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Digital single-operator cholangioscopy: a useful tool for selective guidewire placements across complex biliary strictures

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Abstract

Background Treatment of biliary strictures is challenging. Digital single-operator cholangioscopes (SOCs) equipped with an improved imaging quality, were recently introduced and may be useful for selective guidewire placement in difficult biliary strictures.

Methods A total of 167 digital SOC procedures performed between 2015 and 2018 were retrospectively analyzed for successful guidewire placements across biliary strictures. Only cases with previous failed conventional guidewire placement approaches were included.

Results In total, 30 examinations with a digital SOC-assisted guidewire placement across biliary strictures, performed in 23 patients, were identified. In 52% of all patients, the stricture was benign with post-liver-transplant strictures (75%) as the most frequent finding; in 48% of all patients the stricture was malignant with cholangiocellular carcinoma as the most frequent type (64%). Guidewire placement was successful in 21 of 30 procedures (70%). According to a subgroup analysis, digital SOC-assisted guidewire placements were significantly more successful in patients with benign strictures than those in patients with malignant strictures (88.2% vs. 46.2%; $p=0.02$). Furthermore, the technical success rate tended to be increased in cases of initial examinations (78.3%) than in patients with repeated examinations (42.9%; $p=0.15$). Adverse events, such as post-interventional pancreatitis or cholangitis as well as severe bleeding occurred in 16.7% of all examinations.

Conclusions Digital SOC-assisted guidewire placements have high technical success rates, especially in benign biliary strictures. This technique can help to avoid more invasive procedures such as percutaneous transhepatic or endoscopic ultrasound-guided biliary drainage.

Keywords Biliary strictures · Cholangioscopy · Digital single-operator cholangioscopy · Guidewire placement and SpyGlass DS

Biliary strictures are common in gastrointestinal clinical practice [1]. Most biliary strictures are of malignant etiology with cholangiocellular carcinoma as a frequent cause; however, up to 30% of biliary strictures are benign, including those in primary sclerosing cholangitis and post-liver-transplant settings [1, 2]. Remarkably, up to 40% of all patients after liver transplantation develop benign biliary strictures [3–5].

Routinely, biliary tract obstruction is treated with endoscopic retrograde cholangiography (ERC); however, treatment can be challenging, and success rates in treating biliary strictures are still unsatisfactory [1, 6, 7]. A frequent cause of endoscopic failure is the inability to pass a guidewire through the biliary stricture to allow subsequent balloon dilation therapy and endoprosthesis implantation [7, 8].

Cholangioscopy might help to selectively place a guidewire through a biliary stricture under direct visual guidance [9, 10]. Since 2015, the first digital single-operator cholangioscope (SOC; SpyGlass™ DS System, Boston Scientific, Marlborough, USA) has been available [11]. Compared to the previous fiber-optic Spyglass System, this new SOC provides digital imaging with an up to four-fold higher resolution [11–15]. Furthermore, digital SOCs have a 60% wider

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field of view (120°) and a tapered tip that might support an easier scope-insertion into the biliary tract [11, 15].

To date, only a few small studies and case series have evaluated the efficacy of digital SOCs for guidewire placement across biliary strictures [16–21]. None of these studies included more than ten patients [16–21]. With the exception of one case-series with five patients and one case report with a single patient [20, 21], the treatment of biliary strictures using digital SOC-assisted guidewire placement was only part of a subgroup analysis of the whole study population and the inclusion criteria were heterogeneous and not defined in detail [16–19].

Therefore, the aim of this study was to evaluate the efficacy of digital SOCs to achieve guidewire placement across biliary strictures in cases in which conventional endoscopic methods previously failed to perform a guidewire placement.

Materials and methods

Study design

This retrospective study was performed at the Department of Medicine B for Gastroenterology and Hepatology of the University Hospital Muenster, Germany. Data were collected from the former Department of Transplant Medicine and the former Department of Medicine B, which were merged into the Department of Medicine B for Gastroenterology and Hepatology in October 2017. The study was approved by the Ethics Board of the Westphalian Wilhelms-University of Muenster and the Medical Council of Westphalia-Lippe, Germany and conforms to the ethical guidelines of the 1975 Declaration of Helsinki. As approved by the Ethics Board, informed patient consent was not required for this study because of its retrospective design. Data from all patients ≥ 18 years of age who underwent a digital SOC with the SpyGlass DS System (Boston Scientific, Marlborough, USA) between August 2015 and March 2018 were retrieved from the clinical data system.

Inclusion criteria

Patients with biliary strictures were routinely treated with primary endoscopic management using conventional methods to place a guidewire across a biliary stricture to perform subsequent balloon dilation and/or an endoprosthesis implantation. These conventional methods included the performance of several attempts to pass the stricture using standard guidewires and/or the use of different alternative guidewires. In treatment failures with non-traversable strictures, the investigator used digital SOCs in order to achieve a correct guidewire placement across the biliary strictures under visual guidance. Only these cases were included in the final data set. The final diagnosis concerning the entity of the strictures was based on a detailed evaluation of all available data (imaging findings, endoscopic findings and/or histological assessment of biopsies, or surgical resection specimen).

Technical aspects of digital single-operator cholangioscopy (Spyglass DS)

All examinations were performed by highly experienced endoscopists according to the general accepted guidelines using an endoscopy retrograde cholangiography (ERC) case volume of greater than 200/year [22, 23]. All patients received prophylactic antibiotic treatment. CO_2 insufflation was used during the examination. An endoscopic papillotomy was performed or had been previously performed prior to the digital SOC procedure. The cholangioscope (digital SOC; Boston Scientific, Marlborough, USA) was inserted with guidewire assistance into the biliary duct. After identification of the stricture, a guidewire was placed across the biliary stricture under visual guidance. The therapeutic success of this intervention was defined as the successful placement of the guidewire across the biliary stricture allowing subsequent balloon dilation and/or endoprosthesis placement.

Safety analysis

Complications following SOC were documented as follows: (i) a post-interventional pancreatitis was diagnosed if the onset of abdominal pain was accompanied by a three-fold increase in the serum lipase levels within 48 h of the examination; (ii) a post-interventional cholangitis was defined as the onset of fever and newly or significantly higher inflammatory markers requiring antibiotics within 3 days of the examination; and (iii) severe bleeding was diagnosed if a severe bleeding during intervention was observed, requiring immediate endoscopic therapy or if a drop in hemoglobin of two points or more was observed, requiring endoscopic therapy, too.

Statistical analysis

The data analysis was performed using IBM SPSS Statistics 22.0 (IBM Corp., Armonk, USA). The contingency table-derived data were calculated using StatPages [24].

Results

Study population

Out of 167 digital SOCs, 30 cholangioscopies were identified, that were solely performed due to a previous failure

of conventional endoscopic methods to treat a biliary stricture via a selective guidewire placement (Figs. 1, 2). Of these cases, 23 were initial and 7 were repeated digital SOC procedures (Fig. 1; Table 1). The patients were predominantly female (56.5%) and the median age was 51 years [interquartile range (IQR): 38–63 years]. The vast majority of patients had previous ERC examinations (82.6%).

In 52.2% of all patients, the stricture had a benign etiology with post-liver-transplant strictures (75.0%) as the most frequent finding; specifically, 50.0% had nonanastomotic strictures (ischemic-type biliary lesions; especially type III), and 25.0% had anastomotic biliary strictures. Other causes for benign strictures were cases with primary sclerosing cholangitis (16.7%) and secondary sclerosing cholangitis (8.3%). In 47.8% of all patients, the stricture was malignant with cholangiocellular carcinoma as the most frequent etiology (63.7%) followed by pancreatic carcinoma (9.2%) and other malignomas (27.3%; Table 1).

Therapeutic interventions: guidewire placement across biliary strictures

This study evaluated the efficacy of digital SOCs to successfully place a guidewire across biliary strictures in patients in whom several attempts to conventionally place a guidewire across biliary strictures previously failed.

The overall success rate of the use of digital SOCs to insert a guidewire across a biliary stricture was 70% (21/30), whereas this procedure failed in 30% (9/30) of all included examinations (Table 2; Fig. 2).

According to a subanalysis, the technical success rate of SOC-assisted guidewire insertions across benign strictures was significantly higher than that in malignant strictures (88.2% vs. 46.2%; $p=0.02$; Table 2). Moreover, initial examinations using digital SOCs to place a guidewire had a higher success rate (78.3%) in comparison to repeated SOCs, which had a success rate of only 42.9% ($p=0.15$; Table 2). In detail, all three repeated SOCs with a previous failure to place a guidewire failed, while 3 of 4 SOCs with a previous successful guidewire placement were successful again.

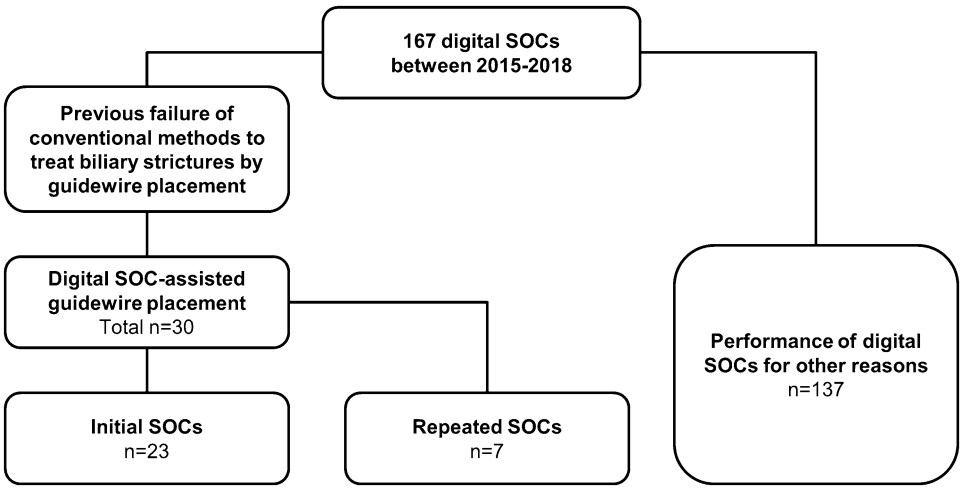

Fig. 1 Participant flow chart of patients in whom a digital single-operator cholangioscope-(SOC)-assisted guidewire placement across a biliary stricture was performed (University Hospital Muenster between 2015 and 2018)

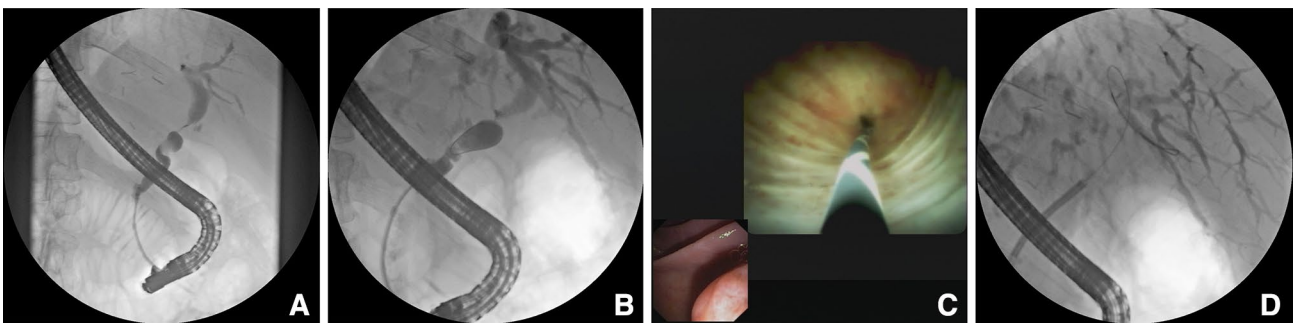

Fig. 2 Imaging of a digital single-operator cholangioscope-(SOC)-assisted selective guidewire placement across a complex anastomotic biliary stricture following liver transplantation. **A, B** The conventional guidewire passage across the biliary stricture failed despite several attempts. **C, D** The use of a SOC enabled visualization of the high-grade biliary stricture and a successful guidewire placement

Table 1 Characteristics of patients undergoing digital single-operator cholangioscopy (SOC) for guidewire placement to treat biliary strictures

Variables	Patients ($n=23$)
Age in years (IQR)	51 (38–63)
Female (%)	13 (56.5)
Male (%)	10 (43.5)
Previous ERC (%)	19 (82.6)
Included cases	
Number of patients	23
Number of digital SOCs	30
Initial examinations	23
Repeated examinations	7
Previous failure of SOC examinations	3
Previous success of SOC examinations	4
Etiology of biliary strictures in 23 patients (%)	
Benign strictures	12 (52.2)
Liver transplantation-associated strictures	9 (75.0)
Non-anastomotic strictures (ischemic-type biliary lesions)	6 (50.0)
Type I (extrahepatic)	1 (8.3)
Type II (intrahepatic)	0 (0.0)
Type III (intra- and extrahepatic)	5 (41.7)
Anastomotic strictures	3 (25.0)
Primary sclerosing cholangitis	2 (16.7)
Secondary sclerosing cholangitis	1 (8.3)
Malignant strictures	11 (47.8)
Cholangiocellular-Carcinomas	7 (63.6)
Pancreas-Carcinomas	1 (9.1)
Other malignomas	3 (27.3)

Only patients were included with a previous failure of conventional endoscopic methods to treat the biliary stricture via guidewire placement. Median and interquartile ranges (IQR) are reported for continuous variables

Subsequently, digital SOC-assisted guidewire placement helped to successfully perform balloon dilation therapy in 33.3% of cases and balloon dilation therapy followed by an endoprosthesis implantation in 36.7% of all included examinations. The cases, in which a guidewire placement failed, needed an alternative rescue approach. In total, three patients received palliative care, two patients had successful biliary drainage via percutaneous transhepatic approaches and in one patient with a non-anastomotic biliary stricture after liver transplantation but no signs of cholangitis, regular non-invasive follow-up examinations were arranged.

Complications following digital SOC-assisted guidewire placement

No adverse events occurred in the majority of cases (83.3%); however, complications were observed in 16.7% of all cholangioscopies. In detail, post-interventional pancreatitis and cholangitis were each documented in two cases (each 6.7%). Additionally, severe bleeding occurred in one case, requiring endoscopic therapy (3.3%; Table 3). Complications tended to occur less frequently after the performance of digital SOCs in patients with benign strictures than in patients with malignant strictures (11.8% vs. 23.1%; $p=0.63$).

All cases of SOC-related complications had a mild clinical course and were treated successfully by conservative therapeutic approaches. No mortalities occurred due to procedure-related side effects.

Discussion

Our study shows that digital SOC is an efficient tool for the treatment of biliary strictures in which previous guidewire passage via conventional ERC has failed. Our results suggest that digital SOC-assisted guidewire placement is successful in 70% of all cases. Furthermore, we showed that digital SOC-assisted guidewire placements across benign strictures were significantly more successful than those across malignant strictures (88% vs. 46%; $p=0.02$).

Up to now, several larger studies evaluated digital SOCs for diagnostic use as well as for the treatment of biliary stones, e.g. [16, 18, 25, 26]; however, only a few studies and case presentations with less than ten patients have reported digital SOC-assisted guidewire placements across biliary strictures [16–21]. The reported technical success rates

Table 2 Technical success of digital single-operator cholangioscopies (digital SOCs) to perform a guidewire placement for treating biliary strictures in patients in whom conventional methods failed

	Success	Failure	p value
Overall digital SOCs ($n=30$)	21/30 (70.0)	9/30 (30.0)	
-Digital SOC in benign strictures ($n=17$)	15/17 (88.2)	2/17 (11.8)	0.02*
-Digital SOC in malignant strictures ($n=13$)	6/13 (46.2)	7/13 (53.8)	
-Initial digital SOC ($n=23$)	18/23 (78.3)	5/23 (21.7)	0.15
-Repeated digital SOC ($n=7$)	3/7 (42.9)	4/7 (57.1)	

Percentages are reported for categorical variables. Differences between the groups were calculated using the Chi square test

*Two-sided p values <0.05 were considered statistically significant

Table 3 Interventions performed during all digital single-operator cholangioscopies (SOCs) and safety data ($n=30$)

Variables	Digital SOCs ($n=30$)
Successful guidewire insertion for… (in % per examination)	21/30 (70)
-Dilation therapy	10/30 (33.3)
-Dilation therapy and endoprosthesis implantation	11/30 (36.7)
Adverse events (in % per examination)	5/30 (16.7)
-Pancreatitis	2/30 (6.7)
-Cholangitis	2/30 (6.7)
-Bleeding requiring endoscopic treatment	1/30 (3.3)

Percentages are reported for categorical variables

ranged between 57 and 100%. Except one study, all were retrospective and only one study with five patients solely concentrated on the treatment of biliary strictures using digital SOC-assisted guidewire placement [20]. In all others, the treatment of biliary strictures via digital SOC-assisted guidewire placement was only part of a subgroup analysis of the whole study population, and the inclusion criteria for the use of digital SOC-assisted guidewire placement across biliary strictures were not well defined [16–19]. In contrast, our study employed strict inclusion criteria: only patients with a bile duct obstruction and previous failure to establish biliary drainage via guidewire placement using ERC were included. Accordingly, we collected data from 30 digital SOCs performed in 23 patients. To date, this is the largest data set of digital SOC-assisted selective guidewire placements across biliary strictures available.

Approximately two-thirds of all biliary strictures are derived from malignant disease, and most of these are caused by cholangiocellular carcinoma [1]. For palliative care, these patients require biliary drainage to minimize symptoms caused by cholestasis or to treat cholestatic-induced cholangitis [2, 27, 28]. In these patients receiving palliative care, more invasive procedures such as percutaneous transhepatic biliary drainage could be avoided by using digital SOC in approximately half of our cases.

Nearly one-third of all biliary strictures have a benign origin and can be caused by various diseases, e.g., primary/secondary sclerosing cholangitis or iatrogenic causes such as post-liver-transplant and postcholecystectomy strictures [1, 29]. Following liver transplantation, up to 40% of all patients develop benign biliary strictures [3–5].

Routinely, benign and malignant biliary obstructions are treated via ERC; however, treatment can be challenging [30–33]. For example, in post-liver-transplant patients, biliary drainage via ERC is successfully established in only 60–80% of cases [5, 6, 33, 34]. Therefore, up to 40% of these patients require more invasive procedures for biliary drainage such as percutaneous transhepatic cholangiography or surgical care [32, 33]. The same applies for malignant strictures. ERC might fail in progressive malignant disease, which requires alternative invasive procedures including percutaneous transhepatic approaches for biliary drainage [30, 31].

A frequent cause of endoscopic failure is the inability to traverse the biliary stricture with the guidewire [7, 8]. Alternative and less invasive devices for the treatment of biliary strictures might be SOCs [9, 10, 16–21]. Initial results for the treatment of biliary strictures using the previous fiberoptic SOC, which was equipped with an impaired imaging quality, indicated the efficacy of this approach [9, 10]. For example, in 15 patients with a post-liver-transplant stricture and a previous failure to place a guidewire across a biliary stricture using conventional ERC methods, a fiberoptic SOC-assisted guidewire placement was used; however, the technical success rate of guidewire placement was only 60% [10].

Particularly in patients with complex strictures, the enhanced imaging quality of the digital SOCs in comparison to the previous fiberoptic device might help to improve the technical success rate of cholangioscope-assisted guidewire placement [11].

In our study, in cases with a previous failure of conventional endoscopic methods to place a guidewire across a biliary stricture, the overall technical success rate was 70%. A comparison to published cases is difficult because previous studies and case reports had very limited examination numbers; however, the technical success rate of digital SOC, observed in our study seems comparable to that of previous studies and might be better than that associated with the use of the former fiberoptic SOC [10, 16–20].

In a subanalysis, we found that digital SOC-assisted guidewire placement was significantly more successful in cases with benign biliary strictures (especially post-liver-transplant etiology) than that in cases of malignant strictures (88% vs. 46%, $p=0.02$). Previously, two small case series with only 4–5 patients reported on cases with post-liver-transplant biliary strictures and guidewire placement via digital SOC-assistance was successful in all cases [19, 20]. The most comprehensive study of patients with post-liver-transplant biliary strictures included 15 patients and was performed using the fiberoptic SOC reporting a lower success rate of 60% [10]. Concluding, digital SOCs have a high technical success rate in guidewire placement, especially across

benign biliary strictures (88%), and might be superior to the previous fiberoptic SOC in terms of technical efficacy.

Our study has several limitations. First, we report data from a single-center study, and our final data set consisted of only 30 cholangioscopies performed in 23 patients; however, it is the largest data set of digital SOC-assisted guidewire placements across biliary strictures available to date. Second, this study is retrospective; however, we were able to collect a homogenous and complete data set featuring detailed endoscopic reports and defined detailed inclusion criteria. Third, we included repeated SOC examinations which might influence our results concerning the overall technical success rates of SOC-assisted guidewire placement; however, to fully address this concern, we report the technical success rate of initial and repeated SOC examinations separately.

Taken together, our data indicate that digital SOCs provide a valuable and less invasive rescue approach to establish biliary drainage across biliary strictures in cases with a previous failure to achieve drainage using conventional methods. Thus, the use of digital SOCs might substantially improve the challenging treatment of strictures. However, further studies are needed to strengthen these findings.

Compliance with ethical standards

Disclosures Dina Gross and Drs. Arne Bokemeyer, Tobias Nowacki, Markus Brückner, Hauke Heinzow, Iyad Kabar, Hansjoerg Ullerich and Frank Lenze as well as Prof. Dr. Dominik Bettenworth and Prof. Dr. Hartmut Schmidt have no conflicts of interest or financial ties to disclose.

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