

Single-use duodenoscopes are an efficient tool for emergency ERCP in real life



Authors

Paul Rivallin¹, Diane Lorenzo¹, Abdellah Hedjoudje¹, Frédéric Prat¹

Institution

¹ Endoscopy Unit, Beaujon Hospital, Clichy la Garenne, France, AP-HP, 100 boulevard du general Leclerc, 92110 Clichy la Garenne, France

submitted 9.2.2022

accepted after revision 20.5.2022

published online 9.8.2022

Bibliography

Endosc Int Open 2022; 10: E1497–E1500

DOI 10.1055/a-1921-2109

ISSN 2364-3722

© 2022. The Author(s).

This is an open access article published by Thieme under the terms of the Creative Commons Attribution-NonDerivative-NonCommercial License, permitting copying and reproduction so long as the original work is given appropriate credit. Contents may not be used for commercial purposes, or adapted, remixed, transformed or built upon. (<https://creativecommons.org/licenses/by-nc-nd/4.0/>)

Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Corresponding author

Diane Lorenzo, Hopital Nord – Gastroenterology Unit, Chemin des Bourrely, Marseille 13915, France

Fax: +33491961311

diane.lorenzo@gmail.com

ABSTRACT

Background Biliary tract emergencies are managed with endoscopic retrograde cholangiopancreatography (ERCP) using duodenoscopes, which are reusable devices that require high-level disinfection to minimize risk of cross-contamination. Recent reports about newly developed single-use duodenoscopes (SUDs) suggest equivalent performance with reusable duodenoscopes, but the effectiveness of SUDs in emergency ERCP has not yet been studied.

Patients and methods We conducted a prospective case series of emergency ERCP procedures using SUDs (EXALT model D-Boston Scientific, United States) in a real-life, tertiary care setting without any possibility of using a back-up reusable duodenoscope.

Results Twenty-one emergent ERCPs (acute cholangitis 48%, severe jaundice 38%, others 14%) were performed in 19 patients (mean age 49.5±15 years). Almost all procedures (20 of 21; 95%) were technically and clinically successful, whereas selective cannulation failed in one case. Among the successful ERCPs, five (24%) were achieved by a novice operator. The image was often considered skewed toward yellow tones (48%), whereas stiffness and pushability for stent insertion were found suboptimal in 5% of the procedures, without any impact on procedure success.

Conclusions SUDs are effective and appropriate devices for emergent situations in real life even in non-expert hands and even if a regular duodenoscope is unavailable as a back-up.

Introduction

Digestive endoscopes are reprocessed after each procedure through a high-level disinfection process to decrease risk of cross-contamination and, therefore, risk of infection in subsequent patients [1, 2]. Because of their particular design, duodenoscopes are particularly prone to contamination [1, 3], and presence of microorganisms of concern has been found in up to 15% of reusable duodenoscopes on systematic sampling [2]. In this context, single-use duodenoscopes (SUDs) recently have been developed as an alternative to scope reprocessing. The usefulness and effectiveness of SUDs has been the subject of a few publications [4–11], including a randomized trial show-

ing equivalent performance for SUDs and reusable duodenoscopes and similar success on low-complexity procedures [4]. Endoscopic retrograde cholangiopancreatography (ERCP), which requires a duodenoscope, is the gold standard procedure for biliary emergencies such as acute cholangitis, urgent biliary drainage or post-sphincterotomy bleeding [3, 4, 11]. However, the availability of regular duodenoscopes can be limited at night or during weekends, when cleaning and reprocessing staff and material are unavailable or in a short supply. While few studies have reported that even complex procedures can be performed by using SUDs [8, 10], the effectiveness of those devices in the specific context of emergency ERCP remains to be assessed. Our objective was to report the efficiency of SUDs

for ERCP emergencies in a real-life setting, when a reusable duodenoscope backup is unavailable.

Patients and methods

Background, inclusion and exclusion criteria, outcome measure definitions

We conducted a prospective consecutive case series of SUD-based procedures involving seven endoscopists in a tertiary care center (Beaujon Hospital). In July 2021, construction in the endoscopy unit precluded storage and reprocessing of our regular (reusable) duodenoscopes for 3 consecutive weeks. This situation forced us to perform emergency ERCPs using SUDs. Endoscopic ultrasound and diagnostic colonoscopy were unavailable during that same period, but upper gastrointestinal endoscopy remained possible on an emergency-only inpatient basis.

Biliary emergencies were defined as: 1) acute cholangitis with severe sepsis or persistent septicemia more than 24 hours after beginning of antibiotherapy; 2) acute biliary pancreatitis with an impacted intra-ampullary stone requiring extraction; 3) severe jaundice (>250 mmol/L) with intractable pruritus and impaired nutritional status; and 4) active hemobilia or post-sphincterotomy bleeding [12]. Patients presenting with other indications for ERCP had their endoscopy postponed until after the full reopening of the unit.

This was a retrospective study on prospective data relating to routine care. According to current French legislation, the data used were anonymized and collected in a database with notice to the Commission Nationale Informatique et Liberté (n°2224486). Moreover, all endoscopies were performed in an emergency after informed consent was received from the patient or a patient-approved third party.

Seven endoscopists participated with different levels of experience: two were novices with less than 2 years of experience and performing mentored-only ERCP, two were experts with more than 15 years of practice, while the three others had 5 to 10 years of experience. Procedures were graded according to their expected difficulty using the American Society for Gastrointestinal Endoscopy (ASGE) grading scale [13].

The main outcome measure was the ERCP success rate, defined as successful achievement of the intended procedure (eg sphincterotomy and complete stone clearance, adequate biliary stricture stenting with complete biliary drainage, effective hemostasis of an active bleeding). Outcome was rated as a partial success in case of incomplete stone extraction or biliary drainage. Secondary outcomes were SUD technical performance as prospectively assessed by operators and nurses.

Device

The duodenoscope used in this study was the sterile, disposable EXALT model D (Boston Scientific, Marlborough, Massachusetts, United States) endoscope. A member of the commercial staff from the supplier was present for training and to help nurses and endoscopists during the first two ERCPs, but not thereafter.

Data

Data were collected at baseline and immediately after ERCP in an anonymous database, including operator experience and previous nurse training, procedure efficiency (technical success), device handling by medical and non-medical staff (cart/duodenoscope installation, global functions and maneuvers, placement over papilla, cannulation), component functionality (tube, knobs, elevator, working channel, etc.), image quality (color, contrast, sharpness, identification of prespecified anatomic features), overall satisfaction (ratings by medical and non-medical staff), and intra-procedure adverse events (AEs).

After each procedure, the endoscopist and nurse were asked to complete a form reporting their assessment of duodenoscope functionality, completion of the exam, and any deficiency encountered. No crossover was allowed, given the unavailability of regular duodenoscopes.

Results

Patient characteristics

Nineteen patients (mean age 49.5 ± 15 years) were enrolled in the study and 21 procedures were performed using SUDs. Indications for emergent ERCP were: acute cholangitis (10 procedures, 48%), severe jaundice (8 procedures, 38%), acute biliary pancreatitis with impacted stones (1 procedure, 5%), hemobilia/post-endoscopic surgery bleeding (2 procedures, 9%). Fifteen ERCPs (79% of patients, 71% of procedures) were performed on a native papilla. The main objective of the procedure was: endoscopic biliary sphincterotomy (N=8, 38%), stone extraction (N=2, 9.5%), biliary stenting (plastic stenting [N=3, 14.5%], metallic stenting [N=10, 48%], plastic stent exchange (N=1, 5%), and local hemostasis (N=2, 9.5%).

Main outcome

Of the 21 procedures, 19 (90%) were a complete success, one (5%) was considered a partial success after a failure to remove a stone upstream of a common bile duct (CBD) stricture, and one (5%) was a failure (CBD intubation failure).

Details of ERCP procedures

Of the successful ERCPs, five (24%) were achieved by the two novice operators (► **Table 1**).

Procedures were ASGE grade 1, 2, 3 and 4 in 14%, 43%, 29% and 14%, respectively. Representative procedures included papillary cannulation (N=19), biliary sphincterotomy (N=7) and infundibulotomy (N=2), stone clearance (N=5), balloon dilation of strictures (N=4), and removal and exchange of stents (N=5). One patient underwent a Spyglass cholangioscopy during the same procedure for intra-hepatic stone destruction (Boston Scientific, Marlborough, Massachusetts, United States). Waste disposal of the SUD was unproblematic in every situation encountered.

When asked to rate SUDs as compared to reusable duodenoscopes after each ERCP, the respective operator deemed cannulation with SUD devices comparable in 73% and inferior in 27% of cases, respectively.

► **Table 1** ERCP details.

| Indications | |
|--|----------|
| ▪ Acute cholangitis | 10 (48%) |
| ▪ Severe jaundice | 8 (38%) |
| ▪ Hemobilia/post-ES bleeding | 2 (9%) |
| ▪ Acute biliary pancreatitis with impacted stones | 1 (5%) |
| Success | |
| ▪ Complete | 19 (90%) |
| ▪ Partial | 1 (5%) |
| ▪ Failure | 1 (5%) |
| ASGE grade | |
| ▪ 1 and 2 | 12 (57%) |
| ▪ 3 and 4 | 9 (43%) |
| Characteristics of procedures | |
| ▪ Native papilla | 15 (71%) |
| ▪ Dilation | 4 (19%) |
| ▪ Stent (plastic or metallic) | 13 (62%) |
| ▪ Hemostasis | 2 (10%) |
| Highlights | |
| ▪ Precut | 2 (10%) |
| ▪ Cholangioscopy | 1 (5%) |
| ▪ Novice operator | 5 (24%) |
| ERCP, endoscopic retrograde cholangiopancreatography; ES, endoscopic surgery; ASGE, American Society for Gastrointestinal Endoscopy. | |

Secondary outcomes

Not a single AE was encountered (► **Fig. 1** and ► **Table 2**). Installation of SUDs was adequate and easy in 100% of procedures.

The function of the SUDs was satisfactory, except for one on which the insufflation button needed to be fixed. Introduction and progression of the SUD to the second duodenum were found easy in 20 of 21 (95%) and 19 of 21 (91%) cases, respectively, but maneuvering inside the duodenum was found tricky during two procedures. Device positioning over the papilla was satisfactory in 17 of 21 cases (80%). Scope position was graded as stable in 15 of 21 cases (71%). Shaft stiffness was considered a likely factor for these minor inconveniences.

Maneuverability was deemed excellent by endoscopists for lateral and vertical directions and overall grip in 13 of 21 (62%), 16 of 21 (76%), and 16 of 21 procedures (76%), respectively. Concerning the elevator: pushability (such as for stent insertion) was deemed excellent, correct, and average in 43%, 52%, and 5% of procedures, respectively, whereas elevator power was rated as excellent, correct, average, and underwhelming in 14%, 62%, 19%, and 5% of procedures, respectively. On two different occasions, the guidewire was not efficiently blocked by the elevator during over-the-wire exchanges. Insuf-



► **Fig. 1** Endoscopic view of the single-use duodenoscope during a sphincterotomy with stone extraction

► **Table 2** Device performance.

| Papilla exposure | 100% |
|--|----------|
| Cannulation comparable to the reusable duodenoscope DR | 15 (71%) |
| ▪ Worse stability | 5 (24%) |
| ▪ Worse vertical maneuverability | 16 (76%) |
| ▪ Worse lateral maneuverability | 13 (62%) |
| ▪ Correct pushability of the elevator | 20 (95%) |
| ▪ Correct insufflation | 19 (90%) |
| ▪ Correct aspiration | 15 (71%) |
| Image quality | |
| ▪ Quality deemed insufficient | 3 (14%) |
| ▪ Discoloration: yellowish tones | 10 (48%) |
| ▪ Insufficient sharpness | 8 (38%) |
| ▪ Lack of contrast | 4 (19%) |

flation and aspiration were rated as excellent in 90% and 71% of procedures, respectively.

Endoscopic imaging

Endoscopic vision was deemed correct in 86% and subpar in 14% of procedures. The main criticisms about vision concerned skewing of color dominance toward yellowish tones (48% of procedures), whereas blurred vision (14%) and lack of contrast were encountered in 19% of cases. Image sharpness was considered excellent in 14%, adequate in 48%, and with a substantial margin for improvement in 38% of procedures, respectively. In the case of post-sphincterotomy bleeding, the image was good quality.

Discussion

This report is the first to address SUDs exclusively for emergent situations in a real-life setting and with no possibility of switching to a regular scope, a stressful situation for operators in a suboptimal context. SUDs were shown to be satisfactory and efficient overall and to be associated with a high rate of procedure completion, similar to what would be expected with reusable duodenoscopes, although most operators were not ERCP experts. All but one of the emergency ERCP procedures could be performed with SUDs, which may justify the purchase of SUDs for overnight and weekend shifts, for patients colonized with multidrug-resistant bacteria or in whom Creutzfeld-Jakob disease is suspected, as well as when logistical hurdles make reusable scopes unavailable (ie repeat scope breakdowns) or preclude reprocessing (ie the situation reported in this study). Finally, one can also imagine potential interest in SUD use when standard devices are unavailable after hours.

However, this study also showed some limitations because the image was often considered skewed toward yellow tones and pushability was an issue in a few procedures.

Although the limited, even marginal indications listed above should not be a matter of serious environmental concern, expanded use of SUDs would certainly make waste disposal and carbon footprint (including manufacturing, supply chains, medical use and disposal) major issues. If use of this type of system becomes more widespread, comparing the carbon footprint as well as the social impact of SUDs and reusable scopes should be a priority [14]. In the meantime, it is probably necessary to clearly define the indications for which SUDs should really be recommended in lieu of regular scopes.

Conclusions

This study showed that SUDs are safe and efficient devices, appropriate for emergent situations in real life even in non-expert hands. This report contributes to defining the place of SUDs in the therapeutic arsenal.

Competing interests

The authors declare that they have no conflict of interest.

References

- [1] Rauwers AW, Kwakman JA, Vos MC et al. Endoscope-associated infections: A brief summary of the current state and views toward the future. *Tech Gastrointest Endosc* 2019; 21: 150608
- [2] Rauwers AW, Voor in't holt AF, Buijs JG et al. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. *Gut* 2018; 67: 1637–1645
- [3] Peter S, Bang JY, Varadarajulu S. Single-use duodenoscopes: where are we and where are we going? *Curr Opin Gastroenterol* 2021; 37: 416–420
- [4] Bang JY, Hawes R, Varadarajulu S. Equivalent performance of single-use and reusable duodenoscopes in a randomised trial. *Gut* 2021; 70: 838–844
- [5] Bulut M, Hjørne F, Knuhtsen S et al. Sterile laparoscopic transgastric ERCP with single-use disposable duodenoscope. *Endoscopy* 2021; doi:10.1055/a-1508-5664
- [6] Ehrlich D, Muthusamy VR. Device profile of the EXALT Model D single-use duodenoscope for endoscopic retrograde cholangiopancreatography: overview of its safety and efficacy. *Expert Rev Med Devices* 2021; 18: 421–427
- [7] Muthusamy VR, Bruno MJ, Kozarek RA et al. Clinical evaluation of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography. *Clin Gastroenterol Hepatol Off Clin Pract J Am Gastroenterol Assoc* 2020; 18: 2108–2117.e3
- [8] Reddy DN, Ramchandani M, Lakhtakia S et al. Single-use duodenoscope in the management of an elderly patient with difficult bile duct stones: laser lithotripsy using a disposable cholangioscope. *VideoGIE* 2021; 6: 319–321
- [9] Ross AS, Bruno MJ, Kozarek RA et al. Novel single-use duodenoscope compared with 3 models of reusable duodenoscopes for ERCP: a randomized bench-model comparison. *Gastrointest Endosc* 2019; S0016510719322011 doi:10.1016/j.gie.2019.08.032
- [10] Slivka A, Ross AS, Sejpal DV et al. Single-use duodenoscope for ERCP performed by endoscopists with a range of experience in procedures of variable complexity. *Gastrointest Endosc* 2021; doi:10.1016/j.gie.2021.06.017
- [11] Napoléon B, Gonzalez J, Grandval P et al. Evaluation of the performances of a single-use duodenoscope: Prospective multi-center national study. *Dig Endosc* 2021; doi:10.1111/den.13965
- [12] Singer M, Deuschman CS, Seymour CW et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3). *JAMA* 2016; 315: 801–810
- [13] Schutz SM, Abbott RM. Grading ERCPs by degree of difficulty: a new concept to produce more meaningful outcome data. *Gastrointest Endosc* 2000; 51: 535–539
- [14] Baker N, Bromley-Dulfano R, Chan J et al. COVID-19 solutions are climate solutions: lessons from reusable gowns. *Front Public Health* 2020; 8: 590275