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Urgent ERCP performed with single-use duodenoscope (SUD) in patients with moderate-to-severe cholangitis: Single-center prospective study

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ABSTRACT

Background and study aims To assess the outcomes of urgent endoscopic retrograde cholangiopancreatography (ERCP) performed with a single-use duodenoscope (SUD) in patients with moderate-to-severe cholangitis.

Patients and methods Between 2021 and 2022 consecutive patients with moderate-to-severe cholangitis were prospectively enrolled to undergo urgent ERCP with SUD. Technical success was defined as the completion of the planned procedure with SUD. Multivariate analysis was used to identify factors related to incidence of adverse events (AEs) and mortality.

Results Thirty-five consecutive patients (15 female, age 81.4±6.7 years) were enrolled. Twelve (34.3%) had severe cholangitis; 26 (74.3%) had an American Society of Anesthesiologists (ASA) score ≥3. Twenty-eight patients (80.0%) had a naïve papilla. Biliary sphincterotomy and complete stone clearance were performed in 29 (82.9%) and 30 patients (85.7%), respectively; in three cases (8.6%), concomitant endoscopic ultrasound-gallbladder drainage was performed. Technical and clinical success rates were 100%. Thirty-day and 3-month mortality were 2.9% and 14.3%, respectively. One patient had mild post-ERCP pancreatitis and two had delayed bleeding. No patient or procedural variables were related to AEs. ASA score 4 and leucopenia were related to 3-month mortality; on multivariate analysis, leukopenia was the only variable independently related to 3-month mortality (odds ratio 12.8; 95% confidence interval 1.03–157.2; $P=0.03$).

Conclusions The results of this "proof of concept" study suggest that SUD use could be considered safe and effective for urgent ERCP for acute cholangitis. This approach abolishes duodenoscope contamination from infected patients without impairing clinical outcomes.

Introduction

The performance of endoscopic retrograde cholangiopancreatography (ERCP) has significantly impacted the natural history of both biliary and pancreatic diseases. The increased amount of ERCP procedures performed worldwide reflects the prevalence of biliary stone disease, malignant biliary obstruction, and biliary pancreatitis. In the near future, ERCP therapeutic

applications will further expand due to aging of population and increasing patient complexity and risk factors [1, 2, 3].

In the last decade, duodenoscope-related cross-infections have been reported, suggesting a potentially life-threating ERCP complication. In 2015, the US Food and Drug Administration suggested the adoption of a strategy to avoid duodenoscope contamination and related infections [4, 5, 6, 7].

Single-use duodenoscopes (SUD) recently have been introduced in clinical practice, based on the hypothesis that the use of a sterile disposable duodenoscope eliminates the risk of patient-to-patient cross-infections [8, 9].

Several clinical studies [10, 11, 12, 13, 14, 15, 16, 17, 18] and two meta-analyses [19, 20] confirmed that ERCP procedures performed with SUDs achieve high cannulation rates, technical performance rates, and have good safety profiles.

A recent survey conducted in our Italian regional area suggested that there is a lack of formal procedures and protocols for the management of patients at high risk for ERCP infections [21].

Since the beginning of the ERCP program at our unit in November 2021, we adopted a strategy to reduce the risk of ERCP-related infection. Because it was impossible to screen patients for carriage of multidrug-resistant microorganisms (MDROs) prior to ERCP procedure in an urgent setting, all patients with acute cholangitis and proven infection of the biliary system underwent urgent ERCP with a disposable SUD [22, 23]. We hypothesized that this strategy would lower the procedure risk to patients, but it also could prevent contamination of the two reusable duodenoscopes available in our facility [17].

While most studies on SUD use for ERCP have been conducted in elective settings, by experienced operators from tertiary-referral centers [10, 11, 12, 13], only a recent French study conducted on patients with different indications (acute cholangitis, jaundice, etc.) showed that SUDs also could be considered for emergent situations in real life [14].

Therefore, we aimed to assess clinical outcomes of urgent ERCP performed with SUD in a prospective study conducted in patients with moderate or severe cholangitis; technical performance and safety profile were also evaluated as secondary outcomes.

Patients and methods

Study design

We conducted a prospective study enrolling all consecutive patients who underwent ERCP for moderate-to-severe cholangitis between November 2021 and June 2023 at the Gastroenterology Unit of the Hospital of Imola, Italy. This “proof-of-concept” study was conducted in accordance with the principles of the Declaration of Helsinki (1975, revised in 2008). Informed consent for endoscopic procedures and anonymous data analysis for research purposes was obtained from each patient. Because of lack of a control group or any kind of treatment allocation or randomization, no registration on dedicated repositories has been performed.

Inclusion criteria were moderate-to-severe acute cholangitis according to Tokyo Guidelines 2018 [22, 23] requiring urgent ERCP, age ≥18 years, and ability to understand and sign informed consent. The exclusion criterion was refusal to undergoing ERCP.

For each patient, more than 30 variables were recorded, including patient demographic characteristics, concomitant medications, laboratory tests on admission or at the time of diagnosis of cholangitis (white blood cell [WBC] count, C-reactive protein, procalcitonin), previous biliary interventions (cholecystectomy, ERCP), post-ERCP pancreatitis prophylaxis, ERCP procedure details, early and late adverse events (AEs), and mortality. Data were collected at the time of the procedure, before discharge, and 3 months after the procedure. Patients were followed up during hospitalization and for 3 months after index ERCP; during follow-up, any additional biliary event or intervention was recorded.

Concomitant medications

Antiplatelet agents were managed according to available guidelines [24]. Anticoagulant agents were shifted to low-molecular-weight heparin (LMWH) at the time of hospital admission or diagnosis of cholangitis. LMWH was suspended 12 hours before ERCP.

Post-ERCP pancreatitis prophylaxis

All patients received rectal diclofenac suppository (100 mg) at the time of ERCP unless they had known allergy to nonsteroidal anti-inflammatory drugs or renal function impairment. Aggressive hydration with lactate Ringer’s solution was administered unless patients had a history of congestive heart failure or end-stage liver or renal disease. The pancreatic stent was left in place after >1 cannulation of the pancreatic duct or in case of advanced cannulation maneuvers to access the common bile duct.

ERCP procedure

All ERCPs were performed under general anesthesia by a single operator (A.L., 4-year experience, >800 ERCP performed) using CO_2 insufflation in supine position. All patients received systemic antibiotics.

Deep biliary cannulation was attempted with the guidewire-assisted technique over a sphincterotome in all cases; use of advanced techniques for cannulation (double guidewire technique, trans-pancreatic septotomy) or biliary precut was left to the discretion of the operator. In case of failure of biliary cannulation or planned biliary drainage or stone extraction, the operator could switch to a reusable duodenoscope (TJF-Q190V, Olympus Corp., Japan). The SUD used in this study, EXALT Model D, is provided by manufacturer (Boston Scientific Corp., United States) in a sterile package that is opened and attached to a dedicated EXALT processor immediately before its use. The SUD has a 15.1-mm outer caliber and an operative working channel of 4.2 mm; technical details are described in a recent American Society for Gastrointestinal Endoscopy review [25].

Definitions

The technical success rate was defined as completion of ERCP with SUD without the need to switch to a reusable duodenoscope. The clinical success rate was defined as resolution of acute cholangitis within 5 days after the procedure without further unplanned biliary interventions or change in antibiotic treatment. AEs were described according to European Society of Gastrointestinal Endoscopy guidelines and graded according to AGREE classification [26].

Sample size calculation

This study protocol represents the adoption of an internal strategy to reduce the risk for ERCP-related infection through the use of a disposable duodenoscope in all patients with acute cholangitis requiring urgent ERCP. According to the hospital internal protocol, an audit was expected 18 months after the beginning of the ERCP program in November 2021. The sample size, therefore, reflects the number of patients admitted for acute cholangitis and requiring urgent ERCP during the 18-month enrollment period.

Statistical analysis

Categorical variables were reported as number and percentage and compared using the Fisher exact test or the Chi-square test. Continuous variables were reported as means±standard deviation (means±SD) or median and interquartile range (median IQR), depending on the distribution, and compare with the Student's *t*-test or Mann-Whitney test, when appropriate. Univariate and multivariate logistic regression have been used to identify factors related to incidence of AEs and 30-day and 3-month mortality. P <0.05 was considered statistically significant. MedCalc Statistical Software version 20.115 (MedCalc Software, Ostend, Belgium; https://www.medcalc.org; 2022) was used.

Results

Study population

During the study period, 35 consecutive patients (15 female, 42.9%) with a mean age 81.4±6.7 years were enrolled. Twelve (34.3 %) had severe cholangitis according to TG18 criteria. Nine patients were American Society of Anesthesiologists (ASA) score 2, 14 ASA 3, while the remaining 12 were ASA 4. Mean age-adjusted Charlson Comorbidity Index (CCI) was 6.2 ±1.3. Nine patients (25.7%) were admitted to the Intensive Care Unit (ICU). Eighteen patients (51.4%) had gallbladder in situ; 28 (80.0%) had a naïve papilla. Patient baseline characteristics are detailed in ▶ **Table 1**.

Concomitant medications

Twenty patients (57.1%) received LMWH, while 16 patients (45.7%) were on antiplatelet agents (10 aspirin, 4 clopidogrel, 2 aspirin + clopidogrel).

▶ **Table 1** Baseline characteristics of the study population.

Characteristic	Total (no. 35)
Demographic	
▪ Gender (female), no. (%)	15 (42.9%)
▪ Age (years), mean±SD	81.4±6.7
▪ ASA score (≥3), no. (%)	26 (74.3%)
▪ Severe cholangitis, no. (%)	12 (34.3%)
▪ Age-adjusted CCI, mean±SD	6.2±1.3
▪ ICU admission, no. (%)	9 (25.7%)
Concomitant medication	
Low-molecular-weight heparin, no. (%)	20 (57.1%)
Antiplatelet agents, no. (%)	16 (45.7%)
▪ Aspirin, no.	10
▪ Clopidogrel, no.	4
▪ Aspirin + clopidogrel, no.	2
Laboratory tests	
▪ White blood cells count, median [IQR]	8700 [5950]–[10450]
▪ C reactive protein (mg/dL), median [IQR]	9.0 [5.0–16.5]
▪ Procalcitonin (ng/mL), median [IQR]	4.3 [2.4–6.1]

CCI, Charlson Comorbidity Index; ICU, intensive care unit; IQR: interquartile range; SD, standard deviation.

Laboratory tests

Median white blood cell count was 8700/mm^3 [5950]–[10450]; median C-reactive protein was 9 [5–16.5] mg/dL; median procalcitonin was 4.3 [2.4–6.1] ng/mL.

Post-ERCP pancreatitis prophylaxis

Twenty-nine patients (82.9%) received rectal NSAIDs, 30 (85.7%) aggressive hydration with lactate Ringer's solution. In four cases (11.4%), a prophylactic 5F × 4-cm pancreatic stent was left in place.

ERCP procedure details

Deep biliary cannulation was achieved in all 35 cases (100%); two patients (5.7%) required biliary precut, as described in ▶ **Table 2**. Endoscopic sphincterotomy was performed in 25 patients (71.4%); endoscopic papillary large balloon dilation (EPLBD) was performed in three patients (8.6%); in four cases (11.4%), both biliary sphincterotomy and EPLBD were necessary; finally, in the remaining three patients (8.6%), no biliary sphincterotomy or EPLBD was performed. Complete stone clearance was achieved in 30 cases (85.7%); failure of stone clearance was due to a distal common bile duct stricture (2 cases) or to presence of multiple large stones (3 cases). A biliary stent was left in place in 12 patients (34.3%): seven 10F plastic stents, two 10-mm fully-covered self-expandable metal stents

▶ **Table 2** ERCP technical details and outcomes.

Characteristic	Total (no. 35)
ERCP procedure details	
▪ Deep biliary cannulation, no. (%)	35 (100%)
▪ Biliary precut, no. (%)	2 (5.7%)
▪ Biliary sphincterotomy, no. (%)	29 (82.9%)
▪ Endoscopic papillary large balloon dilation, no. (%)	7 (20.0%)
▪ Biliary sphincterotomy alone, no.	25
▪ Papillary dilation alone, no.	3
▪ Sphyncterotomy plus dilation, no.	4
▪ No sphincterotomy nor dilation, no.	3
Complete stone clearance, no. (%)	30 (85.7%)
▪ Distal bile duct stricture, no.	2
▪ Multiple large stones, no.	3
Biliary stenting, no. (%)	12 (34.3%)
▪ 10 Fr plastic stent, no.	7
▪ 10 mm SEMS, no.	2
▪ SEMS + plastic, no. (%)	3
EUS-GBD with LAMS, no. (%)	3 (8.6%)
Post-ERCP pancreatitis prophylaxis	
▪ Rectal NSAIDs, no. (%)	29 (82.9%)
▪ Aggressive hydration lactate Ringer's solution, no. (%)	30 (85.7%)
▪ Pancreatic stent placement, no. (%)	4 (11.4%)
Main outcomes	
▪ Technical success, no. (%)	35 (100%)
▪ Clinical success, no. (%)	35 (100%)
▪ 30-day mortality, no. (%)	1 (2.9%)
▪ 3-month mortality, no. (%)	5 (14.3%)
▪ Unplanned biliary interventions, no. (%)	0 (0%)
▪ Recurrent cholangitis, no. (%)	1 (2.9%)
Adverse events	
Adverse events (overall), no. (%)	3 (8.6%)
▪ Post-ERCP pancreatitis, no.	1 (mild)
▪ Infection, no.	0
▪ Delayed bleeding, no.	2
▪ AGREE classification	
▪ Grade II	1
▪ Grade IIIa (endoscopic management), no.	2
Hospitalization	
▪ ICU length of stay (days), median [IQR]	3 [2, 3, 4]
▪ Hospital length of stay (days), median [IQR]	8 [6–11.3]

ERCP, endoscopic retrograde cholangiopancreatography; SEMS, self-expandable metal stent; EUS-GBD, ultrasound-guided gallbladder drainage; LAMS, lumen-apposing metal stent; NSAID, non-steroidal anti-inflammatory drug; ICU, intensive care unit; SD, standard deviation; IQR, interquartile range.

(SEMS), and three 10-mm SEMS with a co-axial plastic stent inside.

Three patients (8.6%) underwent endoscopic ultrasound-guided gallbladder drainage (EUS-GBD) with electrocautery-enhanced lumen-apposing metal stent (LAMS) at the time of index ERCP.

Main outcomes

The technical success rate was 100%, with no need to switch to a reusable duodenoscope. All patients (35, 100%) achieved clinical success, with resolution of cholangitis within 5 days and no need for unplanned additional biliary interventions.

Overall incidence of AEs was 8.6%. One patient had mild post-ERCP pancreatitis. No patient presented with a post-ERCP infection. Two patients (8.0%) reported post-ERCP delayed bleeding; both cases were graded IIIa according to AGREE classification, because both required endoscopic management. In detail, one case had duodenal bleeding from the opposite side from the papilla, due to plastic stent migration and was treated with through-the-scope hemoclip. One case presented with self-limiting bleeding from the duodenal bulb, close to the proximal flange of LAMS deployed for EUS-GBD; a double pigtail soft plastic stent (10F×4 cm) was placed. Univariate analysis did not identify any patient or procedural variable related to the incidence of AEs.

Median ICU length of stay was 3 days (range, 2–4). Median hospitalization was 8 days (range, 6–11.3).

Thirty-day and 3-month mortality were 2.9% and 14.3%, respectively. On univariate analysis, ASA score 4 (odds ratio [OR] 4.88; 95% confidence interval [CI] 2.12–55.3; $P = 0.04$) and leukopenia (WBC count <4000/mm^3) (OR 12.8; 95% CI 1.03–157.2; $P = 0.03$) were related to 3-month mortality. On multivariate analysis, presence of leukopenia on admission was the only variable independently related to 3-month mortality (OR 12.8; 95% CI 1.03–157.2; $P = 0.03$). Univariate and multivariate analyses are reported in ▶ **Table 3**.

Five patients (14.3%) required a second ERCP after 4 to 6 weeks; in two cases, SEMS allowed the calibration of a distal stricture and stone clearance was achieved with a balloon-tip catheter. The remaining three cases required cholangioscopy-assisted electro-hydraulic lithotripsy to achieve stone clear-

▶ **Table 3** Factors related to 3-month mortality.

	Univariate (OR [95% CI])	*P*	Multivariate (OR [95% CI])	*P*
Age (year)	1.04 [0.88–1.23]	0.66	—	—
Gender (male)	1.10 [0.13–9.34]	0.93	—	—
ASA score 4	**4.88 [2.12–55.3]**	**0.04**	ns	ns
Severe cholangitis	2.50 [0.28–22.0]	0.41	—	—
Age-adjusted CCI	0.89 [0.39–2.04]	0.79	—	—
ICU admission	0.83 [0.07–9.69]	0.88	—	—
Leukopenia (WBC <4000/mm³)	**12.8 [1.03–157]**	**0.03**	**12.8 [1.03–157.2]**	**0.03**
C-reative protein	0.90 [0.74–1.11]	0.34	—	—
Procalcitonin	0.90 [0.60–1.37]	0.63	—	—
Complete stone clearance	2.1 [0.15–68.0]	0.98	—	—
Incidence of AEs	0	0.99	—	—

OR, odds ratio; CI, confidence interval; ns, not statistically significant; CCI, Charlson Comorbidity Index; ICU, intensive care unit; WBC, white blood cell; AE, adverse event.

ance. No recurrent cholangitis was observed during follow-up. Biliary stents were removed within 8 weeks.

Discussion

The results of this study confirm the optimal performance in terms of safety and efficacy of SUD in a homogeneous population of patients with moderate-to-severe cholangitis undergoing urgent ERCP [20]. Indeed, all planned biliary procedures were accomplished with SUD use, without the need to switch to a reusable duodenoscope. Moreover, urgent ERCP performed with SUD confirmed the optimal safety profile, with no post-procedure infection or post-ERCP pancreatitis. The two delayed bleeds observed in this study were related to unusual AEs, such as biliary plastic stent migration in the duodenum leading to pression ulcer on the opposite wall and spontaneous delayed bleeding after endoscopic ultrasound gallbladder drainage (EUS-GBD) with LAMS.

To date, the use of disposable endoscopes has been suggested in high-risk cases for ERCP infection. In detail, use of SUD was suggested in patients who received systemic antibiotic treatment in the last 6 months, in patients affected by malignant biliary obstruction due to cholangiocarcinoma requiring stenting, or in patients with previous liver transplant, in order to reduce the risk of infections due to duodenoscope transmission [10, 11]. On the other hand, no clear indication has been provided yet for the risk reduction of duodenoscope contamination. While some centers routinely perform a rectal swab in patients undergoing ERCP to exclude the presence of MDRO carriage, the management of patients with proven biliary infection or gut MDRO contamination has not already been standardized.

In case of patients undergoing urgent ERCP for proven biliary infection, not only a hypothetical increased risk of duodenoscope contamination could be suggested, but also a screening strategy for MDRO carriage cannot be identified [27]. In this specific setting, the cost-effectiveness of single-use vs. reusable duodenoscopes recently has been evaluated and discussed; the authors concluded that a specific evaluation should be performed based on the incidence of MDRO contamination and the impact of duodenoscope-related infections [28].

The results of the present study were in line with available studies conducted in this field, not only in terms of technical and clinical success but also of safety profile. Indeed, our study group conducted a previous meta-analysis of prospective studies of ERCP conducted with SUD. We observed an optimal pooled technical success rate (OR 92.9%; 95% CI 89.9%-95.5%) with very low incidence of AEs rate (OR 6.4%; 95% CI 3.3%-10.3%) [19]. These preliminary findings have been recently confirmed by un updated systematic review, demonstrating a 95% pooled cannulation rate with a 7% total AE rate [20]. While most of these studies included elective procedures, a recent French study confirmed those outcomes also in the setting of emergent ERCPs performed for several indications [14]. Finally, the present study contributes data in a homogeneous, albeit small population.

In this setting, in November 2021, we began an ERCP program at the Gastroenterology Unit of the Hospital of Imola, Italy. Due to the expected ERCP volume of 150 procedures/year, a single duodenoscope with disposable detachable tip (TJF-Q190V, Olympus) was available in our facility. In order to reduce the risk of bacterial contamination of the reusable duodenoscope, we designed an internal protocol for adopting SUD use in patients with proven biliary infection. Therefore, we prospectively enrolled all patients with moderato-to-severe acute cholangitis requiring urgent ERCP with SUD in order to assess the performance of urgent ERCP and patient outcomes. On these bases, we tried to analyze risk factors related to the incidence of AEs in our study; interestingly, no patient characteristics (demographic, medical history, general conditions or con-

comitant medications) or procedure variables (biliary sphincterotomy, papillary large balloon dilation, precut, concomitant EUS-GBD, or stenting) appeared related to the incidence of delayed bleeding. We acknowledge that the few observed events could justify this negative result.

The study population included elderly patients (mean age >80 years) with several comorbidities (mean age-adjusted CCI >6) and concomitant medications, reflecting the ongoing changes in general population worldwide [29]. In this setting, we observed a 14.3% mortality rate at 3 months. Univariate analysis identified ASA score and presence of leukopenia before ERCP as risk factors for 3-month mortality; multivariate analysis identified the latter as the only variable independently related to 3-month mortality. We speculate that leukopenia could be a surrogate marker for anergic response to biliary sepsis, justifying the unfavorable long-term outcome observed in this group, independent of clinical resolution of acute biliary infection.

This study presents several limitations. First, the relatively small sample size (35 cases) cannot allow us to draw definitive conclusions. However, we prospectively collected and analyzed those data to provide one of the few pieces of evidence in the field of SUD use for urgent ERCP. To date, a similar French experience has been published, but in a relatively inhomogeneous group of patients (the authors included not only acute cholangitis but also progressive jaundice due to malignant biliary obstruction) [14]. Another limitation is related to the performance of all procedures by a single operator. In this case, the good ERCP outcomes with SUD use could be related to the previous experience in the French registration study that allowed the operator to test the SUD and have confidence with its mechanical characteristics. Finally, the results observed in the survival and safety analysis cannot be considered definitive because of the small number of observed events.

Conclusions

In conclusion, the results of this small "proof-of-concept" study suggest that SUD use in patients with proven biliary infections requiring urgent ERCP could be considered an alternative strategy able to eliminate the risk of cross-patient infections and duodenoscope contamination without impacting ERCP outcomes in terms of safety and clinical success.

Conflict of interest: Bertrand Napoléon received research grant and teaching sessions from Boston Scientific Corporation. Pietro Fusaroli received consultancy from Boston Scientific Corporation. Dr. Andrea Lisotti has a contract of proctorship for 2021 and 2022 with Boston Scientific Corporation. All the other authors have no conflict of interest to declare.

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