Feasibility of Rectal Stent Development for Fecal Diversion: A Porcine Experiment

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Research note

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Abstract

Objective

Since low rectal anastomosis leakage may cause severe morbidity, surgeons create diversion stoma to prevent complication. However, stoma requires additional surgery with morbidity. Therefore, rectal stent may help prevent these problems. This preliminary report details the development of new rectal stent in animal experiment. Thirteen female 12 week-old pigs weighing 30–35 kg each (four in the control group, nine in the experimental group) were included. Under general anesthesia, pigs underwent laparoscopic low anterior resection. In experimental group, a Niti-S fully covered stent (Taewoong Medical Inc.) was inserted by guidewire, under direct laparoscopic vision, and affixed near the anus. All pigs were sacrificed for autopsy. Including the anastomosis line, 10 cm length of bowel was obtained and a water-air leak and barium leakage X-ray tests were performed to confirm anastomosis integrity.

Results

Among the four control pigs, anastomosis leakage was confirmed in only one. For the experimental pigs, 36-mm-diameter stent was used. The last three pigs were subjected to additional intra-abdominal stent fixation by laparoscopic guidance, but all stents were removed. Despite natural stent removal, there were only two cases of intraoperative leakage. To overcome rectal pressure and fecal bulk, rectal stent development requires further investigation.

Introduction

The Low Anterior Resection is regarded as the globally recognized standard treatment for rectal cancer surgery. For surgeons, one of the most worrisome complications is the anastomosis leakage. The short length of rectal stump causes the risk of anastomosis leakage to be high. (1) For rectal anastomosis, the Double Stapled Anastomosis method is used worldwide. (2) There are several methods available to confirm the anastomosis integrity that include the air leakage test and direct visualization during the colonoscopy. (3, 4) However, these methods are found to not guarantee high anastomosis quality. In order to accommodate this deficiency, surgeons often create a diversion stoma to prevent severe complications. This procedure has been particularly important in cases such as a person with history of preoperative chemoradiotherapy, male with narrow pelvis, and a person with high body mass index. (5)

However, the diverting stoma may not assist the anastomosis leakage healing process and help prevent other severe complications such as sepsis. (6) Stoma repair is also likely to be required in the near future and may carry other risks of surgery-related morbidities. (7)

Therefore, the Rectal Stent may be an alternative option for preventing low rectal anastomosis disruption. The primary purpose of a Rectal Stent is to protect against fecal contamination and decrease intraluminal pressure, and it is expected to substitute for a stoma. The Rectal Stent will function to strengthen the expanding bowel wall and maintain intraluminal space.

A new Rectal Stent was developed in consideration of these factors, particularly the severe complications related to anastomosis leakage. This report details the animal experiment which examines the efficacy and safety of the newly developed Rectal Stent.

Main Text

Methods

New Stent Development

For the use of Rectal Stents, there are some vital issues to consider. Rectal Stent's luminal patency may be well maintained but it can induce pain and migration. (8) Therefore, it is important to prevent migration after its placement. The Rectal Stents should also be removed easily and safely after its use. To solve these issue, several different Rectal Stent Prototypes have been developed after our extensive discussion.

Figure 1 shows the evolution of our invented Rectal Stents. The very first Rectal Stents were developed with partially covered silicon with straight features. Later, in order to increase the smoothness and to facilitate its removal, the Rectal Stents were made using polytetrafluoroethylene (PTFE) instead of silicon. Its proportion of stent coverage was also increased. PTFE and silicone are well known to provide good stent coverage and support the stent functions mentioned above.(9, 10) Finally, the Rectal Stents were fully covered with PTFE and the proximal portion of the Rectal Stents was changed to a funnel shape. The funnel shaped proximal portion would allow more

feces to drain through and was expected to better protect the anastomosis than the straight shape since the space between the Rectal Stent and the bowel wall could be further blocked. The diameter of the bottom part of the Rectal Stent was also slightly reduced in its length to avoid any irritation near the anus.

Preoperative Procedure

This study was approved by the Animal Institutional Review Board of Yonsei University (2015-0051). A total of 13 female pigs that are 12-week-old were used as the subjects. The subjects were divided to include four (4) in the control group, and nine (9) in the experimental group. Each pig had weighed approximately 30–35 kilograms (kg). The facility is following “Guide for the care and use of laboratory animals” from National Research Council. After arriving at the animal facility, the pigs were allowed to acclimate for three to four days and the colon was prepared using 4 Liters of Colyte with electrolyte-rich fluid one day before the surgery.

Operative Procedure

Under general anesthesia, each subject was placed in the supine position and a sterile drape with placing foley catheter. A mid-abdominal incision was made for the camera port and CO₂ insufflation was performed. 5- and 12-mm working ports were placed in the middle and lower abdominal quadrants. After colon identification, the usual low anterior resection was performed. All but the first subject was exposed to surgery without disruption of the mesentery vessels since they had a single-vessel non-collateralized posterior rectal artery blood supply to the rectum.(11) After reaching to deep pelvis, a 45-mm Endostapler (Covidien Inc.) was used for bowel resection. A mini- laparotomy was performed to insert an anvil (EEA, 25 mm; Covidien Inc.) into the end tip of the resected proximal colon. The double stapling method was used and a water-air leakage test was performed. An anastomosis was made 10 cm above the anal verge. In the experimental pig, a Niti-S rectal fully covered stent (Taewoong Medical Inc.) was inserted using a guidewire and unfolded above the anastomosis under direct laparoscopic vision. The stent was affixed near the anus with several Vicryl 3 – 0 stitches. For the last three subjects, a full-thickness intracorporeal suture was placed above the anastomosis where the unfolded stent was exposed.

Postoperative Procedure

The subjects received an intramuscular injection of antibiotics (amoxicillin clavulanate 14 mg/kg) on first postoperative day, while oral pain killers (meloxicam 0.2 mg/kg) were mixed with the diet until the seventh day of postoperative procedure. Colyte was mixed with pig chow until the completion of the experiment. Upon completion of the experiment, 10-cm length of bowel including the anastomosis line was removed from the subjects and the water-air leak and barium leakage x-ray tests were performed to confirm anastomosis integrity (Fig. 2).

Results

Stent Removal and Porcine Sacrifice

Table 1 shows the results from the four control subjects. Initially, three subjects were assigned to the control group; however, one subject marked ‘porcine no.10’ had excessive feces in the rectum that prevented the stent insertion. Thus, porcine no.10 was reassigned to the control group. All subjects were planned to be sacrificed after Postoperative Day 7.

Table 1
Postoperative Results

Porcine (No.)	Group	Resection (cm)	Sacrifice after LAR (day)	Stent removal after LAR (day)	Anastomosis leak during LAR	Anastomosis leak after sacrifice	Rectal stent diameter (mm)	Perianal stent fixation	Intracorporeal stent fixation
1	Control	10	7	-	Yes	Yes	-	-	-
2	Control	10	7	-	No	No	-	-	-
3	Control	10	7	-	No	No	-	-	-
4	Experimental	10	7	5	No	No	36	Yes	No
5	Experimental	9	7	6	No	No	36	Yes	No
6	Experimental	8	7	5	Yes	Yes	36	Yes	No
7	Experimental	10	7	5	No	No	36	Yes	No
8	Experimental	10	7	8	Yes	Yes	36	Yes	No
9	Experimental	8	7	5	No	No	36	Yes	No
10	Control	9	7	-	No	No	-	-	-
11	Experimental	8	7	5	No	No	36	Yes	Yes (1 stitch)
12	Experimental	10	7	5	No	No	36	Yes	Yes (1 stitch)
13	Experimental	10	7	6	No	No	36	Yes	Yes (3 stitch)
*LAR : Low anterior resection									

2L of Colyte was mixed to diet to feed the subjects on purpose of softening the feces. Despite the use of Colyte, the fecal volume was still large and firmer than expected. This was because the meal consumptions for the subjects were unable to be controlled throughout the experiment. Thus, natural stent removal occurred at no more than sixth days into the experiment. Finally, the proximal site of the stent was affixed to the bowel during the surgery. The stents in porcine no.11 and 12 were affixed with a single intracorporeal laparoscopic stitch, while the stent in porcine no.13 was affixed with three (3) intracorporeal laparoscopic stitches (Fig. 2). Even with a single intracorporeal laparoscopic stitch, the stent was removed naturally by Postoperative Day 5 in porcine no. 11 and 12. Porcine no.13 also showed natural stent removal on Postoperative Day 6.

Anastomosis Leakage

Amongst the four subjects in the control group, due to lack of experience, one subject showed anastomosis leakage with a perirectal abscess. No leakage was seen in the other three subjects on the water-air leak or barium x-ray tests (Table 1).

Amongst the nine subjects in the experimental group, two subjects (porcine no. 6 and 8) showed anastomosis leakage on the intraoperative water-air leakage test. However, after rectal stent insertion, the anastomosis leakage site was fully covered by the stent and no leakage was seen on the subsequent water-air leakage test. The stent was removed naturally on Postoperative Day 5 in porcine no.6. Porcine no. 8 expired by sepsis on Postoperative Day 6. Sepsis seems to have originated by leakage site, as severe ischemic colitis was verified in the rectum. The leakage site was confirmed after specimens were obtained from both porcine no. 6 and 8. However, no other subjects in the experimental group showed leakage on the water-air leak or barium leakage x-ray tests.

Discussion

There have been several trials to protect against rectal anastomosis leakage by scientists and colorectal surgeon. Ravo and Ger proposed using an intracolonic bypass tube to protect against rectal anastomosis leakage.(12) Ros tried several drainable tubes in colon anastomosis in rats and found that an intraluminal drainable tube improved survival compared to the control group.(13) A sterilized condom has also been used to protect the rectal anastomosis.(14) All of these trials aimed to prevent fecal contamination and decrease fecal loading, which may affect disruption of the intestinal anastomosis. Also, by using various different types of intracolonic bypass

materials, they attempted to decrease the intraluminal pressure.(9, 10) A transanal tube showed decreased rectal pressure up to Postoperative Day 5.(15) A recent multi-center randomized trial from the Netherlands used a biodegradable drain called a C-seal affixed to the anastomosis line by a circular stapler.(16) However, the results were unsatisfactory, as 10% of cases demonstrated anastomosis leakage, 7.7% required re-intervention, and 5% of controls demonstrated anastomosis leakage. Problems related to the C-seal included detachment from the anvil, difficult stapler removal, and anal pain.

Learning from these previous studies, it was essential for us to devise a simplified method in order to protect the anastomosis without the use of a diverting stoma. We then went back to the beginning to create a concise intraluminal drainage tube.

Among several problems, we found that preventing rectal stent migration was most important. In practice, even in cases of stent placement to avoid obstructions in rectal cancer, stent migration is one of the most common complications.(17) The stent was maintained for no more than six days despite of its maximal width 36 mm and performing a laparoscopic intracorporeal stitch on a proximal stent and bowel. Also, to reduce anal pressure, a diet containing Colyte was used to induce the defecation of loose stool. These efforts were not as effective as we had anticipated as not all subjects could consume required dose of Colyte as humans could.

However, the subjects chosen were still considered to be the best animal to use in this experience since they cannot remove the stent themselves when compared to other mammals. All of the experimental subjects were sacrificed within Postoperative Day 7.

When considering the inconvenience of placing Rectal Stents in patients, and as rectal anastomosis collagen density is highest at one week postoperative,(18) seven day period appears to be the minimum requirement. However, all Rectal Stents were removed naturally within seven days for our experiment. Despite the encountering of the natural stent removal, there were no cases of gross anastomosis leakage seen on the water-air leak or barium leakage x-ray tests. For porcine no.11–13, we did not expect to find any gross leakage since subject's stents were fixed with intracorporeal stitches. These results suggest stent safety in the bowel mucosa and anastomosis site despite insertion and detachment. Only two subjects demonstrated gross anastomosis leakage during and after surgery; however, neither demonstrated leakage on either leakage test.

Although our experiment encountered difficulties due to the natural stent removal, the proper stent placement in humans may be achieved. To our knowledge, so far, no trials have added perianal fixation of Rectal Stents to the experiment. The Rectal Stent developed by our team has a smooth vinyl component at the end with a sufficiently long length for affixing to the buttock area. The design to include narrow stent end diameter will also minimize perianal area irritation. Also, the vinyl is strong enough to not tear off easily. Although all stents in this study were removed naturally, it was not due to the strength of the vinyl, but due to fecal pressure.

Limitation

Even with early natural stent removal, it was a challenging experiment to observe the stent's effect on the anastomosis. The best way to maintain the stent would be to make the subjects fast consistently. Unfortunately, the chosen subjects cannot survive whilst maintaining fasting regiment. However, the humans are able to tolerate fasting regiments by implementing a parenteral nutrition. In this study, it was not possible to control the bowel movement of gilts, but this may be different in patients. Although this study produced insufficient results due to the early natural removal of Rectal Stents, it may have brought significant outcome if diet and fasting regiments of subjects were able to be controlled.

Abbreviations

PTFE
polytetrafluoroethylene, EEA: end to end anastomosis

Declarations

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Authors' contributions

YDH, NKK designed and analyzed the study and coordinated the manuscript. YDH, YYP and JY performed data collection. All authors read and approved the final manuscript.

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Availability of data and materials

The descriptive data and analyzing process of this study are all included in this publication.

Ethics approval and consent to participate

This study was approved by the Animal Institutional Review Board of Yonsei University (No. 2015-0051). All animal facilities are controlled under the guideline of "Guide for the Care and Use of Laboratory Animals". All are approved by Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

Consent to publication

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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Figures

Figure 1

History of Stent evolution 1. Silicone covered stent: Partially silicone covered straight formed initial stent. 2. Partially PTFE covered stent: To remove stent easily, coverage portion has increased and its material has changed to PTFE. 3. Fully PTFE covered stent: Final stent version was PTFEfull covered with funnel type, to make easy removal and to protect anastomosis effectively.

Figure 2

Anastomosis Finding and Stent Fixation (A, Lt.upper): Intraluminal finding of anastomosis (B, Mid upper): Water-air leak test (C,Rt.upper): Barium X-ray test (D, Lt.lower): Stent fixation with intracorporeal suture (E, Rt. lower): Distal fixation of stent near anus with vicryl 3-0

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