Radiological biliary intervention for stone disease

Panagiotis Sardellis^a, Akshay Sethi^b, Miltiadis Krokidis^{b,c}

University of Aberdeen, UK; Aberdeen Royal Infirmary, NHS Grampian, UK; National and Kapodistrian University of Athens, Areteion Hospital, Athens, Greece

Abstract

Gallstones are primarily crystalline cholesterol formations that may present significant medical concerns, often leading to bile duct obstruction. Their genesis is multifaceted, influenced by genetics, diet and age. Over the decades, the biliary stone management domain has undergone a transformation, propelled by clinical demands and technological advances. This review focuses on percutaneous treatments, highlighting the shift from foundational percutaneous transhepatic cholangiography to advanced percutaneous transhepatic cholangioscopy, emphasizing patient safety, efficacy, and outcomes. The significance of patient-reported outcomes, capturing aspects that include pain and post-intervention quality of life, is accentuated. A critical analysis reveals a gap in our understanding of the long-term resilience of percutaneous interventions, particularly with respect to averting stone recurrence or treating chronic strictures. The potential of technological enhancements, including advanced endoscopes and real-time imaging, is acknowledged, though the need for rigorous clinical validation must be stressed. Decision-making challenges, due to the myriads of available interventions, are highlighted, emphasizing the need for evidence-based algorithms. Economically, the cost dynamics, both direct and ancillary, of these interventions come to the forefront. Concluding, the paper advocates for continuous innovation, ensuring that biliary stone management remains efficient, patient-centered, safe, and economically justified.

Keywords Percutaneous biliary intervention, biliary stones, biliary strictures, cholangioscopy, interventional radiology

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Introduction

Gallstones are crystalized particles composed mainly of cholesterol and sometimes bilirubin, typically developing in

^aSchool of Medicine, University of Aberdeen, Aberdeen, UK (Panagiotis Sardellis); ^bDepartment of Radiology, Aberdeen Royal Infirmary, NHS Grampian, Aberdeen, UK (Akshay Sethi, Miltiadis Krokidis); ^c1st Department of Radiology, National and Kapodistrian University of Athens, Areteion Hospital, Athens, Greece (Miltiadis Krokidis)

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Correspondence to: Miltiadis Krokidis, MD, PhD, EBIR-ES, FCIRSE, FRCR, FSIR, Vascular and Interventional Radiologist, Associate Professor of Radiology, 1st Department of Radiology, Areteion University Hospital, Medical School, National and Kapodistrian University of Athens 76 Vas. Sophias Av, 11528, Athens, Greece, e-mail: mkrokidis@hotmail.com

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the gallbladder [1]. Choledocholithiasis is the presence of those calculi (stones) in the common bile duct (CBD) [2]. It is the primary cause of non-malignant bile duct obstruction [3]. The formation of gallst one sis influenced by various clinical conditions and factors, including bile composition, gallbladder motility, genetics, obesity, female sex, and age [4-6]. The most common etiological factor for choledocholithiasis is the migration of gallbladder stones to the CBD and intrahepatic ducts through the cystic duct [7]. This occurs in approximately 3-15% of patients who undergo cholecystectomy [8]. Another common cause of choledocholithiasis is inadequate bile drainage due to obstructions, such as postsurgical bile duct strictures, which can lead to acute cholangitis or other inflammatory conditions [9]. Hepatolithiasis is the formation of stones in the intrahepatic biliary tract [10]. This condition is often recurrent and requires multiple therapeutic interventions [11]. Treatment for choledocholithiasis is necessary for symptomatic patients, and is recommended for asymptomatic patients given the risk of serious complications, such as cholangitis, obstructive jaundice (which can lead to secondary biliary cirrhosis), and pancreatitis [12].

The choice of treatment for lithiasis of the biliary tree depends on a variety of factors, including the patient's symptoms, the size and location of the stones, and the patient's overall health [13]. Currently, ultrasound (US) and

magnetic resonance cholangiopancreatography (MRCP) are the most used noninvasive methods for the diagnosis of biliary lithiasis [14]. However, in cases where these methods are inconclusive, more invasive procedures, such as endoscopic retrograde cholangiopancreatography (ERCP) or percutaneous transhepatic cholangiography (PTC), can be used to confirm the diagnosis, and may also provide therapeutic solutions [15]. ERCP is usually the preferred first-line procedure, but percutaneous radiological methods may be considered in cases where ERCP is contraindicated or unsuccessful [16]. PTC plays a critical role in the management of biliary strictures, particularly in scenarios where endoscopic approaches such as ERCP are technically challenging, contraindicated or unsuccessful [17]. One of the most common indications is in patients with surgically altered anatomy, such as those who have undergone Roux-en-Y hepaticojejunostomy, gastric bypass, or a Whipple procedure, in whom endoscopic access to the biliary tree is either impossible or extremely difficult [18]. This includes patients with narrowing of the duodenum or papilla [19]. PTC is also preferred in high-grade proximal biliary strictures, such as hilar cholangiocarcinomas (Bismuth types III and IV), where endoscopic access is limited, and bilateral drainage may be required for effective decompression [20]. In malignant strictures causing obstructive jaundice, percutaneous intervention provides rapid biliary decompression and can reduce the risk of cholangitis, especially when ERCP has failed or is not feasible [21]. Additionally, percutaneous interventions are advantageous in cases of severe biliary sepsis requiring urgent decompression, where faster biliary access may improve outcomes [22].

Endoscopic US (EUS) has become an essential clinical tool in the evaluation of biliary tract diseases, particularly for suspected choledocholithiasis and indeterminate biliary strictures. The European Society of Gastrointestinal Endoscopy (ESGE) recommends EUS as the first line diagnostic modality after a transabdominal ultrasound, when the CBD stones are suspected, but not confirmed. EUS offers high spatial resolution and the advantage of proximity to the biliary tree, allowing for detection of small stones (<5 mm) or biliary sludge that may be missed by MRCP or computed tomography (CT) imaging. It is also highly sensitive for detecting biliary microlithiasis, a known cause of idiopathic pancreatitis [23]. In cases of suspected biliary obstruction, such as patients with elevated liver function tests and biliary ductal dilation on US but no definite stone visualized, EUS has been shown to be at least equivalent to MRCP [24,25] in diagnostic accuracy, with some studies suggesting superior sensitivity, particularly when the stone burden is small or when MRCP is inconclusive [24,25]. In addition to choledocholithiasis, EUS plays a critical role in the evaluation of biliary strictures. While imaging techniques such as MRCP or CT may suggest a stricture, they often cannot distinguish between benign and malignant causes. In this context, EUS combined with fineneedle aspiration or fine-needle biopsy provides the additional advantage of guided tissue acquisition for histological diagnosis. This is particularly important in the assessment of indeterminate strictures, especially at the hilum or distal CBD, where ERCP brush cytology has limited sensitivity. EUS-guided sampling improves the diagnostic yield and allows for early identification

of malignancy, such as cholangiocarcinoma or pancreatic cancer [26]. EUS is considered a minimally invasive, safe, and well-tolerated procedure with a low complication rate, making it an ideal adjunctive investigation prior to initiating more invasive procedures such as PTC or ERCP, particularly when therapeutic intervention is not immediately needed or ERCP failed [27].

Percutaneous interventional radiology of the biliary system includes both diagnostic and therapeutic procedures. Diagnostic procedures involve the insertion of a needle into the bile duct to obtain images of the bile ducts and liver using contrast or a scope. Therapeutic procedures include the insertion of a drainage catheter into the bile duct to relieve obstruction, the dilation of bile duct strictures, the insertion of stents into the bile ducts, the removal of gallstones, and the delivery of radiation therapy to bile duct tumours.

In this review article, we discuss the indications, techniques and complications of percutaneous treatment of intra- and extrahepatic biliary stones, reviewing the current literature and including the latest advances in techniques and outcomes. This is important for clinicians treating patients with biliary stones, as well as for researchers who are developing new treatments. To ensure the quality and rigor of this narrative literature review, we have adhered to the SANRA (Scale for the Quality Assessment of Narrative Review Articles) guidelines [28].

Materials and methods

Search methods

The following search terms were used:

- Medline: Percutaneous: "percutaneous" [All Fields] OR "percutaneously" [All Fields] OR "percutanous" [All Fields]; Biliary Tree: "biliary tract" [MeSH Terms] OR ("biliary" [All Fields] AND "tract" [All Fields]) OR "biliary tract" [All Fields] OR ("biliary" [All Fields] AND "tree" [All Fields]) OR "biliary tree" [All Fields]; Cholelithiasis: "cholelithiasis" [MeSH Terms] OR "cholelithiasis" [All Fields] OR "cholelithiases" [All Fields]; Common Bile Duct: "common bile duct" [MeSH Terms] OR ("common" [All Fields] AND "bile" [All Fields] AND "duct" [All Fields]) OR "common bile duct" [All Fields]; Stones: "calculi" [MeSH Terms] OR "calculi" [All Fields] OR "stone" [All Fields] OR "stones" [All Fields] OR "stone's" [All Fields]; Intervention: "intervention's" [All Fields] OR "interventions" [All Fields] OR "interventive" [All Fields] OR "methods" [MeSH Terms] OR "methods" [All Fields] OR "intervention" [All Fields] OR "interventional" [All Fields].
- Scopus: percutaneous AND biliary tree OR cholelithiasis OR choledocholithiasis OR hepatolithiasis AND intervention

Inclusion and exclusion criteria

In this narrative literature review, we were interested in articles and studies that involved percutaneous interventions

for the management of stones from the biliary tree or CBD. Our inclusion criteria prioritized clinical trials, observational studies, case series and systematic reviews/meta-analyses that emphasize percutaneous interventions in adult patients (older than 18) regardless of sex. Articles had to provide a comprehensive analysis of outcomes, detailing the success, complications, patient experiences or long-term effects of these interventions. Publications had to be available in English. Conversely, we excluded case reports, letters to the editor, commentaries, and any studies lacking primary data or explicit outcomes. We also excluded unrelated types of stones (such as renal or urinary calculi), and any duplicate or outdated data, possibly setting a date range to ensure the most current techniques were considered. Initially, the date range was set to 5 years, but it was extended to 15 as the primary results were insufficient.

Percutaneous biliary stone management techniques

PTC

PTC is a radiological procedure facilitating both diagnostic and therapeutic avenues in biliary stone management. With its ability to introduce contrast directly into the biliary tree under fluoroscopic guidance, it offers superior visualization of the biliary anatomy, highlighting obstructions, leaks or anomalies [15].

The procedure commences with a needle puncture into the biliary tree, typically the right or left hepatic duct, based on the patient's anatomy and the location of the pathology [20]. Following successful puncture, contrast medium is injected, and real-time fluoroscopic images are captured, allowing for an in-depth analysis of the biliary system's structure and pathologies [29]. One of the core strengths of PTC lies in its capability to bridge to therapeutic interventions. If obstructions, such as stones, are identified, measures can be initiated for their retrieval or dissolution. Biliary drainage catheters can be inserted following the procedure to manage obstructions and prevent subsequent cholangitis, especially if there is an underlying infection or if the obstruction cannot be immediately addressed [30]. According to a meta-analysis by Zhao et al, percutaneous transhepatic biliary drainage demonstrates a therapeutic success rate comparable to that of endoscopic biliary

drainage, with no statistically significant difference between the 2 techniques [31]. In a separate retrospective cohort study, the technical success rate of PTC was reported to be 98.5% in non-transplanted livers and 88.8% in transplanted livers [32]. Reported complications of PTC include intraperitoneal bile leak, 30-day mortality, sepsis and duodenal perforation. PTC performed better in cholangitis and pancreatitis, with odds ratios (OR) of 0.48 (95% confidence interval [CI] 0.31-0.74) and 0.16 (95%CI 0.05-0.52) [33]. However, the incidence of bleeding and tube dislocation was higher for PTC drainage [33] (Table 1).

While PTC stands as a benchmark in biliary imaging, especially when noninvasive techniques prove inconclusive, it is imperative to acknowledge that the procedure is invasive. Hence, a thorough risk-benefit analysis, factoring in the patient's clinical status and potential complications, is essential before proceeding. The deployment of PTC becomes particularly crucial in challenging cases, such as complex stone diseases, ambiguous noninvasive imaging, or when combined diagnostic and therapeutic actions are required [34]. Typical examples are patients with unexplained jaundice, postsurgical suspected biliary leaks, or those with known stones requiring precise characterization before treatment [35]. Furthermore, PTC becomes especially salient in cases with failed endoscopic attempts, where direct percutaneous access offers an alternative route for stone retrieval or drainage [36]. Patients deemed to be at elevated risk for surgical interventions, perhaps due to comorbid conditions or advanced age, might also benefit from PTC as a less invasive solution [37].

To ensure a positive outcome with PTC, an accurate diagnosis and strategic preprocedural blueprinting are required. This entails utilizing an array of imaging modalities, including ultrasound for initial assessment, CT for detailed structural evaluation, and MRCP for a noninvasive perspective of the biliary tree's luminal anatomy. The composite data derived from these modalities ensures a robust patient evaluation, underpinning the decision to proceed with PTC and aiding in preprocedural planning.

Balloon dilation

Balloon angioplasty has emerged as a pivotal radiological intervention tailored for the management of biliary

Table 1 Comparative summary of percutaneous biliary stone management techniques: indications, success rates, durations, and complications

Method	Indications	Success rate	Avg. duration	Complications
PTC	Diagnostic/therapeutic for biliary stones	>98.5% compared to 88.8% in patients with liver transplant	Not specified	PTCD: 61.9%, infectious: 40.6%, non-infectious: 34.4%, 30-day mortality: 17.2%
Balloon dilation	Biliary strictures management	94.1% for stone clearance	65.8±5.3 min	Hemorrhage: lower than sphincterotomy Recurrent stones: 6.3%
PTCS	Direct biliary tree visualization and removal.	Nearly 100% with Spyglass DS	42.42±18.0 min	8%, Recurrence of calculi: 40%
Laser lithotripsy (via PTCS)	Intrahepatic cholelithiasis	Nearly 100% stone fragmentation	42.42±18.0 min	Significant cholangitis: 8%, Stone recurrence: 40%

PTC, percutaneous transhepatic cholangiography; PTCD, PTC drainage; PTCS, percutaneous transhepatic cholangioscopy

strictures [38]. It involves the catheter-guided introduction and inflation of a balloon within the narrowed segment of the biliary system, aiming to dilate the stricture and restore patency.

The procedure commences with precise catheter positioning, typically under fluoroscopic guidance, ensuring that the balloon spans the entirety of the stricture. Once suitably positioned, the balloon is progressively inflated, exerting radial force on the stricture. This dilation facilitates the improvement of bile flow, alleviates symptoms and, importantly, paves the way for further interventions, such as stone removal or stent placement, if deemed necessary. Initially, it is advisable to use a balloon size that is either slightly smaller or equal to the diameter of the bile duct near the stricture. This approach helps reduce the chances of causing a bile leak. If needed, balloons of a larger diameter can be used in later dilations, with sizes potentially 25% to 30% bigger than the estimated diameter of the duct being expanded. Generally, the diameters of balloons used vary between 4 and 12 mm. Strictures in the CBD in adults can typically be safely expanded to a size of 10-12 mm [39-41]. For particularly resistant stenoses, high pressure balloons or cutting balloons may also be used.

One of the intrinsic advantages of balloon cholangioplasty is its relatively conservative nature. In contrast to surgical or more invasive interventions, this procedure minimizes tissue trauma and can be repeated if required. Additionally, balloon cholangioplasty serves as an excellent adjunct to other endoscopic or percutaneous biliary interventions, enhancing their success rates by optimizing the luminal diameter. Balloon cholangioplasty is predominantly indicated in cases of biliary strictures, whether benign or malignant in nature. Common etiologies encompass postsurgical strictures, strictures secondary to chronic pancreatitis or cholangitis, or those following liver transplantation. It also gains precedence in scenarios where patients present with recurrent biliary stones [38], as an adequately dilated duct can significantly mitigate the risk of stone recurrence. The procedure is also immensely beneficial for patients who are not ideal surgical candidates, perhaps because of age or comorbidities, or those who have had unsuccessful previous interventions. Furthermore, in instances of failed endoscopic attempts to manage strictures, balloon cholangioplasty can provide an alternative route for effective dilation and subsequent management [38]. Successful balloon cholangioplasty requires meticulous preprocedural evaluation. Integral to this evaluation is imaging, which includes ultrasound as an initial tool, followed by detailed structural assessment through CT. MRCP stands out as a noninvasive modality, offering luminal visualization of the biliary tree and the precise delineation of strictures, aiding in procedural planning. This multifaceted diagnostic evaluation provides the clinician with a comprehensive insight, facilitating informed decision making and optimizing procedural outcomes (Fig. 1-3).

The success rates of balloon angioplasty for intrahepatic bile duct stone reach as high as 95.23% [11,41] of cases, with an average procedure duration of 65.8 ± 5.3 min. On average, patients stayed in the hospital for 10.7 ± 1.5 days. No instances

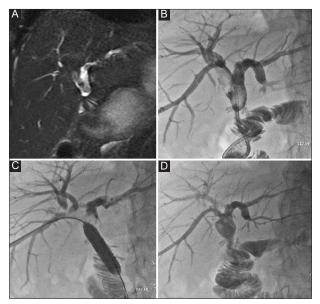


Figure 1 (A) Magnetic resonance cholangiopancreatography (MRCP), confirming the presence of biliary stones in a patient post biliodigestive anastomosis (BDS). Biliary duct dilation indicates the stenosis of the BDS as the underlying factor for stone formation. (B) Percutaneous transhepatic cholangiography and internal external drainage of the biliary system was performed as initial measure to prevent sepsis and to reduce further stone formation. (C) The patient returned 2 weeks later and most of the stones had been reabsorbed. The remainder were pushed via the BDS with a balloon catheter. Dilation of the stenosed BDS followed. (D) an external drainage catheter was left *in situ* for another 3 days in case hemobilia occurred post dilation. No stones are present in the biliary system

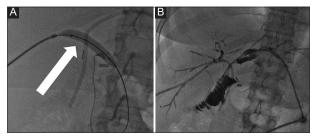


Figure 2 A 45-year-old female patient who developed benign biliary stenosis post laparoscopic cholecystectomy, with presence of stones. (A) Bilateral biliary drainage and dilation of the stenotic anastomosis with a high-pressure balloon (arrow). (B) Long-term drains with discoid end were left *in situ* for several months and the patient returned every 3 weeks for sequential dilation

of pancreatitis, gut issues, or perforations in the biliary duct were reported. Over a follow-up period of 2 years, there were no signs of reflux cholangitis or stone recurrence [11]. Comparing percutaneous transhepatic papillary balloon dilation (PTPBD) with ERCP, the PTPBD technique had a success rate of 99% compared to 98% for the ERCP technique (relative risk 1.02, 95%CI 0.91-1.08; P=0.12). Complication rates were lower for PTPBD at 4% (13 of 360) versus ERCP at 8% (13 out of 171) (relative risk 0.27, 95%CI 0.12-0.61; P<0.001). The PTPBD procedure took more time under

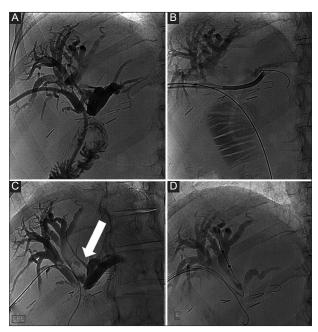


Figure 3 A 48-year-old female patient with benign stenosis post biliodigestive anastomosis. (A) Initial drainage because of multiple small stones. (B) Cholangioscopic inspection to assess the presence of stones that were not visible in the cholangiogram. (C) Three months later, a new cholangiogram revealed the presence of a large stone (arrow). (D) The stone was retrieved with an extraction balloon. Presence of a "buddy-wire" to maintain access to the biliary tree

fluoroscopy and resulted in greater radiation exposure, with an average difference of 28.7 min (95%CI 22.2-35.2) and 384.3 mGy (95%CI 296.5-472). When matched groups were compared using a propensity score analysis, PTPBD displayed a marginally better success rate and notably fewer complications [42] (Table 1).

Percutaneous transhepatic cholangioscopy (PTCS)

PTCS is a medical procedure that allows us to directly visualize the biliary tree using an endoscope [43,44]. The procedure is particularly useful when other imaging techniques are inconclusive. The direct visualization offered by PTCS enhances the accuracy of stone removal and reduces the risk of retained stones, a common complication of conventional

The intrahepatic biliary system can be reached through either the left or right hepatic duct. Typically, an 8-10-Fr biliary tube is initially inserted for drainage before proceeding with PTCS. In cases where cholangitis is a concern, it is essential to allow a period with sufficient biliary drainage before undertaking any further maneuvers. With the biliary tube in position, a cholangiogram is conducted through the tube to confirm the location. A 0.035-inch super stiff wire is then threaded through the biliary tube into the small bowel. Subsequently, the biliary tube is removed over the wire, and an 11-Fr peel-away or 12-Fr, 11-cm vascular sheath is inserted over the wire. A diagnostic

cholangiogram is performed to visualize the anatomy and identify the target lesion, such as a stone, massor stricture. The 11 or 12-Fr sheath is replaced with a modified 16-Fr, 45-cm opaque-tip sheath. This modified sheath allows the passage of equipment by cutting the flow valve at the proximal end. The wire is then placed through the sheath into the small bowel, establishing access. The cholangioscope is advanced over the wire, guided fluoroscopically beyond the target lesion, and into the small bowel. Diagnostic cholangioscopy is carried out while retracting the endoscope from the small bowel, providing a safer approach than moving the endoscope forward. Following the diagnostic run, we gain a better understanding of the clinical situation. In cases of choledocholithiasis, the appropriate technique for stone removal, such as using a basket or performing laser lithotripsy, or electrohydraulic lithotripsy (EHL) is selected. Using more advanced cholangioscopes, the success rate reached almost 100% [45]. On average, each procedure took 42.42±18.0 min. All cases with bile duct stones achieved clearance after 1-3 procedures, with a median of 2. Patients typically stayed in the hospital for 20 days, ranging from 14-30 days. There were no adverse events or deaths related to the procedure [45] (Table 1).

For stone removal with a basket, a multipurpose catheter is advanced over the Glidewire to a position just beyond the region of interest. The Glidewire is then removed, and a retrieval basket or clamshell biopsy forceps is advanced through the catheter. In the case of basket stone extraction, the stone is captured within the basket and retrieved through the access sheath.

Laser lithotripsy is employed for larger stones that cannot be retrieved with a basket. The laser fiber is usually placed through the working channel of the endoscope or advanced through the catheter for larger biliary systems. The laser fiber is marked for length, and direct visualization of the stone is crucial for precise targeting. Laser lithotripsy fragmented the target stones with a success rate of almost 100%, with firstattempt extraction successful in 92%. Lithotripsy had to be repeated in 17% of patients. Eight percent suffered a significant complication, which was cholangitis.

EHL serves as a widely used alternative method, best suited to address complex and resistant stones. EHL functions by generating high-voltage electrical sparks between electrodes located at the end of a bipolar probe. The electrical sparks generate swift fluid expansion along with high-pressure oscillating shock waves that break apart the biliary stones. The probe enters through the working channel of either a cholangioscope or a catheter, and is guided with ongoing endoscopic visualization to achieve precise placement while protecting the biliary epithelium. EHL stands out because it can break down large and tough stones that laser energy cannot effectively treat. Studies show that EHL produces high fragmentation rates when used with direct visualization, and it is considered a safe and efficient procedure. Shockwave transmission through a continuous fluid medium, such as saline, enables the method, and repeated pulses target the stone until it breaks down sufficiently for removal [46,47]. Complications occur rarely but potential risks include mucosal injury or transient cholangitis, which highlights why operator skill and real-time imaging are critical. When considering long-term outcomes, 40% experienced a recurrence of intrahepatic calculi, with these recurrences happening, on average, 31 months post-procedure (ranging from 3-84 months) [48]. At the conclusion of the procedure, the biliary system is allowed to drain through the access sheath. In the outpatient setting, the patient can be discharged the same day with sedation or admitted for extended recovery if transient cholangitis is suspected, with intravenous antibiotics and fluids administered as needed.

Discussion

The domain of biliary stone disease management has seen immense strides over recent decades, fuelled by both clinical exigencies and technological advancement. Percutaneous interventional radiology, as elaborated in this review, offers a nexus between minimally invasive yet efficacious interventions, making it an increasingly preferable choice for managing challenging biliary pathologies. As we scrutinize the current methods of percutaneous techniques, from the foundational PTC to the more refined PTCS, we witness an evolution that prioritizes patient safety, procedure efficacy, and clinical outcomes.

In addition to clinical efficacy, patient-reported outcomes deserve the spotlight. While we have data elucidating success rates, complication profiles and procedural metrics, a more holistic understanding of patient experiences—covering aspects such as pain, recovery times and quality of life post-intervention—can offer pivotal insights for informed clinical decisions.

A limitation of this review is the lack of detailed procedural sequencing in the included studies. Specifically, most studies did not report whether patients underwent PTPBD following failed ERCP, or whether multiple diagnostic or therapeutic interventions were attempted prior to percutaneous access. The absence of these data limits our ability to contextualize the role of PTPBD as a first-line versus second-line approach, and may impact the generalizability of our findings to clinical scenarios involving sequential or combined interventions.

A notable gap in the current model is the long-term durability of percutaneous interventions. While short-to-medium-term outcomes have been encouraging, it is essential to understand how these interventions fare in the long run, especially in preventing stone recurrence or managing chronic strictures.

Technological advances also hold the promise of refining current interventions. The development of more sophisticated endoscopes [45,49,50], better imaging modalities in real time during interventions, or even adjunct technologies such as robotics [51], could potentially redefine the precision and safety of these procedures. These advances, while exciting, need rigorous validation in clinical settings to understand their actual utility versus traditional techniques.

Moreover, given the myriads of interventions available, from endoscopic to percutaneous to surgical, there is an unmet need

to understand the best sequencing of these procedures. For instance, in cases where ERCP fails, should one immediately resort to PTC, or consider alternate endoscopic strategies? Decision algorithms, formulated on the basis of solid evidence, can guide clinicians through such conundrums.

Another frontier is the cost-effectiveness of these percutaneous strategies. As healthcare economics becomes increasingly pivotal, understanding the cost dynamics of these interventions, both direct and indirect (such as hospitalization days saved, or complications averted), can offer valuable insights for healthcare stakeholders.

In conclusion, while the current horizon of percutaneous treatments for biliary stones paints an optimistic picture, the onus is on the scientific community to continually refine, validate and innovate. Through a collaborative approach, bridging clinical acumen, patient insights and technological prowess, we can envisage a future where biliary stone management is not just clinically effective, but also patient-centric, safe, and economically viable.

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