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Original Article

Prospective evaluation of an assessment tool for technical performance of duodenoscopes

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Objective: While single-use and detachable-tip duodenoscopes have been recently developed to overcome risks of infection transmission, there are no reliable tools to objectively assess their technical performance. We evaluated the reliability and validity of a newly developed tool to assess the technical performance of reusable duodenoscopes.

Methods: An assessment tool was developed to measure duodenoscope performance based on three distinct criteria: maneuverability, mechanical/imaging characteristics and ability to perform requisite interventions. The assessment tool was tested prospectively on duodenoscopes used in endoscopic retrograde cholangiopancreatography (ERCP) procedures at nine academic medical centers over a 6-month period. The main outcome was reliability of the duodenoscope assessment tool, which was estimated using Cronbach's coefficient alpha (α). The secondary outcome was validity of the assessment tool.

Results: The assessment tool evaluated technical performance of reusable duodenoscopes in 1080 ERCP procedures. Indications were biliary in 92.8% and pancreatic in 7.2% procedures. The overall Cronbach's coefficient α for maneuverability was 0.81, assessment of mechanical/imaging characteristics was 0.92, and ability to perform requisite interventions was 0.87. On multiple linear regression analysis, prolonged procedure duration, older patient age and pancreatic interventions were significantly positively associated with higher (worse) scores.

Conclusions: The newly developed assessment tool appears reliable and valid for evaluating the technical performance of duodenoscopes.Registration: ClinicalTrials.gov Identifier: NCT04004533.

Key words: duodenoscope, duodenoscope assessment tool, endoscopic retrograde cholangiopancreatography

INTRODUCTION

DUODENOSCOPES PLAY AN important role in the assessment and treatment of diseases of the pancreas and bile ducts and are used in more than 700,000 endoscopic retrograde cholangiopancreatography (ERCP) procedures annually in the United States. ERCP is a technically challenging combined endoscopic/radiographic procedure. While studies on ERCP have focused predominantly on technical and clinical success, adverse events, quality improvement and costs,[1–3] recently, infection outbreaks, including carbapenem-resistant Enterobacteriaceae (CRE), caused by contaminated, reusable, duodenoscopes

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have been reported.[4,5] Due to complex designs that include reusable hard-to-clean components, such as the elevator system and working channel, duodenoscopes containing retained micro bacterium, in rare cases, can lead to patient-to-patient disease transmission. As a result, the U.S. Food and Drug Administration (FDA) has mandated transition away from fixed endcaps to those with disposable caps or even single-use disposable duodenoscopes to minimize or eliminate the risk of infection transmission.[6]

Although ERCP-related mortality is less than 0.5%, its advantage for minimal invasiveness is offset by the potential for serious complications, such as pancreatitis, bleeding, infection, and perforation.[7] There are several factors that determine ERCP outcomes - technical proficiency of the endoscopist, expertise of procedural assistants and the availability of devices and accessories which include an optimally functioning duodenoscope.[1,8] While there have been no major changes to the basic design over the past two decades, given the FDA mandate, disposable-tip and single-use duodenoscopes have recently been developed.[9,10] These new designs should reduce or eliminate transmission of infection from the duodenoscope but if the functionality is suboptimal, it may simply create a trade-off to reduce one complication while increasing others. It is therefore critically important to ascertain whether the newly developed duodenoscopes function equally well, or perhaps better, than the older version, reusable, duodenoscopes.

While reliable methods are available to assess patient-related metrics such as quality of life in cancer or severity of pain in pancreatitis, there are no tools to objectively assess the technical performance of a duodenoscope.[11,12] The development of a tool that takes into consideration distinct criteria such as maneuverability, mechanical/imaging characteristics and ability to perform requisite interventions will enable objective evaluation of duodenoscope performance, provide critical feedback to manufacturers for making technical refinements and possibly serve as a template on which other flexible endoscope platforms can be assessed.

The objective of this prospective study was to evaluate the reliability and validity of a newly developed tool to assess the technical performance of duodenoscopes.

MATERIALS AND METHODS

THIS PROSPECTIVE STUDY evaluated the data on the technical performance of reusable duodenoscopes (TJF 180, Olympus America, Center Valley, PA, USA) in ERCPs using the newly developed assessment tool. The duodenoscope assessment tool was completed by 14 endoscopists at nine tertiary referral centers (two non-University and seven University medical centers) in the United States in ERCP procedures performed by the study endoscopists from July to December 2019. We excluded ERCP procedures that were performed using a colonoscope or double balloon enteroscope, patients with altered surgical anatomy, failed cannulations, trainee involvement and subjects <18 years of age. Failed cannulations were excluded as the inability to perform requisite interventions will preclude a full assessment of the duodenoscope performance, in particular mechanical/imaging characteristics and interventional steps.

Study approval

As the assessment tool involved no greater than minimal risk to participants in a routine clinical setting, the study was exempted from review and the requirement for informed consent was waived by AdventHealth Orlando Institutional Review Board and by the ethics committees of all participating medical centers. A data share agreement was formalized between AdventHealth Orlando and all participating centers.

Development of the assessment tool

We identified three distinct categories relevant to the technical performance of a duodenoscope: (1) maneuverability, (2) mechanical/imaging characteristics and (3) the ability to perform interventions. Each of the three categories had 5, 6 and 13 components (items), and each item was assessed using a 5-point response scale (detailed below). In addition, the assessment tool documented information on patient demographics, procedural indication, number of attempts to cannulate the desired duct, procedural duration and adverse events that were observed intra-procedurally or immediately post-intervention. The final version of the duodenoscope assessment tool used in this study is shown in Appendix S1.

1. Duodenoscope maneuverability

This category aimed to assess the ease with which a duodenoscope navigates the gastrointestinal tract to reach the major papilla and comprised five items: (1) intubation of the esophagus, (2) scope passage into the stomach, (3) navigation across the pylorus, (4) ability to achieve the short-scope position and (5) adequate papillary orientation i.e. positioning enface with the papilla. Each item was assessed on a 5-point scale ranging from 1 to 5, with 1 being easy to perform, 2 minimal difficulty, 3 moderate difficulty, 4 severe difficulty and 5 unable to complete the requisite maneuver.

2.Mechanical/Imaging characteristics

This category aimed to assess the mechanical function and imaging quality of the duodenoscope during ERCP procedures. It comprised six items: (1) duodenoscope stiffness, (2) image quality, (3) image stability, (4) air–water button functionality, (5) elevator efficiency which was measured by the ability to anchor the guidewire or exchange accessories and (6) hand strain.

Each item was assessed using a 5-point response scale but had different definitions. Duodenoscope stiffness was assessed with 1 being easy to perform, 2 minimal difficulty, 3 moderate difficulty, 4 severe difficulty and 5 unable to complete the requisite maneuver. For image quality and stability, responses corresponded to 1 being superior, 2 good, 3 satisfactory, 4 suboptimal and 5 unable to visualize or achieve stability of image resulting in termination of procedure. The air–water button functionality was assessed with 1 being no water leakage or no difficulty in applying suction or inflating air, 2 minimal leakage or minimal difficulty with suction or inflation, 3 moderate leakage or difficulty, 4 severe leakage or difficulty and 5 unable to perform the requisite function. Hand strain was assessed with 1 being no strain, 2 minimal strain, 3 moderate strain, 4 severe strain and 5 unable to complete the procedure.

3.Ability to perform biliary and pancreatic interventions

This category aimed to assess the ease with which interventions are performed using the duodenoscope and comprised 13 items that included procedural steps of sphincterotomy, stricture management, stone management, stent placement, cholangioscopy, and provision to include miscellaneous interventions such as ampullectomy. The complete list of procedural steps for pancreatic and biliary interventions is shown in the Appendix S1. For this category, assessments were expected only for the procedural steps that were performed. Assessment of each procedural step was performed on a 5-point scale ranging from 1 to 5, with 1 being easy to perform, 2 minimal difficulty, 3 moderate difficulty, 4 severe difficulty and 5 unable to complete the requisite maneuver.

Refinement of the assessment tool

Three endoscopists (S.V., J.Y.B., R.H.) pilot tested the assessment tool in 50 consecutive ERCP procedures. This was done in order to minimize redundancy, ensure incorporation of all variables critical to examinations when using a duodenoscope, ensure inclusion of all technical features relevant to the duodenoscope and ensure easy interpretability and generalizability to all endoscopists.

Face validity of the assessment tool

In light of the fact that there are no existing tools to assess the technical performance of a flexible endoscope, the proposed duodenoscope assessment tool was evaluated for face validity by three independent experts (C.M.W., R.K., T.R.) who were not involved in its development. These experts reviewed and judged the assessment tool and reported that all important aspects of the duodenoscopes' technical performance were included.

Statistical analysis

The internal reliability of this duodenoscope assessment tool was assessed using the Cronbach's coefficient alpha (α).[13–15] Cronbach's coefficient α was calculated for each of the three distinct categories (maneuverability, mechanical/imaging characteristics and the ability to undertake pancreaticobiliary interventions). The Cronbach's coefficient α is a measure of the internal reliability of an assessment tool and is considered satisfactory for coefficients $\alpha \geq 0.7$, and robust for coefficients $\alpha > 0.8$.[16] In order to evaluate the potential variability of rating scores for different practice settings, i.e. University vs. non-University medical centers due to potential for variability in endoscopist experience, ERCP case types and procedural volume between these two practice types, rating scores for all items were compared between the two groups and Cronbach's coefficient α were also calculated for each of the two practice types.

In order to assess the validity of the duodenoscope assessment tool, we hypothesized that various procedure and patient-related factors will be correlated with the technical performance. This method of validity assessment was performed as it is not possible to use the same duodenoscope repeatedly in the same patient to assess the reproducibility of the ratings scores. Procedure related factors we included were patient age, gender, procedure type (pancreatic vs. biliary interventions) and total procedure duration (min), where we expected longer total procedure duration and older patient age to be correlated with worse performance scores. For each of the three categories, we first constructed subscale scores by averaging across the item scores within each category. The subscale scores can range from 1 to 5 with 1 corresponding to best performance and 5 to worst performance. We then conducted separate multiple linear regression analyses using each subscale score as the response variable. We also conducted stepwise analyses to identify

factors associated with the mean subscale scores for each category.

Continuous data were summarized as means with standard deviation and medians with interquartile range and range, whereas categorical data were summarized as frequencies with percentages. Categorial variables were compared using the Chi-square or Fisher's exact test as indicated. All statistical analyses were performed using Stata 14.2 (Stata Corp, College Station, TX, USA).

RESULTS

Patient demographics, endoscopist characteristics and procedure details

AFTER EXCLUDING PATIENTS with altered surgical anatomy (n = 21) or failed cannulation (n = 28), 1080 duodenoscope assessments were analyzed. A total of 14 endoscopists participated in the study across nine medical centers. The lifetime experience of endoscopists included a median of 2600 ERCPs (IQR = 2000–4300) per endoscopist and a median of 11 years (IQR = 4–15) post-graduation from gastroenterology fellowship. The median age of patients was 64 years (IQR = 50–74), 50.7% were female, 92.8% were biliary indications and ductal access was achieved with median cannulation attempt of 1 (IQR = 1–4) and median cannulation time of 28.5 s (IQR 10–86). Median of 25 s (IQR = 20–45) was taken to reach the major papilla from the start of the procedure (IQR = 20–45) and the median total procedure duration was 22 min (IQR = 11.3–38).

The overall rate of intraprocedural and post-procedural adverse events was 8.3%. Intraprocedural adverse events comprised bleeding in 31 patients, which were all managed conservatively. Post-procedural adverse events comprised abdominal pain requiring hospitalization in 12, cholangitis in 11, acute cholecystitis in one, bleeding at the sphincterotomy site in four, post-ERCP pancreatitis in 30 and delayed perforation in one patient. Patient demographics and procedural details are shown in Table 1.

Table 1 Patient characteristics and procedure details for all centers (n = 1080)

Age (years)	Mean (SD)	61.4 (16.6)
	Median	64
	IQR	50–74
	Range	18–99
Gender: n (%)	Female	548 (50.7)
	Male	532 (49.3)
Procedure indication: n (%)	Bile duct stones	363 (33.6)
	Biliary stricture/stent placement	500 (46.3)
	Other biliary indications	139 (12.9)
	Pancreatic interventions	78 (7.2)
Patient position for ERCP: n (%)	Left lateral	91 (8.4)
	Prone	810 (75.0)
	Supine	179 (16.6)
No. of attempts at cannulation	Mean (SD)	3.2 (4.0)
	Median	1
	IQR	1–4
	Range	1–45

IQR, interquartile range; SD, standard deviation.

Table 2 Cronbach's coefficient alpha for evaluation of the internal reliability of the duodenoscope assessment tool

	All centers	Non-university medical centers	University medical centers
Duodenoscope maneuverability	0.81	0.88	0.70
Mechanical and imaging characteristics	0.92	0.96	0.84
Ability to perform interventions			
All interventions	0.87	0.90	0.75
Biliary interventions	0.86	0.89	0.75
Pancreatic interventions[†]	0.76	–	–

[†]For pancreatic interventions, Cronbach's coefficient alpha was calculated only for all centers due to the small number of pancreatic procedures performed.

Duodenoscope maneuverability

The duodenoscope assessment tool had satisfactory internal reliability for duodenoscope maneuverability with an overall Cronbach's coefficient α of 0.81 (Table 2). On subgroup analysis, the Cronbach's coefficient α were satisfactory for both non-University and University centers, with α of 0.88 and 0.70, respectively. In addition, there was no significant difference in the rating scores for all items of duodenoscope maneuverability between the two types of practice settings (Table S1).

Mechanical/imaging characteristics

The duodenoscope assessment tool had strong internal reliability for duodenoscope mechanical and imaging characteristics with an overall Cronbach's coefficient α of 0.92 (Table 2). On subgroup analysis, the Cronbach's coefficient

α was robust for both non-University and University centers, with α of 0.96 and 0.84, respectively. In addition, there was no significant difference in the rating scores for all items of mechanical and imaging characteristics between the two types of practice settings (Table S2).

Ability to perform biliary/pancreatic interventions

Biliary interventions were performed in 92.8% (n = 1002) and pancreatic interventions were performed in 7.2% (n = 78) of cases (Table S3). The duodenoscope assessment tool had satisfactory to robust internal reliability for performing biliary and pancreatic interventions with the overall Cronbach's coefficient α of 0.87 for all procedures, 0.86 for biliary procedures and 0.76 for pancreatic interventions (Table 2). On subgroup analysis, the Cronbach's coefficient α was satisfactory for both non-University and University centers, with α of 0.90 and 0.75, respectively, for all interventions and 0.89 and 0.75 for biliary interventions. In addition, with the exception of performing a biliary sphincterotomy and biliary stent insertion, there was no significant difference in the rating scores for the procedure steps between the two types of practice settings (Table S4).

Validation of the duodenoscope assessment tool

Subscale scores had means (SD) of 1.19 (0.38) for maneuverability, 1.14 (0.33) for mechanical and imaging characteristics, and 0.27 (0.49) for ability to perform interventions. On multiple linear regression analysis, prolonged procedure duration was significantly positively associated with higher (worse) scores for all categories (Table 3). Older patient age was significantly positively associated with higher (worse) scores for duodenoscope maneuverability and the ability to perform interventions; pancreatic interventions were significantly positively associated with higher (worse) scores for mechanical/imaging characteristics. With the exception of older patient age for the ability to perform interventions, the above predictors remained significant in the model following stepwise selection.

DISCUSSION

EVEN THOUGH flexible endoscopes are the primary workhorse for the evaluation of the gastrointestinal tract, their assessments have been subjective and poorly standardized.[17] The changing concepts and recent advances in the field of flexible endoscopy warrant the need for a more objective assessment – the development of specific criteria so that the results can be evaluated meaningfully. The endoscopic procedure can be broken down into specific maneuvers or tasks. Once identified, these tasks can be assessed using a standardized tool. The present study attempted to meet this requirement for duodenoscopes.

The proposed assessment tool represents a reliable and valid measure of the technical performance of duodenoscopes. Although the time taken to complete the assessment tool was not documented, in routine practice, it was not more than 1–2 min per procedure. The reliability scores for all three criteria exceeded the requisite threshold, Cronbach's $\alpha \geq 0.7$, suggesting that the assessment tool is reliable, robust for most categories, and thereby has achieved the desired intent. More importantly, our regression models demonstrated that the assessment tool appropriately identified factors that challenge duodenoscope functionality – older patients, pancreatic interventions and prolonged procedural duration, thereby supporting its validity.

Given the findings of our study, we believe that the assessment tool may enable comparison of different types of duodenoscopes: single-use vs. reusable or reusable duodenoscopes by multiple manufacturers. The endoscope is currently designed with a one-size-fits-all concept. In a study of gastroenterology trainees, most fellows with a hand size < 6.5, mostly women, felt that the endoscope was too large for their hands and impeded their ability to learn endoscopy. Consequently, women work far harder than their male counterparts to perform the same task and the risk of repetitive strain injury can be compounded by a suboptimal grip.[18] In the era of single-use endoscopes, constructive assessments via validated tools are likely to provide manufacturers with critical feedback that enable quick product refinements or even design endoscopes tailored to meet individual needs. Also, as the endoscope ages, the cables become much less responsive and additional force may be required to achieve the same degree of tip deflection. By using validated tools to assess endoscope performance, decisions regarding refurbishment or new purchase can be reached more objectively. Additionally, the tool may enable conduction of clinical trials with endpoints that are more objective and better interpretable. Finally, the duodenoscope assessment tool is a first of its kind endeavor that may serve as a template on which assessment tools for other flexible endoscope platforms can be developed. This is particularly relevant at the present time when new technologies are rapidly emerging in the marketplace but with minimal or no standardized validations.

There are several limitations to this study. Firstly, in order to establish baseline and minimize variability, we only assessed duodenoscopes from a single manufacturer. However, this may not be a significant limitation as the

Table 3 Multiple linear regression and stepwise multivariate linear regression analyses

Category	Variable	Regression coefficient	95% CI	*P*-value
Duodenoscope maneuverability	Multiple linear regression analysis			
	Patient age (years)	0.0016	0.00024–0.0030	0.021
	Patient gender: Male vs. Female	−0.016	−0.062–0.029	0.482
	Procedure type: Pancreatic vs. Biliary interventions	0.072	−0.014–0.16	0.102
	Total procedure duration (min)	0.0053	0.0043–0.0064	<0.001
	Stepwise regression analysis			
	Patient age (years)	0.0015	0.00011–0.0028	0.034
	Total procedure duration (min)	0.0053	0.0043–0.0063	<0.001
Duodenoscope mechanical and imaging characteristics	Multiple linear regression analysis			
	Patient age (years)	0.00027	−0.00092–0.0015	0.653
	Patient gender: Male vs. Female	−0.020	−0.060–0.019	0.311
	Procedure type: Pancreatic vs. Biliary interventions	0.11	0.033–0.18	0.005
	Total procedure duration (min)	0.0041	0.0031–0.0050	<0.001
	Stepwise regression analysis			
	Procedure type: Pancreatic vs. Biliary interventions	0.10	0.029–0.18	0.006
	Total procedure duration (min)	0.0040	0.0031–0.0049	<0.001
Ability to perform interventions	Multiple linear regression analysis			
	Patient age (years)	0.0018	0.000060–0.0036	0.043
	Patient gender: Male vs. Female	−0.0026	−0.061–0.056	0.932
	Procedure type: Pancreatic vs. Biliary interventions	0.094	−0.027–0.22	0.127
	Total procedure duration (min)	0.0075	0.0062–0.0089	<0.001
	Stepwise regression analysis			
	Total procedure duration (min)	0.0075	0.0062–0.0089	<0.001

CI, confidence interval.

assessed duodenoscope comprises 80% of the United States market share. Secondly, as only patients with normal anatomy were included in the study, the assessment may not be applicable to patients with altered surgical anatomy. Thirdly, as the main objective of the study was to evaluate the reliability and validity of the duodenoscope assessment tool, only the clinical and procedural information pertaining to this objective was collected. Fourthly, as all procedures were performed by expert endoscopists, the experience of novice or trainee endoscopists was not incorporated.

In conclusion, the newly developed assessment tool appears reliable and valid for measuring technical performance of duodenoscopes.

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CONFLICT OF INTEREST

JI YOUNG BANG: Consultant for Olympus America Inc., Boston Scientific Corporation. Shyam Varadarajulu: Consultant for Boston Scientific Corporation, Olympus America Inc., Covidien, Creo Medical. Robert Hawes: Consultant for Boston Scientific Corporation, Olympus America Inc., Covidien, Creo Medical, Nine Points Medical, Cook Medical. Thomas Rosch: Consultant for Olympus Europe, Amadix Ltd, UniversaldX, received Honorarium from Falk Faoundation Freiburg, Germany, and received Grant support from Erbe Company Tubingen, Karl Storz Company, InterScope Med Inc., Imevax Ltd, Norgine Ltd. Shyam Thakkar: Consultant for Boston Scientific Corp. and Olympus America Inc. Benjamin Tharian: Consultant for Boston Scientific Corp. and Medtronic. Patrick Yachimski: Consultant for Boston Scientific Corp. Priya Jamidar: Consultant for Boston Scientific Corp. Thiruvengadam Muniraj: Consultant for Boston Scientific Corp. Christopher DiMaio: Consultant for Boston Scientific Corp., Covidien,

AbbVie. Nikhil Kumta: Consultant for Boston Scientific Corp., Olympus America Inc., Apollo Endosurgery, Gyrus ACMI, Inc. Amrita Sethi: Consultant for Boston Scientific Corp., Olympus America Inc., Fujifilm. Peter Draganov: Consultant for Boston Scientific Corp., Olympus America Inc., Cook Medical, Lumendi, Microtech. Dennis Yang: Consultant for Boston Scientific Corp., Lumendi, Steris. C. Mel Wilcox, Hyungjin Myra Kim, Ernesto Robalno Gonzaga, Sumant Inamdar, Linda Lee, Talal Seoud, Abhilash Perisetti, Gayatri Bondi, Sachin Kirtane, D. Nageshwar Reddy, Richard Kozarek declare no conflict of interest for this article.

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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.

Table S1 Assessment of duodenoscope maneuverability.

Table S2 Assessment of duodenoscope mechanical and imaging characteristics.

Table S3 Assessment of ability to perform interventions for all centers.

Table S4 Assessment of ability to perform interventions based on the type of medical center.

Appendix S1 The Duodenoscope Assessment Tool.