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Advances in Spyglass DS treatment of intra—and extrahepatic bile duct stones

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Abstract: *With the rapid development of endoscopic technology in recent years, Spy Glass choledochoscope system has been widely used in the diagnosis and treatment of hepatobiliary and pancreatic diseases by virtue of its good maneuverability, high-quality imaging effect, and ultra-fine working channel. This article summarizes and analyzes the current status of the new generation Spyglass DS choledochoscope system in intra- and extra-hepatic bile duct stones by reviewing the relevant literature. The results indicate that Spyglass DS has important clinical value in the treatment of intra- and extrahepatic bile duct stone disease, which is worthy of clinical promotion, but its indications and contraindications need to be strictly mastered.*

Keywords: *Spyglass DS, common bile duct stone, intrahepatic bile duct stones, summarize*

1. Introduction

In recent years, although the proportion of intra- and extra-hepatic bile duct stone disease in gallstone disease has decreased, its absolute number has not been significantly reduced, and it is still a serious threat to the life and health of the majority of patients. Depending on the distribution of its stones, its treatment varies. Intrahepatic bile duct stones are mainly treated individually under the guidance of the 20-word treatment guideline of "removing the lesion, eliminating the stones, correcting the stenosis, smoothing the drainage, and preventing the recurrence of the stone"[1]. Due to the complexity of the cause of the disease and the high rate of recurrence, traditional surgery has always been the most effective way of its treatment[2, 3]. Hepatic resection is the most effective treatment for intrahepatic bile duct stones[4-6]; Choledochotomy and T-tube drainage are seldom used alone in clinical practice due to the difficulty of removing stones above the level III branch bile ducts and the inability to completely remove diseased liver tissues and bile ducts, as well as the high rate of stone retention, easy recurrence, and recurrent biliary infections when used alone, and are usually used in conjunction with partial hepatectomy, or in patients who need to immediately relieve biliary obstruction and control infections[7]. In addition, intrahepatic choledocholithiasis is often combined with bile duct stenosis, and after hepatectomy, most of the hepatic segmental surfaces are class II or III bile ducts, which require cholangioplasty and bile-intestinal anastomosis[8-10]. Although surgery is the treatment of choice for intrahepatic bile duct stones, the diagnostic question for patients with early restrictive hepatic bile duct stones is hepatic resection performed early? Is surgery too traumatic? What is the treatment strategy? There is still controversy[5]. In addition, the problem of diagnosing and treating patients with complex intrahepatic bile ducts who cannot tolerate surgery remains urgent.

In recent years, with the rapid development of minimally invasive surgery, laparoscopic choledochotomy for stone extraction has been used as the main means for hepatobiliary surgeons to deal with choledochal stones[11]. Clinically, according to the thickness of the patient's common bile duct, the size and number of stones, etc., the choice of the common bile duct one-stage suture or leave a T-tube drainage[12]. Endoscopic retrograde cholangiopancreatography (ERCP) combined with endoscopic sphincterotomy (EST) and endoscopic papillary balloon dilatation (EPBD) is the most commonly used method of stone extraction in patients with a thin diameter of the choledochal duct, more underlying diseases, and older age who are not able to tolerate surgical procedures[13-15]. Clinically, ERCP intubation often fails because of abnormal duodenal papilla morphology, location, distal bile duct anatomy, stone impaction, and papillary mucosal edema.

In recent years, with the continuous innovation of endoscopic medical equipment, endoscopy plays

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an increasingly important role in the treatment of intra- and extrahepatic bile duct stones, and the new generation of Spyglass DS plays an important role in the hepatobiliary and pancreatic system with its excellent performance. In this article, we will review the diagnosis and treatment of intra- and extra-hepatic bile duct stones by Spyglass DS.

2. Spyglass DS Cholangioscope System Overview

In 2007, Chen et al[16] reported for the first time the feasibility study of Spyglass DS in the diagnosis and treatment of biliary diseases, so that it began to exert its unique advantages in the clinic[17]; however, the first-generation Spyglass DS system was limited in clinical application due to the problems of easy damage of optical fibers, poor quality of images, and limited maneuverability. The introduction of the second-generation Spyglass DS overcomes many of the limitations and shortcomings of previous choledochoscopes; it adopts digital signal imaging, improves the light source design, enlarges the diameter of the working channel with 4 deflector steering and a dedicated flushing channel, provides a wider and clearer field of view, and substantially optimizes its performance, and now plays a very important role in the diagnosis and treatment of hepatobiliary and pancreatic diseases[18-20].

3. Spyglass DS for Choledochal Stones

Traditional ERCP combined with EST lithotripsy and balloon dilatation lithotripsy have been very well established in choledochal stones, but there are still a number of limitations in clinical practice due to its inability to visualize the biliary system and to deal with large stones. The second generation Spyglass DS cholangioscopy system is equipped with a more advanced image processing system than the first generation Spyglass, which was introduced to overcome the disadvantages of traditional ERCP such as the inability to visualize the lesion site and the need to withstand more radiation. In Korea, Prof. Jungha Shin[21] et al. managed ERCP with Spyglass DS for choledochal stones refractory to ERCP alone and achieved very good results; meanwhile, Prof. Wiriyaporn Ridtiti et al. analyzed 50 matched pairs of patients with choledochal stones by propensity-matched scores to compare the efficacy and safety with conventional ERCP and confirmed that Spyglass DS showed no difference in stone clearance compared to conventional endoscopic retrograde cholangiopancreatography[22] and another study showed that undergoing Spyglass treatment reduces radiation exposure in patients[23]. Laparoscopic common bile duct exploration (LCBDE) was the method of choice for the treatment of huge stones in the common bile duct in the past, and with the introduction of the second-generation Spyglass DS, a number of centers in China have dealt with huge stones of the common bile duct by laser lithotripsy using the Spyglass DS choledochoscopy system under direct vision and achieved good results[24, 25], and the clinical efficacy and safety have been recognized in 90.6% of cases. Li et al. compared the effectiveness of LCBDE and Spyglass DS-guided laser lithotripsy and related complications in 157 cases of giant choledocholithiasis, and found that the first stone removal rate of Spyglass DS-guided laser lithotripsy was 83.3%, while that of LCBDE was 96.2%; the efficiency of Spyglass DS-guided laser lithotripsy for the first time was lower than that of LCBDE, while the total success rate of final stone removal was 92.3% and 96.2%, respectively, and there was no difference in statistical results[19]. With the advantage of its working tube, Paola Fugazzola et al. used the Spyglass DS to remove choledochal stones through the cystic duct during cholecystectomy in patients with gallbladder stones combined with choledocholithiasis, with good intraoperative and postoperative results[20]. Based on the national and international studies, the use of the Spyglass DS in choledochal calculi has been preliminarily proven to be safe and effective; in patients who cannot tolerate surgery or who fail ERCP alone, it can be combined with Spyglass DS.

Theoretically, Spyglass DS is superior to ERCP for diagnosing bile duct strictures and treating bile duct stones. A single-center, large cohort study retrospectively analyzed 183 surgical patients with indeterminate bile duct strictures (n = 93) and bile duct stones (n = 90) who underwent diagnostic and therapeutic treatment with Spyglass DS; all patients with bile duct strictures (93/93) underwent successful Visualization was successful in 95.7% (89/93) of patients with direct biopsy; stones were successfully visualized in 98.9% (89/90) of patients, and stone removal was completed in 92.2% (83/90) of patients[26]. Singaporean scholars used Spyglass DS to treat patients with clinically diagnosed difficult choledocholithiasis and achieved very good results, with a stone clearance rate of 92.9%; clamp biopsy of patients with biliary stenosis was performed, with a sensitivity and specificity of 81.8% and 100.0%, respectively[27]. Therefore, in patients with choledocholithiasis combined with biliary strictures, the Spyglass DS can be used to guide lithotripsy, stone extraction and tissue biopsy in patients with suspected malignant strictures under direct vision.

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4. Spyglass for intrahepatic bile duct stones

Currently, Spyglass DS is mainly used in patients with choledochal stone disease[28] and its use in patients with intrahepatic bile duct stones has been relatively poorly studied. Since intrahepatic bile ducts tend to be thin in diameter, it is difficult to treat intrahepatic bile duct stones with conventional ERCP. ERCP combined with Spy Glass DS brings a new hope for endoscopic treatment of intrahepatic bile duct stones because of the clear imaging in the lumen and the flexible operation, which enables lithotripsy and stone extraction under direct vision[29]. Hirofumi Harima reported a case of a left intrahepatic bile duct stone that was successfully extracted by Spyglass DS with laser lithotripsy after pancreaticoduodenectomy[30]. Recently, experts in China also reported a case of an intrahepatic bile duct stone combined with biliary stricture that was difficult to be extracted with conventional ERCP, and then successfully extracted after biliary dilatation under the direct visualization of Spyglass DS[31]. In recent years, some research centers in China have used the Spyglass DS system to treat intrahepatic bile duct stones and achieved some efficacy[32]. However, grade III or higher intrahepatic bile duct stones were not included; our previous study also achieved very good efficacy in the treatment of early stage limited intrahepatic bile duct stones by ERCP in combination with Spyglass DS, with the technical success rate and clinical success rate being 100% and 91.7%[33]. Another international multicenter study using Spyglass DS for the treatment of complex hepatic bile duct stones that have failed conventional ERCP lithotripsy and are difficult to manage by preoperative evaluation showed a final stone clearance rate of 87.2% and a one-time stone clearance rate of 80.1%[34]. This further confirms the efficacy and safety of the Spyglass DS for the treatment of intrahepatic bile duct stones.

It is worth noting that hepatic resection for hepatic bile duct stones is aimed at removing the diseased liver[35]. The indications include: multiple stones that are difficult to remove in the liver lobe and liver segment, bile duct stenosis and/or cystic dilatation that are difficult to correct, hepatic parenchymal atrophy fibrosis, and intrahepatic cholangiocarcinoma; Despite the advantages of endoscopic therapy, such as rapid recovery and maximum possible preservation of liver tissue, it is still necessary to be vigilant in the diagnosis and monitoring of cholangiocarcinoma, because studies have shown that stone removal in patients with bile duct stricture will increase the risk of cholangiocarcinoma[36]. Therefore, endoscopic treatment should be chosen with caution in patients with intrahepatic bile duct stones who are highly suspected of having biliary malignancy in combination with endoscopic treatment.

Although Spyglass DS provides a new treatment option for patients with intrahepatic bile duct stones, there are relatively few studies on its application to intrahepatic bile duct stones, and they are basically retrospective studies with a small number of samples. For patients with many stones and complex distribution, endoscopic treatment often takes a long time, and some patients may not be able to remove the stones at one time, and need to be removed twice; in addition, for patients with a diameter of less than 3 mm in the branch bile ducts of grade II or above, treatment with Spyglass DS often takes a long time and the one-time removal of stones may be small, or even failed. Therefore, the indications and contraindications of Spyglass DS should be strictly controlled according to the specific conditions of the patients.

5. Spyglass for the treatment of anatomically altered stones in the biliary system

The introduction of the Spyglass DS system has improved the diagnostic and therapeutic efficiency of many patients with multiple surgeries resulting in anatomical changes that pose a challenge in the management of biliary system stones. In a domestic study investigating biliary strictures after liver transplantation and the therapeutic role of Spyglass in difficult strictures, it was found that 80% (12/15) of patients with non-anastomostic stricture (NAS) after liver transplantation were combined with intrahepatic bile duct stones, and that strictures difficult to pass by conventional ERCP, which can be treated by Spyglass, could assist in improving the efficiency of their treatment[37]. Some patients after liver transplantation often need to be treated with bile-intestinal anastomosis and combined liquid electrode lithotripsy because of severe bile duct scarring stenosis, unsatisfactory results of repeated multiple ERCP treatments, and the combination of stone kernel, etc. The Spyglass direct visualization system can intuitively and objectively display the morphological characteristics of the stenosis segment and the structural changes within the biliary tract, and it can also assist the passage of guidewires through the stenosis segment of the bile duct, precisely guiding the clinical treatment protocols Decision-making[38]. Percutaneous transhepatic cholangioscopy (PTCS) is commonly used to diagnose and treat biliary diseases in patients with failed endoscopic retrograde cholangiopancreatography, especially in patients with surgically altered anatomy. Overseas scholars evaluated the efficacy and safety of Spyglass

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DS-assisted PTCS in the treatment of bile duct stones in patients with surgically altered anatomical structures, and the results showed that eight cases of bile duct stones were cleared, which initially proved that Spyglass DS-assisted PTCS can be used for the diagnosis and treatment of biliary diseases in patients with surgically altered anatomical structures[39]. Theoretically, Spyglass DS can play a greater role in the treatment of patients with anatomically altered biliary stones because of its wider and clearer field of view, excellent maneuverability, and its ability to be used in conjunction with laparoscopy and PTCS. However, there are relatively few studies on the application of Spyglass DS in patients with anatomically altered intra- and extra-hepatic gallstones, and some of the study subjects are small in number, so more prospective, multicenter studies are needed to further explore the value of its application.

6. Complications related to Spyglass DS

The clinical complications caused by Spyglass are generally consistent with conventional ERCP. Foreign studies using the Spyglass system through the database analysis of adverse events, from 1743 reports found 62 (3.5%) patient-related events, the most common is bleeding, followed by perforation, infection and pancreatitis, etc[40]. Turowski et al. showed that the incidence of postoperative complications after Spyglass was 13.2%, with cholangitis being the most common, and that prophylactic antibiotics significantly reduced the incidence of cholangitis[41]. Arne Bokemeye et al. showed that 16% of the patients had complications in their study, which mainly consisted of cholangitis and pancreatitis[42]. Most studies have shown that postoperative complications after Spyglass operation are mainly dominated by cholangitis and pancreatitis; therefore, the risk factors for related complications should be assessed clinically in the light of the patient's condition, and necessary measures should be taken to minimize the incidence of complications.

7. Summary and outlook

The Spyglass DS system has proven to be safe and effective in the treatment of intra- and extra-hepatic bile duct stone disease, with advantages over traditional ERCP, especially in cases of complex choledocholithiasis combined with biliary stenosis. Currently, there is a lack of bulk case studies on Spyglass DS for the treatment of intrahepatic choledocholithiasis, especially stones in branches above the tertiary bile duct. Although, the Spyglass DS system has advantages in the diagnosis and treatment of hepatobiliary and pancreatic diseases, the Spyglass DS choledochoscope is relatively more expensive. It is expected that the new generation of choledochoscopes will be more refined and perfected with the continued efforts of the researchers, and it is believed that the Spyglass DS system will be more widely used in the clinic in the future.

Authors' Contribution Statement

Liu Bo was responsible for searching the literature and drafting the article; Kuang Zhijun was responsible for the format of the paper, the structure of the article, and the verification of important arguments in the manuscript; Shu Peng and He Ping were responsible for the writing instruction and reviewing and proofreading of the article.

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