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Original Research

Evaluation of a novel disposable endoscope for retroflexed endoscopic rubber band ligation of internal hemorrhoids: a randomized pilot study

Wen Xu[1], Guili Xia[1], Laihe Li[1], Ge Cao[2], Xianhuan Yan[2], Ling Dong[1], Ying Zhu[1,*]

[1]Department of Gastroenterology, Southern Medical University, Shenzhen Hospital, Shenzhen, Guangdong 518000, China
[2]HuiZhou Xzing Technology Co., Ltd., Huizhou, Guangdong 516000, China

*Corresponding author. Department of Gastroenterology, Shenzhen Hospital, Southern Medical University, Xinhu Road 1333, Baoan, Shenzhen, Guangdong 518000, China. E-mail: zhuying1@smu.edu.cn

Abstract

Purpose Retroflexed endoscopic rubber band ligation (ERBL) for treating Grade II and III internal hemorrhoids using disposable endoscopes has not been previously assessed. We therefore compared the safety and effectiveness of ERBL for internal hemorrhoids using novel disposable endoscopes versus traditional reusable endoscopes.

Methods This prospective randomized controlled trial involved 42 patients who underwent ERBL for Grade II and III internal hemorrhoids using either a disposable endoscope ($n = 21$) or a reusable endoscope ($n = 21$). Safety was assessed by the incidence of equipment failure, device-related adverse events, and in-procedure stability of vital signs. Effectiveness was assessed by the postoperative therapeutic effect, feasibility of retroflexed ERBL, and incidence of complications.

Results In terms of safety, no life-threatening events, equipment failure, or device-related adverse effects occurred during the procedures in either group. The rate of diastolic blood pressure stability was significantly different between the two groups ($P = .049$), but the rates of systolic blood pressure and heart rate stability were similar. In terms of effectiveness, the therapeutic effects on postoperative Day 30 were similar in both groups. Image clarity and endoscopic flexibility in the disposable endoscope group were mildly inferior to those in the reusable endoscope group, but without statistical significance. Matching between the endoscope and ligating device was 100% in both groups. The incidence of complications on postoperative Days 1 and 10 was not significantly different between the two groups.

Conclusion Compared with reusable endoscopes, disposable endoscopes are equally safe, feasible, and reliable in ERBL for internal hemorrhoids.

What is already known on this topic

• Reusable endoscopes cannot be completely sterile even after standard disinfection. Disposable endoscopes can avoid the procedures of sterilizing.

What this study adds

• Retroflexed ERBL for Grade II and III internal hemorrhoids can be performed by disposable endoscopes, as safe and effective as traditional reusable endoscopes.

How this study might affect research, practice or policy

• Disposable endoscopes can be used for retroflexed ERBL for internal hemorrhoids especially in some circumstances such as endemic area or emergency bedside endoscopy.

Keywords: endoscopes; effectiveness; hemorrhoids; ligation; safety

Introduction

The common endoscope is frequently utilized in clinical practice. Endoscopes must be cleaned and sterilized after each use, which is a complicated and time-consuming process. Concerns have been raised over the possibility that reusable endoscopes cannot be fully sterilized [1]. Previous reports regarding low level organisms and even antibiotic-resistant bacteria cannot be totally eliminated in endoscopes after decontamination procedures have also attracted endoscopists' attention [2, 3]. Even after standard disinfection, biofilms still exist and become a potential source of infections especially for endoscopes more than 2 years old [4]. Disposable endoscopes have been developed to reduce the risk of hospital infection and avoid the need for cleaning and sterilizing procedures, especially during the coronavirus disease 2019 (COVID-19) pandemic. The safety and technical performance of disposable endoscopes are comparable to those of reusable

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Table 1. Goligher's classification.

Grade	Degree of prolapse
I	No prolapse
II	Prolapse on defecation with spontaneous reduction
III	Prolapse on defecation requiring manual reduction
IV	Irreducible prolapse

endoscopes used in routine examinations [5]. However, minimally invasive gastrointestinal treatment using disposable endoscopes has not been reported to date.

Endoscopic rubber band ligation (ERBL) refers to endoscopic-assisted ligation of hemorrhoids to create fibrosis of the rectal wall, which can prevent prolapse and bleeding by reducing the blood flow into the hemorrhoidal venous plexus [6]. ERBL is the first-choice treatment for patients with Grade I and II internal hemorrhoids and Grade III internal hemorrhoids with mucosal prolapse [7]. Minimally invasive treatment of internal hemorrhoids using endoscopes has proven effective and safe for patients with Grade I to III symptomatic internal hemorrhoids [8]. Patients with Grade II and III internal hemorrhoids with prolapse are mainly treated with ERBL [9]. As early as 2002, ERBL performed in the retroflexed position was proven to be readily available, safe, and effective in treating symptomatic hemorrhoids [10]. However, whether disposable endoscope-guided retroflexed ERBL is equally as feasible as traditional reusable endoscopes has not been explored.

In this study, we randomly used disposable or reusable endoscopes for ERBL in patients with Grade II and III internal hemorrhoids. We then compared the incidence of endoscopic flexibility, image clarity, device-related adverse events, incidence of complications, and therapeutic effects of these two types of endoscopes.

Patients and methods

Study population

We recruited patients with symptomatic internal hemorrhoids diagnosed at Shenzhen Hospital, Southern Medical University from 14 May 2022 to 7 June 2022. On 7 July 2022, the trial stopped with the end of follow-up of the last recruited patient. This study was conducted in accordance with the Ethical Guidelines of the Declaration of Helsinki. The Medical Ethics Committee of Shenzhen Hospital, Southern Medical University approved this prospective cohort study (NYSZYYEC20210034) on 20 April 2022. Clinical trial registration was completed (ChiCTR2200060014, 14/05/2022). Internal hemorrhoids were graded according to Goligher's classification [11] (Table 1). The inclusion criteria were as follows [12]: (1) age of 18 to 75 years and no limitation according to sex; (2) Grade II or III internal hemorrhoids with accompanying symptoms, such as bleeding, prolapse, or itching; (3) ineffective conservative treatment, such as diet and drugs, for Grade II and III internal hemorrhoids; and (4) unwillingness to undergo hemorrhoidectomy. The exclusion criteria were as follows [13]: (1) Grade IV hemorrhoids, mixed hemorrhoids, or external hemorrhoids; (2) internal hemorrhoids accompanied by incarceration, thrombosis, erosion, or infection; (3) severe systemic diseases resulting in an inability to tolerate endoscopic treatment; (4) perianal infectious diseases or anal fistulae; (5) active inflammatory bowel disease; (6) coagulation dysfunction or use of anticoagulants; and (7) pregnancy.

Patients enrolled in the study were assigned to either the disposable endoscope group (EndoFresh® XZING-W200B; HuiZhou Xzing Technology, Huizhou, China) or the reusable endoscope group (EG-600WR; Fujifilm, Tokyo, Japan) according to the random numbers generated by a computer. All patients were evaluated before treatment with a medical history review, laboratory examination (blood tests, coagulation function tests, and infectious disease screening), and electrocardiography. All patients provided written informed consent for the treatment and were informed of the risks associated with the treatment. All patients underwent whole-bowel preparation before ERBL.

Sample size calculation

Based on historical data of our center, the feasibility of ERBL under a reusable endoscope is >98%, and the feasibility of ERBL under a disposable endoscope was assumed to be 70% with reference to previous data of patients' tolerability and esophageal Z-line detection rate in disposable endoscopes [14, 15]. According to the estimation formula for test sample content using the single-group target value method, at a significance level of 0.05 and test efficiency ($1-\beta$) of 0.8, the estimated sample size was 21 patients in each group.

Endoscopic rubber band ligation

All patients were treated with ERBL. All patients received intravenous anesthesia with propofol (4 mg/kg) by anesthetists. After the multiple band ligation device (Speedband® M00542251; Boston Scientific, Marlborough, MA) was attached to the endoscope, the hemorrhoids were suctioned into the ligating device in a retroflexed position, and an elastic band was released. The above steps were repeated until the prolapsed hemorrhoids were relieved. No more than seven ligations in total were performed per patient (Fig. 1).

Evaluation measures

Safety measures

(1) Primary outcome measures.

Incidence of equipment failure and device-related adverse events.

Equipment failure (such as image interruption, water delivery blockage, or leakage) and adverse events during or within 1 h after the operation (such as mucosa damage, bowel perforation, massive hemorrhage, or instability of vital signs) were recorded.

(2) Secondary outcome measures.

In-procedure stability.

In-procedure vital sign stability was evaluated based on the changes in blood pressure and heart rate measured before anesthesia, during ERBL, and 10 ± 5 min after the procedure. Patients whose blood pressure and heart rate changed by >20% from baseline were defined as unstable [16].

Effectiveness measures

(1) Primary outcome measure.

Therapeutic efficacy.

Evaluation method: All patients underwent outpatient follow-up on postoperative Day (POD) 30 after ERBL to assess the therapeutic efficacy.

Evaluation criteria: (1) Cured: hematochezia and prolapse symptoms disappeared completely and wounds healed completely. (2) Effective: hematochezia and prolapse symptoms were improved, hemorrhoids were reduced or displayed incomplete atrophy, and wounds healed well. (3) Invalid: hematochezia and prolapse symptoms were not alleviated or were aggravated.

(2) Secondary outcome measures.

①Retroflexed ERBL feasibility.

Evaluation method: The operator evaluated the endoscopic image clarity, endoscopic flexibility, clinical operability, and matching between the endoscope and surgical instrument.

Evaluation criteria:

(1) Image clarity was graded as follows: (A) Good brightness, contrast, and clarity: accurate identification of the anal and dentate lines was possible, and internal hemorrhoids could be clearly identified. (B) Fair brightness, contrast, and clarity: rough identification of the anal and dentate lines was possible, and internal hemorrhoids could be roughly identified. (C) Poor brightness, contrast, and clarity: identification of the anal and dentate lines was not possible, and internal hemorrhoids could not be identified.

(2) Endoscopic flexibility was graded as follows: (A) The endoscope could be easily retroflexed from the forward position. (B) The endoscope could be roughly retroflexed from the forward position. (C) The endoscope failed to be retroflexed from the forward position. The time taken to move the endoscope from the forward position to the retroflexed position while withdrawing to the anus was recorded.

(3) Matching between the endoscope and ligating device was graded as follows: (A) The endoscope and ligating device matched perfectly, and the operation went smoothly. (B) The endoscope and ligating device matched roughly, and the operation procedure was slightly affected. (C) The endoscope and ligating device did not match, and the operation failed to proceed.

ERBL feasibility was considered "qualified" if all items were graded "A" or "B." If any one item was graded "C," ERBL feasibility was considered "unqualified." The qualification rate of ERBL feasibility was calculated as follows: (number of "qualified" cases/number of patients in each group) × 100.

Postoperative complications

All patients underwent outpatient follow-up on POD 1 and 10 after ERBL to assess postoperative complications, including bleeding, urinary retention, and anal pain. Anal pain was quantified by a 0- to 10-point visual analogue scale (VAS) in which a score of 0 points indicated no pain, 1 to 3 indicated mild pain, 4 to 6 indicated moderate pain, 7 to 9 indicated severe pain, and 10 indicated excruciating pain [13].

Statistical analyses

Data were analyzed using SPSS Version 26.0 (IBM Corp., Armonk, NY). Because there was no loss to follow-up in this trial, the protocol set population was consistent with the full analysis set population. Measurement data were compared between the two groups using the paired *t*-test or Wilcoxon rank sum test. Variance of repeated measurement analysis was performed for intragroup and intergroup comparisons. Count data are summarized as frequency and percentage [*n* (%)] and were compared using the chi-square test or Fisher's exact test. A *P*-value of $<.05$ was considered statistically significant.

Results

General information

In total, 42 patients were treated with ERBL using a disposable endoscope ($n = 21$) or reusable endoscope ($n = 21$) (Fig. 2). No loss or exclusion after randomization. No significant between-group differences were observed in sex, age, grade of internal hemorrhoids, blood pressure, or heart rate (Table 2).

Safety measures

(1) Primary outcome measure.

Incidence of equipment failure and device-related adverse events.

No equipment failure or operation-related adverse events occurred in either the disposable or reusable endoscope group.

(2) Secondary outcome measure.

In-procedure stability.

During ERBL, the rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 85.71%, 66.67%, and 90.48%, respectively, in the disposable endoscope group and 95.24%, 95.24%, and 90.48%, respectively, in the reusable endoscope group. Only diastolic blood pressure was significantly different between the two groups ($P = .049$).

After the procedure (10 ± 5 min), the rates of systolic blood pressure stability, diastolic blood pressure stability, and heart rate stability were 80.95%, 80.95%, and 85.71%, respectively, in the disposable endoscope group and 90.48%, 80.95%, and 80.95%, respectively, in the reusable endoscope group. The differences between the two groups were not statistically significant.

Effectiveness measures

(1) Primary outcome measure.

Therapeutic efficacy.

In the disposable endoscope group, the numbers of cases regarded as "cured," "effective," and "invalid" were 12 (57.1%), 9 (42.9%), and 0 (0.0%), respectively. In the reusable endoscope group, these numbers were 13 (61.9%), 7 (33.3%), and 1 (4.8%), respectively. The difference in therapeutic effects between the two groups was not statistically significant ($P = .61$).

(2) Secondary outcome measures.

Retroflexed ERBL feasibility.

Image clarity: Grade A was assigned to 18 (85.71%) operations, and Grade B was assigned to 3 (14.29%) operations in the disposable endoscope group. Grade A was assigned to 20 (95.24%) operations, and grade B was assigned to 1 (4.76%) operation in the reusable endoscope group. The difference between the two groups was not statistically significant ($P = .60$).

Endoscopic flexibility: Grade A was assigned to 16 (76.19%) operations, and grade B was assigned to 5 (23.81%) operations in the disposable endoscope group. Grade A was assigned to 21 (100.00%) operations, and grade B was assigned to 0 (0.00%) operations in the reusable endoscope group. The difference between the two groups was not statistically significant ($P = .06$).

The median (interquartile range) retroflex time was 11 (9–15) s in the disposable endoscope group, and 10 (8–12) s in the reusable endoscope group. The difference between the two groups was not statistically significant ($Z = -1.241$, $P = .215$).

Matching between endoscope and ligating device: Grade A was assigned to 21 (100.00%) operations, and grade B was assigned to 0 (0.00%) operations in both groups. The difference between the two groups was not statistically significant.

Qualified ERBL feasibility (grade A and B) was 100% in both groups (Table 3).

Postoperative complications.

The incidence of complications, including bleeding, urinary retention, and anal pain, on POD 1 and 10 was not significantly different between the two groups (Table 4).

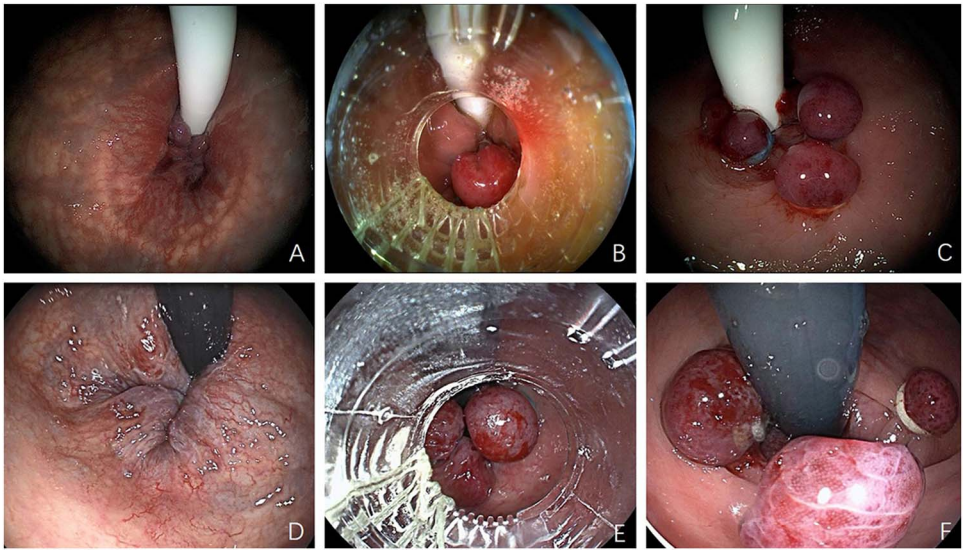

Figure 1 Retroflexed endoscopic view of hemorrhoids before, during, and after ERBL (a-c present disposable endoscopic view, d-f present reusable endoscopic view).

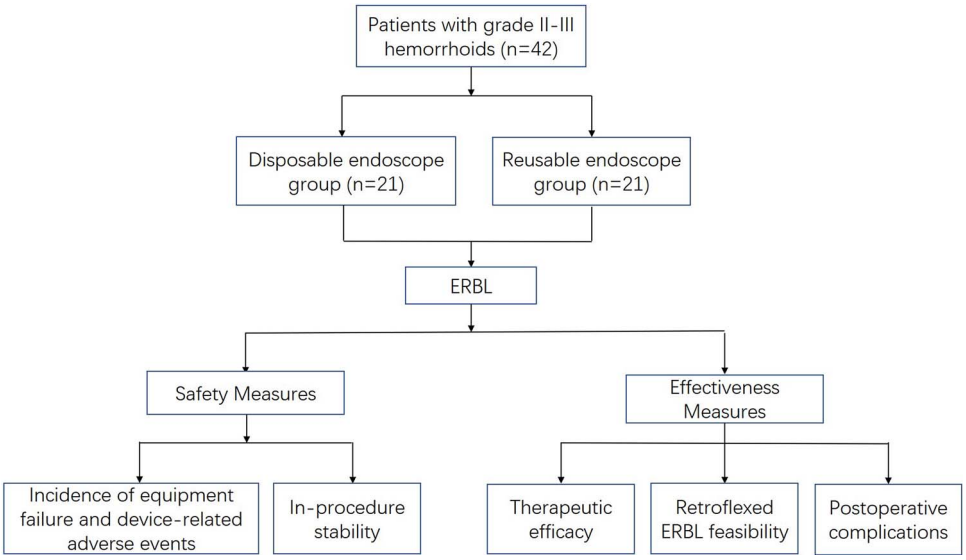

Figure 2 The flowchart of grouping and measures of this study.

Table 2. Baseline characteristics of the patients.

	Disposable endoscope group ($n = 21$)	**Reusable endoscope group ($n = 21$)**	***P*-value**
Age (years)	39.81 ± 7.17	41.48 ± 9.17	.330
Gender, *n* (%)			
Male	9 (42.86%)	9 (42.86%)	1.000
Female	12 (57.14%)	12 (57.14%)	
Classification of Internal Hemorrhoids, *n* (%)			
III	12 (57.14%)	14 (66.67%)	.525
II	9 (42.86%)	7 (33.33%)	
Systolic blood pressure (mmHg)	107.05 ± 9.52	117.76 ± 17.38	.096
Diastolic blood pressure (mmHg)	65.10 ± 7.65	69.95 ± 6.15	.561
Heart rate (beats/minute)	70.33 ± 7.68	72.14 ± 8.81	.674

Table 3. Comparisons of ERBL feasibility between the groups.

	Disposable endoscope group ($n = 21$)	Reusable endoscope group ($n = 21$)	*P*-value
Endoscopic flexibility, *n* (%)			
A	16 (76.19%)	21 (100.0%)	.057
B	5 (23.81%)	0 (0.0%)	
Matching between endoscope and ligating device, *n* (%)			
A	21 (100.0%)	21 (100.0%)	
B	0 (0.0%)	0 (0.0%)	
Acceptable clinical operability, *n* (%)			
A	18 (85.71%)	21 (100.0%)	.231
B	3 (14.29%)	0 (0.0%)	
Image clarity, *n* (%)			
A	18 (85.71%)	20 (95.24%)	.599
B	3 (14.29%)	1 (4.76%)	
Qualified ERBL feasibility, *n* (%)			
Yes	21 (100.0%)	21 (100.0%)	
No	0 (0.0%)	0 (0.0%)	

Table 4. Comparisons of postoperative complications between the groups.

Complications		Disposable endoscope group ($n = 21$)	Reusable endoscope group ($n = 21$)	*P*-value
POD 1				
Bleeding				
	A. No bleeding	18 (85.71%)	20 (95.24%)	.606
	B. Less than 5 ml	2 (9.52%)	1 (4.76%)	
	C. 5–10 ml	1 (4.76%)	0 (0%)	
	D. More than 10 ml	0 (0%)	0 (0%)	
Postoperative urination				
	A. No urination disorder.	16 (76.19%)	18 (85.71%)	.697
	B. Have difficulty when urination.	4 (19.05%)	3 (14.29%)	
	C. Urinary retention.	1 (4.76%)	0 (0%)	
Anal pain				
	A. No pain	13 (61.9%)	12 (57.14%)	.656
	B. Mild pain	4 (19.05%)	7 (33.33%)	
	C. Moderate pain	3 (14.29%)	2 (9.52%)	
	D. Severe pain	1 (4.76%)	0 (0%)	
	E. Excruciating pain	0 (0%)	0 (0%)	
POD 10				
Bleeding				
	A. No bleeding	20 (95.24%)	21 (100%)	1.000
	B. Less than 5 ml	1 (4.76%)	0 (0%)	
	C. 5–10 ml	0 (0%)	0 (0%)	
	D. More than 10 ml	0 (0%)	0 (0%)	
Postoperative urination				
	A. No urination disorder	21 (100%)	21 (100%)	
	B. Have difficulty when urination	0 (0%)	0 (0%)	
	C. Urinary retention	0 (0%)	0 (0%)	
Anal pain				
	A. No pain	20 (95.24%)	21 (100%)	1.000
	B. Mild pain	1 (4.76%)	0 (0%)	
	C. Moderate pain	0 (0%)	0 (0%)	
	D. Severe pain	0 (0%)	0 (0%)	
	E. Excruciating pain	0 (0%)	0 (0%)	

POD, postoperative day

Discussion

This is the first pilot study to compare the safety and effectiveness of disposable and reusable endoscope-guided retroflexed ERBL of internal hemorrhoids.

Endoscopic examination may stimulate the sympathetic nervous system, which leads to changes in blood pressure and heart rate [17]. Cardiovascular events rarely happen but may be life threatening during colonoscopy, including cardiac arrhythmias (0.1%), bradycardia (0.8%), hypotension (1.2%), and death (0.007%–0.2%) [18, 19]. Heart rate fluctuation happened mainly during colonoscopy of the left side of bowel [19]. Severe hemodynamic stress leads to myocardial ischemia, which may even be life-threatening [20]. During ERBL, the shorter retroflex time and better flexibility of the endoscope can shorten the procedure

and reduce the stimulation to patients. In this study, although the diastolic blood pressure fluctuations during the procedure were significantly vaster in the disposable endoscope group, they became stable after the procedure. Additionally, no patients developed life-threatening adverse events related to the endoscopic operation. Thus, this study proves a satisfactory safety of disposable endoscope.

Compared with reusable endoscopes, the overall performance of disposable endoscopes is satisfactory. Although the grades of image clarity and endoscopic flexibility were slightly lower for the disposable than reusable endoscopes (manifesting as a higher rate of Grade B in the disposable endoscope group), all patients in both groups successfully underwent ERBL. Because ligating the hemorrhoids above the dentate line can reduce postoperative pain [21], correctly identifying the anorectal and dentate lines in the retroflexed position is crucial for endoscopists to confirm the location of ligation [10]. Disposable endoscopes have two light-emitting diodes, a 110° view angle, and a 180° upward-bending angle that facilitate recognition of the structure and reaching of the operation site. However, the image brightness, sharpness, and contrast and the curvature of the disposable endoscope may require improvement to meet the needs of more accurate diagnosis and complex operations.

In this study, we found that the "cured" and "effective" rates on POD 30 were comparable between the two groups, indicating that disposable endoscopes have satisfactory operational stability and can be a promising option for retroflexed ERBL. The incidence of complications was also similar between the two groups. Common complications related to ERBL include bleeding (1.7%–15.4%) [22, 23], pain (12.3%–50%) [24], and urinary retention (0.58%–7.7%) [25]. Bleeding mostly occurs 7 to 10 days after ERBL because of the sloughing of the elastic ligating bands [26]. During ERBL, matching between the endoscope and ligating device can guarantee complete suction of the hemorrhoids into the ligating device; this can prevent early slippage of the elastic bands, thus reducing the incidence of postoperative bleeding. For disposable endoscopes, the 10.8-mm outer diameter insertion tube and 3.00-mm diameter instrument channel can fit with multiple band ligation devices, thus avoiding in-procedure equipment failure and reducing the incidence of postoperative complications. Pain, sometimes associated to urinary retention [27], can be prevented by avoiding the dentate line when ligating as mentioned above [28]. Only one patient in the disposable endoscope group developed urinary retention and ultrasound examination proved the diagnosis, but his postoperative VAS was 1 point. His history of prostatic hyperplasia and postoperative anal edema could explain his urinary retention, and his symptoms were relieved soon after perineum hot packing.

Disposable endoscopes have a wide range of clinical applications. First, they can be used directly after they are removed from the packaging and discarded following the medical waste management principles after use [29]. This is suitable in some circumstances, such as in areas with a high rate of infectious diseases or in patients with multi-drug resistance. Second, they are convenient to carry and use in some specific situations, such as bedside endoscopy in the emergency setting and some complex endoscopic operations (such as endoscopic submucosal dissection, endoscopic mucosal resection, or peroral endoscopic myotomy) [30].

Preventing cross contamination is the original intention of disposable endoscope. Although the risk of cross infection in the digestive tract is low, the awareness of eliminating the risk of cross infection will become increasingly important due to human progress and the increasing demand for medical capacity. And single-use is undoubtedly the most direct solution. The use of a disposable endoscope is a preferred option for minimizing the risk of cross infection. In addition, the total maintenance cost of reusable endoscope was 214.74yuan/case, including the cost of endoscopic sterilization 183.15 yuan, the cost of endoscopic repair 25.30 yuan, and the cost of endoscopic storage 6.29 yuan, when the maintenance cost of disposable endoscope can be totally saved. We are looking forward to future studies about disposable endoscope and the development of more related products to address contemporary concerns about iatrogenic infection.

Conclusion

A disposable endoscope can be an appropriate novel option in retroflexed ERBL of internal hemorrhoids because of its similar safety and effectiveness to a reusable endoscope. However, because this was a single-center pilot study, the number of patients was small. The disposable endoscope used in this study just obtained the registration certificate of medical devices issued by China Medical Products Administration at the beginning of 2022, so there is still a certain gap between large-scale use. The purpose of this study was to obtain real clinical use data through a small sample of patients and use these data to guide large-scale clinical application of products after marketing. A multi-center study with more patients and a longer follow-up period are required to guarantee the feasibility of disposable endoscope use.

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Conflict of interest statement

The authors have no relevant financial or non-financial interests to disclose.

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Data Availability

The deidentified participant data and their postoperative feedback details can be provided if other researchers contact our corresponding author through email any time after the article be published.

Author Contributions

The draft of the manuscript was written by W.X. Material preparation was performed by G.X. and L.L. Data collection was performed by G.C. and X.Y. Data analysis was performed by L.D. Y. Z. contributed to the study conception and design. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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