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Original Article

Evaluation of the performances of a single-use duodenoscope: Prospective multi-center national study

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Objectives: A single-use duodenoscope (SUD) has been recently developed to overcome issues with endoscopic retrograde cholangiopancreatography (ERCP)-related cross-infections. The aim was to evaluate SUD safety and performance in a prospective multi-centre study.

Methods: All consecutive patients undergoing ERCP in six French centers were prospectively enrolled. All procedures were performed with the SUD; in case of ERCP failure, operators switched to a reusable duodenoscope. Study outcomes were the successful completion of the procedure with SUD, safety and operators' satisfaction based on a VAS 0–10 and on 22 qualitative items. The study protocol was approved by French authorities and registered (ID-RCB: 2020-A00346-33). External companies collected the database and performed statistical analysis.

Results: Sixty patients (34 females, median age 65.5 years old) were enrolled. Main indications were bile duct stones (41.7%) and malignant biliary obstruction (26.7%). Most ERCP were considered ASGE grade 2 (58.3%) or 3 (35.0%). Fifty-seven (95.0%) procedures were completed using the SUD. Failures were unrelated to SUD (one duodenal stricture, one ampullary infiltration, and one tight biliary stricture) and could not be completed with reusable duodenoscopes. Median operators' satisfaction was 9 (7–9). Qualitative assessments were considered clinically satisfactory in a median of 100% of items and comparable to a reusable duodenoscope in 97.9% of items. Three patients (5%) reported an adverse event. None was SUD-related.

Conclusions: The use of a SUD allows ERCP to be performed with an optimal successful rate. Our data show that SUD could be used for several ERCP indications and levels of complexity.

Key words: biliary stone disease, infection, pancreatic cancer, reprocessing, sterile

INTRODUCTION

ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY (ERCP) was described and introduced in clinical practice several decades ago and dramatically changed the management and natural history of bilio-pancreatic conditions.[1–3] In the last decade, various cases and outbreaks of multi-drug resistant organisms were associated with ERCP, especially in immunocompromised patients (i.e. liver transplantation, cholangiocarcinoma) or in patients requiring biliary stenting.[4,5] The side-viewing endoscopes were suggested to be the potential sources of cross-infection by epidemiological c anatomy and function (lateral lens, elevator, difficult access for brushes due to the tip of the scope), several strategies and solution have been proposed to avoid the risk of duodenoscope-related contamination and infections. Among those strategies, serial microbiologic tests, thorough reprocessing schedules, and use of removable scope cap have been adopted; unfortunately, those strategies did not completely eliminate the potential risk of infection.[4]

In the last years, a disposable single-use duodenoscope (SUD) has been developed to address issues related to scope deterioration and reprocessing; indeed, EXALT Model D (Boston Scientific Corporation, Marlborough, MA, USA) was registered in the United States at the end of 2019 and is

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available in sterile packaging and is intended for a single-use.

In a preclinical bench study performed on an anatomic model, the authors observed similar performance and time required to complete the procedure using the SUD or reusable duodenoscope.[6]

Since FDA registration, the SUD's performance was comparable to reusable duodenoscopes in a multi-center case series and a single-center randomized controlled trial, both conducted in the United States.[7,8] To the best of our knowledge, no data from Europe is available in the field.

The aim of this study was to evaluate the performances and safety of a SUD for ERCP procedures in a prospective multi-center study. The primary outcome of the study was the successful completion of the ERCP procedure with the SUD without the need to switch to a reusable duodenoscope. Secondary outcomes were the SUD technical performances, and SUD-related and ERCP-related adverse events.

MATERIAL AND METHODS

Study design

A PROSPECTIVE SINGLE-ARM multi-center study involving six French centers was conducted in September 2020. Ten consecutive patients requiring ERCP for bilio-pancreatic diseases were prospectively enrolled from each center.

Inclusion criteria were: (i) patients with bilio-pancreatic disorders requiring ERCP based on clinical manifestations, laboratory, or radiological findings; (ii) age ≥18-year-old; (iii) written informed consent for study participation. Exclusion criteria were surgically altered upper gastrointestinal anatomy, pregnancy, major contraindication for ERCP procedure and impossibility to give informed consent.

This study protocol was approved by the French Agence Nationale de la securité du Médicament et des produits de santé (ANSM) and received a registration number for RIPH studies (ID-RCB: 2020-A00346-33). The study was conducted in accordance with the Declaration of Helsinki Ethical Principles for Medical Research involving human subjects.

For each patient, the following variables were recorded: age, gender, clinical presentation, concomitant medications, previous ERCP procedures, previous sphincterotomy, need for a reusable duodenoscope, ERCP completion and success, detailed ERCP procedure information, ERCP complexity score according to ASGE grading system,[9] SUD performance evaluation, and adverse events (AE). The electronic case report form is available on the Appendix S1.

ERCP procedure

All interventions were conducted under general anaesthesia by experienced endoscopists (>200 ERCP/years); ERCPs procedures were performed according to operators' discretion. NSAID suppositories were administered as post-ERCP pancreatitis prophylaxis when not contraindicated; systemic antibiotics were prescribed according to the ESGE guidelines.[3]

All procedures started with the use of the EXALT Model D (Boston Scientific Corporation) connected to a dedicated EXALT processor. In case of failure in any step of the procedure, the operators switched to a reusable duodenoscope.

Study outcomes

The main study outcome was successful ERCP completion without the need to switch to a reusable duodenoscope. The outcome of each biliary, pancreatic and ampullary maneuver was assessed and calculated as the rate of maneuvers successfully achieved out of the maneuver attempted.

The overall SUD performance was assessed using a 10-point VAS scale based on personal endoscopists' evaluation; moreover, for each procedure 22 qualitative items were evaluated. For each item, the operator was asked if the SUD performance was clinically satisfactory and if it was comparable to that of the reusable duodenoscope he generally used. Finally, every SUD dysfunction was recorded. Adverse events were recorded at day 1, 7 and 30.

Technical performance in selective biliary cannulation (success rate, number of attempts, time from sphincterotome insertion to cannulation) with SUD was calculated in patients requiring selective biliary cannulation with no previous sphincterotomy.

Statistical analysis

Based on available literature in the field,[7] a sample size of patients was estimated to allow a SUD success rate of 90% with a 95% confidence interval between 82.4–97.6%. Categorical variables were reported as number (percentage, %) while continuous variables were reported as median (interquartile range, IQR). Statistical analysis was conducted by an external society (Centre de méthodologie Capionis-IQVIA, 80b Rue Paul Camelle, 33000 Bordeaux).

RESULTS

Study population

SIXTY PATIENTS (56.7% females; median age 65.5 years old) were prospectively enrolled.

Table 1 Baseline characteristics of the study population

	Total (n = 60)
Demographic characteristics	
Gender (female), n (%)	34 (56.7%)
Age (year), median (IQR)	65.5 (55–76)
Previous biliary or pancreatic procedures	
Previous ERCP, n (%)	28 (46.7%)
No. of previous ERCP, median (range)	2 (1–15)
Previous sphincterotomy, n	24 (40.0%)
Previous biliary sphincterotomy only, n	16
Previous pancreatic sphincterotomy (major papilla) only, n	3
Biliary and pancreatic sphincterotomy, n	4
Previous pancreatic sphincterotomy (minor papilla), n	1
Stent placement, n (%)	22 (36.7%)
ERCP indication	
Common bile duct stone, n (%)	25 (41.7%)
Malignant biliary obstruction, n (%)	16 (26.7%)
Benign/indeterminate biliary stricture, n (%)	6 (10.0%)
Chronic pancreatitis/pancreatic duct intervention, n (%)	12 (20.0%)
Ampullectomy, n (%)	1 (1.7%)
ERCP complexity	
Grade 1, n (%)	1 (1.7%)
Grade 2, n (%)	35 (58.3%)
Grade 3, n (%)	21 (35.0%)
Grade 4, n (%)	3 (5.0%)
Concomitant medications	
Oral anticoagulant, n (%)	7 (11.7%)
Antiplatelet agents, n (%)	14 (23.3%)
Anti-hypertensive agents, n (%)	18 (30.0%)
Oral antibiotic, n (%)	8 (13.3%)
Antidiabetic agents, n (%)	13 (21.7%)
Analgesics, n (%)	16 (26.7%)
Chemotherapy, n (%)	2 (3.3%)
Immunomodulatory agents, n (%)	4 (6.7%)

ERCP, Endoscopic retrograde cholangiopancreatography; IQR, interquartile range.

Demographic and baseline characteristics are described in Table 1. In detail, 28 patients (46.7%) had previous ERCPs including, 24 with a previous sphincterotomy. Main indications for ERCP were CBD stones (41.7%), malignant biliary obstruction (26.7%) and chronic pancreatitis with pancreatic duct intervention (20.0%). According to ASGE complexity classification, most of the ERCP were considered grade 2 or 3 (58.3% and 35.0%, respectively).

Main study outcomes

Fifty-seven out of sixty procedures (95.0%) were completed using the SUD, without the need to switch to a reusable duodenoscope. The reasons for ERCP failure were a complete duodenal stricture (n = 1), ampullary neoplastic infiltration not allowing cannulation (n = 1) and complete biliary stricture unable to be passed with a guidewire (n = 1). In all cases, the ERCP could not be completed by switching to a reusable duodenoscope. These patients were treated with surgery (Whipple's intervention), EUS-guided drainage with hepatico-gastrostomy and percutaneous transhepatic drainage and rendezvous, respectively.

Table 2 details the ERCP outcomes and the success rate of the single maneuvers attempted. All attempted biliary and ampullary procedures were successfully achieved with the SUD. No issue was found in biliary cannulation, biliary sphincterotomy, CBD stone extraction and biliary stent placement. In six cases, biliary plastic stents were used; of

Table 2 Endoscopic retrograde cholangiopancreatography (ERCP) outcomes

	Single-use duodenoscope (*n* = 60)	Reusable duodenoscope (*n* = 3)
Primary outcome		
Successful completion, *n* (%)	57 (95%)	0/3
Cause of ERCP failure		
Duodenal stricture, *n*	1[†]	Failed
Ampullary tumoral infiltration, *n*	1[‡]	Failed
Bile duct stricture, *n*	1[§]	Failed
Biliary maneuvers outcomes[¶]		
Deep biliary cannulation	54/54 (100%)	0/1
Double guidewire technique for cannulation	4/4 (100%)	–
Septotomy	3/3 (100%)	–
Infundibulotomy	–	–
Biliary sphincterotomy	35/35 (100%)	–
Biliary large balloon dilation	1/1 (100%)	
CBD stone clearance	25/25 (100%)	–
Mechanical lithotripsy (CBD stone)	2/2 (100%)	–
Biliary stent placement	20/20 (100%)	–
Biliary stent removal	9/9 (100%)	–
Biliary stent exchange	8/8 (100%)	–
CBD stricture dilation	6/6 (100%)	–
CBD stricture biopsy	3/3 (100%)	–
CBD stricture brushing for cytology	1/1 (100%)	–
Cholangioscopy	–	–
Pancreatic maneuvers outcomes[¶]		
MPD cannulation	10/10 (100%)	–
Minor papilla cannulation	2/2 (100%)	–
Major papilla pancreatic sphincterotomy	1/1 (100%)	–
Minor papilla pancreatic sphincterotomy	–	–
MPD stone clearance	3/3 (100%)	–
Mechanical lithotripsy (MPD stone)	–	–
Pancreatic stent placement	8/8 (100%)	–
Pancreatic stent removal	5/5 (100%)	0/1
Pancreatic stent exchange	3/3 (100%)	–
MPD stricture dilation	2/2 (100%)	–
Pancreatoscopy	–	–
Ampullary maneuvers outcomes[¶]		
Major papilla biopsy	2/2 (100%)	–
Ampullectomy	1/1 (100%)	–

CBD, common bile duct; MPD, main pancreatic duct; n/a, not attempted.
[†]The patient was surgically treated with pancreatectomy (Whipple operation).
[‡]The patient underwent EUS-guided trans-mural drainage through an EUS-hepaticogastrostomy.
[§]The patient was treated with a percutaneous trans-hepatic drainage.
[¶]Results are shown as number and percentage of successful procedures/case attempted.

them, in four patients a single stent was placed while in the other two cases, two and three stents were respectively placed. The diameter of biliary plastic stent was 8.5 Fr in one case, 10 Fr in four cases and 11.5 Fr in the remaining case. Seventeen patients received a biliary self-expandable metal stent. In one case, ampullectomy was successfully completed, followed by prophylactic pancreatic stent placement. All pancreatic interventions attempted (major and minor papilla cannulation, pancreatic sphincterotomy, stone clearance, stricture dilation and stent placement) were successfully obtained with the use of a SUD. In 12 cases, pancreatic plastic stents were used; the diameter of plastic stent was 4 or 5 Fr (n = 7), 7 Fr (n = 2) and 10 Fr (n = 3). Selective biliary cannulation was planned in 54 patients; of

them, 21 had previous ERCP with biliary sphincterotomy and was not considered in this analysis. In one case, biliary cannulation was not even attempted due to the presence of duodenal stricture. Among the remaining 32 cases, selective biliary cannulation was achieved in 30 cases (93.8%). As described above, in one case, failure was due to ampullary neoplastic infiltration and in one case, even if biliary cannulation was achieved, the operator was unable to pass with the guidewire through a complete stricture of the common hepatic duct. Median number of guidewire attempts was 1.5 (1–4), with a median time of 1 min (1–4). In five cases (15.6%), an advanced technique for selective biliary cannulation was required (no. 2 septotomy, no. 2 double guidewire technique, no. 1 double guidewire and septotomy).

SUD performance

The median overall endoscopists' satisfaction for the SUD, evaluated using a VAS score 0–10, was 9 (7–9). In two cases (3.3%), the operator reported a satisfaction score of 5; in both cases, the reason was a malfunction of the insufflation valve leading to irrigation of a small amount of water in the lumen, limiting the visibility. There were no statistical differences for the median overall endoscopists' satisfaction depending on the grade of difficulty: grade 1 + 2 VAS score 8.0 (7–9); grade 3 + 4 VAS score 9 (8–9) $P = 0.25$. Table 3 reports the evaluation of the qualitative assessment of the 22 items proposed. SUD performance was considered clinically satisfactory in a median of 100% (100–100%) of items; in 21 out of 22 items the SUD was considered 100% clinically

Table 3 Single-use duodenoscope performance

		Total (n = 60)
Overall satisfaction		
Endoscopist satisfaction (VAS 0–10), median (IQR)		9 (7–9)
Endoscopist satisfaction <6, *n* (%)		2 (3.3%)
Value and cause, case no. 1		5, Insufflation valve issues
Value and cause, case no. 2		5, Insufflation valve issues
	Clinically satisfactory	Comparable to a reusable duodenoscope
Qualitative assessment[†]		
Oesophagus intubation	100%	96.7%
Crossing stomach and pylorus	100%	94.9%
Crossing duodenal bulb and superior angle	100%	100%
Reaching the deepest point of the duodenum	100%	96.7%
Range of manoeuvrability	100%	98.3%
Suction performance	100%	96.7%
Scope in short or long position as required	100%	93.9%
Image quality and brightness	100%	91.5%
Evaluation of the papilla	96.7%	91.4%
Twisting the scope and orienting the tip	100%	96.4%
Scope stability during cannulation	100%	100%
Elevator's function	100%	89.8%
Performing selective cannulation	100%	98.3%
Sphincterotome control during cannulation	100%	98.0%
Scope stability during sphincterotomy	100%	97.7%
Device position in the field of view	100%	100%
Visualization of landmark on screen	100%	100%
Elevator guidewire holding capability	100%	100%
Passing devices through the operative channel	100%	100%
Passing devices through the CBD or MPD	100%	100%
Carrying out all planned ERCP tasks	100%	93.2%
Removing the scope	100%	100%

CBD, common bile duct; MPD, main pancreatic duct.
[†]Results are shown as percentage of positive evaluation among whom evaluated this single item.

satisfactory, while in two cases out of 60 the evaluation of the papilla was not considered adequate (96.7%).

The performance of SUD was comparable to a reusable duodenoscope in a median of 97.9% (94.9–100%) of the evaluated items.

Adverse events

Three patients (5%) reported an AE. All the AEs were considered not related to the use of the SUD. Of them, two AEs were considered mild (one biliary pain after placement of a biliary metal stent and a mild acute pancreatitis) and did not require any further intervention. The other patient died 7 days after the procedure because of worsening of the underlying disease (metastatic pancreatic ductal adenocarcinoma).

DISCUSSION

THE RESULTS OF this study confirm that the use of a SUD allows the successful completion of ERCP; indeed, we observed a 95% successful rate and the only three cases of ERCP failure were not related to the scope but to conditions that make the ERCP impossible (i.e., duodenal stricture, ampullary infiltration or complete bile duct stricture). Moreover, no SUD-related adverse event was observed.

Our study confirms, in a different setting, the few data available in literature; in fact, in their randomized trial, Bang *et al.*[8] achieved a selective cannulation in 46/48 patients (95.8%), while in their multi-center case series Muthusamy *et al.*[7] reported a 58/60 (96.7%) of successful procedure. To date, no SUD-related adverse event was ever reported.[7,8,10]

Our study included patients with different indications for ERCP and, therefore, several techniques and procedures of all levels of complexity have been performed using various endoscopic devices. The operators involved in our study were able to perform all planned biliary interventions, including advanced cannulation techniques, stone clearance, stent placement and retrieval, stricture dilation and tissue acquisition. Among pancreatic interventions, planned maneuvers were completed in 100% of cases. Finally, a successful ampullectomy followed by prophylactic pancreatic stent placement was completed. The good SUD performance was confirmed when selective biliary cannulation in patients with naïve papilla was taken into account. The optimal cannulation rate, small number of attempt and time for cannulation should be confirmed in real-life settings as it could be have been influenced by the high expertise of the operators.

The operators involved in the study positively judged the overall performance of the SUD, with a median rating of 9 out of 10; moreover, when considering 22 qualitative items, the SUD was considered clinically satisfactory in up to 100% of cases and comparable to a standard reusable scope in up to 97.9% of cases. The complexity of the ERCP was not associated with any significant variation of the operator's satisfaction which suggests that the use of the material can be done indifferently.

The evaluation of these observations, together with available data, suggests that despite several strong points the SUD technology may present some weaknesses. Indeed, as previously reported, insufflation valves may irrigate the duodenal lumen with water, leading to a reduced visibility during ERCP. Indeed, while no study reported any issue with scope mechanics (i.e., esophagus intubation, reaching second duodenum, torching and maneuvrability), the image produced by the EXALT model D was reported to be suboptimal, in terms of brightness. On the other hand, the elevator's ability to lock the guidewire and to deal with different devices seems optimal.[6–8]

An assessment tool for duodenoscope technical performance was validated after the study completion and recently published; Bang *et al.*[11] found that a newly developed score was reliable for evaluating the technical performance of duodenoscopes. In the next future, this score should be used to assess the reproducibility of our results, and to confirm the strengths and weaknesses that have emerged so far.

This study presents some limitations. First, the study design lacks a control group to directly compare the SUD with reusable duodenoscopes; however, the cross-over to a reusable scope demonstrated that ERCP failures were not related to the scope but to patients' underlying conditions. Another limitation is the involvement of high-experience operators from high-volume centers; it is well known and demonstrated that the outcomes of ERCP are significantly affected by operators experience and yearly volume; a post-marketing phase-IV study will be necessary to assess the effective SUD performances in real-life practice. Moreover, none of the included patients required a cholangioscopy or pancreatoscopy therefore we are not able to draw any conclusions regarding the performance of the SUD in combination with the single-use digital choledochoscope.[12] Finally, as stated in the dedicated section, many authors have possible conflict of interest with the manufacturer company of the SUD; we tried to overcome this limitation by the compilation of the eCRF form by personnel not involved in the study, during the ERCP procedures, and through the management of the database and statistical analysis by external third-party companies.

In conclusion, the results of this prospective multi-center study confirm that the performances of an SUD to complete ERCP are at least comparable to those of a reusable duodenoscope. Our data show that the SUD could be used for several ERCP indications and maneuvers with optimal operators' satisfaction. The clinical applications and systematic use of SUDs will be assessed in future dedicated trials, including pharmaco-economic perspectives.

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CONFLICT OF INTEREST

B. NAPOLÉON RECEIVED RESEARCH grant and teaching sessions from Boston Scientific Corporation. JM Gonzalez, P Grandval, A Laquière, C Boustière, T Ponchon, and G Vanbiervliet are consultants for Boston Scientific Corporation. M Barthet and T Ponchon received a research grant from Boston Scientific Corporation. The other authors have nothing do declare. Single-use duodenoscope used in this study were provided by the manufacturer, Boston Scientific Corporation. The funding source, Ramsay Santé Group, had no role in the design, practice or analysis of this study.

FUNDING INFORMATION

RAMSAY SANTÉ GROUP is the study promotor. Boston Scientific Corporation unrestrictedly provided the single-use duodenoscopes to accomplish the study. The authors received no support or funding for this study.

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SUPPORTING INFORMATION

ADDITIONAL SUPPORTING INFORMATION may be found in the online version of this article at the publisher's web site.

Appendix S1 Electronic case report form (eCRF) – French language.