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Protective effect of intraluminal fecal diverting device against colonic wall erosion induced by wrapping bands: A post-hoc pathological analysis

Sung Il Kang[1], Sohyun Kim[1], Mi Jin Gu[2], Jae Hwang Kim[1]

[1] Department of Surgery, Yeungnam University Faculty of Medicine, Yeungnam University Medical Center, Daegu, South Korea
[2] Department of Pathology, Yeungnam University Faculty of Medicine, Yeungnam University Medical Center, Daegu, South Korea

ABSTRACT

Objective: Materials wrapping the bowel elicits tissue erosion gradually. We experienced several bowel wall erosions with no serious clinical consequences in our two previous animal experiments aimed at the safety and efficacy of the COLO-BT developed for intra-luminal fecal diversion. We tried to find out why the erosion is safe by investigating histologic changes of the tissue.

Material and Methods: Tissue slides at the COLO-BT fixing area from the subjects which had COLO-BT over three weeks acquired from our two previous animal experiments were reviewed. For the classification of the histologic change, microscopic findings were classified for six stages (from minimal change of stage 1 to severe change of stage 6).

Results: A total of 26 slides of 45 subjects were reviewed in this study. Five subjects (19.2%) had stage 6 histological change; three of stage 1 (11.5%), four of stage 2 (15.4%), six of stage 3 (23.1%), three of stage 4 (11.5%), and five of stage 5 (19.2%). All subjects which had a stage 6 histologic change survived. The phenomenon from which the back of the band is passed through is replaced by a relatively stable tissue layer due to fibrosis of the necrotic cells in the stage 6 histologic change.

Conclusion: We found that thanks to the sealing effect of the newly replaced layer, no leakage of the intestinal content occurs even if perforation by erosion develops according to this histologic tissue evaluation.

Keywords: Colonic wall erosion, foreign body, mesh, COLO-BT

INTRODUCTION

Traditionally, several materials have been surgically implanted to treat the human body permanently or temporarily. For example, foreign materials are used in gastric banding procedures in the management of morbid obesity. Despite the established safety of gastric banding procedures, newly placed foreign materials may cause complications. During the gastric banding procedure, the pressure induced by the wrapping of the stomach with the banding material may damage the stomach wall. These damages include gastric wall erosion, ulcers, necrosis, and perforation although the incidence has been reported to be <5% (1,2). Patients experiencing these complications require emergent surgery to avoid poor outcomes.

Recently, the development of intraluminal fecal diverting devices has garnered the attention of researchers due to its ability to avoid stoma after proctectomy. These devices, e.g., CG-100™ and Colovac™ (Colospan), require intraluminal and/or extraluminal fixation using foreign materials to maintain the device location in the colon for several days or weeks to protect the anastomotic site (3-5). Preliminary animal and human studies regarding these devices have reported positive results (3-9); however, concerns regarding the clinical and histological changes of the colonic wall which is the device fixing site by foreign materials remain, similar to gastric banding.

Our group developed a new type of intraluminal fecal diverting device named, COLO-BT (previously reported name as fecal diverting device, FDD, tentatively). The efficacy and safety of this device as a substitution for dysfunctional stoma have been reported in our previous studies (6-9). In these studies, several cases of colon-

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Corresponding Author
Sung Il Kang
E-mail: sungiry@naver.com

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ic wall erosion have been observed in both the animal and clinical studies; however, none developed severe complications requiring further intervention. Considering these results, we realized the need to investigate the histological changes in colonic wall erosive lesions caused by foreign materials.

Therefore, this study aimed to investigate the histologic changes in erosive lesions of the colonic wall by reviewing the slides of our two previous animal experiments.

MATERIAL and METHODS

In order to evaluate the efficacy and safety of COLO-BT, we previously conducted two animal experiments in mongrel dogs (6,7). All dogs were euthanized at the end of the study period, and macroscopic findings were recorded. In cases of premature deaths, the specimen was obtained the day the dogs died. After macroscopic investigations, tissues were fixed in 10% formalin, embedded in paraffin, and stained with hematoxylin and eosin (H&E) in several sections. Specifics of the COLO-BT procedure and experimental design have been described in our previous animal studies (6,7).

Since the maintenance period of COLO-BT was more than three weeks, slides from subjects unable to maintain the device or that died before three weeks were excluded. In one animal study, all 30 subjects were applied with the COLO-BT device and 16 remained alive for over three weeks (7). In the other animal study, which was designed as a randomized controlled study, 15 were applied with the COLO-BT among 30 subjects and 10 remained maintaining the COLO-BT and alive for over three weeks (6). Therefore, histological slides from 26 dogs that maintained their COLO-BT over three weeks were included in this study (Table 1).

Tissue slides fixated between the mesh band and colonic wall from these two animal studies were reviewed. All tissue slides were retrospectively reviewed by an experienced pathologist (MJ Gu) and discussed with three surgeons.

The histological changes were classified as follows:

Table 1. COLO-BT maintenance period in two previous animal experiments

	Studies	
	Kim et al. (7) (n= 30)	Kang et al. (6) (n= 15)
<1 week*	5*	3**
1-3 weeks	9	2
>3 weeks	16	10

*Four of the five dogs died within 1 week.
**all died within 1 week.

Stage 1. Mesh material enclosed by a thick fibrotic capsule was found in the serosa or subserosa. Inflammation was sparse (Figure 1).

Stage 2. A well-demarcated fibrotic nodule containing mesh was impinging upon the outer longitudinal muscle. Acute and chronic inflammatory cell infiltration was observed in the fibrotic capsule (Figure 2).

Stage 3. The mesh penetrated the inner circular muscle and the muscularis propria. Fibrosis formation was observed more posteriorly compared to internally (Figure 3).

Stage 4. The mesh was located in the inner muscle and submucosa. The external area was surrounded by mature fibrosis with neovascularization. Inflammation was sparse (Figure 4).

Stage 5. Mesh was found from the mucosa to the subserosa and surrounded by fibrotic tissue without tears or perforations (Figure 5).

Stage 6. Formation of a deep ulcer and exposure of the mesh in the lumen while being surrounded by the fibrotic capsule (Figure 6).

No animal sacrifices were required for this study, and approval from the Institutional Animal Care and Use Committee (IACUC) was waived.

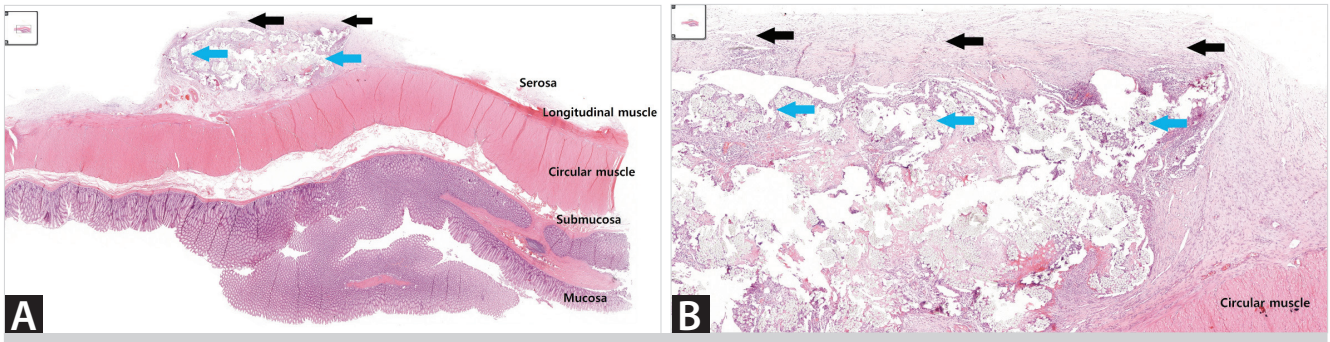

Figure 1. Stage 1. Mesh material was found in the serosa or subserosa enclosed by a thick fibrotic capsule. Inflammation is sparse. H&E stain, **(A)** x 40 **(B)** x 100. Black arrow, fibroblast; blue arrow, mesh materials.

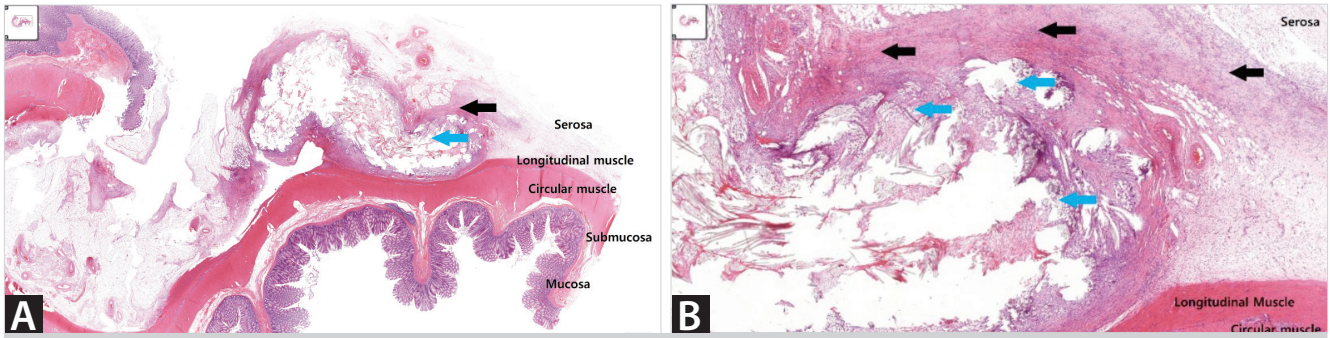

Figure 2. Stage 2. Well demarcated fibrotic nodule containing mesh was impinging upon the outer longitudinal muscle. Acute and chronic inflammatory cells infiltration was seen in the fibrotic capsule. H&E stain, **(A)** x 40 **(B)** x 100. Black arrow, fibroblast; blue arrow, mesh materials.

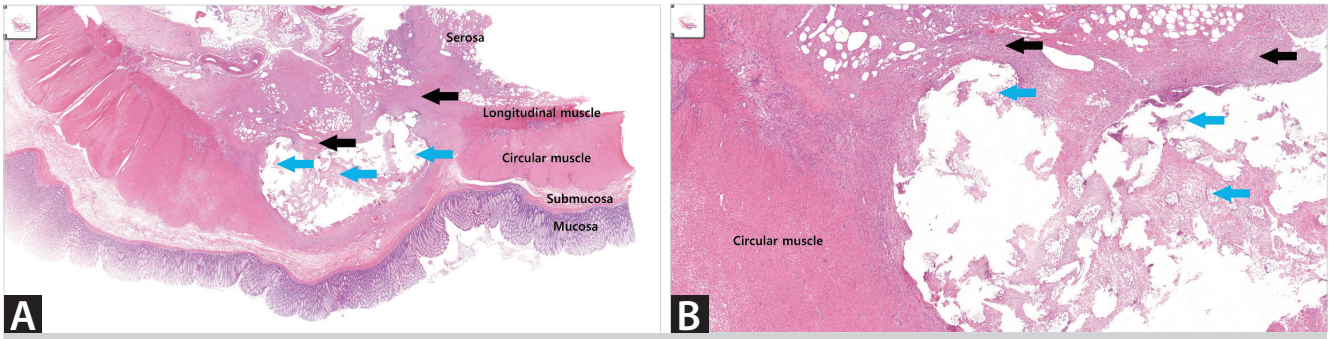

Figure 3. Stage 3. The mesh was penetrating the inner circular muscle and muscularis propria. Fibrotic formation of collagen fibers was observed more in the posterior side compared to the internal area. H&E stain, **(A)** x 40 **(B)** x 100. Black arrow, fibroblast; blue arrow, mesh materials.

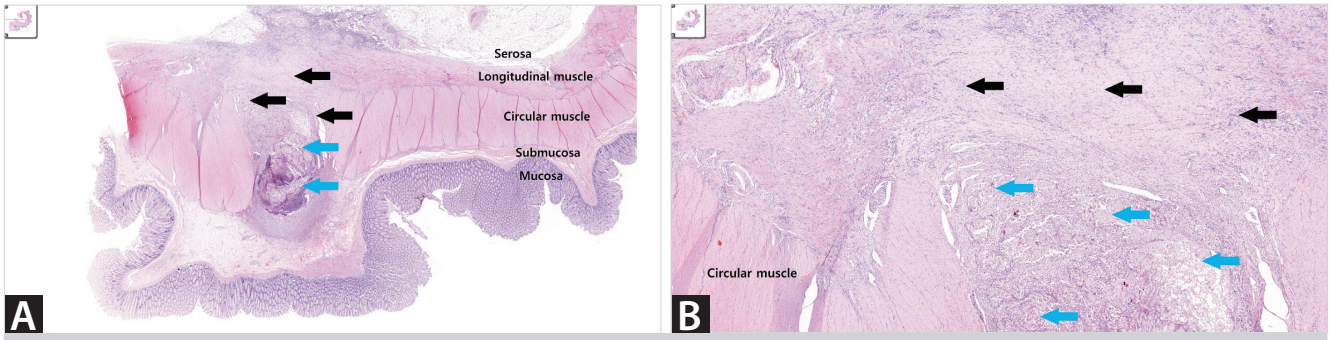

Figure 4. Stage 4. Mesh located in the inner muscle and submucosa. The external area was completely surrounded by mature fibrosis with neovascularization. Inflammation is sparse. H&E stain, **(A)** x 40 **(B)** x 100. Black arrow, fibroblast; blue arrow, mesh materials.

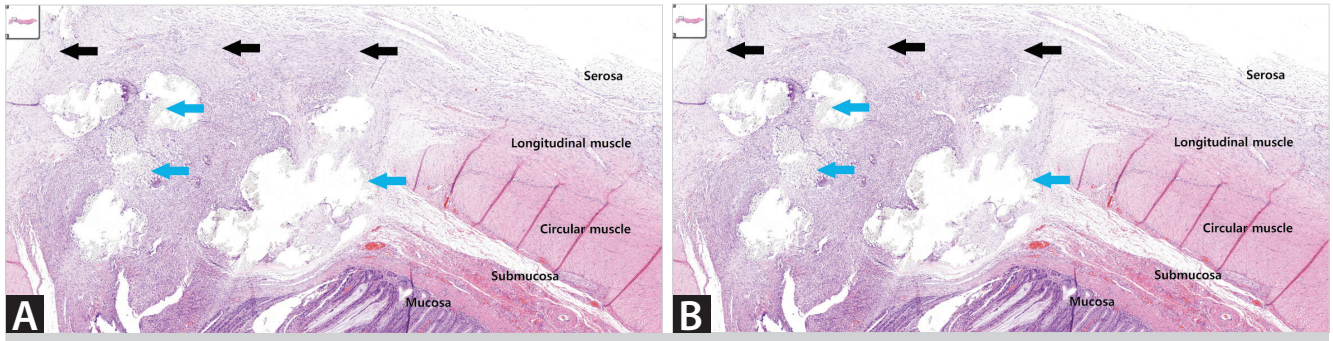

Figure 5. Stage 5. Mesh was found from the mucosa to subserosa and surrounded by fibrotic tissue without tear or perforation. H&E stain, **(A)** x 40 **(B)**x 100. Black arrow, fibroblast; blue arrow, mesh materials.

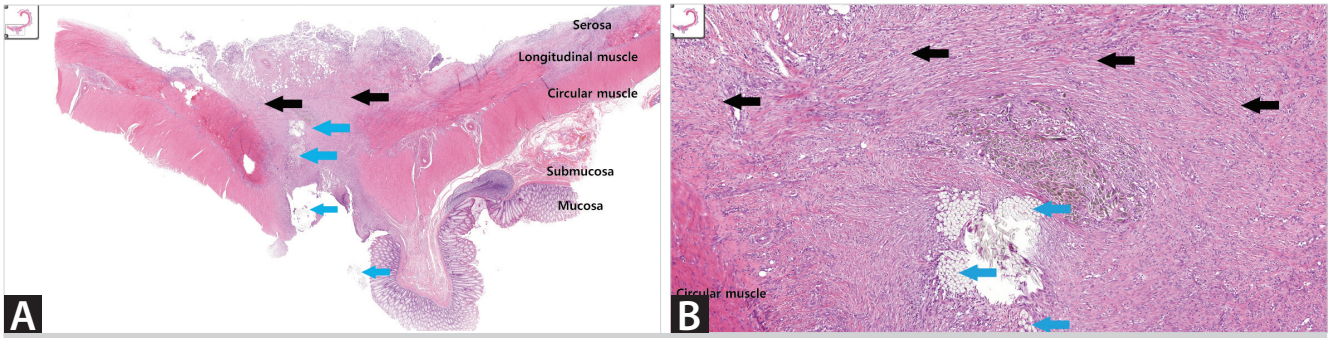

Figure 6. Stage 6. Deep ulcer was formed and mesh was exposed in the lumen, but mesh was still well surrounded. H&E stain, **(A)** x 40 **(B)** x 100. Black arrow, fibroblast; blue arrow, mesh materials.

Table 2. Stages of histologic change

	n= 26 (n, %)	Survival, %
Stage 1	3 (11.5)	100
Stage 2	4 (15.4)	100
Stage 3	6 (23.1)	100
Stage 4	3 (11.5)	100
Stage 5	5 (19.2)	100
Stage 6	5 (19.2)	100

RESULTS

Each of the two previous studies included 16 and 10 dogs. Among the 16 dogs, stage 6 histological changes were observed in three dogs at the band fixed site. Others were classified into stage 1 (n= 2), stage 2 (n= 2), stage 3 (n= 4), stage 4 (n= 2), and stage 5 (n= 3). Among the 10 dogs, stage 6 histological changes were observed in two dogs at the band fixed site. Others were classified into stage 1 (n= 1), stage 2 (n= 2), stage 3 (n= 2), stage 4 (n= 1), and stage 5 (n= 2).

Overall, five dogs (19.2%) from a total of 26 that maintained COLO-BT over three weeks, demonstrated stage 6 histological changes. However, not all subjects experienced local or systemic sepsis due to severe histological changes (Table 2). Additionally, fibrotic changes in stage six dogs were observed; particularly, the replacement of the posterior of the band by a relatively stable tissue layer.

DISCUSSION

Several intraluminal fecal diverting devices have been developed as substitutes for temporary stoma. Maintenance of the colonic wall without developing severe complications is an important issue for these devices. To affix the device in the colonic lumen, a suturing method has been applied to the mucosal and submucosal layers. However, this method has been found to have a high failure rate in maintaining the device causing impaired healing of the anastomotic site due to tissue necrosis (10,11). Therefore, extra- and/or intraluminal pressure is inevitable to affix an intraluminal fecal diverting device in the colonic lumen. However, persistent and excessive wall pressure causes complications such as wall ischemia, necrosis, or perforation. Therefore, an appropriate amount of pressure is necessary to maintain the device in the colonic lumen while avoiding complications.

COLO-BT is composed of two fixation systems: an extra-balloon system for intraluminal fixation and an extra-luminal mesh band.

In this review of two animal studies, we found that 19.2% of the experimental subjects demonstrated stage 6, severe histological changes, deep ulcerations and luminal mesh exposure at COLO-BT fixing area. Despite this severity, it is emphasized that none of the dogs developed systemic sepsis or death.

Implanting foreign substances for temporary or permanent management of certain diseases is necessary. However, foreign body implants may cause pressure injury by impinging upon adjacent organs. A representative procedure that causes pressure by a foreign body is gastric banding for morbid obesity. However, advancements in gastric banding procedures have caused a decrease in the incidence of pressure injuries (12). Research regarding colonic erosions due to wrap bands is limited; therefore, we reviewed other situations related to gastrointestinal wall erosion, particularly regarding gastric banding for morbid obesity.

The mechanism for the histological changes of gastric wall erosion due to mesh has been recognized. In summary, early erosive changes occur soon after the procedure; thereafter, the physiologic movement of the stomach causes stronger shearing forces between the mesh and the gastric wall. Constant repetition of this process can cause gastric wall perforation (13,14). Another mechanism is related to the immune response. The immune response produces chronic inflammation causing tissue fibrosis, contraction, and subsequent erosion (15,16). Gastrointestinal wall erosion can cause serious clinical symptoms and problems. Therefore, most gastric wall erosions have been treated endoscopically and/or surgically through the removal or replacement of the wrap band (17,18).

Our hypothesis regarding the histological changes induced by the fixation of the COLO-BT to the colonic wall is similar to the mechanisms for gastric wall erosion due to wrap-banding; particularly, injured tissue repair is caused by scar formation. Injury to a tissue, such as muscle (which has limited regenerative capacity), induces inflammation, which clears any dead cells and microbes. The formation of vascularized granulation tissue and deposition of extracellular matrix for scar formation follows inflammation (19).

COLO-BT causes alternating intermittent minimal and increased peristalsis. This variation in peristaltic movement pushes the colonic wall to the mesh material generating pressure that causes tissue damage to the colonic wall. In most cases, the pressure on the colonic wall is immediately resolved preventing lasting damages to the colonic wall. However, constant pressure causes tissue injury. In patients who underwent COLO-BT procedure, these changes occurred over a long period of time; therefore, immediate colonic wall perforation caused by rapid tissue necrosis was not observed. Tissue damage, which progresses slowly due to intermittent pressure, is repaired by fibrotic scar tissue in the posterior direction of the mesh. This blocks the movement of intestinal contents to the outside of the intestine. Therefore, no severe complications were observed even when intestinal wall erosion occurred.

Even in stage 6 dogs, we found no serious complications related to the histological changes of the COLO-BT fixing site. Similar results were found in our previous clinical studies; however, histological examinations are yet to be performed (8,9). In these two clinical studies, 10% of the patients experienced colonic wall erosions similar to the stage 5-6 histological changes in this study; however, no severe co-morbidities related to COLO-BT fixing site was found in all studies. All patients who exhibited colonic wall erosion at the COLO-BT fixing site were managed conservatively or thru observation only; despite this, none experienced clinical problems during the two-year follow-up (20). Our hypothesis of the mechanism related to this result is as follows:

1. Increases in the intermittent pressure of the band causes tissue cell necrosis.

2. Pressure causes inflammation, cell necrosis, fibrosis, and other phenomena in necrotic tissues.

3. The posterior side of the band is replaced by a relatively stable tissue layer due to fibrosis of the necrotic cells.

4. This newly replaced layer seals the intestinal contents preventing leakage even if perforation by erosion occurs.

The maintenance of the appropriate pressure between the colonic wall and wrap band is the most essential to prevent severe histological changes of the colonic wall. Inadequate pressure causes easy detachment of the COLO-BT; on the other hand, excess pressure leads to colonic wall necrosis. In our previous studies, we applied an automatic tension measuring instrument (ATMI, JSR Medical Inc., Daegu, Korea) to measure the band length for wrapping the colonic wall with appropriate pressure (7,8)

In addition, absorbable mesh use helps in preventing the severe histologic change of the colonic wall. In our animal studies, a non-absorbable mesh band was used because an appropriate absorbable mesh was yet to be developed. In our clinical studies, we used an absorbable mesh band (NEOSORB MESH®, Samyang Biopham. Co. Daejeon, Korea), with a half-life of six weeks (8). Therefore, the pressure due to the mesh band was relieved after six weeks.

This study has several limitations. First, the results originated from previous studies. Histological examinations at the COLO-BT fixed site were not designed in the previous animal studies since COLO-BT was a newly developed device; no information or similar studies were available to refer to. Therefore, most of the studies used research regarding gastric banding procedures as reference. Moreover, we decided not to conduct a prospective study since it requires further euthanizing of animals and slides from our previous animal studies were available. Second, histological changes over time were not evaluated due to the retrospective nature of the study. Instead, we described various changes occurring in the colon wall after maintaining the COLO-BT for more than three weeks. We believe that this is important because COLO-BT should be maintained for approximately three weeks for effective fecal bypass from an anastomotic site. Furthermore, the type of study is not feasible for humans. Therefore, the results of this study may not be consistent with clinical results. However, similar results may be anticipated due to the absence of symptoms and similarities in the morphological and histological changes observed in the past clinical and current studies, respectively.

In summary, from our two previous animal experiments, we found that 19.2% of the subjects who maintained COLO-BT for more than three weeks demonstrated severe histological changes at the COLO-BT fixing site. However, no clinical complications due to histological changes were observed. We hypothesize that the sealing effect of the newly replaced layer prevented the leakage of intestinal content even in dogs with perforation due to erosion, as demonstrated by histological evaluation.

Ethics Committee Approval: It is only a retrospective review of the histological slides obtained from two previous animal studies, which were already published in peer-reviewed journals. Thus, a new ethical approval was not obligatory.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – SK, JHK; Design – MJG, JHK; Supervision – MJG, JHK; Materials - SK, MJG, JHK; Data Collection and/ or Processing – SK, MJG, JHK; Analysis and/or Interpretation – SK, SK, MJG; Literature Search – SK, SK; Writing Manuscript – SK, SK, MJG; Critical Reviews – All of authors.

Conflict of Interest: The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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ORİJİNAL ÇALIŞMA-ÖZET
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Sarıcı bantların neden olduğu kolonik duvar erozyonuna karşı intralüminal fekal yönlendirici cihazının koruyucu etkisi: Post-hoc patolojik bir analiz

Sung Il Kang[1], Sohyun Kim[1], Mi Jin Gu[2], Jae Hwang Kim[1]

[1] Yeungnam Üniversitesi Sağlık Merkezi, Yeungnam Üniversitesi Tıp Fakültesi, Cerrahi Anabilim Dalı, Daegu, Güney Kore
[2] Yeungnam Üniversitesi Sağlık Merkezi, Yeungnam Üniversitesi Tıp Fakültesi, Patoloji Anabilim Dalı, Daegu, Güney Kore

ÖZET

Giriş ve Amaç: Bağırsakları saran malzemeler yavaş yavaş doku erozyonuna neden olur. Lümen içi fekal saptırma için geliştirilen COLO-BT'nin güvenliğini ve etkinliğini amaçlayan önceki iki hayvan deneyimizde ciddi klinik sonuçları olmayan birkaç bağırsak duvarı erozyonu yaşadık. Dokudaki histolojik değişiklikleri inceleyerek erozyonun neden güvenli olduğunu bulmaya çalıştık.

Gereç ve Yöntem: Önceki iki hayvan deneyimizden elde edilen COLO-BT'ye üç hafta boyunca sahip olan deneklerden COLO-BT sabitleme alanındaki doku slaytları gözden geçirildi. Histolojik değişikliğin sınıflandırılması için, mikroskopik bulgular altı evre için sınıflandırıldı (1. evredeki minimal değişiklikten 6. evredeki şiddetli değişikliğe kadar).

Bulgular: Bu çalışmada toplam 45 denek arasından toplam 26 slayt incelendi. Beş denekte (%19,2) altıncı evre histolojik değişiklik vardı; üçü 1. evre (%11,5), dördü 2. evre (%15,4), altısı 3. evre (%23,1), üçü 4. evre (%11,5) ve beşi de 5. evredeydi (%19,2). 6. evre histolojik değişikliği olan tüm denekler hayatta kaldı. Sarıcı bandın arka tarafa geçişiyle ortaya çıkan durum, 6. evre histolojik değişiklikteki nekrotik hücrelerin yerini alan fibrozisin oluşturduğu görece stabil bir doku katmanıyla desteklendi.

Sonuç: Bu histolojik doku değerlendirmesine göre, yeni değiştirilen tabakanın sızdırmazlık etkisinden dolayı, erozyon ile perforasyon meydana gelse bile, bağırsak içeriğinde sızıntı olmadığını bulduk.

Anahtar Kelimeler: Kolonik duvar erozyonu, yabancı cisim, yama, COLO-BT

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