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Original Article

Evaluation of a novel disposable esophagogastroduodenoscopy system in emergency, bedside and intraoperative settings: Pilot study (with video)

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Background & Aims: The disposable esophagogastroduodenoscopy (EGD) system is a novel endoscopic device which is highly portable and is designed to eliminate the risk of cross-infection caused by reusable EGD. This study aimed to investigate the feasibility and safety of disposable EGD in emergency, bedside, and intraoperative settings.

Methods: This was a prospective, single-center, non-comparative study. Disposable EGD was used for emergency, bedside, and intraoperative endoscopies in 30 patients. The primary endpoint was the technical success rate of the disposable EGD. Secondary endpoints included technical performance indicators including clinical operability, image quality score, procedure time, the incidence of device malfunction and/or failure, and the incidence of adverse events.

Results: A total of 30 patients underwent diagnosis and/or treatment with disposable EGD. Therapeutic EGD was performed on 13/30 patients, including hemostasis (3), foreign body retrieval (6), nasoenteric tube placement (3), and percutaneous endoscopic gastrostomy (1). The technical success rate was 100%: all procedures and indicated interventions were completed without changing to a conventional upper endoscope. The mean image quality score obtained immediately after procedure completion was 3.72 ± 0.56. The mean procedure time was 7.4 (mean ± SD 7.4 ± 7.6) min. There were no device malfunctions or failures, device-related adverse events, or overall adverse events.

Conclusion: The disposable EGD may be a feasible alternative to the traditional EGD in emergency, bedside and intraoperative settings. Preliminary data shows that it is a safe and effective tool for diagnosis and treatment in emergency and bedside upper gastrointestinal cases. (Registered at http://www.chictr.org.cn, study ChiCTR2100051452.)

Key words: bedside and intraoperative settings, disposable esophagogastroduodenoscopy, emergency endoscopy

INTRODUCTION

GASTROINTESTINAL (GI) ENDOSCOPY has become the most common medical procedure for diagnosing and treating GI disorders. However, its widespread use is accompanied by a series of challenges, including expensive maintenance and cleaning costs, need for preoperative inspection, and imperfect endoscopic reprocessing.

Although several guidelines for endoscopic reprocessing have been published, microorganisms frequently remain on reusable endoscopes, posing the potential risk of infection from endoscopy.[1] One study reported that among 697 inpatients who underwent GI endoscopy, 7.9% had post-endoscopic infections.[2] Several studies have attempted to optimize endoscopic reprocessing procedures to reduce incidence of post-endoscopic infections. However, two recent randomized prospective trials comparing single vs. double high-level disinfection failed to show a difference in post-reprocessing endoscopes culture-positivity rate.[3,4]

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Therefore, endoscopy-associated infections remain a problem to be solved.

A recent guideline has proposed use of disposable endoscopes as a potential strategy to eliminate the risk of infection.[5] Based on their comparable performance with reusable endoscopes,[6–8] the US Food and Drug Administration has approved single-use duodenoscopes and esophagogastroduodenoscopes (EGD) for endoscopic examination and/or treatment.

Although a previous study demonstrated the non-inferiority of disposable EGD in routine gastric cancer screening, there is still a lack of evidence for therapeutic endoscopy.[8] In clinical practice, disposable endoscopes may be a more attractive option than their reusable counterparts during on-call and bedside procedures as compared to routine examinations in a relatively controlled setting. The disposable endoscope system is more compact than a traditional endoscopy travel car. It can also obviate the need for a complicated reprocessing protocol and eliminate the risk of post-endoscopic infection, which could potentially benefit patients with impaired immune systems and high infection risk. Therefore, this study aimed to evaluate the feasibility and safety of disposable EGD in emergency, bedside and intraoperative settings.

METHODS

Study design and patient selection

THIS WAS A prospective, single-center, non-comparative study performed at Nanfang Hospital, Southern Medical University (Guangzhou, China). The disposable EGD system (XZING-W200B) (Fig. 1) was used for emergency, bedside or intraoperative endoscopy in all study patients.

The study was reviewed and approved by the Medical Ethics Committee of Nanfang Hospital, Southern Medical University (Registration number: NFEC-2021-270). A written informed consent was all obtained prior to endoscopic procedures.

Patients who visited Nanfang Hospital, Southern Medical University for diagnosis only or treatment from November 01, 2021 to January 27, 2022, were recruited for this study. Patients were eligible for inclusion if they were aged 18–75 and intended for a procedure outside of the endoscopy suite for an urgent GI indication. Upper GI foreign bodies and symptomatic GI bleeding were indications for emergency upper GI endoscopy. Those patients with severe disease in the Intensive Care Unit (ICU) or located in the emergency room (ER) were considered for bedside endoscopy. Intraoperative endoscopies were performed based on the needs of the requesting surgical team. Exclusion criteria in this study included contraindications to upper GI endoscopy, severe spinal deformity, inability to obtain informed consent, pregnant or lactating women, participation in other clinical trials within 1 month, and history of severe allergic reactions to narcotics and/or sedating agents. A total of 48 patients were evaluated for inclusion during the recruitment period for this study. After rigorous screening of patients based on the above inclusion and exclusion criteria, 30 patients were eventually enrolled, as shown in Figure 2.
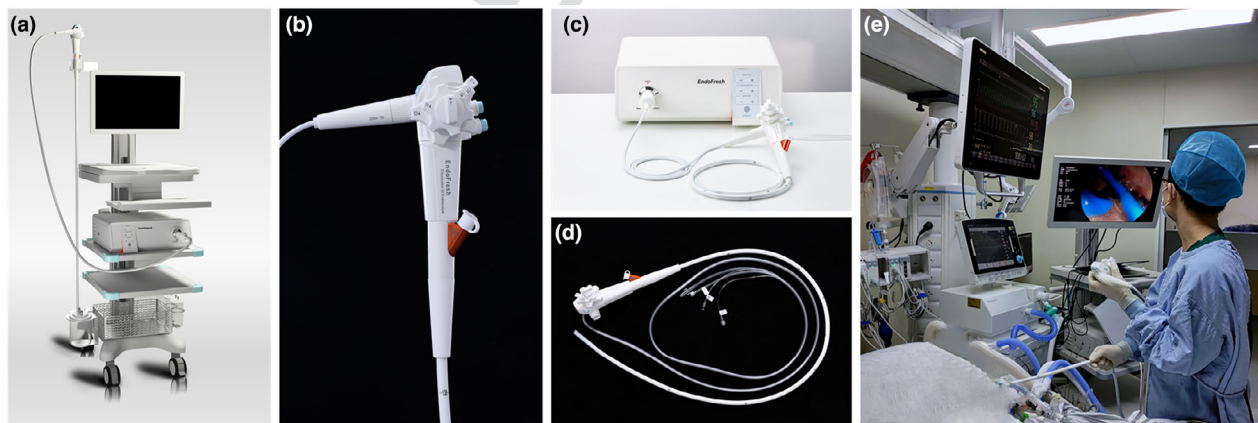

Figure 1 Disposable endoscope system XZING-S2. (a) Endoscopic trolley car; (b, d) Disposable endoscope (Model: XZING-W200B) and the air/water lines including the suction channel, water supply channel, air/CO_2 supply channel, and auxiliary water supply channel (from left to right); (c) Endoscopic mainframe with the imaging processor (XZING-S2); (e) An endoscopic expert using disposable esophagogastroduodenoscopy to perform bedside endoscopy in the Intensive Care Unit for suspected esophageal fistula.
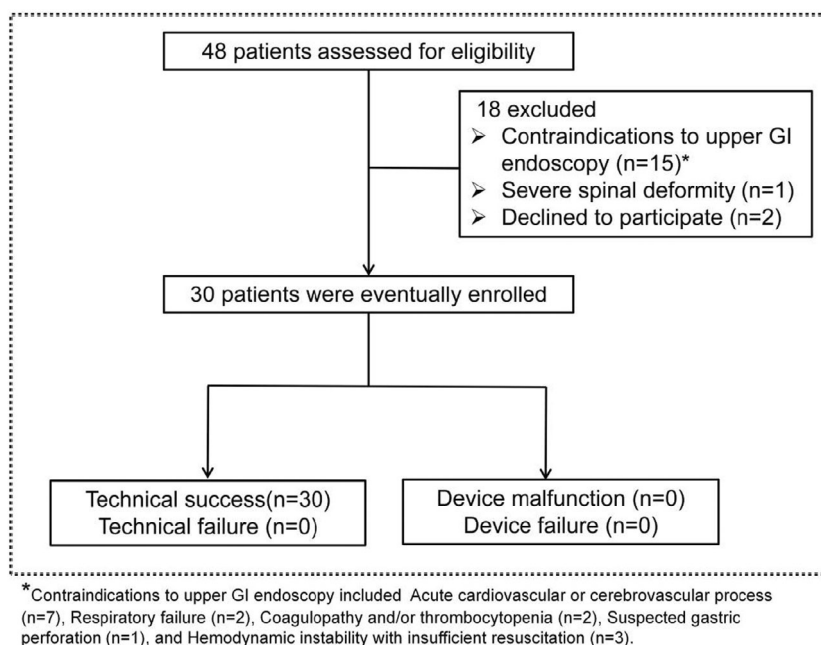
Figure 2 Eligibility, patient selection and endpoints.

Disposable EGD system

The disposable EGD system was developed by Huizhou Xianzan Technology Co., Ltd., which mainly includes an endoscopic mainframe with an imaging processor (XZING-S2), an endoscopic trolley car and a disposable endoscope (Model: XZING-W200B). The technical specifications of the disposable EGD system can be seen in Table 1.

Endoscopic procedure

Most enrolled patients were fasted for a minimum of 6 h prior to the procedure; blood products were administered when clinically indicated. Each patient was placed in standard, left lateral decubitus position for upper GI endoscopy. After administering 10 mL of dyclonine spray and 1 mL of simethicone solution with water, all endoscopic procedures were performed by the experienced endoscopists with a minimum of 3000 EGDs and 5 years of endoscopic experience. Midazolam and pethidine-induced sedation or propofol and sufentanil-induced anesthesia were administered on a case-by-case basis depending on patient stability and EGD indication. Endoscopic maneuvers and treatment were performed based on the findings and at the discretion of the performing endoscopist. Blood pressure, pulse, respiratory frequency, and body temperature were monitored before, during and after the procedure. A follow-up visit was conducted within 24 h after the procedure to determine whether any delayed symptoms or adverse events had occurred.

Study endpoint
Primary endpoint

Technical success rate. Technical success was defined as successful completion of the endoscopic procedure and all its diagnostic and/or therapeutic (where applicable) aims without requiring a change to a conventional upper endoscope.

Secondary endpoint

1. Clinical operability

Clinical operability was evaluated based on 11-point scale divided into four main categories: endoscopic flexibility, auxiliary features, therapeutic maneuvers and imaging quality. Each indicator was evaluated as A (Good), B (Fair), or C (Poor), with detailed definitions depicted in Table S1. The performing endoscopists were asked to complete the instrument operability evaluation immediately after completing the procedure. If therapeutic maneuvers were not performed during the procedure, this category was omitted.

Table 1 Technical specifications of the disposable esophagogastroduodenoscopy system

1. Disposable endoscope (Model: XZING-W200B)		
Total length		$1645 \pm 10\%$ mm
Head section	Outer diameter of head opening	$\leq \Phi 11$ mm
Bending section	Outer diameter of bending part	$\leq \Phi 11$ mm
	Angulation range	Up $\geq 180°$, Down, Left, Right $\geq 160°$
Insertion section	Outer diameter of insertion tube	$\leq \Phi 11$ mm
	Working length	$1300 \pm 10\%$ mm
	Auxiliary water/air channel	Yes
	Auxiliary suction channel	Yes
Instrument channel	Inner diameter of channel	$\geq \Phi 3$ mm
Optical system	Field of view	$110° \pm 10\%$
	Direction of view	Forward viewing
	Field of depth	3–100 mm
Accessibility	Water supply	50 mL/min
	Air supply	850 mL/min
	Suction	500 mL/min
2. Imaging processor (XZING-S2, serial number: S221060102)		
Dimensions	138 mm × 447 mm × 400 mm	
Total mass	11.8 kg	
Imaging system type	Complementary Metal Oxide Semiconductor (CMOS)	
Signal output	Digital Visual Interface (DVI) (1080P)	
3. Endoscopic trolley car		
Volume	510 mm × 510 mm × 1630 mm	
Floor space	0.26 m^2	

When all applicable subcategories were scored as A or B, clinical operability was considered acceptable.

2. Imaging quality score

Image quality was evaluated using a previously published numerical scale assessing completeness of photo acquisition and image clarity[9] (Table S2). The entire procedure was meticulously documented and at least one image of the following sites was obtained: proximal esophagus, distal esophagus, gastroesophageal junction, cardia/fundus (retroflexion view), gastric body and lesser curve (retroflexion view), gastric body and greater curve (forward view), gastric angle and antrum, duodenal bulb and descending duodenum. If the anatomical sites to be photographed and recorded were missing due to upper GI surgery, these sites were omitted. Additional photos were taken if GI pathology was identified. All images were evaluated in random order by six independent investigators (three experts and three non-experts, defined as endoscopists with operating experience of at least 3000 and less than 500 cases respectively) who were blinded to the patients' medical history and endoscopic examination results. A second round of evaluations was conducted 1 month later by the same six investigators to assess intra-observer reliability.

3. The incidence of device malfunction/failure

The endoscopic experience was closely monitored for any signs of device malfunction or failure. Device malfunctions included any software malfunctions, visual display abnormalities attributable to the image processor, image capture obstacles, and any pre-existing structural abnormalities in the disposable endoscope system that interfered with normal operation. If any device malfunctions resulted in an incomplete or aborted procedure, they were deemed device failures.

4. Procedure time

A research assistant recorded the duration of the procedure from insertion to withdrawal with an electronic stopwatch.

Safety endpoint
The incidence of adverse events

The incidence of overall adverse events was defined as the proportion of patients who experienced any adverse events during the procedure or within 24 h after procedure. Device-related injuries were also recorded and included but not

limited to any injury to the upper GI tract requiring intervention and retention of any disposable endoscope components or endoscopy accessories.

Statistical analysis

Based on previously published findings of 100% success rate of disposable EGD and our preliminary study data, the technical success rate for disposable EGD is assumed to be 97% with a threshold rate of 80%. Using the single-group target value method, we calculated that a sample size of 30 would maintain the power at 80%, with a two-sided α level of 0.05. Continuous variables and categorical variables were expressed as mean (standard deviation) and count (percentage), respectively. Kappa statistics were used to estimate intra- and inter-observer variation. Statistical analyses were performed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Patient demographics

DURING THE STUDY period, 30 patients (12 women and 18 men) underwent upper GI endoscopy with the disposable EGD in emergency, bedside or intraoperative settings. The characteristics of all patients are shown in Table 2.

Study endpoints

The technical success rate was 100% (30/30): all procedures were completed to the intended extent and therapy performed successfully when indicated with the disposable EGD system (Table 3). GI bleeding (16/30, 53%) and foreign bodies (7/30, 23%) were the most common indications for EGD. Therapy was performed in 13/30 (43%) patients, including hemostasis of acute bleeding (3, 10%), foreign body retrieval (6, 20%), nasoenteric tube insertion (3, 10%) and venting percutaneous endoscopic gastrostomy placement (1, 3%) (Fig. 3).

As shown in Table 4, 12/16 (75%) patients with GI bleeding were diagnosed with peptic ulcer disease. In order of decreasing frequency, ulcers were identified in the following locations: duodenal bulb (6), gastric antrum (4), gastric angle (2), gastrojejunal anastomosis (2), gastric pylorus (1), and junction of duodenal bulb and descending (1). Two emergency cases in the ER and one bedside case in ICU were successfully treated with titanium clips for high-risk lesions. One case in ICU presented with active ulcer-related bleeding in the duodenal bulb; the Forrest classifications and locations of the remaining lesions are detailed in

Table 2 Patient demographics

	Experimental group (N = 30)
Age, Mean (SD), years	50.57 ± 15.76
Sex, *n* (%)	
Female	12 (40)
Male	18 (60)
Previous comorbidity, *n* (%)[†]	15 (50)
Previous upper gastrointestinal surgery, *n* (%)	5 (17)
Previous medication, *n* (%)	
Antiplatelet drugs	4 (13)
Anticoagulant drugs	4 (13)
Long-term NSAIDs or Glucocorticoids	4 (13)
Existing pathogen infection, *n* (%)	11 (37)
Types of endoscopy, *n* (%)[‡]	
Emergency endoscopy	23 (77)
Bedside endoscopy	10 (33)
Intraoperative endoscopy	1 (3)
Place of operation, *n* (%)	
Emergency room	19 (64)
Intensive care unit	9 (30)
General ward	1 (3)
Surgery room	1 (3)

[†]Comorbidities included hypertension, diabetes, coronary heart disease, cerebrovascular disease and/or chronic renal insufficiency.
[‡]Four patients (3 in intensive care unit and 1 in general ward) with symptomatic GI bleeding during hospitalization underwent emergency bedside endoscopy.

Table 3 Procedure details

Indication	Patient (*n*, %)	Technical success (*n*, %)	Replacement with reusable endoscope (*n*, %)
Intraoperative localization	1 (3)	1 (100)	0 (0)
Foreign body	7 (23)	7 (100)	0 (0)
GI bleeding	16 (54)	16 (100)	0 (0)
Nasoenteral access	3 (10)	3 (100)	0 (0)
Gastrostomy	1 (3)	1 (100)	0 (0)
Other[†]	2 (7)	2 (100)	0 (0)
Total	30 (100)	30 (100)	0 (0)

[†]Procedure performed for 1. Concern for esophageal fistula after gastrostomy and 2. Suspected parasitic infection.

Table 4. An esophageal mass was identified in one case and mass tissue was successfully obtained for pathology.

The foreign bodies treated in our cohort were primarily animal bones (5/7) (Table 4). In one of the seven cases, an
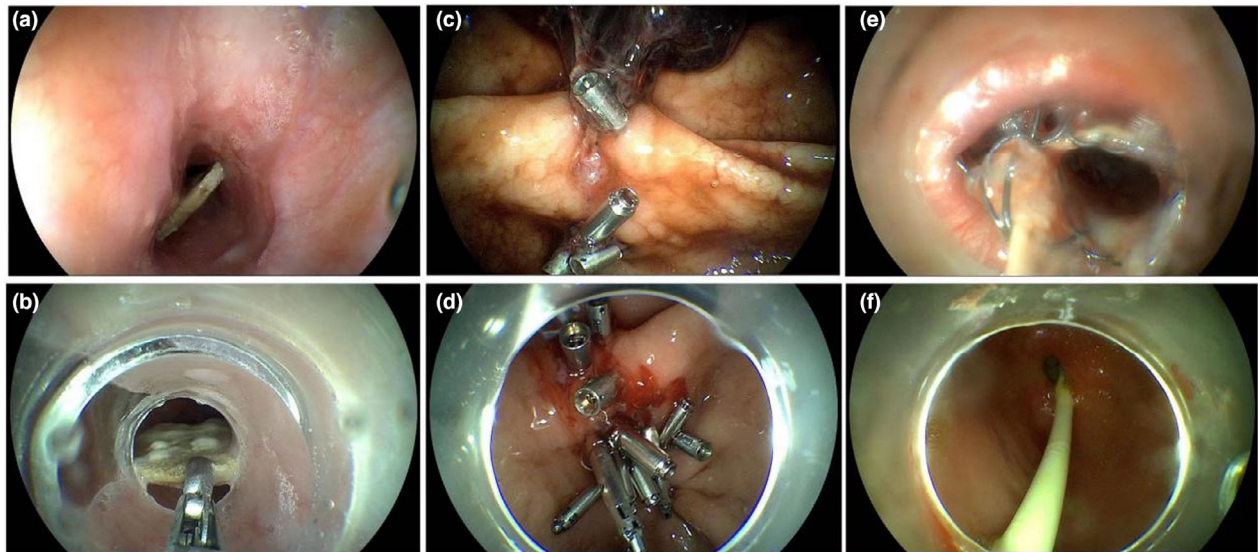
Figure 3 Case illustration of disposable endoscopic treatment. (a, b) Retrieval of a bone shard from the distal esophagus with forceps; (c) Forrest IIa antral lesion with large clot and clips previously placed at an outside hospital followed by (d) Successful hemostasis for rebleeding with additional clips; (e, f) Removal of a migrated esophageal stent in a patient with tracheo-esophageal fistula, and subsequent placement of a post-pyloric feeding tube for nutrition and medication.

animal bone appeared to have migrated distally prior to procedure. The remaining six were removed with forceps (6/7) and one snare (1/7). One patient developed some oozing secondary to trauma when a foreign body was removed, which was treated successfully with clips.

A single case of intraoperative localization was performed with the disposable EGD system after an urgent request from our surgical colleagues: the lesion was identified, and the patient underwent uneventful surgical intervention. Of note, one patient with nasojejunal tube placement also underwent simultaneous esophageal stent removal and tissue biopsy.

The overall clinical operability was deemed acceptable in all 30 patients. Table 5 shows the scores assigned to each subcategory in all study subjects. The mean image quality score obtained immediately after procedure completion was 3.72 ± 0.56 (Video S1). The mean inter- and intra-observer kappa values of experts in the independent review committee were 0.883 (range 0.874–0.890) and 0.807 (range 0.720–0.867) respectively. The mean inter- and intra-observer kappa values among the non-experts were 0.862 (range 0.837–0.904) and 0.784 (range 0.677–0.839) respectively. Table S3 shows the breakdown of the mean image quality score of each member of the independent review committee. The mean procedure time was 7.4 (mean $\pm$ SD 7.4 ± 7.6) min. No device malfunctions or failures occurred in our cohort. In addition, no device-related or overall adverse events were observed during the procedure or within the 24-h follow-up period.

DISCUSSION

TO OUR KNOWLEDGE, this pilot study is the first to investigate the feasibility and safety of disposable endoscopes in emergency, bedside and intraoperative settings. The technical success rate was 100% in this study, which consisted primarily of upper GI bleeding and foreign body cases. Although no bleeding source was identified in three cases suspected of upper GI bleeding, this indicated that our study cohort reflects some of the challenges encountered in routine service and on-call cases. While endoscopic therapy was not indicated in all study patients, all therapy attempts were successful with the disposable EGD.

The overall clinical operability of disposable EGD was deemed acceptable in all study patients. Imaging quality is another important indicator in evaluating the feasibility of disposable EGD. There was excellent inter-rater and intra-rater reliability in both expert and non-expert evaluator groups. Finally, there were no device-related or overall adverse events reported during the procedure or within 24 h post-procedure. These results suggest that disposable EGD may be a promising alternative to reusable EGD in a setting where therapy is anticipated.

Table 4 Procedure findings of GI bleeding and foreign body cases

Indication	Experimental group
1. GI bleeding (*n* = 16)	
Bleeding symptom, *n* (%)	
Hematemesis	6 (38)
Black Stool	12 (75)
Hematochezia	3 (19)
Anemia, *n* (%)	
Normal	2 (13)
Mild anemia	5 (31)
Moderate anemia	4 (25)
Severe anemia	5 (31)
Cause of bleeding, *n* (%)	
Ulcer	12 (75)
Single ulcer	8 (50)
Multiple ulcer	4 (25)
Mass	1 (6)
Other[†]	3 (19)
Active bleeding on endoscopy, *n* (%)	1 (6)
Forrest classification of peptic ulcer, *n* (%)[‡]	
Type Ia	0 (0)
Type Ib	1 (6)
Type IIa	2 (13)
Type IIb	2 (13)
Type IIc	0 (0)
Type III	8 (50)
Endoscopic treatment, *n* (%)[§]	3 (19)
2. Foreign bodies (*n* = 7)	
Esophageal stricture, *n* (%)	1 (14)
Type of foreign body, *n* (%)	
Animal bones	5 (72)
Orange	1 (14)
Metal dentures	1 (14)
Foreign body retention site	
Esophagus	5 (72)
Stomach	1 (14)
Other[¶]	1 (14)
Endoscopic treatment, *n* (%)	6 (86)

[†]GI bleeding in three patients was attributed to vascular malformation (1), colon tumor (1), and large rectal polyp (1).
[‡]One patient was found with Forrest III gastric lesion and Forrest Ib duodenal lesion.
[§]Treatment sites including duodenal bulb (1), antral curvature (1) and gastric angle (1).
[¶]No foreign body was found during endoscopy.

Table 5 Instrument operability results

Indicators	A (Good)	B (Fair)	C (Poor)	NA	Total
Body rigidity	24 (80)	6 (20)	0 (0)	0 (0)	30 (100)
Knob operation	25 (83)	5 (17)	0 (0)	0 (0)	30 (100)
Sharp angle adaptability	24 (80)	6 (20)	0 (0)	0 (0)	30 (100)
Air supply	27 (90)	3 (10)	0 (0)	0 (0)	30 (100)
Water supply	28 (93)	2 (7)	0 (0)	0 (0)	30 (100)
Suction	28 (93)	2 (7)	0 (0)	0 (0)	30 (100)
Lesion biopsy	2 (7)	0 (0)	0 (0)	28 (93)	30 (100)
Lesion treatment	13 (43)	0 (0)	0 (0)	17 (57)	30 (100)
Identification of lesions	20 (66)	5 (17)	0 (0)	5 (17)	30 (100)
Identification of cavities	27 (90)	3 (10)	0 (0)	0 (0)	30 (100)
Identification of small vessels	21 (70)	9 (30)	0 (0)	0 (0)	30 (100)

successfully and safely achieved complete colonoscopy in humans in a 2016 study.[10] Investigations are ongoing at our institution examining the utility of an endoscopist-operated disposable colonoscope; preliminary results have been promising. More recently, Luo *et al.*[8] demonstrated the non-inferiority of the disposable EGD to conventional EGD for routine examination of the upper GI tract. Currently, clinical trials evaluating the performance and safety of disposable EGD for EMR, ESD (Video S2) and POEM (Video S3) are also ongoing at our institution and others.

Of note, all cases in this study were performed outside of the endoscope center. It is well known that upper endoscopy is an important tool for the diagnosis and treatment of GI emergencies, especially for non-varicose upper GI bleeding.[11–14] For critically ill patients, bedside endoscopy may be the best alternative in selected cases due to ICU needs and additional patient transfer requirements. The disposable EGD is lighter weight (Table S4), more flexible and the system occupies less space, representing an alternative to reusable endoscopes when emergent or bedside endoscopy is necessary. Disposable EGD may find a niche in treatment of patients with exceptional circumstances such as remote and underserved regions, infectious disease wards, mobile hospitals, and when COVID status is positive or unknown.[15]

Although disposable endoscopes have many advantages, cost may hinder widespread use in clinical practice. Currently, there is a paucity of data on the cost-effectiveness of disposable upper endoscopes. However, prior studies on other disposable endoscopes have identified several factors that impact cost-effectiveness. A study on

To overcome shortcomings of reusable endoscopes, disposable endoscopes have been developed in recent years. Disposable endoscopes can avoid labor and costs involved in cleaning and maintenance of equipment and eliminate transmission of infectious diseases caused by improper cleaning. Self-propelled disposable colonoscopes have

colonoscopy showed that the cost in high-volume centers was about one third of that in low-volume centers in the USA ($189 vs. $501).[16] A 2020 analysis showed that the cost of single-use duodenoscopes primarily depends on the infection rate and annual volume of procedures.[17] As the most commonly performed GI procedure, disposable EGD may prove to be feasible from the financial standpoint, especially in on-call cases during which endoscope reprocessing is performed outside of regular business hours. Further investigation on cost-effectiveness is pending at our institution.

The currently available disposable EGD lacks electronic magnification and optical staining typically found in reusable endoscopes (Table S4). While this represents a disadvantage of the disposable scope, the lack of these features may not be clinically relevant in emergent, bedside or intraoperative settings.

One limitation of this study was the small patient numbers, though the goal of our study was to establish feasibility and safety of the disposable EGD system. While variceal bleeding was not excluded, there were no cases included as patients identified for recruitment during the study period were often too critically ill to provided informed consent. As another frequently encountered emergent indication for endoscopy, this population will be of particular interest in future investigations and should be captured in a larger study cohort.

Thus far, our preliminary data suggests that the disposable EGD system is a feasible and safe alternative to the reusable upper endoscope in both diagnostic and therapeutic settings, and may have a unique role in bedside cases. Future directions include a pending head-to-head comparison of the disposable EGD system with reusable endoscopes in urgent and emergent GI indications and cost-effectiveness analysis.

CONFLICT OF INTEREST

AUTHORS 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 Clinical Operability Scale.

Table S2 Image Quality Scale.

Table S3 The mean image quality score of each member of the independent review committee.

Table S4 Comparison of endoscopic systems.

Video S1 A 58-year-old male presented with fresh melena and anemia. Endoscopy performed with the disposable system showed a duodenal bulbar ulcer (Forrest Class III) but no active bleeding in the upper GI tract, as well as a small submucosal tumor in the gastric fundus.

Video S2 A 52-year-old male presented with acid regurgitation, heartburn and dysphagia. The patient had a prior history of endoscopic submucosal dissection (ESD) over the mid-esophagus in an external hospital for a high-grade intraepithelial tumor. Upper endoscopy showed an early esophageal cancer over the distal end of the previous ESD scar which was confirmed by histopathology, suggesting a recurrent disease. ESD was successfully performed using disposable EGD.

Video S3 A 29-year-old female diagnosed as achalasia of cardia (AC) repeatedly presented with dysphagia after drug treatment. Per-oral endoscopic myotomy (POEM) was successfully performed at the lower esophagus by using the disposable EGD.