Letter to the Editor

Surgical application of an implantable biliary access device in the treatment of refractory recurrent cholangiolithiasis

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Introduction

Cholelithiasis diseases, such as gallbladder stones, intrahepatic bile duct (IBD) stones, and extrahepatic bile duct stones, are significant causes of gastrointestinal hospitalization (1). Bile duct stones have long been one of the main problems treated with biliary surgery. Bile duct stones affect almost 20% of the general population and can cause serious and life-threatening conditions, such as cholangitis, pancreatitis, and sepsis, all of which can lead to death (2,3). The current primary clinical treatment for this illness is surgery to remove the lesions, clean the stones, correct strictures, recover the drainage, and prevent a recurrence. Two minimally invasive surgical approaches to treat common bile duct stones (CBDS) are endoscopic retrograde cholangiopancreatography (ERCP) plus endoscopic sphincterotomy (EST) with common bile duct exploration (CBDE) and stone extraction or laparoscopic common bile duct exploration (LCBDE) with stone removal (4-6). Currently, LCBDE with stone extraction is the preferred method for treating CBDS (7).

The recurrence of bile duct stones after stone extraction is a frequent challenge for clinicians. The recurrence of bile duct stones is defined as stones that are detected more than 6 months after the index function (8,9). Some studies have reported a recurrence rate of between 4% and 24%, and patients with recurrent bile duct stones are more susceptible to the reformation of subsequent stones (10,11). In one study, a patient underwent 13 ERCP + EST with CBDE procedures but still had reoccurring CBDS (12). Certain patients with multiple recurrences and a short recurrence interval are considered to have refractory recurrent bile duct stones. The surgical management of refractory recurrent bile duct stones is complex, and there are few professional guidelines on how to treat these cases.

Although patients with refractory recurrent bile duct stones also have abdominal adhesions after multiple abdominal surgeries, traditional open surgery is still effective and safe. However, traditional open surgery is also associated with considerable trauma to the patient. Recent literature indicates that open surgery has advantages over ERCP in clearing CBDS; however, there appears to be no difference in the clearance or morbidity or mortality (20% *vs.* 19% and 1% *vs.* 3%, respectively) between open surgery and LCBDE in clearing CBDS (13,14). The recurrence of bile duct stones after stone clearance is still a well-known continuation of open surgery, and the recurrence interval may be as long as 15 years (11). Open surgery requires drainage to obtain successful long-term outcomes without recurrent jaundice or cholangitis (10). T-tube drainage is usually carried out after the operation and retained for 4 to 8 weeks depending on the patient's recovery. The insertion

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of a T-tube allows for biliary system decompression, cholangiography management, and the prevention of postoperative bile leakage (15,16).

For patients with refractory and recurrent bile duct stones, the duration of T-tube placement is often prolonged clinically. When the T-tube is present, percutaneous treatment is a viable alternative that does not cause much trauma for patients. Even though a T-tube seems to solve the problem of reoperation, the long placement time has a series of adverse consequences. This paper explores a new type of implantable biliary access device (IBAD), clinically also known as implantable venous access ports or port, as an implant in the treatment of refractory recurrent bile duct stones. We hope to reduce the recurrence of stones, avoid more invasive surgery, and improve the quality of survival. IBAD implantation will provide a new method and concept in treating refractory recurrent bile duct stones. The procedure is reported below, and its safety and feasibility are discussed.

IBAD placement

An IBAD consists of a puncture base, catheter lock, and catheter. The IBAD puncture base is built from titanium and polyacetal resin, and the catheter is made of polyurethane. The base is topped with an automatic-healing silicone puncture septum that can be punctured up to 3,000 times or more. All of these materials are histocompatible and resistant to erosion and aging, allowing them to be safely placed in the bile duct for an extended period. In the procedure for this study, a fiberoptic choledochoscope was used to provide access to the duodenum. We placed a guidewire and implanted the IBAD catheter along the guidewire, confirming that the end of the catheter was in the duodenum. To further ensure that the IBAD was in the correct position, we chose to inject the contrast agent into the IBAD and obtain X-rays. No postoperative complications were observed in 4 patients treated with this procedure. No recurrence of bile duct stones was observed in the follow-up after the patients were discharged from the hospital.

The data of the whole treatment of case 1 are reported as an example of the treatment process. The patient was proposed for IBAD implantation 3 months after undergoing T-tube drainage (*Figure 1*). The patient was laid supine on the digital subtraction angiography (DSA) operating table. After removing the T-tube, a fiberoptic choledochoscope was routinely placed into the intra- and extrahepatic bile ducts to observe the presence of residual stones. A fiberoptic choledochoscope allowed access to the duodenum through the duodenal papilla. After confirming the entry into the duodenum by viewing the duodenal mucosal folds, a guidewire was placed, and then an IBAD catheter was placed along the guidewire (*Figure 2*). After confirming the end of the catheter was located in the duodenum, we withdrew the guidewire and the fiberoptic choledochoscope, and a contrast agent was injected to confirm the position of the catheter (*Figure 3*). The catheter was trimmed to retain the appropriate length. A small incision close to the T-tube sinus tract was selected. After a local anesthetic incision was made, a tunneling needle was used to penetrate the subcutaneous layer through the small incision, enter the T-tube sinus tract, and lead the IBAD catheter out of the small incision. The IBAD base was firmly attached and adequately secured, and the skin was sutured. The IBAD was implanted in the subcutaneous layer of the abdominal wall (*Figure 4*). The contrast agent was injected again through the IBAD base to confirm that the catheter was well positioned. Attention was paid to maintaining a strict aseptic operation throughout the procedure to prevent infection after IBAD implantation.

Routine postoperative observation was administered. Dressings for small abdominal incisions were changed every other day. If there was no implant infection and the T-tube sinus tract healed well without bile leakage, the stitches could be removed 7 days after surgery.

All procedures performed in this study were conducted in accordance with the Helsinki Declaration (as revised in 2013). This study protocol was reviewed and approved by the Ethics Committee of Nanchang University Infectious Disease Hospital (No. 2022-12). Written informed consent was obtained from the patients to publish this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

Case presentation

Case 1 was a 75-year-old female who underwent cholecystectomy and choledochotomy with T-tube drainage for gallbladder stones and CBD stones in 1983. Since then, the patient has undergone surgical treatment for recurrent intra- and extrahepatic bile duct stones with cholangitis on 6 occasions. The last treatment was in April 2020. Each time, the procedure was a choledochotomy and CBDE for stone removal and T-tube drainage after CBDE. In July 2020, the patient came to Nanchang University Infectious

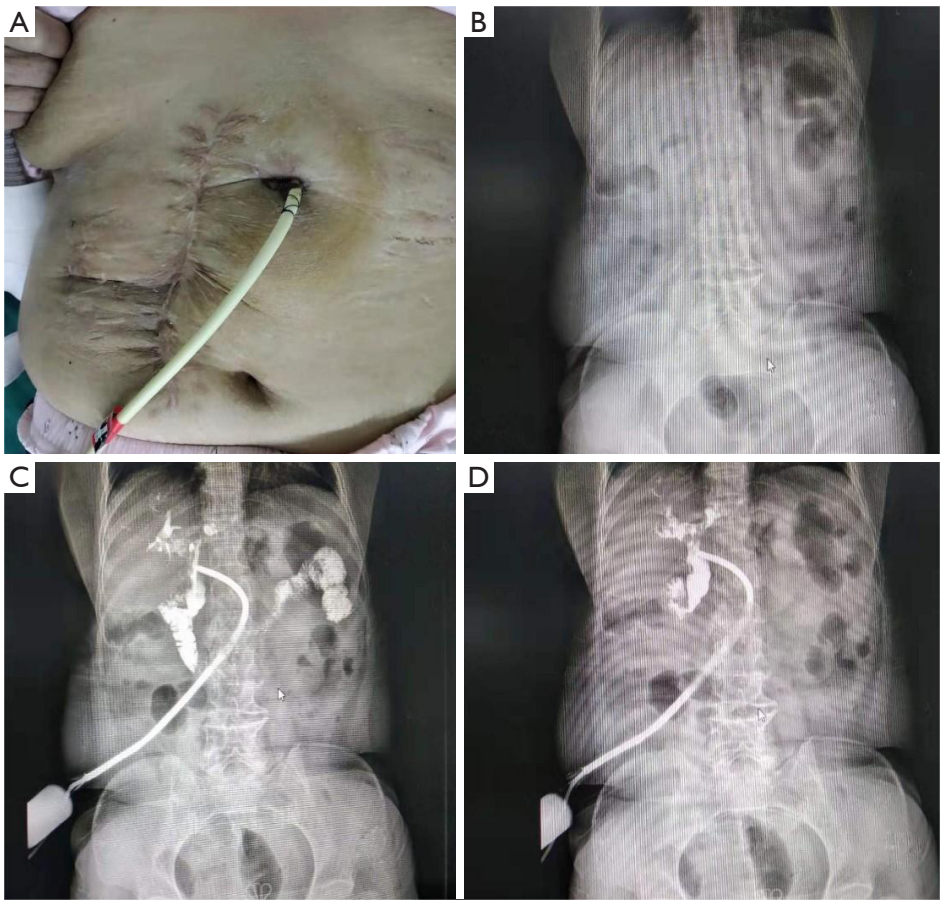

Figure 1 Preoperative imaging data of the patient. (A) Multiple previous surgical scars and T-tube can be seen in the abdomen. (B) The plain abdominal image. (C) The image of a common bile duct and duodenum after the injection of T-tube contrast agents. (D) The image of the intrahepatic bile duct. No stones were found.

Disease Hospital with a T-tube. Our department performed a fiberoptic cholangioscopy to confirm that no residual stones were found in the intra- and extrahepatic bile ducts. As the patient was 75 years old and had repeated bile duct stones, the IBAD was implanted to prevent a recurrence after seeking the patient's consent.

Case 2 was a 48-year-old male who underwent cholecystectomy and choledochotomy with T-tube drainage for gallbladder stones and CBD stones in 2010. In 2014, the patient had a recurrence of CBD stones and underwent a choledochotomy with T-tube drainage. In 2018, the patient had a recurrence of CBD stones with symptoms of cholangitis and underwent a choledochotomy with exploration to remove the stones and perform T-tube drainage after the operation. In July 2021, the patient was again admitted to the hospital with abdominal pain, fever, and jaundice and was diagnosed with recurrent CBD stones and cholangitis after a thorough examination. Choledochotomy with exploration for stone extraction and T-tube drainage after CBDE was performed. Three months after the operation, a fiberoptic choledochoscope was performed to remove the bile duct stones via the T-tube sinus tract, and an IBAD was implanted.

Case 3 was a 44-year-old male who underwent cholecystectomy and choledochotomy with exploration and T-tube drainage for gallbladder stones and CBD stones in 2009. In 2016, the CBD stones recurred, and he underwent a choledochotomy with exploration to extract the stones and perform T-tube drainage. In December 2021, the patient was again admitted with abdominal pain, fever, and jaundice and was diagnosed with CBD stones and cholangitis after complete examinations. Then, choledochotomy was performed with exploration to remove the stones and perform T-tube drainage after CBDE. An

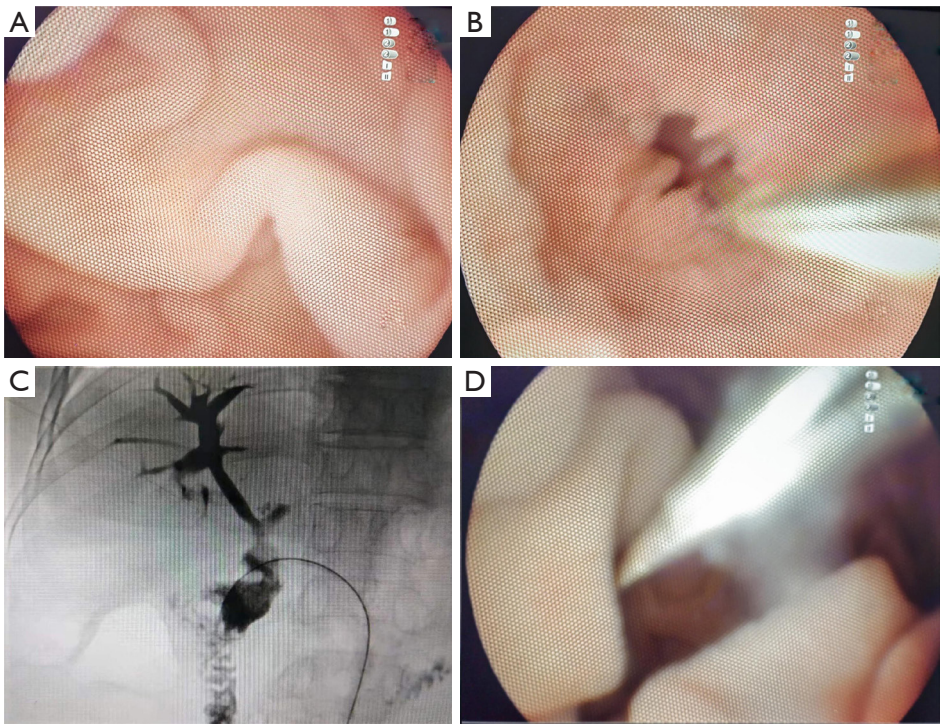

Figure 2 The view from the choledochoscope. (A) Choledochoscopy in the duodenum showing duodenal mucosal folds. (B) The guidewire inserted through the duodenal papilla. (C) The guidewire in the duodenum. (D) The guidewire in the duodenum.

IBAD was implanted 3 months after the operation.

Case 4 was a 51-year-old female who was admitted to Nanchang University Infectious Disease Hospital in June 2021 with recurrent right upper abdominal pain, fever, and jaundice, which she had experienced for more than 10 years. Through a thorough screening, the diagnosis of multiple stones in the intra- and extrahepatic bile ducts and cholangitis was made. Cholecystectomy, CBD exploration and lithotomy, and T-tube drainage were performed. The numerous IBD stones had bile duct segmental stenosis, and the stones could not be absolutely removed intraoperatively. Therefore, a T-tube was left in place. Three months after the operation, several fiberoptic choledochoscopies were performed through the T-tube sinus tract to remove the stones, but the stones could not be obliterated completely. The patient strongly requested that the T-tube be removed. To avoid future cholangitis attacks and the need for reoperation, an IBAD was implanted to preserve biliary access for future needs.

All patients had recurrent intra- and/or extrahepatic bile duct stones with or without cholangitis and continued to face a high recurrence rate of bile duct stones after surgical stone extraction.

Patients were followed up every 2 to 3 months after discharge to check for any foreign body reactions to the implant. In addition, the normalization of liver function indicators and the presence of stone recurrence on imaging were also closely monitored. The IBAD required no special care. One flush with 20 mL of saline through the IBAD base into the lumen every 2 to 3 months was sufficient. In case of recurrent bile duct stones in the future, we can dilate the sinus tract of the IBAD and perform a choledochoscopy to remove the stones.

On imaging, no recurrence of intra- or extrahepatic bile duct stones was observed in the 4 patients during the follow-up. Thus far, no abdominal pain, fever, jaundice, or liver function abnormalities have occurred in any of the patients. The long-term effect will be observed further.

Discussion

Bile duct stones might recur even after they have been removed completely. Unfortunately, patients with refractory recurrent bile duct stones always have several recurrences with a short recurrence interval. Patients in these situations face many operations and a substantial healthcare expenses.

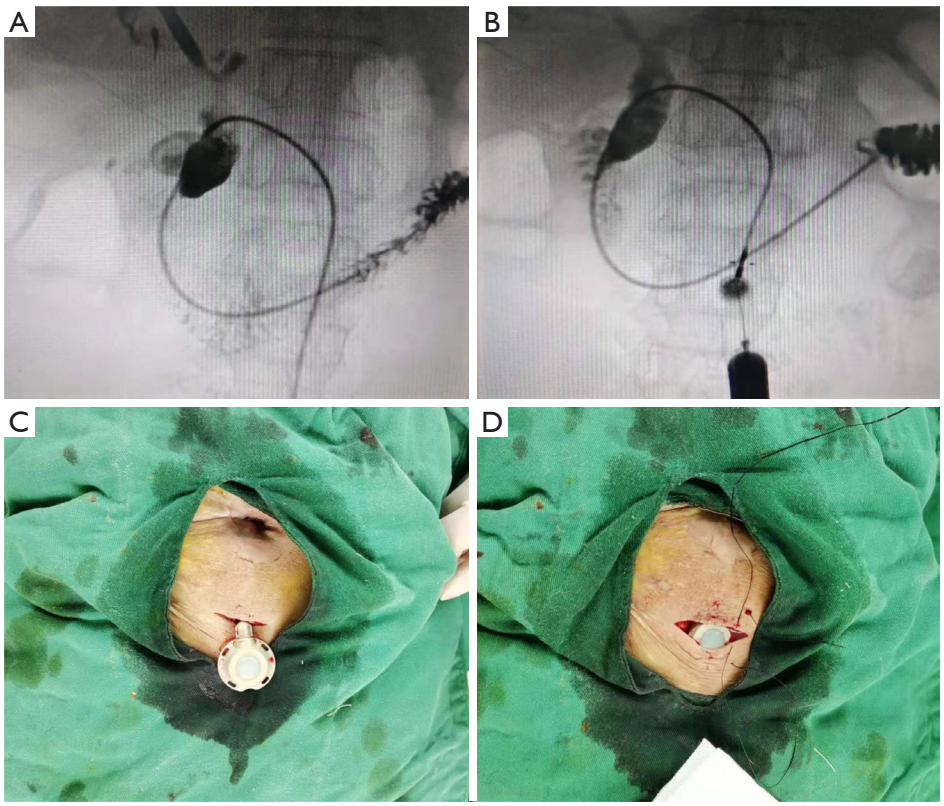

Figure 3 The view in DSA. (A) The IBAD catheter in the duodenum. (B) The IBAD base is connected, and the duodenum can be seen after the injection of the contrast agent through the IBAD base. (C) A small incision close to the T-tube sinus tract. (D) The IBAD implanted in the subcutaneous layer of the abdominal wall. DSA, digital subtraction angiography; IBAD, implantable biliary access device.

The best approach to treat recurring bile duct stones is still under debate. Options to clear recurrent bile duct stones include surgical treatment only (open or laparoscopic surgery) or endoscopic combined with surgical treatment (laparoscopic cholecystectomy with preoperative, intraoperative, or postoperative ERCP).

Difficult biliary stones, typically described as multiple (>3), large (>15 mm), barrel-shaped, intrahepatic duct, or impacted stones, cannot be successfully removed with routine ERCP in roughly 10% to 15% of patients (17-19). Furthermore, ERCP might irreversibly damage the sphincter of Oddi, which can cause duodenal juice reflux, leading to recurring episodes of cholangitis, choledocholithiasis, and even bile malignant tumors (20-22). ERCP can also result in several complications, including bleeding, pancreatitis, and perforation (23-26). In addition, the inability to insert the T-tube after ERCP dramatically limits its use in patients with bile duct stones.

With the emergence of laparoscopy, LCBDE as a minimally invasive alternative to ERCP has enabled shorter hospital stays and cheaper expenditures (27-30). LCBDE can be performed with the transcystic technique or CBD resection associated with primary duct closure or T-tube drainage. T-tube drainage for CBD has become a widely accepted type of open surgery. However, a history of abdominal biliary surgery is a possible contraindication to LCBDE. Abdominal adhesions are unavoidable after surgery, and the incidence of adhesions is between 67% and 93% (31).

Two or more previous surgeries and a history of biliary surgery and laparotomy, were found to promote the development of postoperative adhesion (32). In general, it is impossible to estimate the range and extent of postoperative adhesion after abdominal surgery. Patients with refractory recurrent bile duct stones have almost all undergone 1 or more abdominal biliary tract surgeries, resulting in a series of complications due to abdominal adhesion. First, any organs or tissues adherent to the abdominal wall may be damaged during the insertion of the Veress needle or the first trocar. Second, adhesiolysis may be related to

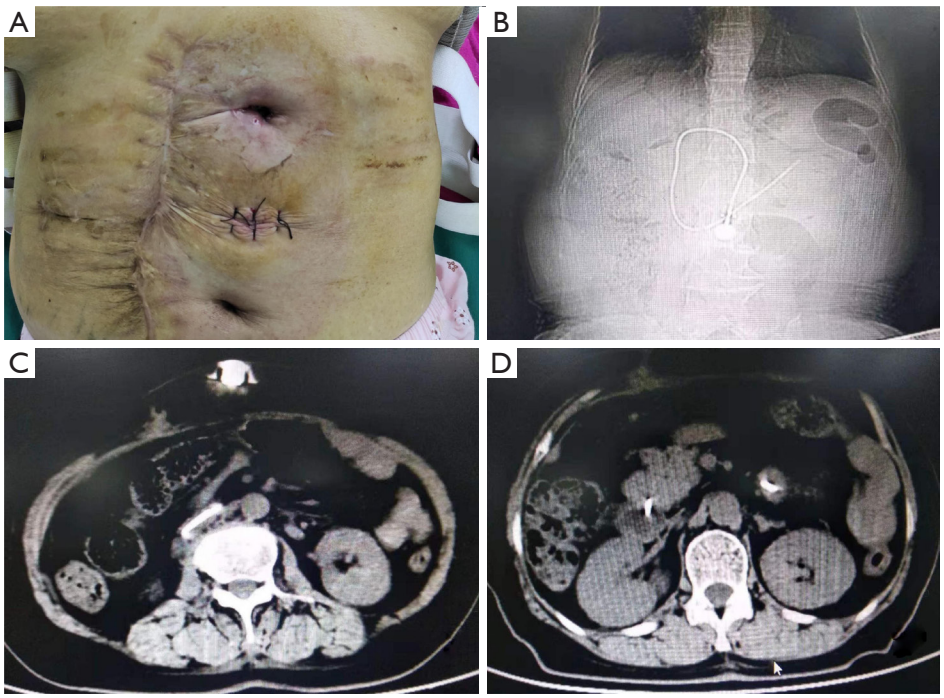

Figure 4 Placement of the IBAD. (A) The implantation of the IBAD was completed, the T-tube was removed, and the small incision was sutured. (B) The X-ray view after IBAD implantation. (C,D) After IBAD implantation, a CT scan showed that the IBAD base was located subcutaneously in the abdominal wall, and the IBAD catheter was located in the duodenum. IBAD, implantable biliary access device; CT, computed tomography.

intraoperative complications, such as bleeding and damage to biliary structures. Finally, extensive adhesions may make it more difficult to expose the CBD, which may increase the danger of conversion to open surgery. A laparoscopic technique for bile duct reoperation is not suggested due to the intricacy of postoperative adhesions.

Open surgery with CBD exploration and T-tube drainage is routinely performed for patients with refractory recurrent bile duct stones. However, some adverse factors, such as significant trauma and slow recovery, may occur. T-tube cholangiography after surgery to confirm the clearance of bile duct stones is a standard procedure before T-tube removal. One of the motivations for T-tube drainage is to decompress the CBD when the duodenal papilla sphincter is under pressure. The T-tube can be inserted to support the cut section in the CBD, preventing bile build-up owing to transient swelling and bile leakage. Another rationale is to allow leftover stones to be extracted via the T-tube tract (33,34). This procedure is routinely used if a choledochoscope is not accessible and bile duct stone removal cannot be confirmed. T-tube retention would allow for stone re-extraction through the sinus, avoiding the need for ERCP, EST, or even reoperation.

Before extraction, a contrast agent can be injected into the T-tube, and an X-ray can be taken to see if any stones remain. Once it is determined that there are no residual stones, the T-tube will be removed (34,35). The formation of the T-tube sinus tract is a prerequisite for T-tube extubation, which takes no less than 3 weeks. As a result, depending on the patients' symptoms after T-tube clamping, the T-tube can be kept in place for 4 to 8 weeks. If the patient develops gastric distention or pain after T-tube clamping, the T-tube will be reopened for 1 to 2 days before the next clamping. A T-tube cholangiography will be performed without further clamping if the symptoms persist for more than 8 weeks after the operation. However, once any obstructed bile duct stones are identified, a choledochoscopy is required to diagnose and remove the stones.

Surgeons use a long-term indwelling T-tube to treat patients with refractory recurrent bile duct stones to avoid reoperation. However, other methods or devices are needed due to the potential complications, possible extended hospital stays, increased costs of care associated with T-tube,

and decreased quality of life. To solve this urgent problem, we have explored the use of the IBAD, a new type of IBAD for treating refractory recurrent bile duct stones.

Multiple variables are linked to the production of biliary stones. According to one study, genetic, shared, and unique environmental influences accounted for 25%, 13%, and 62%, respectively, of cholelithiasis (36). Several gallstone-predisposing gene mutations, including alterations in the *ABCB4* and *ABCG5/G8* genes, have been described as hereditary factors (37,38). Cholestasis (impaired bile flow and/or delayed bile emptying) is a major nongenetic component in bile duct stone etiology. Cholestasis has been linked to CBD dilation and angulation, periampullary diverticula, biliary strictures, papillary stenosis, and cholecystectomy (9). Bile duct stones can also be categorized as primary and secondary bile duct stones based on their origin (39). Stones expelled from the gallbladder are the most common cause of subsequent bile duct stones (40). Cholestasis and bacterial infections are hypothesized to be linked to primary bile duct stones generated by structural and functional abnormalities of the duodenal papilla (41). The prevalence of minimally invasive surgery has increased the rate of secondary bile duct stones' recurrence, possibly due to the dysfunction of the duodenal papilla caused by surgical injury (42,43). Despite the type of surgery performed, there is a somewhat significant incidence of postoperative recurrence for primary bile duct stones (43-46). Structural and functional abnormalities of the duodenal papilla and migration of duodenal bacteria into the bile duct may cause cholestasis in CBD (47). As a result, duodenal papilla dysfunction is critical for primary bile duct stone development. Although surgical therapy can clear bile duct stones completely, the source of bile duct stones is rarely addressed (48). Thus, bile duct stones invariably recur after surgery.

Similarly to a T-tube, an IBAD catheter can dilate the biliary tract and play a supporting role in duodenal papilla, preventing the build-up of bile and the recurrence of bile duct stones. In addition, contrast agents (49) can be injected into the IBAD, and an X-ray can be used to confirm the presence or absence of residual stones. Most importantly, an IBAD can permanently preserve the biliary passage so that the stone can be removed through this passage using a choledochoscope once the recurrence of the bile duct stones is found. As with the procedure with a T-tube, bile duct stones can be removed safely and efficiently during indwelling, and surgical operation is avoided.

Concurrently, the IBAD also has some advantages that a T-tube cannot achieve. First, the IBAD can remain in the patient's body for a long time, permanently preserving the biliary access. Second, the IBAD can be wholly implanted into patients, which is convenient for patients and not easily found by others so that the psychological burden of patients will not increase. Third, the IBAD will not affect the patient's daily activities, significantly improving the patient's quality of life. Fourth, a fully implanted IBAD can reduce the risk of infection in patients. Fifth, the care for IBAD is relatively simple and does not need to consume too much time.

To summarize, in selected cases, we propose to manage refractory recurrent cholangiolithiasis by implanting a new device, the IBAD. This strategy preserves biliary access for patients with refractory recurrent cholangiolithiasis and allows for stone extraction without incision if bile duct stones recur in the future. The potential advantages of this new strategy include the significant improvement in patient quality of life, its simple care, few complications, low cost, and its ability to reduce the recurrence of postoperative bile duct stones. In addition, it is technically safe and feasible, has great applications, and can be performed in most hospitals. As the number of cases continues to grow, more studies could be conducted to quantify the benefit of using the IBAD.

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Footnote

Conflicts of Interest: All the authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-22-922/coif). The authors report that this work was supported by the Nanchang Science and Technology Support Plan Program (No. HONGKEZI2021129). The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were conducted in accordance with the Helsinki Declaration (as revised in 2013). This study protocol was reviewed and approved by the Ethics

Committee of Nanchang University Infectious Disease Hospital (No. 2022-12). Written informed consent was obtained from the patients to publish this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

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