New detachable occlusion balloon unit for transrectal natural orifice translumenal endoscopic surgery

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Title page

New detachable occlusion balloon unit for transrectal natural orifice translumenal endoscopic surgery

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Table of contents

Abstract

Introduction: Transrectal natural orifice translumenal endoscopic surgery (NOTES) requires a good endoluminal view and adequate intrarectal bacterial clearance in the working area. We developed a new occlusion balloon unit with an easily detachable inflation device, which allows the surgeon a clear working area distal to the balloon. Materials and methods: The effectiveness of the sealing balloon and the extent of macroscopic and histopathological injury to the bowel wall at the site of balloon placement were examined in 12 pigs. Results: The mean time to place and inflate the balloon unit was 12.0 ± 3.5 min, Effective air-tightness lasted for 21.0 ± 12.0 min. There was no leakage of dye (methylene blue) past the balloon when pressure was maintained above 6.70 ± 0.08 kPa (6.62–6.78 kPa). After gut irrigation, good visibility was maintained in the working area for 6 hours, and adequate bacterial clearance was maintained for 3 hours. There were no macroscopic signs of intestinal wall damage at the site of balloon placement. Histopathological examination showed only patchy mucosal damage and submucosal thrombus at the site of balloon placement. Conclusion: This newly-developed occlusion balloon unit helps to establish good visibility and adequate bacterial clearance for endoluminal surgical procedures.

Introduction

Natural orifice translumenal endoscopic surgery (NOTES) has been reported in humans since

2004 [1]. However, there are ongoing challenges to performing NOTES, as outlined in the

Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) white paper [2-4].

Local bacterial clearance is of particular concern when using the transcolonic route. Several

studies have reported the occurrence of intraperitoneal abscesses after transcolonic surgery,

despite attempts to sterilize the working area in the bowel [5-9]. We considered that improvement

of bacterial clearance in the colon would increase the safety of transrectal NOTES, and developed

a method of transrectal bowel irrigation. This method uses an occlusion balloon unit that provides

a water-tight occlusion of the intestinal lumen to achieve bacterial clearance with a high-speed

irrigation device, and an air-tight seal to maintain visibility in the working area.

The present study assessed the balloon unit in terms of water-tightness, air-tightness, ability to

maintain bacterial clearance, balloon inflation pressure, effectiveness in maintaining visibility in

the working area, and intestinal wall damage.

Materials and Methods

Specifications of the balloon unit

The design of the occlusion balloon unit is shown in **Figure 1(I-A–I-F)**. The occlusion balloon is

capsule-shaped to reduce intestinal injury. The balloon is oval in shape and is made of

biocompatible silicone. These features allow the balloon to change shape during intestinal

peristalsis, thus minimizing the risk of injury to the bowel wall. The balloon measures 70 mm in

length and 11 mm in width when deflated, and has a maximum diameter of 80 mm when inflated.

The most important design feature of this unit is the ability to detach the inflation device

(**Figure1: I-C, II-a–II-e**) from the balloon unit to allow the surgeon a clear working area distal to

the balloon. The balloon unit also features radio-opaque line (**Figure1: I-F**).

The inflation device used in this study was developed by us. The unit includes a power supply,

pressure gauge, and inflation device, and inflates the balloon at 0.18 L/min, requirements of an

occlusion balloon unit for used in endoluminal surgery are shown in **Table 1**.

In vivo study

Twelve female pigs, weighing approximately 40 kg each, were used in this study. Two experimental

models were used: a model to study visibility in the working area, and a model to study bacterial

clearance in the working area. All animals were fed cereal preoperatively (Miniature Swine Diet

M-16; CLEA Japan, Inc., Tokyo, Japan). Under general anesthesia, the balloon unit was inserted

through the anus and advanced to the target position in the colon with endoscopic guidance. The

balloon was then inflated to occlude the intestinal lumen **(Figure 2-A, B, and C)**. After balloon

inflation, the two wire anchoring loops connecting the inflation device to the balloon unit were

loosened. The entire inflation device was pushed towards the check valve attached to the balloon, and

the anchoring loops were extended, which pushed the wires along the 45° slope on the outside of the

anchoring hooks and released the loops **(Figure 2-D and E)**. After bowel irrigation **(Figure 2-F)**, the

spiral deflation tube (1.5 m length, 0.7 mm diameter) of the balloon that was pulled through the

endoscope channel to the outside of the body. The end was cut off the deflation tube with scissors,

and a 10-mL syringe was connected to the deflation tube stump deflate the balloon **(Figure 2-G and**

H). The balloon was then withdrawn through the anus (**Figure 2-I**).

The rectum contained a large amount of solid stool because no purgative had been used prior to

the procedure. A high-speed irrigation device (HydroFlex Multi-application Irrigation Pump;

BARD, RI, USA) connected to the endoscope channel easily cleared the space between the anus

and the peritoneal reflection of the rectum for balloon insertion.

Assessment of balloon placement time

The time taken to position and inflate the balloon was recorded. The displacement of the balloon

over time and the time for balloon withdrawal were also measured.

Assessment of water-tightness and bacterial clearance

Assessment of occlusion

Ten measurements were performed in each of two pigs. The balloon unit was placed 60 cm to the

anal verge with endoscopic guidance, and the balloon was inflated to enable laparoscopic

identification of the site. Two ligatures were placed around the colon at 70 cm proximal to the

anal verge, using 1-0 silk/3-0 nylon. Methylene blue (**Figure 3-A**) (20 mL) was injected into the

bowel between the ligatures and the balloon. The balloon pressure was then gradually reduced,

and a pressure sensor (AP-V80; Keyence, Tokyo, Japan) (**Figure 3-B**) was used to determine the

pressure at which methylene blue leaked into the past balloon to the anal side (**Figure 3**).

Assessment of effectiveness of irrigation

The balloon was placed 20 cm proximal to the desired working area and inflated. The high-speed

irrigation device (HydroFlex Multi-application Irrigation Pump; BARD, RI, USA) was used to

irrigate the gut on the anal side of the balloon at a flow rate of 500 mL/min. The time required to

fill the intestinal lumen was measured.

Residual stool was removed until the intestinal lumen had the same macroscopic appearance as

would be expected after routine administration of polymer purgatives for oral

endoscopy .Bacterial were then measured. The irrigation solutions used were distilled water,

isotonic saline, and 1% neomycin solution.

Assessment of air-tightness and the effectiveness of maintaining visibility in the working area

8

After balloon occlusion, the bowel was insufflated via an endoscope placed 15 cm from the anal

verge .The time required to establish visibility in the working area and the inflation requirements

were recorded. The length of time that visibility of the working area was maintained, was also

measured. The time from maximum visibility in the working area until a 50% reduction in

volume, when treatment was considered difficult to perform, was recorded.

To assess whether bacterial clearance was maintained in the working area during surgery,

cholecystectomy was performed in two pigs by transrectal hybrid NOTES using a 3-mm diameter

forceps [10]. Injury to the bowel wall was assessed macroscopically and histopathologically.

The effectiveness of using the occlusion balloon during endoscopic submucosal dissection (ESD)

was assessed was performed in two pigs. A hook (PCF-H180AL/I; Olympus, Tokyo, Japan) was

used to simulate a rectal lesion 20 mm in diameter on the anal side of the balloon. Maintenance of

visibility in the working area and the efficiency of clearance of smoke from electrocoagulation

were assessed. The lesion was located on the left wall of the rectum at 20 cm from the anal verge,

and the balloon was placed 10 cm proximal to the lesion. Electrocoagulation was performed for

30 s, with concurrent inflation and aspiration through the endoscope. The time from the start to

completion of ESD was recorded, and the inflation status of the balloon was monitored.

Assessment of complications of balloon placement

Physiological adverse effects of balloon placement were assessed by monitoring heart rate and arterial oxygen saturation during balloon inflation in three pigs. Balloon inflation time (to a diameter of 80 mm was set to 3 seconds .Physiological effects were assessed at three different balloon locations20, 40, and 60 cm) from the anal verge.

Injury to the bowel wall caused by balloon inflation was assessed macroscopically and histopathologically. The bowel wall was examined at the site of balloon inflation and on both the oral and anal sides of the occlusion site. The bowel was examined macroscopically for signs of mucosal rupture, bleeding, hematoma, and edema, and microscopically for signs of submucosal thrombus and inflammation.

The study protocol was registered with and approved by the Animal Ethics Committee and Animal Center at Medical Sciences Kyushu University (permission number A-21-165).

Results

Assessment of effectiveness of balloon placement

The relatively short length of the balloon and its excellent ability to mold to the intestinal tract resulted in good maintenance of its position. The balloon moved 1–2 cm towards the anus during intestinal peristalsis and then back towards the mouth during intestinal relaxation, maintaining its position overall.

The time required to place and inflate the balloon when there was no air leakage was 10.0 ± 2.5 min. We assessed the mechanism for detaching the inflation device from the balloon unit and the ease of inflating and withdrawing the balloon, which were the most important requirements of the unit, In two of the pigs , we verified that the inflation device could be detached from the balloon when the unit had bilateral anchoring wires. The original unit with a single anchoring wire was used in four of the pigs, and was also detached easily. Air leaked from the check valve after detachment of the inflation device in two of the pigs. The balloon therefore cannot be relied on to maintain its inflation in clinical settings.

Removal of the deflation tube from the balloon and subsequent deflation were performed

efficiently in all animals. Endoscopic withdrawal of the balloon assisted by gentle pulling on the

deflation tube was very easy. The time required for balloon withdrawal was 2.0 ± 1.0 min.

Assessment of water-tightness and effectiveness of bacterial clearance

Gentian violet solution leaked past the balloon at a mean pressure of 6.70 ± 0.08 kPa (6.62–6.78

kPa) and a mean balloon diameter of 7.15 ± 0.95 cm (6.2–8.1 cm).

High-speed irrigation after balloon inflation reduced the total bacterial counts .The reduction in

bacterial count differed depending on the irrigation solution used. Post-irrigation changes in

bacterial counts over time are shown in **Table 2**.

Assessment of air-tightness and effectiveness of visual field maintenance

The distance of the balloon from the anal verge (20, 30, 40, and 60 cm), time required to establish

visibility in the working area, inflation requirements, and time until 50% loss of volume in the

working area were as follows. All inflations were at high speed, using the PCF-H180AL/I hook.

Deflation time was 2.05 ± 0.25 s (1.8–2.3 s) at 20 cm, 3.45 ± 0.65 s (2.8–4.1 s) at 30 cm, 3.55 ±

0.25 s (3.3–3.8 s) at 40 cm, and 5.0 ± 0.2 s (4.8–5.2 s) at 60 cm. The time until 50% loss of volume

in the working area was 10.5 ± 1.5 min (12.0–9.0 min) at 20 cm, 12.5 ± 1.5 min (14.0–11.0 min) at

30 cm, 28.5 ± 6.5 min (35.0–22.0 min) at 40 cm, and 29.5 ± 1.5 min (31.0–28.0 min) at 60 cm.

Inflation in small volumes increments was found to rapidly establish visibility in the working area,

and sustain visibility for a long time. However, the working area was lost more quickly when the

balloon was placed closer to the anus.

The mean time to inflate the balloon was 9.0 ± 3.5 min , the mean time to deflate the balloon was

2.0 ± 1.0 min, and the mean time for bowel preparation was 11.0 ± 4.5 min; The time to completion

of irrigation therefore was <10 minutes. Intestinal wall damage at the site of balloon placement in

the two pigs that underwent cholecystectomy by NOTES was so minimal that it could not be

recognized macroscopically.

Once visibility of the working area was established, it was maintained relatively well. A good

visual field was maintained during ESD, and the procedure was easy to perform.

Effectiveness of balloon occlusion

We saw no leakage of intestinal contents (solid or liquid) from the proximal side of the balloon during the 6 hours after gut irrigation.

Assessment of complications due to balloon placement

The physiological effects of balloon placement were assessed by monitoring heart rate and arterial oxygen saturation in six pigs. No changes in these vital signs were observed, even when the balloon was inflated to its maximum diameter.

The macroscopic and histopathological examinations findings of the intestinal wall after balloon occlusionare shown in **Figure 4**. No macroscopic signs of mucosal rupture, bleeding, hematoma, or edema were observed at the balloon placement sites. Histopathological examination showed localized mucosal injury and submucosal thrombus. Submucosal edema was also observed on the anal side of the balloon placement site. There were no microscopic findings indicating rupture of the bowel wall.

Discussion

We developed a new occlusion balloon unit and demonstrated that this device may help to improve the endoluminal view and bacterial clearance during transrectal NOTES.

Previous animal and human studies of occlusion balloon devices have reported balloon placement times of 18 min or longer [11-13]. In this study, the maximum time required for balloon placement was only 12 min. The balloon unit is placed using a conventional endoscope and conventional biopsy forceps, and is easy to operate. We therefore believe that surgeons will find it relatively easy to introduce it into clinical practice.

We showed that irrigation of the bowel in preparation for transrectal NOTES can be performed in the immediate preoperative period. Furthermore, the total bacterial count in the bowel did not increase over time-while the balloon was inflated, confirming that the balloon contributes to maintenance of adequate bacterial clearance. This reduces the risk of peritoneal infection by transrectal NOTES [14, 15]. The short time required for bowel preparation was verified when we performed cholecystectomy using transrectal NOTES. Currently, bowel preparation rarely involves the use of antibiotic solutions. We are investigating establishment of a completely antiseptic environment by balloon occlusion and irrigation with low-concentration ozone water.

When performing colonic ESD, air insufflation to a relatively high intraluminal pressure may be necessary to visualize the surgical field. This may lead to postprocedural pain due to colonic distension. We consider that the present balloon unit, which was shown to markedly improve the ability to visualize the working area, could effectively be used for in ESD of extensive early colon cancer.

Previous studies which used miniature endoscopes to place inflatable balloons in the bowel demonstrated the safety of such procedures [11-13, 16-20].

Physiological assessment of three pigs in this study during the balloon placement procedure did not show any adverse effects. However, we did observe physiological effects when the entire colon was distended by a large volume of air. This indicates that our procedure may be useful for reducing physiological adverse effects, because it allows procedures to be performed with delivery of a smaller volume of air to a restricted area of the colon.

Some studies have evaluated the effects of localized pressure on the wall of the small intestine in terms of blood flow, and subsequent ischemia or necrosis [21-26]. However, there are no reports of such studies of the large intestine. In this study, we evaluated the pathological changes

16

resulting from localized pressure on the bowel wall. Because of ethical considerations in animal experiments, it is impossible to fully evaluate the relationship between the localized pressure and ischemia or necrosis. However, some clinical reports have described ischemia or necrosis of the bowel wall that were considered to be caused by excessive localized pressure [27-29]. We are considering future studies to clarify the relationship between localized pressure on the bowel wall and ischemia or necrosis, if they are approved by our animal ethics committee.

The most important consideration when placing a balloon in the colon is avoiding injury to the bowel wall at the site of balloon placement. In this study, we observed only localized damage to the mucosa at the site of balloon placement. We speculate that this is because of the ability of the balloon to mold to the gut and move slightly with peristalsis. We judged it possible to safely perform balloon occlusion of the colon if the design of the balloon did not cause excessive friction. Movement of the balloon associated with intestinal peristalsis carries a risk of gradual leakage of stool past the balloon. This risk can be reduced by reducing balloon movements and increasing the ability of the balloon to mold to the intestinal mucosa. However, such features may cause damage to the bowel wall. We therefore used a silicone balloon to reduce friction. In future studies, we plan to place an antiseptic tampon that is easy to withdraw on the anal side of the balloon.

It is not possible to constantly monitor balloon pressure using our device, because the balloon unit is detached from the inflation device. We intend to address this in future studies. In addition, the immunological and bacteriological consequences of balloon occlusion should be studied further.

Although NOTES is still in the developmental stages, hybrid NOTES has already been used in clinical practice. As NOTES is the ultimate minimally invasive surgery that causes minimal stress to the patient's body, it will hopefully become established as a routine modality in clinical practice in the near future [30, 31].

In conclusion, our newly-developed occlusion balloon unit with an easily detachable inflation device was found to improve endoluminal views and maintain a useful working area for endoluminal surgery. Its ability to prevent fluid leakage makes it a promising device for providing an irrigated endoluminal surgical field. Furthermore, use of the unit may improve the intraperitoneal visual field by reducing the need for bowel distension during NOTES.

Disclosure

Drs. Hao Xu, Takeshi Ohdaira, Yoshihiro Nagao, Norifumi Tsutsumi, Megumu Mori, Munenori Uemura, Kazutaka Toyoda, Satoshi Ieiri, and Makoto Hashizume have no conflicts of interest or financial ties to disclose.

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Table

Table 1. Requirements of the balloon unit

1. Molding during intestinal peristalsis
2. A balloon deflation mechanism for emergencies
3. An easy method of detaching the inflation device from the balloon unit during procedures
4. A mechanism for manual withdrawal of the balloon
5. Radio-opaque marking

Table 2. Total bacterial counts (colony forming units /field)

Irrigation solutions, n = 6	Time after irrigation			
	Immediate	1hour	2hours	3hours
Unirrigated part of the colon	4886	4882	4872	4881
Distilled water	326	335	330	342
Isotonic saline	162	173	178	182
1% neomycin solution	6	11	10	12

Figure and Figure Legends
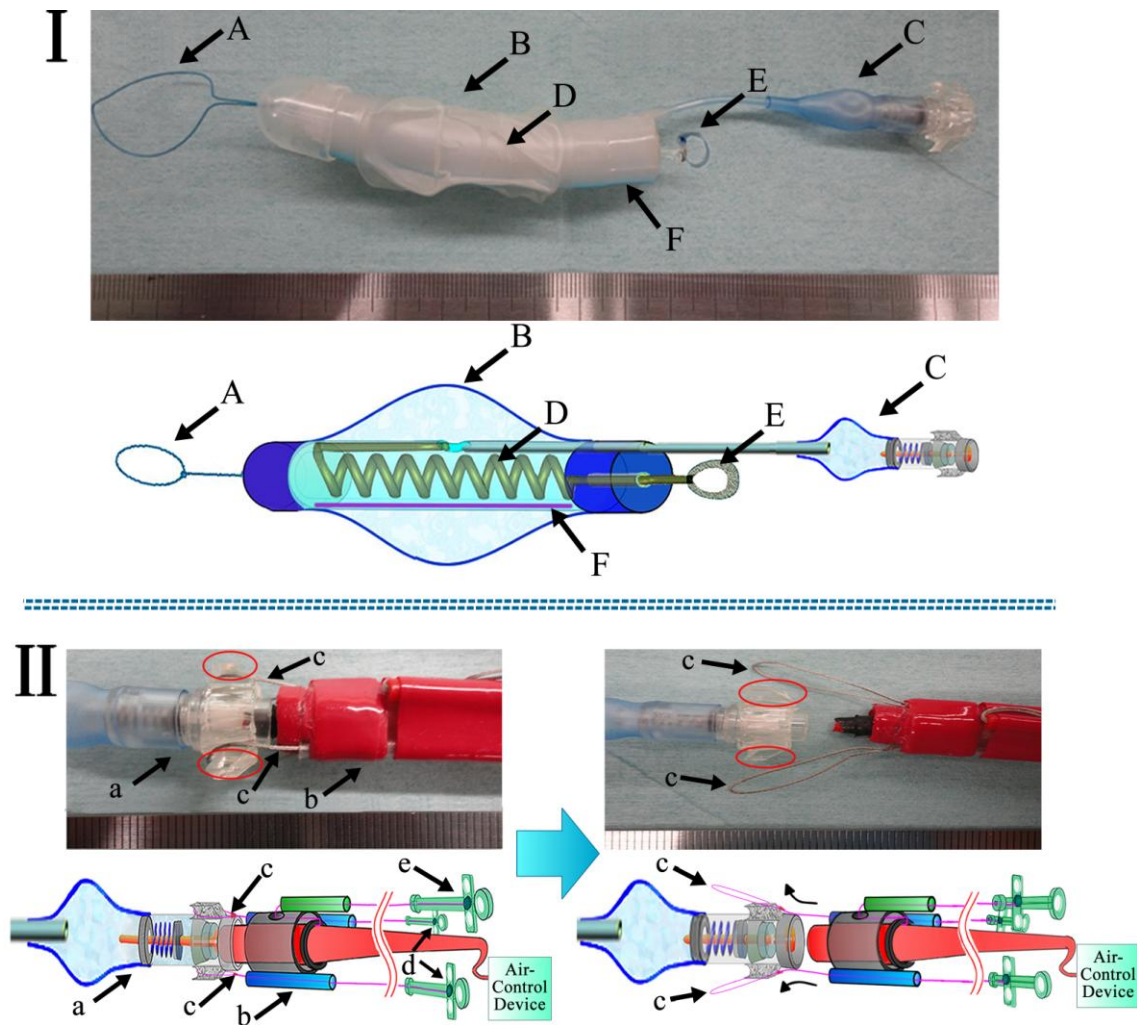
Figure 1. Design of the balloon unit and the procedure for detaching the inflation device from the balloon

(I) Design of the balloon unit:**(A)** ring used for traction by the balloon unit during placement. **(B)** occlusion balloon. **(C)** check valve. **(D)** deflation tube. **(E)** ring for grasping the of deflation tube **(F)** radio-opaque line

(II) Procedure for detaching the inflation device from the balloon unit. Left: the inflation device is attached to the check valve of the balloon unit. Right: the anchoring wire rings are unhooked and the inflation device is detached from the balloon unit. (a) check valve. (b) proximal end of the inflation device. (c) anchoring wire. (d) controls to extend the proximal end of the inflation device. (e) control to extend the anchoring ring wires and the check valve. Red circles: hooks for the anchoring wires, with a 45° slope on the outer edge.
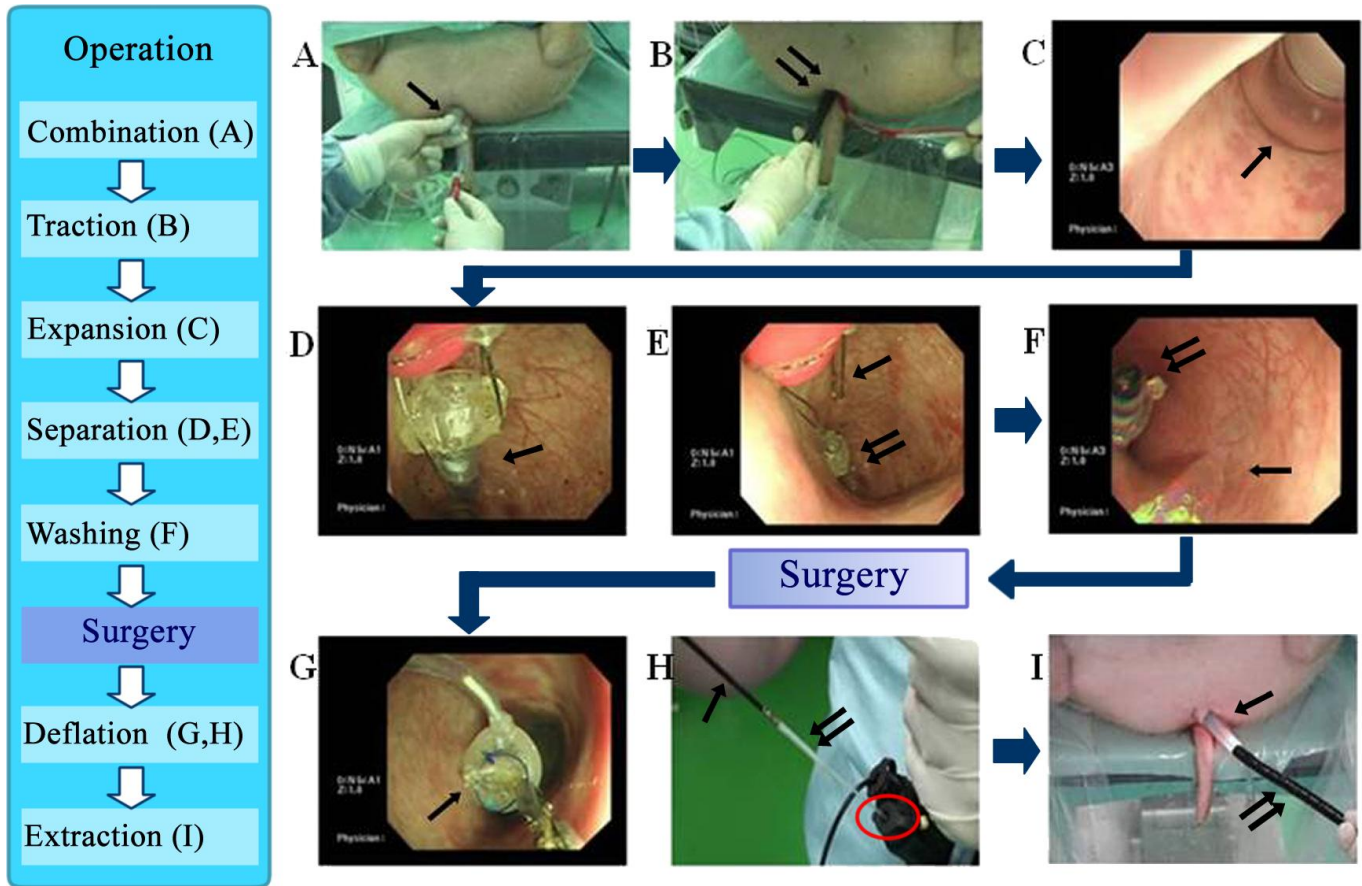
Figure 2. Use of the occlusion balloon during in vivo operations

(A) The balloon unit is connected to the inflation device and inserted into the anal canal, followed by the endoscope. Single arrow: occlusion balloon. **(B)** The inflation tube is pushed in proportion to the insertion speed of the endoscope. Double arrow: endoscope. **(C)** The ring on the proximal end of the balloon unit is grasped with forceps to position the unit. The balloon is then inflated to occlude the intestinal lumen. Single arrow: inflated balloon. **(D)** The balloon is completely inflated, and the anchoring wires are unhooked to detach the inflation device from the balloon unit. Single arrow: check valve. **(E)** The balloon unit and inflation device are completely detached. Single arrow: anchoring ring wire. Double arrow: check valve. **(F)** Irrigation is initiated immediately after balloon inflation. Single arrow: water jet from the tip of the endoscope. Double arrow: check valve. **(G)** The forceps are passed through the endoscope channel and the ring of the spiral deflation tube is grasped. Single arrow: ring of the spiral deflation tube. **(H)** The spiral deflation tube of the balloon is withdrawn through the endoscope channel and guided to the outside of the body. Single arrow: endoscopic forceps. Double arrow: spiral deflation tube. Red circle: endoscope channel. **(I)** The spiral tube is used to deflate the balloon and guide it through the anal canal to the outside of the body. Single arrow: occlusion balloon. Double arrow: endoscope.
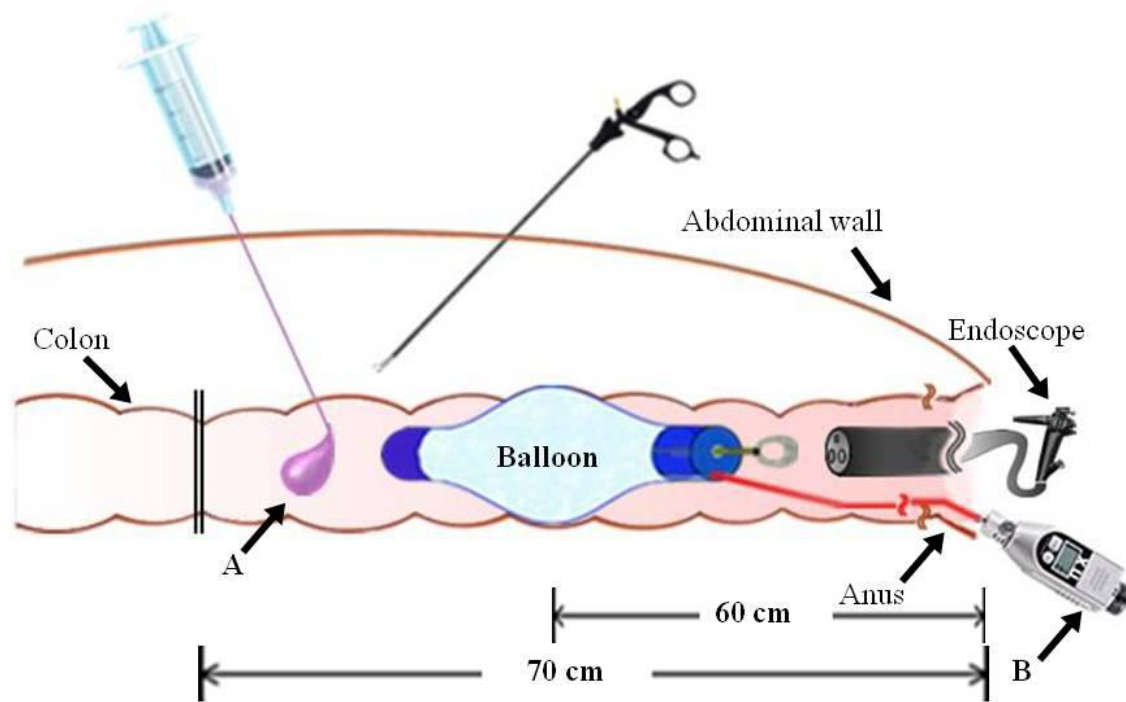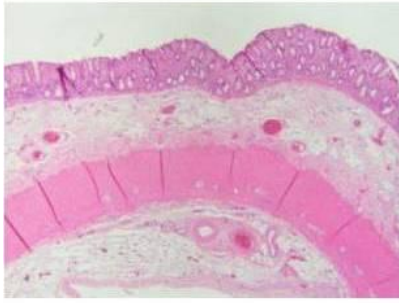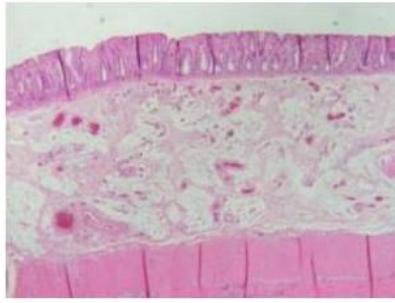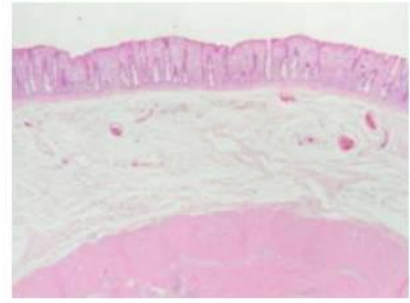
Figure 3. Balloon fluid leak test using methylene blue solution

(**A**) methylene blue. (**B**) pressure gauge.
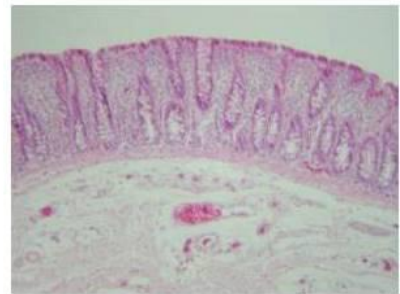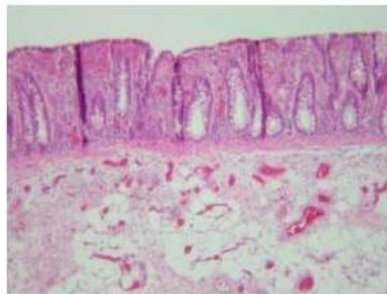
Oral side   Balloon site   Anal side

Figure 4. Microscopic submucosal thrombus was observed in a very limited area at the site of balloon placement

Edema was observed in the bowel wall on the oral side of the balloon placement site. No significant change was seen on the anal side of the balloon placement site. No mucosal changes were observed in the bowel wall (hematoxylin-eosin staining, ×40, ×100).