DOI: 10.37990/medr.1347604 Med Records 2023;5(Suppl 1):169-73

MEDICAL RECORDS-International Medical Journal

Research Article

The Effect of Circular Stapler Design Used in Hemorrhoidopexy on Medical Outcomes in terms of Medical Engineering

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Abstract

Aim: The aim of this study is to examine the advantages and disadvantages of the design of the circular stapler device by sharing our hemorrhoidectomy results with circular stapler, and to examine whether changes in the design of the circular stapler device have an effect on these complications.

Material and Methods: This study which was planned as retrospective archive search and approved by the Etlik Zubeyde Hanim Gynecology Training and Research Hospital Medical Specialization Education Board (TUEK) with decision number 17 dated November 15, 2019. Moreover, cases with missing or unclear data weren't included to the study. Descriptive patterns were revealed by examining the records of the patients in terms of length of hospital stay, pain level according to Visual Analogue Scale (VAS: 1-10), bleeding and other complications. In terms of descriptive analyses, percentage and frequency values were evaluated with mean and standard deviations in continuous variables.

Results: Between January 2014 and July 2018, a total number of 21 hemorrhoid cases were treated with circular stapler hemorrhoidopexy. All of the patients were in the young male age group (21-26), with a mean age of 23.5±1.2. The mean hospital stay was 1.95±0.75 (1-4) days. In the intraoperative period, anal bleeding was observed only in one patient. When the pain occurring in the first 24 hours after surgery was examined according to the VAS, there were 11 patients (52%) painless, 7 patients (33%) had mild pain, 2 patients (10%) were moderate pain and 1 patient (5%) was describing severe pain.

Conclusion: The circular stapler is a surgical instrument that stands out with its specific engineering features, and when used in the correct position and in the correct manner, it is an advantageous surgical tool with low complication rates for the surgeon in advanced hemorrhoids and mucosal sagging.

Keywords: Hemorrhoidopexy, circular stapler, anorectal surgery, surgery technique, medical engineering, hemorrhoid

INTRODUCTION

For hemorrhoids; the theory of slipping of the anal cushions put forward by Thomson is the most widely accepted theory (1). Constipation, chronic diarrhea, chronic straining, occupations requiring prolonged standing and pregnancy were the factors accused in the etiology of hemorrhoidal disease. Hemorrhoidal disease causes many clinical conditions such as bleeding, pain and itching that adversely affect people's social life. There are authors who divide hemorrhoidal disease into two groups: internal hemorrhoidal disease originating above the dentate line and external hemorrhoidal disease originating below the dentate line (2). Antonio Longo first described the stapled hemorrhoidopexy method in prolapsed symptomatic hemorrhoidal disease in 1998. In this method, approximately 3-4 cm of the dentate line is defined as suspending prolapsed hemorrhoid packs in their normal anatomical places as a result of disconnection of the superior rectal artery feeding both hemorrhoids and loosening of Thomson's Park's ligament by performing a mucosal-submucosal resection over the hemorrhoids (3). On the other hand, it is thought that the technique applied to the area where there is no pain sensation without touching the anoderm compared to conventional methods will theoretically result in less

CITATION

Albuz O, Aydin F, Halaclar B. The Effect of Circular Stapler Design Used in Hemorrhoidopexy on Medical Outcomes in terms of Medical Engineering. Med Records. 2023;5(Suppl 1):169-73. DOI:1037990/medr.1347604

Received: 21.08.2023 **Accepted:** 15.09.2023 **Published:** 11.10.2023
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postoperative pain and therefore shorter hospitalization time (4,5). Considering that the pain can be very severe in some patients, especially after hemorrhoid surgeries, we can see that this method created a lot of excitement in the first days of its introduction (5). Because, in this method, the suture line stays on the dentate line, where sensation is less, and the postoperative pain will be equally less. As we mentioned above, in this technique, if the circular stapler (circular cutter and circular tissue stapler) device is incorrectly placed and this procedure is applied to the dentate line or lower region, a series of complications, especially pain, will occur. Although the footprints of the surgical stapler used today go back to the works of Humer Hültl in the early 1900s, today's instruments are spread over a much wider range thanks to the work of innovators such as Von Petz and Ravitch (6), and in this study, we will review the surgical experience of this surgical instrument. We shared our opinions and results on this subject by presenting the advantages and disadvantages of the state of the design of the device related to its use.

MATERIAL AND METHOD

This study, which was planned as retrospective research, was approved by the Etlik Zubeyde Hanim Gynecology Training and Research Hospital Medical Specialization Education Board (TUEK) with the approval date November 15, 2019 and decision number 17.

In this study, in which data between January 2014 and January 2018 were analyzed as a retrospective archive scan, descriptive patterns were revealed by examining the records of the patients in terms of length of hospital stay, pain level according to Visual Analogue Scale (VAS: 1-10), bleeding and other complications.

Surgical Approach

The cases were performed under general anesthesia in the lithotomy position. A slight dilatation was achieved by placing the anoscope of the circular stapler kit, together with its dilator, into the anal canal (Figure 1).

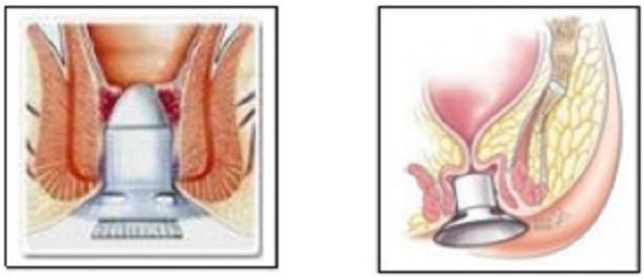

Figure 1. From Barlas (2008) (13)

After the dilator was removed, the 4 holes on the outside of the anascope were fixed to the perianal region with silk sutures. With the help of the kit's transparent anascope, a clear view of the endoscopic anatomy of the anal canal and rectum was provided. A circular purse-string suture was passed on the condition that it passes through the mucosa and submucosa with a 2-0 5/8 27 mm maxon approximately 4 cm above the dentate line (Figure 2).

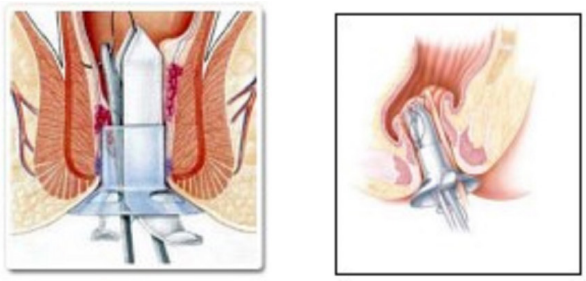

Figure 2. From Barlas (2008) (13)

The stapler was fully opened and a knot was tied by inserting the anvil into the purse-string suture. Both free ends of the suture were removed from the canals of the stapler with the help of a hook, and these ends were knotted and pulled outward slightly to provide traction on the stapler (Figure 3).

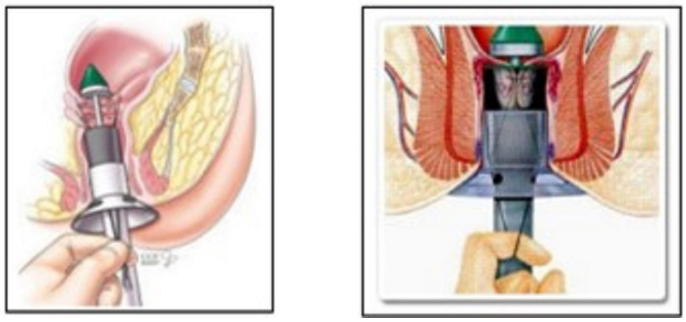

Figure 3. From Barlas (2008) (13)

At this time, the circular stapler was slowly pushed into the anal canal. When the dial on the device reached the level of 4 cm, the pushing process was terminated. The correct position of the stapler in the anal canal was reviewed one last time, the device was turned to the end point and fired. In order to provide hemostasis in the anastomosis line, it was waited for 20 seconds during the firing. Then, the device was slowly removed from the anal canal after one turn, and the operation was completed (Figure 4).

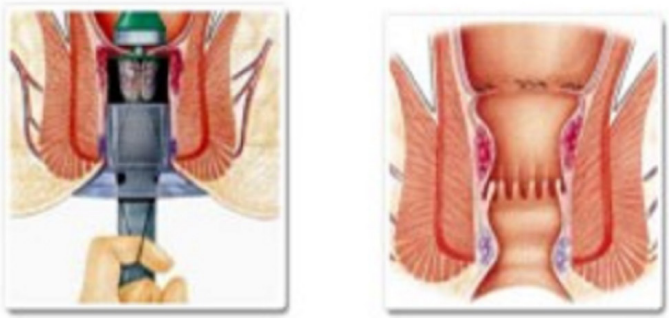

Figure 4. From Barlas (2008) (13)

RESULTS

A total of 21 hemorrhoid cases were treated with circular stapler hemorrhoidopexy between January 2014 and July 2018. All of the patients were in the young male age group (21-26). The mean age was 23.5±1.2 (21-26). Spinal anesthesia was applied to all of the patients. In the intraoperative period, anal bleeding was observed in

one patient. When the pain occurring in the first 24 hours after surgery was examined according to the visual analog scale, there were 11 (52%) painless patients, while 7 (33%) patients had mild pain, 2 (10%) patients were on moderate pain and only 1 (5%) patient described severe pain (Table1). We encountered hemorrhage in only one case (5%)(Table2). The mean operation time was 42.65±8.2 (30-55) minutes, and the mean hospital stay was 1.95±0.75 (1-4) days (Table 3).

Table 1. Pain occurring in the first 24 hours after surgery

	The VAS score distribution				
	Painless	Mild pain	Moderate pain	Severe pain	Very severe pain
n	11	7	2	1	0
Percentage (%)	52	33	10	5	0

VAS: Visual Analogue Scale

Table 2. Monitored complications

	n	Percentage (%)
Intraoperative bleeding	1	5
Severe pain	1	5

Table 3. The hospital length of stay

n	12	6	2	1	HLOS
Day	2	1	3	4	1.95±0.75 (1-4)

HLOS: hospital length of stay

DISCUSSION

The border between the normal skin containing hair follicles, sweat and sebaceous glands at the entrance of the anus and the anal canal skin deprived of these appendages is called the anal verge (verge) and is considered as the border in distance determinations (7,8). On the other hand, when we look at the term anal canal, its inner covering has changed mainly in two directions: It is the mucosa above and the skin below. The border between the two covers is called linea pectinea or linea dentata (pectinate line and dentate line, respectively). The surgical anal canal is defined to be the 3-4 cm section between the anal verge and the anorectal ring. The dentate line is located in the middle of the surgical anal canal (7,8).

The stages of the classification of disease stages in hemorrhoids suggested by Goligher et al. (1984), which is still in use, are the following:

Stage 1: Hemorrhoidal pads are located above the dentate line, they do not go down with straining.

Stage 2: Hemorrhoidal pads hang below the dentate line by straining, and return spontaneously after defecation.

Stage 3: Hemorrhoidal pads come out of the anal canal during straining, do not return spontaneously, but can be pushed in manually.

Stage 4: The hemorrhoidal pads are constantly hanging out of the anal canal and do not be pushed in manually (2).

Surgery is recommended for 3rd and 4th stage hemorrhoidal pouches. Standard surgical techniques consisting of ligation and removal of hemorrhoidal packs are still the most frequently used methods in the world and have been offered as the gold standard in the treatment of stage 3 and 4 hemorrhoids for a long time (9).

External hemorrhoids are located distal to the dentate line and covered with anoderm. In other words, they develop under the skin around the anus and because the innervation of the anoderm is rich, thrombosis of external hemorrhoids causes severe pain. On the other hand, internal hemorrhoids are located proximal to the dentate line and are covered by anorectal mucosa with numb morgagni columns. So they are inside the rectum. Internal hemorrhoids may prolapse, bleed, and do not cause pain. Severe pain develops in stage 4 internal hemorrhoids because of malnutrition. Finally, combined internal and external hemorrhoids are described as both internal and external hemorrhoids overlapping above and below the dentate line (10).

Circular stapler line placed under the dentate line may cause an operation that cannot reach its target, especially in the case of severe pain, because the mucosa is removed from an inappropriate place and an end-to-end anastomosis is performed. It may also lead to other serious complications such as abscess, gas, stool incontinence, and anal stenosis (11-13). Additionally, pain after hemorrhoidectomy has been one of the most important factors preventing patients from undergoing surgery. On the other hand, since there is no surgical incision or wound on the anus skin with the Longo method, there will be no need for post-operative dressing and sitting baths. Contrary to the expectation of most patients, when there is a need for defecation after surgery, there will not be excessive pain. Most of the patients are able to return to work within 3-5 days (13). There are two basic steps in the Longo method; The first step is to pass the perimeter seam. The second stage can only be passed after an ideal perimeter seam has been passed. In the second step, the punch is placed and fired, which is a mechanical process (14).

In the time period following the announcement of the Longo technique, more than 50,000 cases across Europe underwent surgery with this method (15). There are studies in the literature describing low pain scores and a shorter hospital stay in this period (16,17). While increasing the popularity of the technique, which began to be named after Longo, there were also studies published in the opposite view over time. Cheetham et al. (2000) observed pain in 31% of the patients they operated with stapled hemorrhoidopexy (18), while Ravo et al. (2002) reported severe pain in 5% of the patients at the end of the first week in their study, which included 1107 patients in 12 centers in Italy (19). These findings are similar to the study of Ougris et al. (2005), in which they examined the early and late complications of the technique and explained the severe pain rate as 2.3% (20). A clinical study by Thaha et al. (2005) compared multicenter randomized stapled hemorrhoidopexy with

closed hemorrhoidectomy, and observed post-defecation pain, which was defined as a complication specific to the technique using only staples, and which was not observed in any other study (21). Despite all these results, the number of publications reporting the superiority of stapled hemorrhoidopexy in postoperative pain control in studies comparing conventional methods is also quite high.

When our study was examined in terms of the pain occurring on the first postoperative day according to the Visual Analog Scale (22), 11 patients were painless (53%) 7 patients had mild pain (33%), and 2 patients were describing moderate pain (10%). Severe pain was detected with 1 patient (5%) and there was no patient with very severe pain. In all patients, the complaint of pain regressed within the first 72 hours. When the daily patient records are examined, it was observed that the anastomosis line was just at the border of the dentate line, as a result of the anoscope examination of the patient who complained of severe postoperative pain. It is thought that the reason for this severe pain is due to the stapler suture line being adjacent to the dentate line. The difference in pain sensitivity between the upper and lower dentate line is also due to the different nerve conduction of these two separate regions (4,5,13).

Abandoned bleeding is also a complication, which definitely needs to be stopped. It is usually due to the presence of the injury of the branches of the superior mesenteric artery, which provides 80% blood supply to the dentate line (23). In our study, a significant bleeding was detected in 1 case (5%) after completing the resection and anastomosis with circular stapler, and after removing the relevant instrument. In the later evaluation, the cause of the bleeding here was evaluated to be the possibility of opening the anvil and retraction of the circular stapler without waiting for at least 20 seconds of waiting time after the circular stapler was fired (for the suture line to settle and to provide hemostasis). At this point, the question of whether a double-row stapler mechanism can be made to reduce the risk of bleeding in the circular stapler in the field of surgical instrument engineering in the future still comes to mind. The use of three-row circular staplers independently reduced the risk of anastomotic leak and related morbidity after left-sided colorectal resection (24).

Although we did not encounter it in our study, and it is rarely reported in the literature, it is also important to determine the condition anorectal ring, 3-4 centimeter above from the anal verge, because this anorectal ring can be injured via circular stapler in the surgical treatment of abscess, fistula, grade 3-4 hemorrhoidal diseases, and rectal prolapses. Although the complete cutting of the anorectal ring in surgical interventions almost always results in incontinence, partial losses that may occur in the internal and external sphincter do not usually cause serious stool incontinence problems (11-13).

Anal stricture, on the other hand, is a rarely seen complication. A meta-analysis by Allen et al. (2008) reported that the risk of stricture in surgical igniters containing large-surface metal staples applied to the upper gastrointestinal tract is 2 times less than that of small surfaces surgical igniters (25). Peeters et al. (2016) observed in their study using three different types of circular staplers (Chex CPH32, Chex CPH 34 and Ethicon EndoSurgery PPH03) that anal stenosis occurred in 5 cases with Chex CPH32 circular stapler. They observed no stenosis developed in cases where they used PPH03 circular stapler (26). We did not observe in our study development of stenosis for the cases in which circular staplers were used. We attribute this to Allen et al. (2008), who stated that less stricture develops in the use of large-surface metal staples for the upper gastrointestinal tract (25). In addition, having a flat surface of the head part of the circular igniter, called anvil, removes the relevant mucosa all around, and contributes to the prevention of unnecessary tissue collection, as per the literature on the anvil surface (27). We further think that it may be important in preventing the development of anal stenosis.

Another complication is bleeding, which can be caused by the forced opening of the circular stapler sutures, as a result of the difficulty of the removal of the instrument from the staple (suture) line to separate it from the remaining intact tissue. The reason might be the instrument or the operator error; because, when the instrument is tried to be removed before the anvil is fully opened after ignition, it may damage the anastomosis by pulling the tissue behind it. However, less tension can be generated on the tissue, creating an anastomosis with less strain on the stapler suture line, thanks to the fixed anvil design feature of an important medical device used for this type of operations (28). As mentioned before, we encountered hemorrhage in only one case (5%) and we think that it may be related to the premature opening of the anvil.

CONCLUSION

We consider the large surface area of the staple metal suture material clips of the instrument used, as well as the flatness of the anvil surface, to be advantageous aspects. We think that operator errors will be reduced with the development of a circular stapler with a double row of seams in future works. Multicenter prospective studies will therefore yield much clearer results.

Financial disclosures: *The authors declared that this study has received no financial support.*

Conflict of Interest: *The authors declare that they have no competing interest.*

Ethical approval: *This study, which was planned as retrospective research, was approved by the Etlik Zubeyde Hanim Gynecology Training and Research Hospital Medical Specialization Education Board (TUEK) with the approval date November 15, 2019 and decision number 17.*

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