Outcomes of balloon vs basket catheter for clearance of choledocholithiasis: A systematic review and meta-analysis

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Conflict of Interest: The authors declare that they have no conflict of interest.

Abstract:
Aim: Endoscopic retrograde cholangiopancreatography (ERCP) is the mainstay for treatment of choledocholithiasis. It is unclear whether balloon or basket catheters are better for extraction of stones ≤10 mm in size. We performed a meta-analysis of studies comparing rates of complete stone extraction and adverse events after ERCP using balloon vs basket catheters for bile duct stones ≤10 mm in size.

Methods: Cochrane database, PubMed, Web of Science, and Embase were searched from inception to October 2021. Randomized control trials comparing outcomes of balloon vs basket catheter were included. Data extraction of articles was carried out by 2 authors using predefined inclusion criteria. Meta-analysis was carried out using the Revman 5.4.1. software using a random effects model.

Results: 3 studies with a total of 508 patients were included in the final analysis. For common bile duct stones ≤10 mm, balloon catheters had higher complete stone clearance rates than basket catheters [Relative risk 1.1, confidence interval 1.03, 1.18, p=0.006]. Heterogeneity among studies was low (Tau2=0.0; p=0.47, I2=0%). There was no difference in the rate of complications.

Conclusion: Meta-analysis of 3 studies indicates that balloon catheters have a higher success rate compared to basket catheters for complete stone extraction for choledocholithiasis ≤10 mm with no significant difference in the rate of complications.

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Title: Outcomes of Balloon vs Basket Catheter for Clearance of Choledocholithiasis: A Systematic Review and Meta-analysis

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Conclusion: Meta-analysis of 3 studies indicates that balloon catheters have a higher success rate compared to basket catheters for complete stone extraction for choledocholithiasis ≤10 mm with no significant difference in the rate of complications.
LIST OF ABBREVIATIONS:
ERCP: Endoscopic retrograde cholangiopancreatography; CBD: common bile duct; EST: endoscopic sphincterotomy; USA: United States of America; BDS: bile duct stones; ML: mechanical lithotripsy; ASGE: American Society for Gastrointestinal Endoscopy; ESGE: European Society of Gastrointestinal Endoscopy; BOC: Balloon occlusion cholangiography; RCT: randomized controlled trial; PRISMA: Preferred Reporting Items for Systematic Review and Meta-analysis; EPLBD: endoscopic papillary large balloon dilatation

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is the standard of care for management of common bile duct (CBD) stones with a success rate of over 80-90%.[1, 2] Since cannulation of the ampulla of Vater in 1960s, and endoscopic sphincterotomy (EST) with stone extraction in 1970s, these procedures have virtually obviated the need for surgical CBD exploration.[3-5] An estimated 1,606,850 ERCPs were carried out in the United States of America (USA) between 2007-2016.[6]

Bile duct stone (BDS) removal is recommended even if asymptomatic as they can lead to complications including obstructive jaundice, cholangitis, and pancreatitis.[2, 7] The initial approach is EST followed by BDS extraction with a catheter that uses either a balloon or basket for extraction. This is usually sufficient for CBD stones ≤ 10 mm in diameter. Larger stones may require advanced methods such as mechanical lithotripsy(ML), laser lithotripsy, cholangioscopic lithotripsy etc.[2, 8] Both American Society for Gastrointestinal Endoscopy (ASGE) and European Society of Gastrointestinal endoscopy (ESGE) have published guidelines for management of CBD stones, but there is no evidence to support the use of either device over the other.[2, 7]
Each device has advantages and disadvantages. Conventional basket catheters have four wires which are used to trap and extract stones. Balloon catheters are inflated above the stone and pulled back sweeping the stone/s with them. ASGE prefers balloon catheters as basket catheters run the risk for impaction, a serious complication, especially with larger stones or inadequate sphinterotomy. Balloon catheters can be deflated and easily removed in such a situation. Additionally, small stones can slip through the wires of basket catheters. Balloon catheters are inflated to occlude the CBD, hence might be better suited for smaller stones or sludge. In a survey, 98.6% American gastroenterologists preferred balloon catheters as they are considered safer, easier to use, and allow for balloon occlusion cholangiography (BOC). ESGE does not have any preference. Many European and Japanese centers actually prefer basket catheters as they provide better traction, while balloon catheters can slip past stones, or push stones into the intrahepatic duct, cystic duct or the corner pocket at the lower end of the CBD during extraction. Basket catheters are considered more durable, while balloons can rupture. Some basket catheters can also be sterilized and reused.

While there are some distinct advantages and disadvantages with the use of the respective catheter, both have been presumed to have similar efficacy. In recent years, a small number of randomized controlled trials (RCT) have been carried out to compare rates of complete stone extraction and complications using balloon vs basket catheters. Due to discrepancies in the results, we carried out a meta-analysis of these studies.


Search strategies were developed by a health sciences librarian with expertise in systematic reviews and primary author for Cochrane database, Pubmed, Web of Science, and Embase.
Databases were searched from inception to October 2021. Mesh Terms used were ‘cholangiopancreatography, endoscopic retrograde’, ‘choledocholithiasis/surgery’, ‘common bile duct/surgery’ (Figure 1) To maximize sensitivity, no pre-established database filters were used. Citation list of included papers were searched using Scopus.

2.1 Study selection

RCTs comparing balloon vs basket catheters for BDS extraction were included. All were well-designed high-quality studies (Table 1). Retrospective and observational studies,[12] letters to the editor, and abstracts[13] were excluded. R.S. and V.S. independently screened the database and agreed on final articles for inclusion (Figure 2). Data was collected independently by R.S. and V.S. and included the primary endpoint of complete stone clearance and complications of ERCP. Reasons for failure of complete stone clearance were recorded. The study was conducted according to the Preferred Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.

2.2 Study Characteristics

2.2.a. Study design

All studies were prospective, single country RCTs. The study by Ekmektzoglou et al. was a single center RCT at a high-volume center in Greece with two participating endoscopists with >20 years’ experience.[9] Studies by Ozawa et al. and Ishiwatari et al. were multicenter RCTs conducted in Japan.[10, 14] Ozawa et al. had six high-volume ERCP centers with endoscopists proficient in ERCP. Ishiwatari et al. had 12 high-volume centers with 39 endoscopists, 17 experts (≥ 4 years’ experience) and 22 trainees (<4 years’ experience). If trainees were unsuccessful, the procedure was completed by an expert.

2.2.b. Inclusion and exclusion criteria for patients
All studies included patients scheduled to undergo ERCP for choledocholithiasis. Ekmektzoglou et al. and Ishiwatari et al. included patients with BDS ≤10mm and CBD diameter ≤15mm, Ozawa et al. with BDS diameter ≤11mm. Common exclusion criteria included age (<18 years for the Greek study, <20 years for the Japanese studies), biliary stenosis/stricture, gastrectomy apart from Billroth-I, INR > 1.5, platelet count <50,000/mL. Other exclusion criteria were prior ERCP, EST or stent insertion; endoscopic papillary large balloon dilatation (EPLBD), prophylactic pancreatic duct stenting, failure to reach papilla, difficult cannulation, cannulation failure, intrahepatic stones, active pancreatitis, severe cholangitis, severe cardiorespiratory disease, Eastern Cooperative Oncology Group performance status ≥4, American Society for Anesthesiology status ≥4, pregnant or breast feeding, inappropriate per physician’s judgement, unable or unwilling to consent. Ishiwatari et al. included patients with severe cholangitis or on anticoagulation. Patients underwent ERCP with stenting or nasobiliary drainage and were included after cholangitis or coagulopathy had resolved. Ekmektzoglou et al. excluded patients with difficult CBD cannulation as it could affect complication rates.

2.2.c. Primary and secondary endpoints

Primary endpoint for all studies was rate of complete CBD clearance by the assigned catheter. Ozawa et al. additionally required this to be completed within 10 minutes from CBD cannulation.

Secondary endpoints included adverse events as defined by the ASGE Standards of Practice Committee.[15, 16] Two studies recorded time taken to complete the procedure.[9, 14]
study recorded radiation exposure.[9] For Ozawa et al., complete stone extraction in one endoscopic session, irrespective of initial extraction device, was a secondary endpoint.

2.2.d. Randomization

Patients were randomized 1:1 to either the balloon or basket group. Ozawa et al. and Ekmektzoglou et al. randomized patients after stones were identified and measured during ERCP.[9, 10] Ishiwatari et al. randomized patients based on pre-ERCP imaging and excluded them after randomization if they did not meet inclusion criteria on ERCP.

2.2.e. Procedure techniques

All patients received EST. Ekmektzoglou et al. passed a fully expanded 4-wire basket beyond the stones and used it to capture and extract the stones. If this failed, the process was repeated with the basket partially closed. For multiple BDS, stones were removed individually starting with the most distal stone and moving proximally for both catheters. Complete stone clearance was assessed by contrast injection through the assigned catheter and confirmed on BOC. In case of incomplete clearance with balloon catheter, basket catheter was used and vice versa.

Ozawa et al. used a 4-wire basket and multiple stones were removed individually starting with the most distal stone. The balloon catheter was inflated above the stone(s) and pulled back. Complete stone extraction was confirmed on cholangiogram presumably with the assigned catheter.

Ishiwatari et al. used two varieties of basket and balloon catheters. Both baskets had 8 wires distally and 4 wires proximally. For all catheters stones were extracted individually starting with the most distal stone. Complete stone clearance was confirmed on cholangiogram through assigned catheter followed by balloon sweep and BOC.
In all studies, patients were discharged after 24 hours if no complications occurred. If complications occurred, patients were discharged after appropriate treatment.

2.3 Statistical analysis

Statistical analysis was carried out using Review Manager 5.4.1 statistical package. Meta-analysis for each outcome of interest was conducted with a random effects model using inverse variance weighting and relative risk as the main effects measure. Heterogeneity between studies was assessed with the $I^2$ statistic, $I^2 > 50\%$ and $p<0.05$ were considered significant. Funnel plot was generated to qualitatively assess for presence of publication bias (Figure 3). Results are reported as pooled estimates of the effect size with 95% confidence intervals and $p$ value for the overall effect. Risk of publication bias was assessed using a Funnel plot. A comprehensive risk of bias assessment was carried out by R.S. and V.S. using the Cochrane Collaboration’s tool for assessing risk of bias.

3. Results

Three studies were included in the meta-analysis with 255 patients in the balloon group and 253 patients in the basket group. Rate of complete stone clearance was higher in the balloon (229/255; 89.8%) vs basket (207/253; 81.8%) group and this difference was statistically significant on meta-analysis (RR 1.1, CI 1.03, 1.18, $p=0.006$). Heterogeneity among the studies was low ($\text{Tau}^2 = 0$; $P = 0.47$, $I^2 = 0\%$) (Figure 4). The meta-analysis did not find any significant difference in the rate of complications such as pancreatitis, cholangitis, bleeding, and perforation (Table 2) (supplementary figures).

Twenty-six patients in the balloon group did not achieve complete clearance, reasons being (i) Stone migrating into intrahepatic or cystic duct (6) (ii) Stone impaction above the papilla (4)
Stone impaction in the corner pocket at the lower end of the CBD
Balloon slipping past the stone
Acute angulation or stenosis of CBD
ML needed
Stone lost to sight
Complete stone clearance was achieved by exchanging to a basket catheter in 11 patients, after EPLBD in 1 patient, and after ML in 3 patients. Fourteen patients required a second ERCP.

In the basket group, 46 patients failed to achieve complete stone clearance. The reasons were
Failure to capture the stone
Residual stone on BOC
Stone migrating into intrahepatic or cystic duct
Stone impaction above the papilla
Basket impaction
Stone lost to sight
Acute angulation or stenosis of the CBD
Need for ML
The procedure time extended beyond 10 minutes in 4 patients, 3 of whom achieved complete clearance by persistent use of basket catheter. Twenty-seven patients achieved complete clearance by exchange to a balloon catheter, 6 required ML, and 10 needed a second ERCP. Ozawa et al. have documented need for ML as a reason for failure but did not specify why ML was needed. Funnel plot showed a symmetrical distribution of studies without evidence of a publication bias (Figure 3). Review of individual studies for risk of bias did not reveal any high-risk features in the studies that could have significantly altered the study results.

4. Discussion

ERCP is the first line treatment for management of choledocholithiasis and has a success rate of over 80-90%. In most cases an EST followed by stone extraction using either a balloon or basket catheter is sufficient. There is no clear consensus for which of these two is preferable. ASGE prefers balloon catheters because of risk of impaction with basket catheters.
no preference, and many centers in Europe and Japan prefer basket catheters as they are sturdier and provide better traction.[1, 11]. We carried out a meta-analysis of three RCT comparing the efficacy of balloon vs basket catheters for complete stone clearance for CBD stones ≤10mm. Meta-analysis indicated that balloon catheter had greater success rate than basket catheters with no difference in the incidence of complications. This difference was statistically significant. However, there is a need for further randomized controlled clinical trials to ascertain whether this also translates into a clinically significant difference for patients undergoing these procedures.

The most common reason for failure within the basket group was failure to grasp the stone. Traditional basket catheters have 4 wires through which stones, especially small stones, can slip.[9] A catheter with a different structure may overcome this issue.[17] For example, Ishiwatari et al. used a catheter with 8 wires distally and had the lowest number of patients in whom failure to grasp the stone was a reason for failed extraction (2/17 or 11.8%) (Table 3).

Ozawa et al. did not find a better outcome with balloon extraction in their study. However, they did mention that most of their endoscopists had preferentially used basket catheters prior to the study. Thus, lesser experience with the balloon catheters may be a reason for lower success rates with the balloon catheter in their study.

One of the perceived downfalls of balloon catheters is that they can cause passage of stones into the intrahepatic or cystic duct, or the corner pocket at the lower end of the CBD. Combined results from the three studies show that stones passed into the intrahepatic or cystic duct in 6 patients in both the groups (Table 3). Impaction at the lower end of the CBD was seen in 8
patients in the balloon group (4 above the papilla and 4 in the corner pocket) and 6 patients in the basket group (4 above the papilla and 2 basket impaction) (Table 3).

It is recommended that multiple stones be extracted individually starting with the most distal stone to prevent stone impaction.[18] This was adhered to in most cases, however according to the procedure description by Ozawa et al. they passed the balloon above the stone(s) before pulling them out. This could introduce procedural bias as it would increase the risk of stone impaction. All 4 cases of stone impaction at the corner pocket at the lower end of the CBD belong to this group indicating importance of removing stones individually (Table 3).

An interesting finding by Ishiwatari et al. was that BOC is superior to conventional cholangiography for detecting residual stones. Residual stones not demonstrated on conventional cholangiography were found on BOC in 9 patients (Table 3). Clinical significance of residual stones is unclear.[19, 20] The treatment goal for choledocholithiasis is complete clearance.[2] While 2-3 mm stones may pass, larger stones can get impacted, especially with papillary edema in the aftermath of ERCP, causing cholangitis.

For Ishiwatari et al. the CBD was swept by a balloon prior to BOC and one can argue that had balloon sweep been omitted, residual stones may have been detected in an even greater number of patients in the basket group.[21] Ability to carry out BOC without changing the catheter is another advantage of a balloon catheter. Ozawa et al. found diameter <6mm to be independently associated with failed stone extraction.

Some minor differences were noted. Ozawa et al. had a cut off ≤11 mm for BDS diameter, which was ≤10 mm for the other two studies. They did not have a cut off for CBD diameter. Ekmektzoglou et al. was a single center study with two highly skilled endoscopists ensuring
minimal procedural variation. The Japanese studies were multicenter studies with multiple participating endoscopists. Ishiwatari et al. additionally involved trainees. While we would expect more variation with methodology, it also makes the results of the study more generalizable.

Ekmektzoglou et al. and Ozawa et al. randomized patients after confirming CBD and BDS diameter on ERCP. Ishiwatari et al. randomized them based on pre ERCP imaging. Exclusion of patients after randomization could introduce selection bias. Ishiwatari et al. used two different types of balloon and basket catheters, but there was no difference in rate of stone extraction within each group.

The limitation of our study is that only three RCT have been conducted on this topic, and these were only for stones ≤10 mm in diameter. Some disadvantages of basket catheters may be overcome with larger stones. There are also minor variations in the individual methodologies that may introduce a bias as discussed above.

5. Conclusion:
Meta-analysis of 3 studies showed that balloon catheters are superior to basket catheters for complete stone extraction for choledocholithiasis ≤10 mm with no significant difference in the rate of complications. These findings favor the use of balloon catheters over basket catheters for initial stone extraction for BDS ≤10mm. The reason balloon catheters are used in USA is safety. However, based on our study, balloon catheters may also be superior to basket catheters for stone extraction. These findings are relevant for review of current clinical practice in institutes and countries where use of basket catheters is the preferred method. More
 multicenter trials are needed to confirm the findings from our metanalysis and guide practitioners regarding the most appropriate choice of catheters for stone extraction in patients with choledocholithiasis ≤10 mm in size. More studies are also needed to investigate the use of 8 wired basket catheters, especially for smaller stones.

References


13. Choo L, Cho SS, Bell CJ et al. Extraction balloon is superior to wire basket technique in the management of CBD stones less than or equal to 10mm - Preliminary results of a prospective, randomised trial. Gastrointestinal Endoscopy 2011; 73: AB357. DOI: 10.1016/j.gie.2011.03.773


Table Legends

Table 1: The Newcastle-Ottawa scale is used to assess the quality of case control studies. The scale assigns up to 4 asterisks for comparability, 2 asterisks for selection, and 3 asterisks for outcome.

Table 2: Pooled data for results for primary and secondary outcomes for studies included in the metaanalysis.

Gray (Gy); Not applicable (N/A)

Table 3: Pooled data for rate of complications, reasons for failure of stone extraction and final outcomes associated with patients undergoing CBD stone extraction using balloon vs basket catheters from all three studies. Only applicable to Ishiwatari et al. †Only applicable to Ozawa et al. ‡Basket catheter was used in patients initially treated with balloon catheter and vice versa.

Common bile duct (CBD), Endoscopic papillary large balloon dilatation (EPLBD), Endoscopic retrograde cholangiopancreatography (ERCP)
Figure legends:

Figure 1: Database search strategies

Figure 2: Prisma flow diagram for search strategy to identify studies to be included

Figure 3: Funnel plot for results of complete stone clearance.

Figure 4: Metanalysis showing that the rate of complete stone clearance in patients with common bile duct stones was significantly higher with use of balloon catheters compared to basket catheters

Keywords: choledocholithiasis, endoscopic retrograde cholangiopancreatography, complete stone clearance.
### PRISMA 2020 Checklist

<table>
<thead>
<tr>
<th>Section and Topic</th>
<th>Item #</th>
<th>Checklist item</th>
<th>Location where item is reported</th>
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<tbody>
<tr>
<td>TITLE</td>
<td>1</td>
<td>Identify the report as a systematic review.</td>
<td>Title</td>
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<tr>
<td>ABSTRACT</td>
<td>2</td>
<td>See the PRISMA 2020 for Abstracts checklist.</td>
<td>Abstract</td>
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<tr>
<td>INTRODUCTION</td>
<td>3</td>
<td>Describe the rationale for the review in the context of existing knowledge.</td>
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<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of the objective(s) or question(s) the review addresses.</td>
<td>3</td>
</tr>
<tr>
<td>METHODS</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Eligibility criteria</td>
<td>5</td>
<td>Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.</td>
<td>4</td>
</tr>
<tr>
<td>Information sources</td>
<td>6</td>
<td>Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.</td>
<td>4</td>
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<tr>
<td>Search strategy</td>
<td>7</td>
<td>Present the full search strategies for all databases, registers and websites, including any filters and limits used.</td>
<td>4, Figure 1</td>
</tr>
<tr>
<td>Selection process</td>
<td>8</td>
<td>Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.</td>
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<td>Data collection process</td>
<td>9</td>
<td>Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.</td>
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<tr>
<td>Data items</td>
<td>10a</td>
<td>List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.</td>
<td>4</td>
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<tr>
<td>Study risk of bias assessment</td>
<td>11</td>
<td>Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.</td>
<td>Figure 4</td>
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<tr>
<td>Effect measures</td>
<td>12</td>
<td>Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.</td>
<td>7</td>
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<tr>
<td>Synthesis methods</td>
<td>13a</td>
<td>Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).</td>
<td>4-7</td>
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<td>13b</td>
<td>Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.</td>
<td>NA</td>
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<td>13c</td>
<td>Describe any methods used to tabulate or visually display results of individual studies and syntheses.</td>
<td>7, Figure 4</td>
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<td>13d</td>
<td>Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.</td>
<td>7</td>
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<td>13e</td>
<td>Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).</td>
<td>7</td>
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<td>Describe any sensitivity analyses conducted to assess robustness of the synthesized results.</td>
<td>7</td>
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<td>Item #</td>
<td>Checklist item</td>
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<td>Reporting bias assessment</td>
<td>14</td>
<td>Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).</td>
<td>NA</td>
</tr>
<tr>
<td>Certainty assessment</td>
<td>15</td>
<td>Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.</td>
<td>7</td>
</tr>
<tr>
<td>RESULTS</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Study selection</td>
<td>16a</td>
<td>Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.</td>
<td>4-5, Fig 2</td>
</tr>
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<td>16b</td>
<td>Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.</td>
<td>7</td>
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<td>Study characteristics</td>
<td>17</td>
<td>Cite each included study and present its characteristics.</td>
<td>4-7</td>
</tr>
<tr>
<td>Risk of bias in studies</td>
<td>18</td>
<td>Present assessments of risk of bias for each included study.</td>
<td>9-11, Figure 4</td>
</tr>
<tr>
<td>Results of individual studies</td>
<td>19</td>
<td>For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.</td>
<td>Figure 4</td>
</tr>
<tr>
<td>Results of syntheses</td>
<td>20a</td>
<td>For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.</td>
<td>9-11</td>
</tr>
<tr>
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<td>20b</td>
<td>Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.</td>
<td>7,8, Figure 4</td>
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<td>20c</td>
<td>Present results of all investigations of possible causes of heterogeneity among study results.</td>
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<td>20d</td>
<td>Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.</td>
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<td>Reporting biases</td>
<td>21</td>
<td>Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.</td>
<td>NA</td>
</tr>
<tr>
<td>Certainty of evidence</td>
<td>22</td>
<td>Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.</td>
<td>7, Figure 4</td>
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<tr>
<td>DISCUSSION</td>
<td></td>
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<td>Discussion</td>
<td>23a</td>
<td>Provide a general interpretation of the results in the context of other evidence.</td>
<td>10-12</td>
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<td>23b</td>
<td>Discuss any limitations of the evidence included in the review.</td>
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<td>Discuss implications of the results for practice, policy, and future research.</td>
<td>11, 12</td>
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<td>OTHER INFORMATION</td>
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</tr>
<tr>
<td>Registration and protocol</td>
<td>24a</td>
<td>Provide registration information for the review, including register name and registration number, or state that the review was not registered.</td>
<td>Not registered</td>
</tr>
<tr>
<td></td>
<td>24b</td>
<td>Indicate where the review protocol can be accessed, or state that a protocol was not prepared.</td>
<td>4, Figure 2</td>
</tr>
<tr>
<td></td>
<td>24c</td>
<td>Describe and explain any amendments to information provided at registration or in the protocol.</td>
<td>NA</td>
</tr>
<tr>
<td>Support</td>
<td>25</td>
<td>Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.</td>
<td>Supported by</td>
</tr>
</tbody>
</table>
### PRISMA 2020 Checklist

<table>
<thead>
<tr>
<th>Section and Topic</th>
<th>Item #</th>
<th>Checklist item</th>
<th>Location where item is reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competing interests</td>
<td>26</td>
<td>Declare any competing interests of review authors.</td>
<td>None</td>
</tr>
<tr>
<td>Availability of data, code and</td>
<td>27</td>
<td>Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.</td>
<td>NA</td>
</tr>
<tr>
<td>other materials</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>


For more information, visit: [http://www.prisma-statement.org/](http://www.prisma-statement.org/)
<table>
<thead>
<tr>
<th>Study</th>
<th>Type of Study</th>
<th>Blinding</th>
<th>Selection</th>
<th>Comparability</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>Ekmektzoglou et al. 16</td>
<td>RCT</td>
<td>Single</td>
<td>****</td>
<td>**</td>
<td>***</td>
</tr>
<tr>
<td>Ishiwatari et al. 26</td>
<td>RCT</td>
<td>Single</td>
<td>****</td>
<td>**</td>
<td>***</td>
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<tr>
<td>Ozawa et al. 27</td>
<td>RCT</td>
<td>No</td>
<td>****</td>
<td>**</td>
<td>***</td>
</tr>
</tbody>
</table>

**Table 1**: The Newcastle-Ottawa scale is used to assess the quality of case control studies. The scale assigns up to 4 asterisks for comparability, 2 asterisks for selection, and 3 asterisks for outcome.
<table>
<thead>
<tr>
<th></th>
<th>Ekmektzoglou et al. 2020</th>
<th>Ozawa et al. 2016</th>
<th>Ishiwatari et al. 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Balloon</td>
<td>Basket</td>
<td>Balloon</td>
</tr>
<tr>
<td>Time for complete stone clearance (minutes)*</td>
<td>4.06 (1.52-7.26)</td>
<td>4.52 (3.33-3.75)</td>
<td>N/A</td>
</tr>
<tr>
<td>Radiation (Gy)*</td>
<td>1245.45 (89,34-5634.34)</td>
<td>1534.43 (245.55-6824.44)</td>
<td>N/A</td>
</tr>
<tr>
<td>Pancreatitis</td>
<td>2</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Bleeding</td>
<td>3</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

*data represented in median and range

Table 2: Pooled data for results for primary and secondary outcomes for studies included in the metanalysis.

Gray (Gy); Not applicable (N/A)
Table 3: Pooled data for rate of complications, reasons for failure of stone extraction and final outcomes associated with patients undergoing CBD stone extraction using balloon vs basket catheters from all three studies. *Only applicable to Ishiwatari et al. †Only applicable to Ozawa et al. ‡Basket catheter was used in patients initially treated with balloon catheter and vice versa.

<table>
<thead>
<tr>
<th></th>
<th>Balloon</th>
<th>Basket</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total patients</td>
<td>255</td>
<td>253</td>
</tr>
<tr>
<td>Complete stone clearance</td>
<td>229</td>
<td>207</td>
</tr>
</tbody>
</table>

**Complications**

- Pancreatitis: 7, 7
- Cholangitis: 6, 8
- Bleeding: 9, 5
- Perforation: 0, 0

**Reason for failure of complete stone extraction**

- Failure to capture stone: 0, 17
- Residual stone on BOC: 0, 9
- Stone migrated into intrahepatic or intracystic duct: 6, 6
- Stone impaction above the papilla: 4, 4
- Stone impaction in the corner pocket at the lower end of the CBD: 4, 0
- Balloon slipped past stone: 4, 0
- Procedure extended beyond 10 minutes*: 0, 4
- Acute angulation or stenosis of the CBD need for ML: 4, 1
- Basket impaction: 0, 2
- Stone lost to sight during procedure: 1, 2

**Final outcome**

- Exchange to basket/balloon catheter*: 11, 27
- EPLBD needed: 1, 0
- ML needed: 3, 6
- second ERCP needed: 14, 10
- Persistent use of same catheter beyond 10 minutes *: 0, 3

Common bile duct (CBD), Endoscopic papillary large balloon dilatation (EPLBD), Endoscopic retrograde cholangiopancreatography (ERCP)
PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources

Identification of studies via databases and registers

Records identified from databases= 5617
PubMed=1558
Embase=3080
Web of Science=878

Records removed before screening: Duplicate records removed=1750

Records screened (n = 3767)

Records excluded (n = 3648)

Reports sought for retrieval (n = 119)

Reports not retrieved (n = 0)

Reports assessed for eligibility (n = 119)

Reports excluded: (n=116)
Addressing a different question (97)
Retrospective reports of ERCP outcomes (n =11)
Abstracts (n=4)
Review article (n=3)
Survey (n=1)

Studies included in review (n = 3)
Reports of included studies (n = 3)
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Balloon</th>
<th>Basket</th>
<th>Risk Ratio</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Weight</td>
<td>IV, Random, 95% CI</td>
</tr>
<tr>
<td>Ishikawa 2016</td>
<td>72</td>
<td>78</td>
<td>64</td>
<td>80</td>
</tr>
<tr>
<td>Ozawa 2017</td>
<td>78</td>
<td>93</td>
<td>74</td>
<td>91</td>
</tr>
<tr>
<td>Elmokhtogli 2020</td>
<td>79</td>
<td>84</td>
<td>69</td>
<td>82</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>255</td>
<td>253</td>
<td>100.0%</td>
<td>1.10 [1.03, 1.18]</td>
</tr>
</tbody>
</table>

**Total events:** 229 | 207

Heterogeneity: $I^2 = 0.00$; $Q_{tot} = 1.52$, df = 2 ($P = 0.47$); $P = 0$

Test for overall effect: $Z = 2.79$ ($P = 0.006$)

**Risk of bias legend**

A (Random sequence generation (selection bias))
B (Allocation concealment (selection bias))
C (Blinding of participants and personnel (performance bias))
D (Blinding of outcome assessment (detection bias))
E (Incomplete outcome data (attrition bias))
F (Selective reporting (reporting bias))
G (Other bias)