] To overcome this problem, the gallstones can be removed by minimally invasive

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Abbreviations

PCCL	Percutaneous cholecystolithotomy
LCCL	Laparoscopic cholecystolithotomy
EHL	Electrohydraulic lithotripsy
GA	General Anesthesia
ASA	American society of anesthesiology
APACHE	Acute physiology and chronic health evaluation

percutaneous approach, which is known as percutaneous cholecystolithotomy (PCCL). Although, there is no study comparing the outcomes of percutaneous cholecystostomy alone versus percutaneous cholecystostomy followed by PCCL in high-risk patients, however, the latter is an emerging technique, as it obviates the need of long-term cholecystostomy tube and low rates of recurrent gallstones.

PCCL was first described more than three decades ago, it is recently gaining popularity because of its use in high-risk patients.[5,6]

We aimed to conduct a systematic review to get the best evidence regarding the adoption of this technique in high-risk surgical patients.

Methods

Search strategy

The systematic review was performed using Cochrane and PRISMA guidelines.[7,8]

We used the following search question "(percutaneous extraction of gallstone OR Percutaneous gall stone extraction OR percutaneous gallstone removal OR Percutaneous cholecystolithotomy* OR cholecystolithotomy*) AND (high risk OR non-operable OR morbid)" in the following databases to identify the relevant articles: the USA National Library of Medicine's life science database (MEDLINE), EMBASE, Cochrane Central Register of Controlled Trials – CENTRAL, CINAHL, Clinicaltrials.gov, Google Scholar and individual journals.

Studies that had higher number of patients and reported on relevant outcomes were included.

In May,2021, all published studies were screened with no restriction on date, or country. A broad search approach was conducted owing to the expected scarcity of randomized clinical trials. No search filter was applied for study type. To update the results, the search was identically repeated in January 2022.

Study selection

Following selection criteria were used in this review.

Inclusion criteria:

1. All studies which reported outcomes of percutaneous gallstone stone removal in high-risk patients.
2. The studies which included both high and low risk patients, every effort was made to segregate the data of high-risk patients. If the data cannot be segregated, we had included only those studies in which high-risk patients were in majority.

Exclusion criteria:

1. Studies in which low-risk patients were in majority.
2. Case reports or case series n < 7, so as to include studies from center with reasonable experience to get more robust evidence.
3. Studies in language other than English.

Data extraction and analysis

Reviewers (EAL and In) identified studies that appeared to fit the inclusion criteria for full review. The reviewers independently selected studies for inclusion. Any disagreement between the two authors was settled by mutual consensus. If unresolved, it was referred to an expert reviewer (OMA) for final consensus.

Authors were contacted wherever the data were not available or not clear, to be able to adequately assess inclusion of their study. If data were not extractable, provided or clarified, it was excluded.

Outcome measures

The following outcome measures were evaluated: Success rates, complications including mortality, recurrence, retained stones and length of hospital stay.

We defined successful extraction as clearance of all stones after the percutaneous procedure irrespective of the number of procedures performed. Retained stones are defined as residual stones after the gallstones were successfully cleared. Recurrence is defined as stones in the biliary tree after 6 months of successful procedure.

Statistical analysis and quality assessment

We extracted the following data from each study for inclusion in our review: Age, gender, American society of anesthesiology (ASA) scores, number of procedures, overall technique success rate, reasons for failure, and various major and minor complications. Using descriptive statistical analysis, the variables were described as number, proportion, and mean. We used NIH quality assessment tool to assess the quality of included studies.[9]

Results

The literature search yielded 426 studies, of which 383 were excluded due to duplicates or non-relevance based on titles and abstracts. Full manuscripts were evaluated in 43 studies, of which, 12 were included into the systematic review (Fig: 1).[6,10–20]

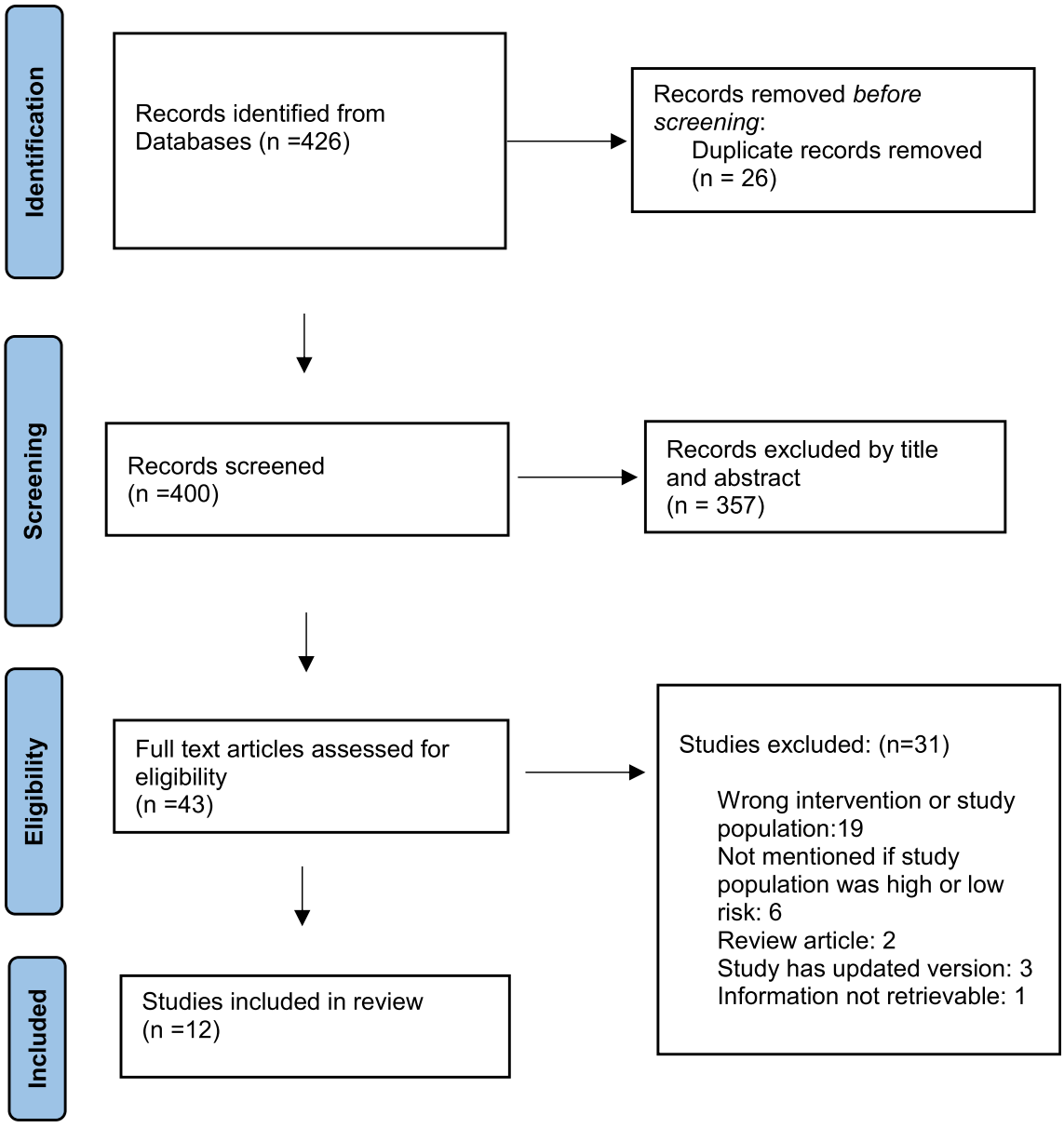

Fig. 1 – PRISMA flowchart.

While reviewing the studies, two studies fulfilled our inclusion criteria but they have used a device "Rotary lithotrite" to mechanically fragment the stones in the gallbladder. Due to the high rate of complications associated with this experimental device, it is non-existent in current practice and largely became historical.[21,22]That's why we have excluded these two studies.

Heterogeneity of study results did not allow for formal meta-analysis to be performed. Therefore, only pooled analysis of mean results and narrative descriptions have been carried out.

Characteristics of the included studies

All studies reported on individual center's experience with percutaneous extraction of stones. None of the included studies were randomized controlled trials.

Majority of the studies were retrospective and two were prospective.[12,19] The studies span over a period of 36 years from 1985 to 2021. All of the included studies were single center. Of the studies included, 4 were from China, 3 from United states, 2 each from Korea and Canada and 1 from United Kingdom. There were nine studies which included exclusively high-risk patients.[6,11–16,18,20] The rest of the studies included both high and low-risk patients, with majority being high-risk.[10,17,19] Of 12 studies, 3 mentioned the ASA scores[6,10,17] whereas only one study mentioned the Acute physiology and chronic health evaluation (APACHE) score of their study population.[13] All of the studies mentioned the co-morbidities of their study subjects which made them high-risk for surgical cholecystectomy.

One study compared PCCL technique with laparoscopic cholecystolithotomy (LCCL). As, LCCL is not the standard of

Table 1 – Demographics.

Study	Location/ country	Year	Type	Total patients, n	Mean Age (years)	Sex (Male: Female)	Reasons of performing PCCL (n)	ASA score (%)
Wang et al.[10]	China	2021	Retrospective	16	63.4 (±14.9)*	7:9	- High risk due to comorbidities (n = 13) - Patients wished to preserve gall-bladder (n = 3).	ASA 3 or 4 (81%)
Stirrat et al.[6]	Canada	2021	Retrospective	75	75 (±13.9)*	39:36	- High risk due to comorbidities (n = 47). - Technical concerns e.g., extensive intraabdominal adhesions and obliterated biliary anatomy (n = 15) - Both high anesthetic risk and technical concerns (n = 8) - Advanced cirrhosis (n = 5)	ASA 3 or 4 (90%)
Patel et al.[11]	USA	2018	Retrospective	13	65 (48–90)**	10:3	- High risk due to comorbidities (n = 12) - Technical concern due to cholecysto-duodenal fistula (n = 1)	Nm
Liu et al.[12]	China	2018	prospective	17	65.8 (±8.9)*	10:7	High risk due to comorbidities (n = 17)	Nm
Zhang et al.[13]	China	2017	Retrospective Comparative	19	68.74	6:13	All patients were high risk with mean APACHE score of 11.4 ± 1.8 (n = 19)	Nm
Kim YH et al.[14]	Korea	2011	Retrospective	63	76 (55–91)**	33:30	- High-risk due to co-morbidities (n = 60) - Technical reasons due to recurrent cholecystitis because of residual stone after cholecystectomy (n = 3)	Nm
Kim HJ et al.[15]	Korea	2000	Retrospective	26	67 (±2)*	20:13	High-risk due to comorbidities (n = 26)	Nc
Wong et al.[16]	China	1999	Retrospective	11	78.5 (71–89)**	7:10	High-risk due to co-morbidities (n = 11)	Nm
Majeed et al.[17]	UK	1997	Retrospective	81	67 (20–91) ¥	22:59	- High risk due to comorbidities (n = 53) - Wished to avoid GA (n = 11) - Wished to preserve gallbladder (n = 17)	ASA III or IV = 65%
Picus et al.[18]	USA	1992	Retrospective	58	67 (29–97)**	31:27	High-risk due to co-morbidities (n = 58)	Nm
Cope et al.[19]	USA	1990	Prospective	20	62 (33–85)**	5:15	- High-risk patients (n = 13) - Wished to avoid surgery (n = 7)	Nm
Gibney et al.[20]	Canada	1987	Retrospective	36	73 (45–93)**	18:18	High risk due to co-morbidities (n = 36)	Nm

* = (±SD).
** = (range).
¥ = Median(range).
Nm = Not mentioned.
Nc = Not clear.

care, therefore, we excluded the data of LCCL. The same study was the only one which reported cost analysis.[13]

Patient demographics

In total, there were 435 patients. Female to male ratio was 1.2. The mean age of the patient was 69 (range:20–98) years. The reasons of performing PCCL are shown in Table 1.

Indication and technique

All patients were symptomatic from gallstone disease, majority of them had acute cholecystitis (Table 2).

Type of anesthesia used was mentioned in all studies. In half of the studies, more than one anesthetic modality was used.[6,14,17–20] Of 12 studies, 3 used general anesthesia (GA) in their study subjects.[6,11,17]

Table 2 – Technical details.

Study	Indications	Type of anesthesia, n	Type of Access n (%)	Time interval between Cholecystostomy and PCCL	Technique Used
Wang et al.[10]	Acute cholecystitis	Sedation, n = 16	Transhepatic, n = 16 (100%)	6–7 days	Fluoroscopy, FREDDY laser
Stirrat et al.[6]	Acute cholecystitis	GA, 45.3%[a] Sedation, 54.7%	Transperitoneal, n = 75 (100%)	6 weeks	Flexible Choledochoscopy, EHL, basket and wires
Patel et al.[11]	Acute cholecystitis	GA, n = 13	Transhepatic, n = 11 (85%) Transperitoneal, n = 2 (15%)	151, (11–321) days, mean (range)	Choledochoscopy (Flexible and rigid both), Electrohydraulic lithotripsy, nitinol baskets, ultrasonic lithotripsy and percutaneous thrombectomy devices
Liu et al.[12]	35% Acute cholecystitis 54% acute cholangitis 11% Pancreatitis	Intravenous anesthesia, n = 17	Transhepatic, n = 17 (100%)	1 week	Fluoroscopy, Stone expulsion into duodenum using balloon dilatation
Zhang et al.[13]	Acute cholecystitis	Regional anesthesia, n = 19	Dual access, n = 19 (100%)	4–8 weeks	Choledochoscopy, stone extractors, electrohydraulic lithotripsy
Kim YH et al.[14]	Acute cholecystitis Empyema of gallbladder	Local anesthesia and sedation, n = 63	Transhepatic, n = 63 (100%)	2–3 days	Fluoroscopy, stone basket, snare wire
Kim HJ et al.[15]	Acute cholecystitis	Sedation, n = 26	Transhepatic, n = 26 (100%)	13 days	Cholangioscopy, Electrohydraulic lithotripsy, Dormia basket
Wong et al.[16]	Acute cholecystitis	Sedation, n = 11	Transhepatic, n = 2 (18%) Transperitoneal, n = 9 (82%)	More than 4 weeks	Flexible choledochoscope, EHL, Holmium YAG laser
Majeed et al.[17]	Majority Chronic cholecystitis	Epidural n = 50 GA, n = 25 Intercostal nerve block, n = 4 Local anesthesia, n = 2	Mini-cholecystostomy, n = 81 (100%)	Nm	Rigid choledochoscope, EHL, forceps
Picus et al.[18]	72% acute cholecystitis 28%Chronic cholecystitis, biliary colic	Local anesthesia and sedation, n = 58	Transhepatic, n = 35 (61%) Transperitoneal, n = 22 (39%)	Nm	Flexible choledochoscope, EHL, baskets and graspers
Cope et al.[19]	Chronic cholecystitis	Sedation, n = 6 Epidural, n = 14	Transperitoneal, n = 20 (100%)	Immediately	Rigid endoscope, baskets, EHL
Gibney et al.[20]	67% Acute Cholecystitis 33% Biliary colic	Local anesthesia and sedation, n = 36	Mini-cholecystostomy, n = 36 (100%)	7–10 days	Fluoroscopy, Stone crushing forceps and baskets

Nm=Not mentioned.
[a] =mentioned as percentage of total procedures.

The type of access used for PCCL was mentioned in all studies. Cholecystostomy was successful in almost all cases except in one, which failed due to shrunken and fibrotic gallbladder.[18] Of 434 patients who had successful cholecystostomy, 39% underwent the procedure via trans-hepatic route,29% by trans-peritoneal route, 27% by mini-cholecystostomy by making a small incision on the abdominal wall and 4% by dual access.[6,10–20] In dual access technique, trans-hepatic route was used for irrigation of fluid into the gallbladder and the trans-peritoneal access to fragment and remove the gallstones.[13]

After gaining the access, various techniques were used to fragment the stones including electrohydraulic lithotripsy (EHL), lasers, crushing baskets and forceps. Of 12 studies, 8 used endoscopies to remove the gallstones under direct vision. The rest, used fluoroscopic guidance.[10,12,14,20] The technical details are shown in Table 2.

Success and failure rate

The overall success rate was 91% (395/435). Of 12 studies, 5 reported 100% success rates (Table 3).[10–13,15] Of 40 patients, in

Table 3 – Summary of outcomes.

Study	Mean hospital stay (Days)	No. of procedures		Clearance of stones, n (%)	Recurrence of GB stones, % (n/followed patients)	Mean Follow up
		Total (n)	Procedure per patient, mean			
Wang et al.[10]	Nm	21	1.3 (+/−0.5)*	16 (100%)	19% (3/16)	2 years
Stirrat et al.[6]	1.3 (+/− 1.7)*	96	1.3 (+/− 0.7)*	68 (90%)	7% (5/68)	2.8 (0.2–15.4)** years
Patel et al.[11]	4 (1–32)**	16	1.2 (+/−0.6)*	13 (100%)	8% (1/13)	Nm, (12–1825) days**
Liu et al.[12]	15.9 (+/− 2.2)*	18	1 (+/− 0.2)*	17 (100%)	0% (0/17)	24 months
Zhang et al.[13]	2.8 (±0.7)*	Nm	Nm	19 (100%)	21% (4/19)	24 months
Kim YH et al.[14]	8.3 (5–80)**	Nm	Nm	59 (94%)	0% (0/59)	608 days
Kim HJ et al.[15]	Nm	Nm	2.2 (1–4)**	26 (100%)	14% (3/22)	27 months (12 months-5 years)**
Wong et al.[16]	10.2 (4–20)**	17	2 (1–4)**	7 (64%)	14% (1/7)	17.2 (2–31)**Months
Majeed et al.[17]	3 (1–11) ¥	Nm	Nm	66 (81%)	6% (4/62)	1.8 year (5months-3 years) ¥
Picus et al.[18]	Nm	94	1.6 (+/−0.9)*	56 (97%)	Nm	Nm
Cope et al.[19]	4 (±0.7)*	23	1.4 (+/−0.5)*	17 (85%)	0% (0/17)	Nm, (3–36) months**
Gibney et al.[20]	Nm	Nm	1.5 (1–6)**	31 (86%)	3% (1/36)	Nm

Nm = Not mentioned.
*= (+/-SD).
**= (range).
¥ = Median(range).

whom PCCL failed, 58% (n = 23) underwent successful cholecystectomy, 13% (n = 5) were managed conservatively, 2.5% (n = 1) with ERCP and 2.5% (n = 1) with percutaneous drain to treat bile leak.[14,16–20] While the outcome was not mentioned in 25% (n = 10) of patients.[6,17]

Length of stay

The length of stay was reported in 8 studies with variable outcomes. The mean length of stay was 7 days and ranged from 1 day to 80 days.[11,14] Prolonged hospitalization for more than 30 days occurred in 5 patients due to exacerbation of heart failure, rupture of empyema, septic shock, and multiple remnant cystic duct stones.[11,14]

Complications

All the studies reported the complications of the procedures; however, only one study classified the complications into the Clavien-Dindo classification.[6] Overall complication rate (including both major and minor) was 28%. Common complications reported are bile leakage (4%), catheter displacement (2.8%), wound infection (3%), and post procedure common bile duct stones (2%) (Table: 4).

The procedure related mortality was 0.7%. Recurrence rate was 7% (22/320). Of 22 patients who had recurrent gallstones during the follow-up, subsequent cholecystectomy was performed in five,[6,11,20] cholecystostomy in two,[6] ERCP in one,[16] oral dissolution therapy in one,[17] and six patients did not require any further treatment.[15,17] While in 7 patients, the outcome was not mentioned.[10,13]

The follow-up period was variable across different studies and ranged from 12 days to 15 years.[6,11]

Quality assessment of studies

All studies included data that was mentioned in their objectives with no missing data unaccounted for. The study intervention, outcomes and key findings were clearly described. As the majority of studies were retrospective, there is an inherent risk of selection and reporting bias. Based on NIH criteria,[9] all the studies were judged to be of good or fair quality, none being of poor quality (Table 5). Regarding the hierarchy of evidence for each study, the studies were considered to be of low quality, despite each study was conducted well and methodically. However, collectively, the pooled analysis strengthens the level of evidence.

Table 4

Nature of complication	Frequency (n)	Percentage (%)
Bile leak	18	4
Gallbladder hematoma	4	0.9
Gallbladder/cystic duct perforation	3	0.7
Fistula	8	1.8
Delayed tract closure	2	0.5
Bleeding	5	1.1
Wound infection	14	3
Post procedure retained CBD stones	9	2
Retained stones (Not specified)	14	3
CBD stones during follow up	9	2
Dehydration	2	0.5
Catheter displacement	12	2.8
Hepatic abscess	1	0.2
Pancreatitis	4	0.9
Cholangitis	3	0.7
Cholecystitis	5	1.1
Vasovagal/intolerance to procedure	2	0.5
Wound hematoma	1	0.2
GI bleeding	1	0.2
Bowel injury	1	0.2
Loss of anchoring device	3	0.7
Myocardial Infarction	1	0.2
Broken wire	1	0.2
Mortality	3	0.7
Total	126	28

Table 5

Criteria	Wang et al.[10]	Stirrat et al.[6]	Patel et al.[11]	Liu et al.[12]	Zhang et al.[13]	Kim YH et al.[14]	Kim HJ et al.[15]	Wong et al.[16]	Majeed et al.[17]	Picus et al.[18]	Cope et al.[19]	Gibney et al.[20]
1. Was the study question or objective clearly stated?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
2. Was the study population clearly and fully described, including a case definition?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
3. Were the cases consecutive?	Yes	Yes	Yes	Yes	CD	Yes	Yes	Yes	CD	Yes	No	CD
4. Were the subjects comparable?	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
5. Was the intervention clearly described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
6. Were the outcome measures clearly defined, valid, reliable, and implemented consistently across all study participants?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
7. Was the length of follow-up adequate?	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	No	No	NR
8. Were the statistical methods well-described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
9. Were the results well-described?	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

NR: Not reported.
CD: Cannot determine.

Discussion

Summary of main outcomes

To the best of our knowledge, this is the first systematic review demonstrating the safety and efficacy of PCCL technique in high-risk patients.

In the present review, PCCL has an overall success rate of 91% (range: 64–100%) with an overall morbidity of 28%. An average of 1.5 sessions (range 1–6) per patient are required to achieve complete clearance of stones. The overall mortality related to procedure is 0.7%.

PCCL can be performed with choledochoscopy, under fluoroscopic guidance, or combination of both.[6,14,18] The choledochoscopy has various advantages. First, the gall bladder is visualized which helps not only to assess the stone burden and plan extraction/fragment techniques, but also identifies any suspicious lesions within the gallbladder mucosa.[15] Second, the gallstones are grasped, crushed and removed under direct vision. Third, if stones are large, EHL or lasers can be applied to fragment the stones.[15,23] Although, choledochoscopy is advantageous, however, in this review the incidence of retained stones is found to be higher in the choledochoscopy 6% as compared to fluoroscopy group 3%. This can be explained as majority of retained stones occurred in those studies which used rigid endoscopes, which lack the clarity and maneuverability of modern flexible endoscopes.

The failure rate of PCCL in present review is 9% (n = 40). The common reasons of failure are, inability to secure access 4% (n = 17), loss of access 2% (n = 9), impacted stone 1.4% (n = 6) and excessive tortuosity of cystic duct 0.7% (n = 3). Other less common causes each 0.2% (n = 1) were, bleeding from gallbladder wall, intolerance of procedure, bile leak, inability to remove stones due to phrygian cap and mistakenly "missing" the cystic duct stone.

In present review, the main reason for deferring cholecystectomy in high-risk patients was prohibitive risk of anesthesia. However, in two of the largest series of PCCL, i.e., Stirrat et al.(n = 75) and Majeed et al.(n = 81), despite the majority of patients had high ASA score, general anesthesia was still used in 45% and 31% respectively. Similarly, high risk patients who were considered "unfit" for general anesthesia, still underwent the PCCL procedure exclusively under GA in series reported by Patel et al.[11] The point is, if the patients can undergo GA for PCCL, why not to offer cholecystectomy once the sepsis has resolved after cholecystostomy and general condition has been optimized!

Interestingly, of 40 patients, in whom PCCL failed, 23 patients went on to have uneventful surgical cholecystectomy, which implies that cholecystectomy could have been performed in the first place. This notion is supported by CHOCOLATE trial which demonstrated the feasibility of laparoscopic cholecystectomy in high-risk patients (mean APACHE II of 9.5) with a major complication and mortality of 12% and 3% respectively.[24] Similar outcomes of laparoscopic cholecystectomy performed on ASA 3 and ASA 4 patients, were observed recently by Musbahi et al.(2020) which demonstrated morbidity and mortality of 15% and 0.8%

respectively.[25] This highlights the importance of identifying those subsets of high-risk patients who could potentially benefit from cholecystectomy rather than subjecting them to PCCL.

The overall complication rate of PCCL in present review is 28% with a mortality rate of 0.7%. The most common complication is bile leakage 4%. Which was more frequent with trans-peritoneal approach 8.5% as compared to those with trans-hepatic approach 3.7%. In transhepatic approach to gallbladder, the risk of bile leak is believed to be less due to its relative fixity by hepatic attachments and stable platform for tract dilatation.[14]

Limitations

The major limitation of present review is that the majority of studies included are retrospective in nature, apart from the two studies which are prospective.[12,19] Furthermore, there was no global consensus from the selected studies of what success rate meant. Some have defined success rate as complete stone clearance in one session,[6] while others have in multiple.[11] Similarly, retained/residual stones and recurrence rates were not pre-defined.

Although, the included studies do mention about the anesthesia risk assessment, however, it is not mentioned clearly if re-assessment was carried out after cholecystostomy when the septic condition has resolved before embarking on PCCL. This is important to single out the patients in whom optimization of the comorbidities could make surgical intervention possible.

Given the fact that in some studies, granularities of complications were missing, it becomes difficult to classify all the complications into Clavien-Dindo, which gives a more practical overview towards safety of the technique in clinical practice.

All the included studies in the review are classified as low-level evidence, majority being level 4, however, collectively the pooled analysis strengthens the level of evidence.

Recommendations for clinical practice

Based on the results of this review, we recommend that, every effort should be made to optimize the co-morbidities of the patient after cholecystostomy once the sepsis has resolved, as cholecystectomy is the only definitive treatment for symptomatic gallstone disease. Second, careful identification of only those patients who cannot undergo surgical intervention after being re-assessed by anesthesiologist, to be considered for PCCL. Third, the risks versus benefits of PCCL should be carried out by taking into consideration not only the risk assessment tools like ASA score or charlson comorbidity index,[26] but also other aspects like life expectancy and quality of life. Finally, PCCL should ideally be carried out in a high-volume unit with sufficient experience in choledochoscopy and fluoroscopy underpinned by trained team of surgeons, nurses, interventional radiologists and anesthesiologists.

Future recommendation

We suggest the future work should include reporting of the minimum of parameters like ASA score, Charlson comorbidity index, APACHE score, length of stay, duration of procedure and cost analysis. Furthermore, the standardized terminology of success rate, retained stones, recurrence rate, and complications based on Clavien-Dindo should be adopted so that data can be extracted and compared in a meaningful way. Finally, well designed prospective studies and randomized control trials are needed to validate the results of PCCL.

In conclusion

The evidence of PCCL is limited by the lack of randomized controlled trials and well-designed prospective studies. Despite the limitations of present review, it can be concluded that PCCL has a role in selected high-risk patients in whom laparoscopic cholecystectomy is contraindicated.

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Declaration of competing interest

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REFERENCES

1. Okamoto K, Suzuki K, Takada T, Strasberg SM, Asbun HJ, Endo I, et al. Tokyo Guidelines 2018: flowchart for the management of acute cholecystitis. *J Hepatobiliary Pancreat Sci* 2018;**25**(1):55–72. https://doi.org/10.1002/jhbp.516.
2. Melloul E, Denys A, Demartines N, Calmes J-M, Schäfer M. Percutaneous drainage versus emergency cholecystectomy for the treatment of acute cholecystitis in critically ill patients: does it matter? *World J Surg* 2011;**35**(4):826–33. https://doi.org/10.1007/s00268-011-0985-y.
3. Joseph B, Scalea T. The consequences of aging on the response to injury and critical illness. *Shock* 2020;**54**(2):144–53. https://doi.org/10.1097/SHK.0000000000001491.

4. Corbetta Machado MJ, Gray A, Cerdeira MP, Gani J. Short- and long-term outcomes of percutaneous cholecystostomy in an Australian population. *ANZ J Surg* 2020;**90**(9):1660–5. https://doi.org/10.1111/ans.15726.
5. Burhenne HJ, Stoller JL. Minicholecystostomy and radiologic stone extraction in high-risk cholelithiasis patients. Preliminary experience. *Am J Surg* 1985;**149**(5):632–5. https://doi.org/10.1016/S0002-9610(85)80144-6.
6. Stirrat J, Patel NR, Stella SF, Mafeld S, Ho CS, Shlomovitz E. Safety and efficacy of percutaneous gallstone extraction in high-risk patients: an alternative to cholecystectomy or long-term drainage? *J Am Coll Surg* 2021;**232**(2):195–201. https://doi.org/10.1016/J.JAMCOLLSURG.2020.09.019.
7. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al. In: Higgins JPT, Thomas J, Chandler J, et al., editors. *Cochrane Handbook for Systematic Reviews of Interventions*; 2019. https://doi.org/10.1002/9781119536604. Wiley.
8. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Ann Intern Med* 2009;**151**(4):W65–94. https://doi.org/10.7326/0003-4819-151-4-200908180-00136.
9. Study Quality Assessment Tools. *NHLBI, NIH*. https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools. [Accessed 5 November 2021].
10. Wang W, Wang W, Liu B, Li Y. Fluoroscopy-guided percutaneous lithotripsy using FREDDY laser for giant gallstones: preliminary experience. *Laser Surg Med* 2021. https://doi.org/10.1002/lsm.23477.
11. Patel N, Chick JFB, Gemmete JJ, Castle JC, Dasika N. Saad WE interventional radiology-operated cholecystoscopy for the management of symptomatic cholelithiasis: approach, technical success, safety, and clinical outcomes. *AJR Am J Roentgenol* 2018;**210**(5):1164–71. https://doi.org/10.2214/AJR.17.18690.
12. Liu B, Wu DS, Cao PK, Wang YZ, Wang WJ, Wang W, et al. Percutaneous transhepatic extraction and balloon dilation for simultaneous gallbladder stones and common bile duct stones: a novel technique. *World J Gastroenterol* 2018;**24**(33):3799–805. https://doi.org/10.3748/WJG.V24.I33.3799.
13. Zhang H, Chen G, Ma X, Liu Y, Wang T, Tang L. Clinical compare between ultrasound-guided double tract percutaneous cholecystostomy combined with a choledochoscope for performing cholecystolithotomies and laparoscopic-choledochoscopy-assisted cholecystolithotomy after cholecystostomy in high-risk surg. *Int J Clin Exp Med* 2017;**10**(2):2496–504.
14. Kim YH, Kim YJ, Shin TB. Fluoroscopy-guided percutaneous gallstone removal using a 12-Fr sheath in high-risk surgical patients with acute cholecystitis. *Korean J Radiol* 2011;**12**(2):210–5. https://doi.org/10.3348/KJR.2011.12.2.210.
15. Kim HJ, Lee SK, Kim MH, Yoo KS, Lim BC, Seo DW, et al. Safety and usefulness of percutaneous transhepatic cholecystoscopy examination in high-risk surgical patients with acute cholecystitis. *Gastrointest Endosc* 2000;**52**(5):645–9. https://doi.org/10.1067/MGE.2000.107286.
16. Wong SK, Yu SC, Lam YH, Chung SS. Percutaneous cholecystostomy and endoscopic cholecystolithotripsy in the management of acute cholecystitis. *Surg Endosc* 1999;**13**(1):48–52. https://doi.org/10.1007/S004649900896.
17. Majeed AW, Reed MWR, Ross B, Peacock J, Johnson AG. Gallstone removal with a modified cholecystoscope: an alternative to cholecystectomy in the high-risk patient. *J Am Coll Surg* 1997;**184**(3):273–80.
18. Picus D, Hicks ME, Darcy MD, Vesely TM, Kleinhoffer MA, Aliperti G, et al. Percutaneous cholecystolithotomy: analysis of results and complications in 58 consecutive patients. *Radiology* 1992;**183**(3):779–84. https://doi.org/10.1148/RADIOLOGY.183.3.1533946.
19. Cope C, Burke DR, Meranze SG. Percutaneous extraction of gallstones in 20 patients. *Radiology* 1990;**176**(1):19–24. https://doi.org/10.1148/RADIOLOGY.176.1.2353089.
20. Gibney RG, Fache JS, Becker CD, Nichols DM, Cooperberg PL, Stoller JL, et al. Combined surgical and radiologic intervention for complicated cholelithiasis in high-risk patients. *Radiology* 1987;**165**(3):715–9. https://doi.org/10.1148/RADIOLOGY.165.3.3317502.
21. Gillams A. *The Treatment of Symptomatic Cholecystolithiasis. 1993. p. 837–42*.
22. Lindberg CG, Berggren T, Lindstedt E, Lundstedt C, Stridbeck H. Percutaneous rotational lithotripsy of urinary bladder stones: clinical results with the rotolith lithotriptor. *Acta Radiol* 1993;**34**(3):270–2. https://doi.org/10.3109/02841859309175367.
23. Lamanna A, Maingard J, Bates D, Ranatunga D, Goodwin M. Percutaneous transhepatic laser lithotripsy for intrahepatic cholelithiasis: a technical report. *J Med Imaging Radiat Oncol* 2019;**63**(6):758–64. https://doi.org/10.1111/1754-9485.12952.
24. Loozen CS, Van Santvoort HC, Van Duijvendijk P, Besselink MG, Gouma DJ, Nieuwenhuijzen GA, et al. Laparoscopic cholecystectomy versus percutaneous catheter drainage for acute cholecystitis in high risk patients (CHOCOLATE): multicentre randomised clinical trial. *BMJ* 2018;**363**. https://doi.org/10.1136/BMJ.K3965.
25. Musbahi A, Abdulhannan P, Bhatti J, Dhar R, Rao M, Gopinath B. Outcomes and risk factors of cholecystectomy in high risk patients: a case series. *Ann Med Surg* 2020;**50**:35–40. https://doi.org/10.1016/J.AMSU.2019.12.003.
26. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chron Dis* 1987;**40**(5):373–83. https://doi.org/10.1016/0021-9681(87)90171-8.