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Single-use duodenoscope for ERCP: a prospective feasibility study

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Background: Single-use duodenoscopes were developed to eliminate the risk of duodenoscope-related cross-contamination associated with reusable instruments. Although their technical performance has been evaluated in high-income countries, evidence from low-middle-income settings remains limited. This study evaluated the feasibility, technical performance, safety, and operator satisfaction of a single-use duodenoscope for endoscopic retrograde cholangiopancreatography (ERCP) in a South African tertiary academic hospital.
Methods: This prospective, single-arm feasibility study included 15 patients with obstructive jaundice who underwent ERCP using a single-use duodenoscope (SUD). Data collected included patient demographics, ASA grade, procedural characteristics, cannulation attempts and times, completion and crossover rates, complications, and operator satisfaction. Patients were followed for 30 days for serious adverse events.
Results: All 15 procedures (100%) were completed using the SUD, with no crossover to a reusable duodenoscope (RD). Mean cannulation time was 4.9 ± 2.0 minutes and mean procedure time 14.7 ± 4.7 minutes. The mean number of cannulation attempts was 1.47 ± 0.52. Operator satisfaction was high, with a median score of 9/10 for handling, positioning, and image quality. All 15 procedures (100%) were completed using the single-use duodenoscope, with no crossover to a reusable duodenoscope. Mean cannulation time was 4.9 ± 2.0 minutes, mean procedure time was 14.7 ± 4.7 minutes, and the mean number of cannulation attempts was 1.47 ± 0.52. Operator-reported scores were favourable, with median scores of 9/10 for handling, scope positioning, image visualisation and overall satisfaction. Four patients (26.7%) developed post-ERCP complications: mild pancreatitis (n = 2), moderate pancreatitis (n = 1), and mild bleeding (n = 1). Only the patient with moderate pancreatitis required prolonged hospitalisation and subsequent nutritional support. No perforations or deaths occurred, and the median hospital stay was 2 days.
Conclusion: The feasibility study of a single-use duodenoscope for ERCP in our setting achieved complete procedural success with high operator satisfaction. The small sample size precludes meaningful conclusions regarding complication rates. Larger studies are needed to establish its role in practice.
Keywords: endoscopic retrograde cholangiopancreatography, ERCP, single-use duodenoscope, obstructive jaundice, feasibility, South Africa

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an established therapeutic intervention for a wide range of pancreaticobiliary disorders, including biliary obstruction due to stones, strictures and malignancy. Access to ERCP, however, remains limited in many low- to middle-income countries (LMICs), including South Africa, where shortages of trained endoscopists, inadequate infrastructure, equipment failure and limited access to fluoroscopy can delay treatment, particularly outside tertiary academic centres.[1-3]

Reusable duodenoscopes (RDs) remain the standard platform for ERCP but require meticulous cleaning and high-level disinfection between procedures. Despite adherence to recommended reprocessing protocols, duodenoscope-associated transmission of multidrug-resistant organisms continues to be reported. The complex design of the duodenoscope, particularly the elevator mechanism and internal channels, may make effective decontamination challenging and contribute to persistent contamination.[2-10] These concerns have driven the development of duodenoscopes incorporating disposable components and fully single-use duodenoscopes (SUDs), which eliminate the need for reprocessing between patients and may reduce the risk of device-related cross-contamination.[11-13]

Several prospective studies have demonstrated high technical success and favourable procedural performance with SUDs, including studies evaluating their use across operators with different levels of experience and procedures of varying complexity.[14-18] However, much of the published evidence has originated from high-income healthcare systems, and experience with SUDs in LMICs remains limited. In particular, the practical value of a single-use device may extend beyond infection prevention. In settings where reprocessing facilities are limited or unreliable, ERCP volumes are low, or equipment and trained support staff are intermittently unavailable, a SUD may provide an alternative means of maintaining or extending ERCP services. Its portability may also facilitate selected outreach procedures where appropriate infrastructure is available but access to a functioning reprocessing service is limited.

The principal limitation to wider adoption of SUDs is their higher per-procedure acquisition cost. Economic analyses suggest that RDs may remain more economical in high-volume centres, whereas the balance may shift in lower-volume institutions or settings with limited reprocessing capacity.[19,20] These considerations favour a selective rather than universal approach to the use of SUDs, with potential application in specific clinical or service-delivery circumstances rather than routine replacement of RDs.

To our knowledge, no published South African clinical study has evaluated a SUD for ERCP. Furthermore, although previous studies have evaluated SUDs, the clinical experience with the Ambu® aScope™ Duodeno remains relatively limited.[14-18] We therefore conducted a prospective feasibility study to evaluate the technical performance of a single-use duodenoscope during therapeutic ERCP at a South African tertiary academic hospital, with particular attention to successful procedure completion, procedural complexity and operator experience.

Methodology

Study design

This prospective, single-arm feasibility study evaluated the use of a SUD for therapeutic ERCP. Patient management followed the unit's standard clinical protocol. Data were collected prospectively during ERCP and immediately thereafter, with patients followed for 30 days after discharge to identify delayed complications and other clinical outcomes.

The study was designed as an exploratory feasibility study rather than a comparative or safety study. Twenty patients were initially planned for enrolment; however, only 15 SUDs were available and therefore 15 patients were included. The sample size was determined by device availability and was not intended to provide statistical power for comparison of complication rates or clinical outcomes.

Study setting and device

The study was conducted in the Endoscopy Unit of Dr George Mukhari Academic Hospital (DGMAH), a tertiary academic institution affiliated with Sefako Makgatho Health Sciences University. The unit provides ERCP services to the northern Tshwane community and receives referrals from Limpopo, North West and Mpumalanga provinces.

The device evaluated was the Ambu® aScope™ Duodeno SUD (Figure 1) used with the Ambu® aBox™ Duodeno imaging system. The devices were donated to the hospital and were not part of the institution's routine equipment stock. The manufacturer had no involvement in study design, patient selection, data collection, analysis, interpretation of the findings, manuscript preparation or the decision to publish.

Patient selection

Consecutive adults aged ≥ 18 years with obstructive jaundice due to distal common bile duct stones or malignancy who required ERCP were eligible for inclusion. Written informed consent was obtained from all participants. Patients with pregnancy, altered anatomy or other conditions precluding conventional ERCP, participation in another conflicting study, or clinical circumstances making ERCP inappropriate were excluded.

Patients were recruited using purposive sampling during the study period, with enrolment limited by the availability of SUDs.

ERCP procedure

All ERCP procedures were performed by a single experienced endoscopist with more than 2 000 lifetime ERCP procedures. The use of a single operator was deliberate to minimise operator-related variability and allow the technical performance of the device to be assessed under relatively consistent procedural conditions. This approach also limits the generalisability of the findings to other operators and centres.

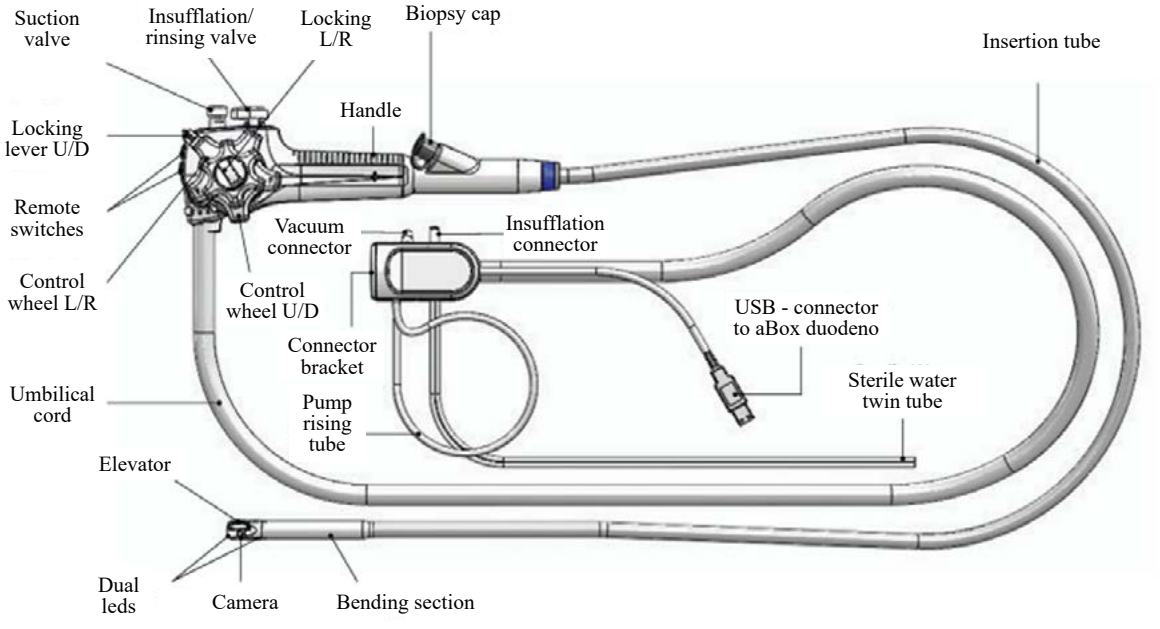


Figure 1: Ambu® aScope™ Duodeno by Ambu used in our study[21]

Procedures were performed in the dedicated endoscopy suite using standard institutional ERCP protocols. Patients were positioned according to procedural requirements, with the prone position used whenever appropriate. Anaesthesia or sedation was administered according to routine institutional practice. Prophylactic nonsteroidal anti-inflammatory medication was administered according to availability at the time of the procedure.

Selective biliary cannulation was performed using standard guidewire-assisted techniques. Needle-knife-assisted access was undertaken when required for difficult cannulation. Therapeutic interventions were performed according to the underlying indication and included biliary sphincterotomy, stone extraction, biliary stent placement and other interventions as clinically indicated.

Procedural complexity was classified according to the American Society for Gastrointestinal Endoscopy (ASGE) ERCP complexity grading system.[22] The specific therapeutic intervention performed, ASGE complexity grade, cannulation technique, number of cannulation attempts, cannulation time and total procedure time were recorded prospectively.

Technical feasibility and device performance

The primary outcome was technical feasibility of the SUD for therapeutic ERCP. A technically successful procedure required successful deep cannulation of the intended bile duct, completion of the planned therapeutic intervention, absence of device-related technical failure and completion of the procedure without crossover to a RD.

Device-related technical problems, including loss of image, impaired elevator function, difficulty with accessory passage, inadequate scope positioning or other malfunction requiring device exchange, were recorded prospectively. Any requirement to replace the SUD with a RD was recorded as crossover and considered technical failure.

Operator evaluation

Because this was a feasibility study of a novel endoscopic platform, operator experience was included as a secondary outcome. Immediately after each procedure, the operating endoscopist completed a structured assessment using a 10-point scale. The assessment recorded scores for scope handling, scope positioning, image visualisation and overall satisfaction.

The assessment tool was developed by the principal investigator and was not a validated comparative instrument. Its purpose was to provide a consistent assessment of the operator's experience with the device and to permit descriptive comparison with previously published studies using similar assessments.

Outcome definitions and follow-up

Post-ERCP complications were recorded prospectively and classified according to accepted ERCP adverse-event definitions. Post-ERCP pancreatitis was diagnosed when patients developed new or worsening abdominal pain accompanied by a post-procedure amylase level of at least three times the upper limit of normal and requiring unplanned hospital admission or prolongation of the planned hospital stay. Pancreatitis severity was classified according to duration of hospitalisation and clinical course.

Bleeding, perforation and other post-procedural complications were recorded and graded according to their clinical severity. Hospitalisation, level of postoperative care, additional treatment and mortality were recorded during the index admission.

All patients were followed for 30 days after ERCP. Follow-up was undertaken through clinical review and assessment of hospital records to identify delayed complications, readmission, additional interventions and mortality.

Data collection and descriptive and comparative analysis

Data were collected prospectively by the principal investigator and verified by the research supervisor and/or endoscopist. Variables included demographic characteristics, ASA physical status, referral source, inpatient or outpatient status, cause of biliary obstruction, cholangitis, relevant comorbidities, therapeutic procedures, ASGE complexity grade, cannulation attempts and time, total procedure time, device-related technical problems, crossover, operator assessment, hospitalisation, complications and 30-day outcomes.

Continuous variables were summarised using means and standard deviations or medians and ranges, as appropriate, while categorical variables were presented as frequencies and percentages. Given the small sample size and exploratory nature of the study, analyses were primarily descriptive and no formal statistical comparisons were undertaken.

For contextual comparison, findings from the present study were compared descriptively with selected prospective studies evaluating SUDs for ERCP.[14-18] Studies were selected because they reported prospective clinical experience and included measures of procedural completion or technical success and/or operator assessment. Published data were not

Table I: Comparison of selected prospective studies evaluating SUDs for ERCP

Study	Patients *n*	Technical success	Operator assessment	Principal study characteristic
Bang et al.[14]	98	95.8%	Lower ratings for image quality, image stability, ease of passage and air–water function than RD	Randomised comparison with RD
Muthusamy et al.[15]	60	96.7%	Median overall satisfaction 9/10	Multicentre clinical evaluation
Slivka et al.[16]	200	96.3%	Median overall satisfaction 8/10	Operators with varying experience and procedures of variable complexity
Bruno et al.[17]	552	97.5%	Overall operator satisfaction 8/10	Large international prospective study
Bhenswala et al.[18]	52	90.4%	Operator assessment reported; no directly comparable overall satisfaction score	Single-centre preliminary clinical evaluation
Present study	**15**	100%	Median overall satisfaction 9/10	First prospective South African clinical evaluation

subjected to statistical comparison because of differences in study design, patient populations, procedural complexity and outcome definitions. The comparative data are presented in Table I.

Results

Patient characteristics

Fifteen patients underwent ERCP using the SUD. The mean age was 51.2 years (range 26–73), with 10 (66.7%) women and 5 (33.3%) men. Ten patients (66.7%) were inpatients. Referrals originated from the study institution in 4 patients (26.7%), other academic centres in 4 (26.7%), and non-academic centres in 7 (46.7%). Six patients (40.0%) were ASA I, eight (53.3%) ASA II and one (6.7%) ASA III.

Benign biliary obstruction accounted for 9 cases (60.0%) and malignant obstruction for 6 (40.0%). Ascending cholangitis was present in 11 patients (73.3%), comprising mild disease in 4 (36.4%), moderate disease in 5 (45.5%) and severe disease in 2 (18.2%). Eleven patients (73.3%) had at least one medical comorbidity, with hypertension being the most common.

Therapeutic procedures and procedural complexity

All 15 ERCPs were completed successfully using the SUD, with no crossover to a RD. Eleven procedures (73.3%) were classified as ASGE Grade 1–2 and four (26.7%) as Grade 3; no Grade 4 procedures were undertaken. The median procedure time was 15 minutes (range 7–23), and the median cannulation time was 5 minutes (range 2–9), with a mean of 1.47 ± 0.52 cannulation attempts. Guidewire-assisted cannulation was performed in 11/15 (73.3%) procedures and needle-knife-assisted cannulation in 4/15 (26.7%).

Therapeutic interventions are shown in Table II. Stone extraction was successfully completed in all nine procedures in which it was attempted, while plastic and metal biliary stent placement were successfully completed in all four and six procedures, respectively. Some patients underwent more than one therapeutic intervention during the same ERCP.

Technical performance

Successful completion of the intended ERCP was achieved in all 15 patients (100%), with no device-related crossover to a RD. There were no reported device failures preventing completion of the planned procedure. Procedures included both lower- and higher-complexity ERCPs, with successful completion across all ASGE grades represented in the study.

Operator evaluation

Table III shows the operator-reported evaulation scores that were favourable across all four assessed domains. Median scores were 9/10 for handling, scope positioning, image visualisation and overall satisfaction. Image visualisation received the highest mean score (9.4 ± 0.5), while handling had the lowest (8.7 ± 0.9).

Eleven patients (73.3%) experienced no post-procedural complications. Four patients (26.7%) developed complications: three cases of post-ERCP pancreatitis (20.0%) and one episode of mild bleeding (6.7%). The pancreatitis cases were classified as mild in two patients and moderate in one. All three patients who developed pancreatitis had undergone ASGE Grade 3 procedures.

The median post-procedural hospital stay was 2 days (range 0–7). One patient with moderate pancreatitis required nutritional support and was classified as Clavien–Dindo Grade II. No perforations or deaths occurred during the index admission or 30-day follow-up. All patients completed 30-day follow-up.

Discussion

This prospective study demonstrates the technical feasibility of using a SUD for therapeutic ERCP in a South African tertiary academic hospital. All 15 procedures were completed without crossover to a RD, including ASGE Grade 1–3 procedures and therapeutic interventions involving stone extraction and biliary stent placement. Operator-reported assessments were favourable across all domains evaluated. These findings are consistent with previous international prospective studies and provide prospective clinical experience with a SUD for ERCP in a South African tertiary hospital.

The 100% procedural completion rate and favourable operator assessments in the present study are broadly consistent with previous prospective evaluations of SUDs (Table III).[14-18] Direct comparison is nevertheless limited by differences in device type, patient selection, procedural complexity, operator experience and definitions of technical success. Most procedures in our cohort were ASGE Grade 2,

Table II: Therapeutic procedures performed using the SUD according to ASGE complexity grade

Therapeutic procedure*	ASGE Grade 1-2 (successful/attempted)	ASGE Grade 3-4 (successful/attempted)
Benign disease		
Stone extraction	6/6	3/3
Plastic stent insertion	3/3	1/1
Malignant disease		
Metal stent insertion	5/5	1/1

* Patients may have undergone more than one therapeutic intervention during the same procedure

Table III: Operator evaluation of the SUD post-ERCP outcomes

Domain	Mean (SD)	Median (IQR)	Min– Max
Handling	8.7 (0.9)	9 (8–9)	7–10
Scope positioning	8.9 (0.7)	9 (8–9)	8–10
Image visualisation	9.4 (0.5)	9 (9–10)	9–10
Overall satisfaction	9.0 (0.7)	9 (8.3–9.3)	8–10

with none classified as Grade 4; successful stone extraction and plastic and metal stent placement therefore provide more meaningful evidence of therapeutic feasibility than procedure time or cannulation attempts. Operator satisfaction scores were favourable (median 9/10 across all domains), although these findings should be interpreted with caution because the assessment was non-validated and performed by a single experienced operator. Bang et al.[14] identified lower ratings for specific device characteristics, including image quality and stability, highlighting the importance of not interpreting operator satisfaction as evidence of equivalence or superiority over RDs.

The therapeutic procedures undertaken provide additional evidence of device capability. Stone extraction was successful in all nine procedures in which it was attempted, while all attempted plastic and metal stent insertions were completed successfully. The device was therefore successfully used for several common therapeutic ERCP interventions across ASGE Grade 1–3 procedures. However, no Grade 4 procedures were undertaken, and the small number of procedures prevents conclusions regarding performance in more complex therapeutic interventions.

The safety findings in this small cohort provide limited information on complication rates. Four patients experienced post-ERCP complications: three cases of pancreatitis and one mild bleeding episode; only the patient with moderate pancreatitis required prolonged treatment and nutritional support. The observed PEP rate of 20% exceeds the ESGE quality benchmark of < 10%,[23] but represents only three patients. All three cases followed ASGE Grade 3 procedures, and inconsistent NSAID prophylaxis may have contributed.[24,25] Variation in PEP rates according to patient selection and procedural risk further limits comparison with published studies.[26,27] No perforations or deaths occurred, but the study was not designed to assess safety.

The potential value of SUD in South Africa may therefore lie in selective rather than universal use. Their principal practical advantage is elimination of the need for reprocessing between procedures, which may be particularly relevant where reprocessing facilities are inadequate or unreliable.[3-5,10,14] Selective use may also be considered for patients with highly transmissible infections, including those with multidrug-resistant tuberculosis, where minimising potential contamination of reusable equipment may be advantageous. Their portability may further facilitate selected outreach services where appropriate fluoroscopy, anaesthetic support and post-procedural care are available. These potential applications require appropriate infrastructure and should not be interpreted as justification for ERCP outside suitably equipped clinical environments.

Limitations

The sample size was small and determined by device availability, limiting the precision of the findings, particularly complication estimates. The single-centre design and performance of all procedures by one highly experienced ERCP endoscopist limit generalisability. There was no RD comparator, and microbiological surveillance was not performed; consequently, the study cannot assess comparative performance, contamination or infection transmission. Cost is an important consideration in the adoption of SUDs that was not evaluated in this study.[19,20]

Conclusion

This prospective study demonstrates the technical feasibility of a SUD for therapeutic ERCP in a South African tertiary hospital, with successful completion of all procedures undertaken and favourable operator assessment. The small sample size precludes meaningful conclusions regarding complication rates. The cost effectiveness in resource-limited settings therefore requires further assessment. Larger studies are needed to establish its role in practice in the South African setting.

Conflict of interest

The authors declare no conflict of interest.

Funding source

No funding was received for this study.

Ethical approval

Ethical clearance was obtained from the Sefako Makgatho Health Sciences University Ethics Committee with the following ethics number (SMUREC/M/283/2024:PG). Informed written consent was obtained from all patients for being included in the study.

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