Stapled Surgery for Hemorrhoidal Prolapse: From the Beginning to Modern Times

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Abstract: *Introduction:* Hemorrhoidal disease is the most common proctologic condition in adults. Among the different surgical procedures, one of the greatest innovations is represented by the stapled hemorrhoidopexy. The history of this technique started with a single stapler use passing through a double stapler technique to resect the adequate amount of prolapse, finally coming to the use of high volume devices.

Methods: Nevertheless, each device has its own specific feature, the stapler is basically made up with one or more circular lines of titanium staples whose height may be variable. The procedure is based on different steps: Introduction of the CAD, evaluation of the prolapse, fashioning purse string or parachute suture, the introduction of the stapler head beyond the suture, pull the wires through the window, close the stapler and keep pulled the wires of the suture held together with forceps, fire using two hands, open the stapler and remove it and check the staple line and then check the specimen. One of the latest innovations in stapled surgery is Tissue Selective Therapy. It is a minimally invasive procedure in which there is a partial circular stapled hemorrhoidopexy focused on the prolapsing piles with bridges of normal mucosa left.

Results: Several studies have reported that SH is a safe and effective procedure to treat hemorrhoidal prolapse. It is a quicker procedure with a shorter hospital stay and earlier return to work if compared with the conventional treatment. This is due to less postoperative pain, postoperative bleeding, wound complications and constipation. Furthermore, the first generation devices had worse outcomes if compared with those of the new generation stapler that showed lower postoperative complication rates with better anatomical and symptomatic results.

Conclusion: Stapled procedure for the treatment of symptomatic hemorrhoidal prolapse represents one of the most important innovations in proctology of the last century bringing with it the new revolutionary concept of the rectal intussusception as a determining factor involved in the natural history of the disease. Stapled hemorrhoidopexy marked an era in which the surgeon may offer the patients a safe, effective treatment with less pain and fast recovery.

Keywords: Stapled Hemorrhoidopexy, hemorrhoids, hemorrhoidal prolapse, PPH, high Volume hemorrhoidopexy, stapler complications.

1. INTRODUCTION

1.1. History of a New Idea

ARTICLE HISTORY

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Hemorrhoidal disease (HD) is the most common proctologic condition in adults with a prevalence of around 4.4% in the United States [1]. The age range mainly involved is between 45 and 65 years old, with a peak at 45 and 65 years [2]. Nowadays, there are several different treatments for the hemorrhoidal prolapse such as rubber band ligation [3], sclerotherapy [4, 5], hemorrhoidal dearterialization with stitches or laser associated or not with mucopexy [6-8] and conventional excisional surgery [9] (Milligan-Morgan, Ferguson), but one of the greatest innovations is undoubtedly represented by the Circular Stapled Hemorrhoidopexy (CSH) [10]. It was introduced in 1998 as an alternative approach to the conventional to excisional surgery. It was based on the concept that the rectal intussusception is the primum movens of the hemorrhoidal prolapse shifting the attention not directly to the hemorrhoids themselves but to the rectal wall above the prolapsed hemorrhoids. The procedure is based on a cylindrical full thickness rectal wall resection (Fig. 1) at the ano-rectal junction, just above the internal hemorrhoids [11]. This leads to a lifting of the prolapsed hemorrhoids inside the anal canal to their original site. It is also characterized by an

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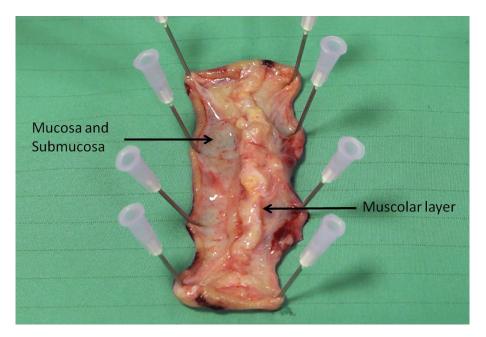


Fig. (1). Specimen after stapled hemorrhoidopexy. The full thickness resection with all the layers.

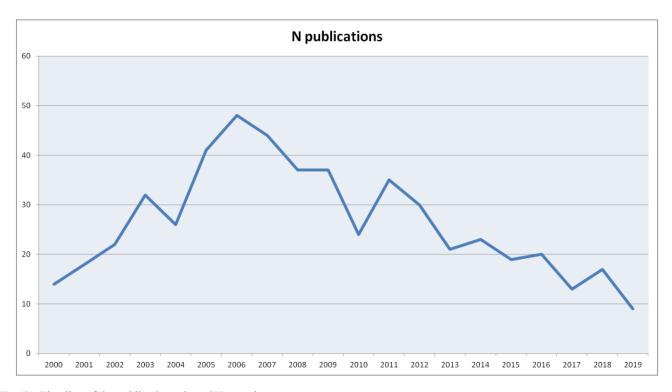


Fig. (2). Timeline of the publications about SH over the years.

interruption of the vascular blood supply inducing a volume reduction. The diffusion of Stapled Hemorrhoidopexy (SH) at the beginning of the new millennium was very quick because this technique gave the possibility to the surgeon to propose an alternative treatment to the classical "six weeks pain" procedure that frequently scared the patients. The interest in this new procedure was so high that lots of papers were published about the technique and the short and mid-term outcomes. Fig. (2) shows the timeline of publications about SH. However, the diffusion of SH with its surprising good results had an unpredictable effect upon the results of the conventional treatment reported in the literature,

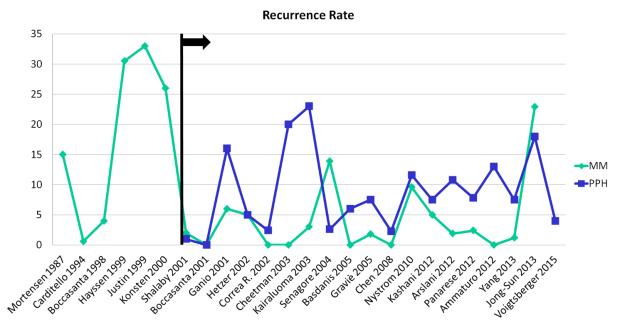


Fig. (3). Graphical representation of the "Longo Effect" with the reduction of the recurrence rate of excisional surgery after the introduction of SH.

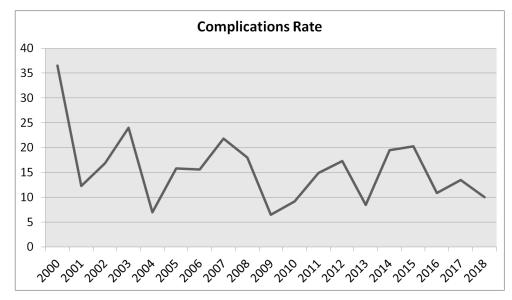


Fig. (4). Graphical representation of the reduction of the reported complication rate after SH during the years.

as shown in Fig. (3). This is what we are used to call "Longo effect" that led to an unexpected reduction in the reported recurrence rate with better outcomes after excisional surgery. In fact, from the graph, it is clearly evident that the results of excisional surgery were worse before SH. This might be related to a disruptive introduction of a new procedure based on a new device which pushed the colorectal surgical community to be more focused on the hemorrhoidal disease. Just after a wide diffusion of the technique, it was quickly evident that it needed adequate training, despite the fact that it appeared easy to do. In fact, SH is both a simple and insidious procedure with lots of complications published at the beginning of the stapled era. After the first five years of the learning curve, the literature showed a significant reduction in the severe complication rate (Fig. 4). The only ways to reduce recurrence and complications were: learning curve to have experienced surgeons in stapled procedures, use correct indications and also technological improvement of the devices.

1.2. Double Stapled Hemorrhoidopexy

After the first good clinical results, the recurrence rate started to increase, inducing the surgeons to think about why it happened. The hypothesis was that the main cause of recur-

rence could be the impossibility to resect an adequate amount of internal rectal prolapsed (IRP) due to a volumetric insufficiency of the PPH device casing. In fact, the calculated casing volume after an accurate analysis was 17 cm³, but the volume of a prolapse which goes inside the Circular Anal Dilator (CAD) for half of his length (total length 3 cm) after adequate exposition manoeuvre, is 14.4 cm^3 (Fig. 5). For this reason, using only one PPH device was impossible to treat a prolapse which arrives at the end of the CAD because its volume would be more than 17 cm³. Therefore, using the length of the prolapse inside the CAD as a parameter to decide the type of the procedure (Fig. 6), if the internal prolapse exceeds half of the CAD, it was needed to use two PPH devices performing the Double Stapled Hemorrhoidopexy (DSH) which represents only a variation of the original technique [12].

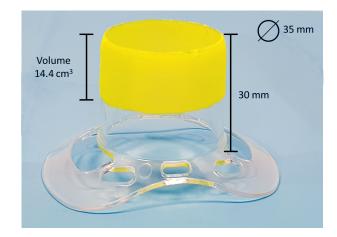


Fig. (5). Circular Anal Dilator with his total length of 3 cm, a diameter of 35 mm. The calculated volume of half of the CAD is 14.4 cm^3 .

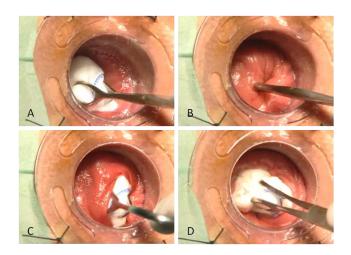


Fig. (6). Evaluation of the prolapse to decide the type of technique to be used. If the IRP \geq the half of CAD length = DSH. Using, instead, the High Volume Device, If the IRP \geq the half of CAD length = parachute while If the IRP \leq the half of CAD length = pure string.

The Formula was: $IRP \ge$ the Half of CAD Length = DSH

DSH is usually and historically considered as treatment for the obstructed defecation under the term STARR (Stapled Trans-Anal Rectal Resection). This is a common and spread misunderstanding because, from the above-mentioned explanation, it is evident that DSH and CSH share the same pathophysiological concept, as well as the type of resection. The only difference is that DSH is a CSH performed two times, using two devices for the anterior and posterior rectal wall. The depth of resection and the involvement of the muscular layer is the same.

Hence, transanal rectal resection with double PPH for hemorrhoids was a brilliant adaptation of devices to allow a larger resection but has its own flaws. In fact, the crossing suture represented weak and fixed points in the rectum.

1.3. High Volume Devices

Starting from the concept that the rectum is a cylinder, the next step was the idea to resect a regular cylinder of internal rectal prolapsed overcoming the limits of single (low casing volume) and double (weak and fixed points of the crossing suture) SH. From this idea, the High Volume Devices were developed and delivered on the market. They allowed a tailored surgery of the internal rectal prolapse. The surgeon, indeed, may decide the amount of the resection through an intraoperative evaluation using the same device, changing only the purse-string or parachute level, to check and adjust (by the finger traction) the amount of the prolapse pulled into the device under direct vision.

The advantages of the newest High Volume Devices are:

- Simple procedure easier than the double stapler
- Better view and control of the operative field (no more blind surgery)
- Easier operation which means reducing the likelihood of technical error
- Better technology of the device
- Reduction of the costs using only one device

One of the first criticisms about these devices was the CAD dimension, but there were no sphincter injuries reported after 34 or 36 mm CAD placement [13].

1.4. Tissue Selective Therapy

One of the latest innovations in stapled surgery coming directly from China is Tissue Selective Therapy (TST). It is a minimally invasive procedure in which there is a partial circular stapled hemorrhoidopexy focused on the prolapsing piles with bridges of normal mucosa left. It is associated with fewer wounds and complications [14-16].

2. MATERIAL AND METHODS

2.1. Stapler Technology

The technology has improved a lot from the first introduction of this device to treat hemorrhoids and each factory involved in this market has its own specific feature. The stapler is basically made up of one or more circular lines of titanium staples whose height may be variable. Especially, the newest high volume has a new patented system that allows a bigger casing maintaining the stability of the stapler head during the fire. Some of them also have a system with a mega window through which it is possible to directly view the pulled prolapsed during the procedure.

2.2. Indications and Contraindications

To choose the best patient suitable for the stapled procedure, it is needed to consider 5 items:

2.3. CSH with High Volume Device

Anatomical presentation: Circumferential hemorrhoidal prolapse associated with internal rectal prolapse.

Type of symptoms: Bother prolapse (independently from II-III Goligher degree), bleeding, and discharge.

Frequency of symptoms: Frequent (at least once per week) or always present (everyday).

Associated diseases: Obstructed Defecation (OD) due to rectal intussusceptions and rectocele may improve if associated with the hemorrhoidal prolapse.

Contraindications: Anal stenosis, which prevents adequate CAD placement and impaired anal continence.

We prefer the High Volume Devices for the clearly stated advantages, however in the case of tiny women with small IRP associated with symptomatic hemorrhoidal prolapse without any obstructed defecation symptoms, we recommend to use 33-mm stapler. In case of impossibility to insert the High Volume Devices CAD, if the normal CAD may be introduced, CSH or DSH (depending on the amount of IRP) may be performed.

2.4. TST

Anatomical presentation: Small and asymmetrical prolapsed with a well detectable hemorrhoidal pedicle.

Type of symptoms: Bleeding (as a major symptom), discharge.

Frequency of symptoms: Frequent (at least once per week) or always present (everyday).

Associated diseases: It is possible to perform in case of anal fistula, fissure, mild impaired anal continence.

Contraindications: Anal stenosis, which prevents adequate CAD placement stable external prolapse.

3. SURGICAL TECHNIQUE

3.1. Patient Placement

A correct patient placement is the base of a safe and comfortable procedure. Gynecological position, the height of the operating table should be such that the height of the patient's anus is slightly less than that of the surgeon's eyes with about 10-15 $^{\circ}$ inclination upside down (Trendelenburg position).

3.2. Anesthesia

Spinal anesthesia is recommended if there are no contraindications because it allows a good muscle paralysis. During the procedure, especially during the fire step, the patients may feel a stretching sensation in the hypogastric area. To avoid any movements due to this kind of sudden sensation, the patients need to be completely awake or completely sleeping. We recommend avoiding superficial sedation in which the patients can make some unconscious movements that can be the cause of intraoperative complications.

If general anesthesia is performed, a complete muscle paralysis is necessary.

3.3. CSH

The surgical procedure is based on different steps, as shown in Fig. (7):

3.3.1. Introduction of the CAD

It should be very well lubricated and then anchored to the skin with four stitches. The CAD is well placed when the whole hemorrhoidal tissue is covered by the CAD itself. This means that there should be no hemorrhoids exceeding at the inner edge of the CAD. If it would happen, it may use a different CAD (longer if needed or with a different shape of the external edges used to be fixed to the perineal skin). In fact, sometimes, especially in men, there is tight perineum with a low distance between the two ischial tuberosity, whereby it is recommended to use the better shape to get the optimal placement. In case of difficulties of CAD placement, even with different shapes or lengths, change the type of procedure to conventional treatment. A correct CAD placement protects the whole anal canal preventing any anal sphincter lesion.

3.3.2. Evaluation of the Prolapse

The entity of the internal rectal prolapse should be assessed using a gauze upon surgical forceps. This is a fundamental step to decide the amount of the prolapsed to be resected according to the level reached inside the CAD whose length is 3 cm. (Example: if it reaches 2 cm this means 4 cm to be resected).

3.3.3. Purse String Suture/Parachute

If the prolapse does not exceed the half of the CAD, it is fashioned a purse string suture at the level decided above the dentate line using a 2/0 PDS. The beginning of the purse string suture is at 12 o'clock.

If the prolapse exceeds half of the CAD, a parachute technique is used, putting six stitches at 1-3-5-7-9-11 o'-clock (Fig. 8).

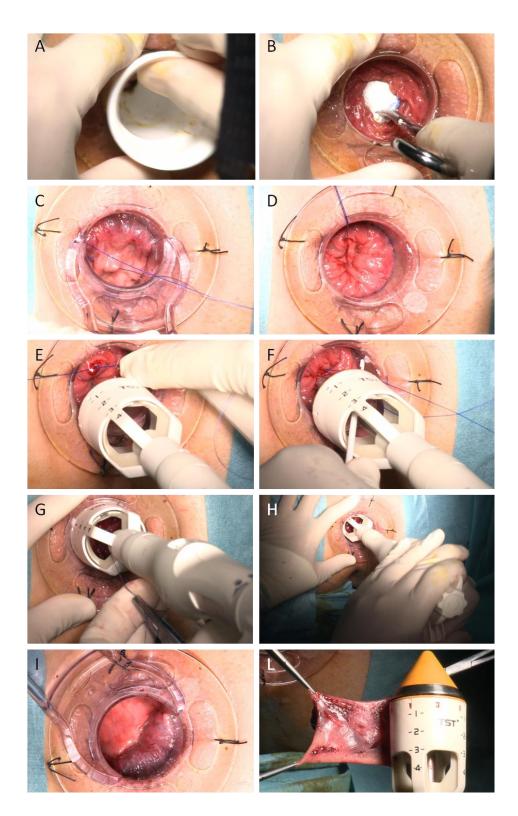


Fig. (7). <u>Circular Stapled hemorrhoidopexy:</u> Introduction of the CAD (A), Evaluation of the prolapse (B),Purse String suture using 2/0 PDS (C-D), Introduction of the stapler head beyond the suture, close the purse string (E), pull the wires through the window (F), Close the stapler and keep pulled the wires of the suture held together with forceps (G), Fire using two hands (H), Open the stapler and remove it and check the staple line (I), Check the specimen (L).

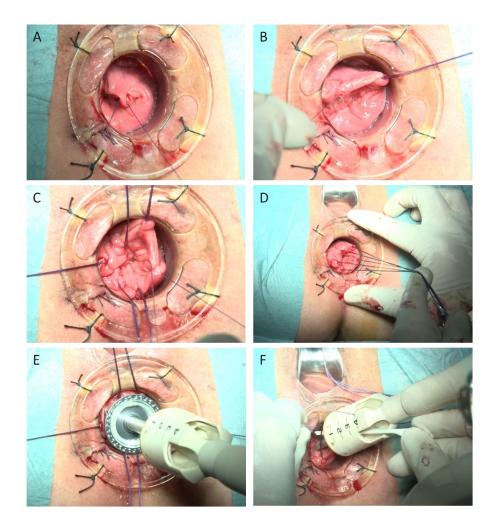


Fig. (8). <u>Parachute technique</u>: If the prolapse exceeds half of the CAD, a parachute technique is used, putting six reabsorbable stitches at 1-3-5-7-9-11 o'clock (A-B-C-D). Introduction of the stapler head beyond the stitches line (E) and the wires held together (11 and 1 o'clock - 5 and 7 o'clock - 3 o'clock - 9 o'clock) through the windows (F).

3.3.4. Introduction of the Stapler Head Beyond the Suture

It should be performed with a single and fluid movement. Just after the stapler is held by the assistant and the first operator can tight the suture, only in case of pure string suture, and pull the wires through the lateral holes /window of the casing.

3.3.5. Close the Stapler and Fire

The staple should be close till the line on the handle reaches the green range that means adequate tissue compression is achieved. Avoid closing the stapler completely because the final shape of the staples would not be adequate to guarantee the seal and the hemostasis. Keep pulling the wires of the suture held together with forceps. Then, with two hands, it should be fire with a quick movement maintaining the grip for 10-15 seconds then release. Before firing in the female patients, it is mandatory to check the posterior vaginal wall using a vaginal valve that should be maintained inside for the complete duration of the procedure.

3.3.6. Open the Stapler and Remove it

Open the stapler by turning the knob counterclockwise for half turn. It is usually enough to remove it. In case of difficulty, it is suggested to completely open the stapler to remove it with safety.

3.3.7. Check the Specimen

Control the cylindrical specimen and its integrity. Identify the anterior wall (by placing forceps) before removing the specimen from the staple so that in case of wall deficit, it is possible to reinforce the suture in the specific site involved, knowing exactly the place.

3.3.8. Check the Staple Line and Remove the CAD

In case of dehiscence of the staple line or bleeding, put reabsorbable stitches. Leave inside the anus and haemostatic sponge with a 24-Fr Foley catheter to control potential bleeding. It will be used to perform a little wash using a saline solution before the discharge the day after surgery.

3.4. Partial Stapled Hemorrhoidopexy (PSH) or TST

The procedure is the same as the CSH. The main difference is that the CAD is longer with two or three windows separated by two or three plastic bridges depending on how many piles need to be treated. This leads to a resection of only the part or rectum in which the purse string suture passes through. At the end of the procedure, the staple line bridges should be cut and if necessary, a reabsorbable stitch is used to close the four/six dog ears. The steps of the procedure are shown in Fig. (9).

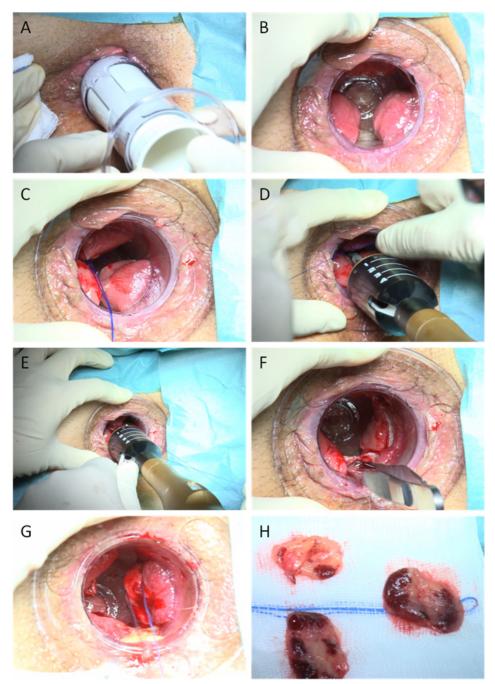


Fig. (9). <u>Tissue Selective Therapy</u>: Introduction of the fenestrated CAD with 3 windows (A), Evaluation of the correct position with the three prolapsing piles (B),Purse String suture using 2/0 PDS involving the three separated piles (C), Introduction of the stapler head beyond the suture, close the purse string (D), pull the wires through the holes (E), After firing, open the stapler, remove it and check the staple line that has the bridges that need to be cut (F), Put stitches at the edges of the six dog ears (G), Check the three specimens (H).

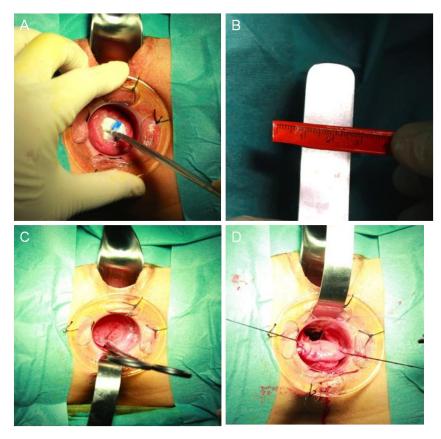


Fig. (10). <u>Double Stapled hemorrhoidopexy:</u> Introduction of the CAD and evaluation of the prolapse (A), Thin spatula used to maintain the anterior and posterior rectal wall separated (B), Always start from the anterior wall. After firing, open the stapler, remove it and check the staple line that has a posterior bridge that needs to be cut (C), Prepare the posterior rectal wall to be resected (D).

3.5. DSH

It is basically the same as the CSH in which the purse string suture involves only half of the circumference. To prevent any involvement of the opposite half-circumference of the rectum, a thin malleable spatula is put through the hole of the edge of the CAD stuck between the anal wall and the CAD itself maintaining the anterior and posterior rectal wall separated. We resect the anterior rectal wall first and then the posterior. After the first fire, the staple line bridge should be cut (Fig. 10). During the second fire, the two residual dog ears are involved by the second purse string suture and excised. In the end, the specimens resected are two trapezoidal pieces of the rectum in which the second contains the two dog ears with staples inside (Fig. 11). The final circular staple line has two crossing sutures representing two fixed and weak points (Fig. 12).

4. RESULTS

4.1. Personal Experience

4.1.1. CSH

A recently published paper has investigated the very long-term results after SH. One hundred seventy-one pa-

tients were phone called after a mean follow-up of 12 years. All the patients underwent stapled hemorrhoidopexy using a PPH03 stapler, from January 2003 to December 2005. The study analyzed the anatomical and symptomatic recurrence and patient's satisfaction after surgery. The postoperative complications recorded were hemorrhage (4.1%), hematoma (0.6%), urinary retention (3.5%), anastomotic stenosis (1.7%), persistent anal pain (2.3%), tenesmus, and impaired anal continence evaluated, also with dedicated scores. Anatomical self-reported prolapse recurrence was 40.9%, with 75.6% of patients-reported symptoms improvement. The overall complication rate was 56.7%, subdivided as follows: overall tenesmus rate of 38.2% and overall impaired continence rate was 39.1%. Medical therapy was still required occasionally by 40.3% of the patients and only 9.3% of them needed further surgery for recurrence. However, the patient's satisfaction rate was good (≥ 3 on a scale of 1 to 5) in 81.2% of cases [17].

This paper clearly showed that the treatment of hemorrhoidal prolapsed with the first-generation devices is safe and feasible but associated with a high recurrence rate. For this reason, to improve the results, more accurate selection criteria are needed, associated with the use of new generation devices such as the high volume staplers that were advocated to improve the long-term outcomes.

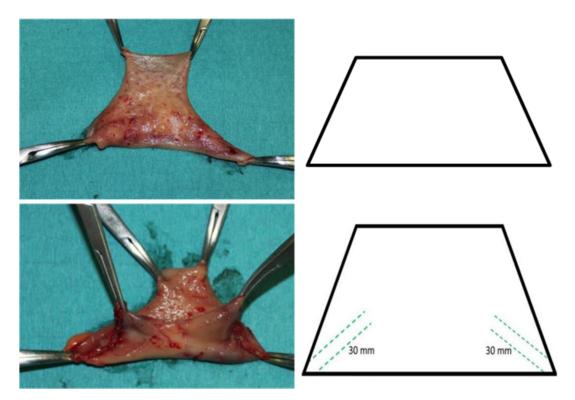


Fig. (11). The specimens after DSH are trapezoidal. The upper image (picture on the left and schematic version on the right) represents the specimen firstly resected. The lower image (picture on the left and schematic version on the right) represents the second specimen resected, which contains the two dog ears with the partial staple line of the first fire.

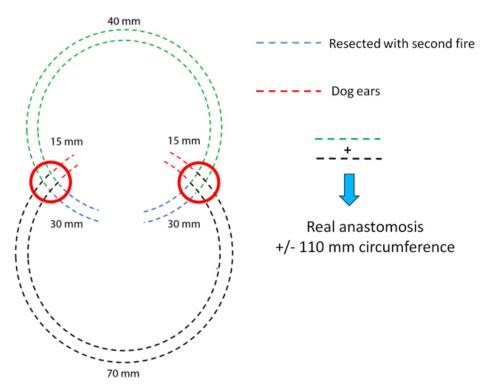


Fig. (12). Schematic representation of the DSH. The final circular staple line has two crossing sutures, which are fixed and weak points.

4.1.2. High Volume Device

Personal experience regarding the use of High Volume Devices was first published in 2014. It was a multicentric international study whose aim was to assess the safety, efficacy and feasibility of stapled transanal procedures performed with a new dedicated device, TST STARR+, for tailored transanal stapled surgery. One hundred sixty consecutive patients were enrolled in the study and the authors concluded that the new device seemed to be safe and effective for a tailored approach to ano-rectal prolapse [18].

After this, in 2015, another paper was published assessing the outcomes of fifty-two patients after transanal rectal resection for hemorrhoidal prolapse. Urgency rate within a week after surgery was 17.1%, but it decreased to 5.7% at 14.5 months median follow-up. The occasional bleeding rate was 7.7%. No complete prolapse recurrence was recorded, only one patient had a partial recurrent prolapse of a downstaged single pile. Hence, the authors concluded that the new technology of the stapler seems to reduce some postoperative complications, as well as the recurrence rate [13].

4.1.3. Last Update

<u>4.1.3.1. CSH</u>

The last update about CSH (TST-33) includes 107 patients from 2014 to 2018. The recurrence rate was 6.5%. The bleeding rate was 5.6% without any surgical revision. No stapled line dehiscence was reported, an urgency rate of 5.4% with an impaired anal continence rate of 1.9%, and symptomatic stenosis of only 0.9%. The mean satisfaction grade (0-10) was 8,3. All the patients treated with CSH (TST-33) were frequently tiny women with small IRP associated with symptomatic hemorrhoidal prolapse without any obstructed defecation symptoms.

4.1.3.2. High Volume Devices

The last update about SH using High Volume Devices (TST-36) includes 197 patients from 2012 to 2018. The recurrence rate was 5.8% and only a third of these patients needed further surgical treatment. The bleeding rate was 9.8%, with 2.2% of surgical revision. Dehiscence rate was 1.3%, impaired anal continence 2.2% and symptomatic stenosis only 0.4%. The mean satisfaction grade (0-10) was 8,7. All the patients treated with High Volume Devices (T-ST-36) had big IRP with symptomatic hemorrhoidal prolapse frequently associated with OD symptoms, according to the reported surgical indications (Material and Methods - Paragraph 2.1).

4.1.4. Treatment of Recurrence

In case of anatomical or symptomatic recurrence after stapled surgery for haemorrhoids, the first-line treatment is always medical therapy based on flavonoids (systemic and/or topical) which may be associated with local antiinflammatory (suppositories or topical ointment), stools softener if necessary trying to get normal defecation with normal behavior. If the symptoms tend to persist over time, recur after medical therapy or in case of relevant anatomical recurrence, a redo surgery is usually suggested. Excisional surgery is usually performed, but in case of internal rectal prolapse persistence, a second step stapled surgery may be performed too.

4.2. Review of the Literature

Several studies have reported that SH is a safe and effective procedure for the treatment of hemorrhoidal prolapse. SH is a quicker procedure with a shorter hospital stay and earlier return to the normal activities if compared with the conventional treatment. These postoperative effects are due to less postoperative pain, postoperative bleeding, wound complications and constipation [19]. Moreover, the postoperative outcomes of the first generation devices were worse than those of the new generation staplers. In fact, they have lower postoperative complication rates with better anatomical and symptomatic results, maintaining a very high satisfaction rate [18, 20].

4.3. Management of the Complications

There are lots of different complications of SH, varying from minor to major and life-threatening. The knowledge of all the possible complications is at the base of an adequate quick treatment reducing the time for a correct diagnosis [21].

4.3.1. Bleeding

Most of them may be managed with medical therapy. It is suggested to check the postoperative bleeding through washing with a saline solution using a Foley catheter inserted through the anus. In case of persistent active bleeding, a surgical revision is mandatory. It is recommended to use only single stitches without any running suture and the numbers of the stitches depend on the local condition until the complete hemostasis is achieved.

4.3.2. Stenosis

The Early Identification is usually treated with local antiinflammatory and outpatient dilation if necessary. Sometimes the height of the suture may represent a difficulty because the common anal dilators do not reach it easily. The late identification generally needs a surgical treatment removing the stenotic scar containing the stapled line. Any direct correlation between the type of stapler and stenosis rate was not found. Theoretically, wider the diameter lesser this risk, but it is still undemonstrated.

4.3.3. Urgency and/or Anal Incontinence

The best treatment is the pelvic floor rehabilitation. In this case, the knowledge of the preoperative history is fundamental because a preoperative impaired anal continence is an absolute contraindication for stapled surgery, while irritable bowel syndrome and local inflammation such as proctitis may represent a relative contraindication that needs to be assessed case by case. Moreover, there is a huge difference between urgency that means urgent stimulus without any leakage from anal incontinence that may be active or passive and, in both cases, is related to a real anal leakage.

4.3.4. Chronic Pain

An important element is the height of the staple line that should be just above the dentate line (around 1 cm), at the apex of the hemorrhoidal tissue, thus preventing a very high suture with the hourglass-shaped rectum and also a direct fixation of the staple line to the pubo-rectalis muscle. In fact, in the case of the last event, the staple line is too adherent to the muscle, whereby its physiologic movement during defecation is limited inducing pain derived by the overstretched rigid muscle that tends to persist over time. However, it remains still undemonstrated if there is any difference for the onset of chronic pain depending on purse string or parachute suture. The therapeutic options are medical treatment with neuroleptic and anxiolytic or surgical treatment. The surgical approach consists of the removal of the scar tissue, particularly the most painful and stenotic portion of the anastomosis, mobilizing the adherent areas from the pelvic floor muscles. Indeed, scar removal is a feasible surgical procedure with low morbidity and high efficacy with a pain resolution of 71.4% and pain improvement of 14.3%. A crucial point is the interval time after stapled surgery, in fact, the operation should be done as soon as possible, because revisional surgery within 3 months showed to have the highest good results [22].

4.3.5. Pararectal Hematoma

It is the most important life-threatening complication. It usually drains through the suture line in the rectum and may be treated with a conservative approach (total parenteral nutrition and antibiotics). In these cases, an angio-CT scan is suggested. Rarely, it may require surgical treatment, but in those cases in which it is not self-drained and it needs to be drained through small incisions at the stapler line. Sometimes angio-embolization is necessary, in particular, in those patients who have active bleeding with unstable hemodynamic conditions (Fig. **13**). In some cases, there may also be an intramural hematoma extended proximally that may induce hemoperitoneum [23]. In this condition, the laparoscopic abdominal approach is always recommended.

4.3.6. Pararectal Abscess

It is usually a consequence of an infected pararectal hematoma. It needs to be surgically drained. The association with antibiotic therapy is recommended.

4.3.7. Recto-Vaginal Fistula

It is generally related to an intraoperative mistake that can be avoided with adequate control of the posterior vaginal wall using a vaginal valve. The treatment is difficult because it is necessary to remove all the staples to close the opening allowing its final healing, but rectal mucosa is stiff after stapled procedure preventing to mobilize a good flap. In this rare case, the transvaginal approach is recommended [24].

4.3.8. Staple Line Dehiscence

If it is diagnosed intraoperatively, it is treated with a direct transanal repair. Instead, in the case of postoperative diagnosis, the wait and see approach without any signs of sepsis is generally recommended.

4.3.9. Mucocele/Rectal Pocket

Mucocele is a rare complication considered as a variant of a rectal pocket [25]. It derives from a rectal plication during the fire of the stapler leading to the creation of a pararectal cavity. It is completely separated from the rectal lumen differently from the rectal pocket which is a pseudodiverticulum with a direct connection with lumen [26]. Mucocele contains mucus inside and its wall has the normal stratification of the rectum. When it becomes wide because of the mucus collection, it may give perineal discomfort. In this case, after accurate differential diagnosis with pararectal lesions, transanal surgery to drain it, creating a wide connection to discharge the mucus, is recommended. Diverticulectomy associated with a direct rectal wall repair has been reported to treat rectal pocket but a more conservative approach should be the first approach [27].

4.3.10. Perineal and/or Rectal Necrosis

It is a mandatory, aggressive and demolitive approach with laparoscopic or laparotomic drainage and fecal diversion. In some cases of rectal necrosis, proctectomy and colostomy are necessary [28].

CONCLUSION

Stapled procedure for the treatment of symptomatic hemorrhoidal prolapse represents one of the most important innovations in proctology of the last century. The new concept of rectal intussusception as a determining factor involved in the natural history of the disease associated with the circular view of the anus during surgery using the CAD has upset the scenario of such spread and bother disease. In fact, for a long time, it was considered less important and interesting than many other coloproctological diseases. Dr. Antonio Longo and his innovation had the merit to propose not only a valid alternative to the conventional treatment but also to let the attention of a great colorectal community to be focused upon this disease and more in general on the proctological field. SH marked an era in which the surgeon has not only the availability to offer the patients a safe and effective treatment of the hemorrhoids with less pain and fast recovery, but he also may offer his own professionalism and knowledge about a disease deeply studied and debated.

Moreover, most of the new procedures to treat hemorrhoidal prolapse have begun from the same concept of internal rectal prolapse. In fact, Doppler or non-Doppler-guided dearterialization with mucopexy [29] or tailored mucopexies [30] aims to treat the rectal prolapse above the prolapsing hemorrhoids with a theoretical less effective approach. There could be a difference between a cylindrical full thickness rectal resection with subsequent complete devascularization and single dearterialization achieved with stitches associated



Fig. (13). Pararectal hematoma treated with angiographic embolization.

with columnar uneven suspension of the hemorrhioidal piles. Nevertheless, the theoretical differences do not reveal statistically different outcomes reported in the literature. Hence, probably the surgeons need only to choose the right procedure to the right patients being aware of real outcomes and complications in their own hands.

LIST OF ABBREVIATIONS

- HD = Hemorrhoidal Disease
- IRP = Internal Rectal Prolapse
- CAD = Circular Anal Dilator
- DSH = Double Stapled Hemorrhoidopexy
- TST = Tissue Selective Therapy
- CSH = Circular Stapled Hemorrhoidopexy
- PSH = Partial Stapled Hemorrhoidopexy
- OD = Obstructed Defecation

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APPENDIX

Short Interview with Dr. Gabriele Naldini, developer of a new High Volume Device.

Q1: When did the idea of high volume come to mind?

A1: Around 2006-2008, in an uncoordinated and absolutely spontaneous manner, a movement of surgeons performed mainly the double PPH approach for the hemorrhoidal prolapse. This idea arose from the dissatisfaction with the resection with the old PPH (single or double) and the necessity to reduce recurrences.

Q2: What reason led you to modify an existing device? What was the need?

A2: The strength of stapler surgery has always been the theoretical simplicity of execution. I say theoretically because it is not really so simple and it certainly needs dedicated training. For this reason, adding technical difficulties such as the use of the double stapler or Transtar could only increase the risk of technical errors. We remind you that any technological improvement should aim to make the operation simple, reproducible and safe as much as possible. The need was to have a tool that allowed us to perform a tailored prolapse surgery, deciding the amount of prolapse to be resected without volumetric and instrumental limitations (we must not always resect as much as possible but what we think necessary for that anatomical presentation) and adjusting the intervention under direct visual control.

Q3: How long did it take to develop it?

A3: From the first brain storming to the creation of the final product it took about 2 years for the difficult search of the materials to be used to support the innovations contained in the basic idea which were:

- High volume, whereby slight increase in size but important increase of forces and pressures

- Mega windows to increase visibility and potential size of the casing

- Barrier free to make the whole casing really available for the prolapse resection (removal of that part contained in the casing that was used to increase the stability of the rod that at the same time reduce the space. This kind of support was displaced inside the stapler itself)

- Modification of accessories to simplify the procedure

After this stage, it needed other 2 years for the improvement of the chosen technological solutions.

Q4: Was it hard to realize this ambitious idea?

A4: It was certainly difficult to make people understand our necessity. It was so difficult that the two main companies that were involved in this field at the time did not show interest. A Chinese start-up has shown an interest in developing the idea and has drawn the line for the subsequent technological movement that has followed over the last 10 years. I must say that, despite the great enthusiasm and the great competence of the Chinese R&D team, it was very difficult and extremely gratifying to realize the idea practically.

Q5: What the future of stapler surgery for hemorrhoids will be?

A5: As a friend of mine, Alfonso Carriero, precursor of the evolution of the technique with stapler, always said, it will be a surgery only for specialized and high volume centers. This will lead to an evolution of indications (it is not correct to propose a single technique as a resolution of a disease as heterogeneous as hemorrhoids, and if it is not correct for stapler surgery, it is even more incorrect for the other techniques), to a standardization of the technique, to a reduction of complications and to a better ability to manage complications. Currently, I am convinced that proctological and pelvic floor diseases, due to their complexity and their psychosocial impact, must be addressed only in dedicated and specialized centers, as it is increasingly happening all over the world.

REFERENCES

- Abramowitz L, Benabderrahmane M, Pospait D, Philip J, Laouénan C. The prevalence of proctological symptoms amongst patients who see general practitioners in France. Eur J Gen Pract 2014; 20(4): 301-6. [http://dx.doi.org/10.3109/13814788.2014.899578] [PMID: 24702041]
- [2] Gallo G, Sacco R, Sammarco G. Epidemiology of hemorrhoidal disease. Coloproctology 2018; 2: 3-7.
 - [http://dx.doi.org/10.1007/978-3-319-53357-5_1]
- [3] Albuquerque A. Rubber band ligation of hemorrhoids: A guide for complications. World J Gastrointest Surg 2016; 8(9): 614-20. [http://dx.doi.org/10.4240/wjgs.v8.i9.614] [PMID: 27721924]
- [4] Miyamoto H, Hada T, Ishiyama G, Ono Y, Watanabe H. Aluminum potassium sulfate and tannic acid sclerotherapy for Goligher Grades II and III hemorrhoids: Results from a multicenter study. World J Hepatol 2016; 8(20): 844-9. [http://dx.doi.org/10.4254/wjh.v8.i20.844] [PMID: 27458504]
- [5] Lobascio P, Minafra M, Laforgia R, et al. use of sclerotherapy with polidocanol foam in the treatment of second degree haemorrhoidal disease – a video vignette Color Dis 21:codi 2018; 14498
- [6] Ratto C, Campenni P, Papeo F, Donisi L, Litta F, Parello A. Transanal hemorrhoidal dearterialization (THD) for hemorrhoidal disease: a single-center study on 1000 consecutive cases and a review of the literature. Tech Coloproctol 2017; 21(12): 953-62. [http://dx.doi.org/10.1007/s10151-017-1726-5] [PMID: 29170839]
- [7] Hoyuela C, Carvajal F, Juvany M, et al. HAL-RAR (Doppler guided haemorrhoid artery ligation with recto-anal repair) is a safe and effective procedure for haemorrhoids. Results of a prospective

study after two-years follow-up. Int J Surg 2016; 28: 39-44. [http://dx.doi.org/10.1016/j.ijsu.2016.02.030] [PMID: 26876958]

- [8] Giamundo P. Advantages and limits of hemorrhoidal dearterialization in the treatment of symptomatic hemorrhoids. World J Gastrointest Surg 2016; 8(1): 1-4.
 - [http://dx.doi.org/10.4240/wjgs.v8.i1.1] [PMID: 26843909]
- Bhatti MI, Sajid MS, Baig MK. Milligan-Morgan (Open) Versus Ferguson Haemorrhoidectomy (Closed): A Systematic Review and Meta-Analysis of Published Randomized, Controlled Trials. World J Surg 2016; 40(6): 1509-19.
 [http://dx.doi.org/10.1007/s00268-016-3419-z]
 [PMID: 26813541]
- [10] Longo A. Treatment of hemorrhoids disease by reduction of mucosa and hemorrhoidal prolapse with a circular-suturing device: a new procedure. Proceedings of the sixth world congress of endoscopic surgery. Rome, Italy. 1998.
- [11] Naldini G, Martellucci J, Moraldi L, Romano N, Rossi M. Is simple mucosal resection really possible? Considerations about histological findings after stapled hemorrhoidopexy. Int J Colorectal Dis 2009; 24(5): 537-41.
 [http://dx.doi.org/10.1007/s00384-009-0636-z] [PMID: 19169693]
- [12] Naldini G, Martellucci J, Talento P, Caviglia A, Moraldi L, Rossi M. New approach to large haemorrhoidal prolapse: double stapled haemorrhoidopexy. Int J Colorectal Dis 2009; 24(12): 1383-7.
 [http://dx.doi.org/10.1007/s00384-009-0750-y] [PMID: 19547990]
- [13] Naldini G, Fabiani B, Menconi C, Giani I, Toniolo G, Martellucci J. Tailored prolapse surgery for the treatment of hemorrhoids with a new dedicated device: TST Starr plus. Int J Colorectal Dis 2015; 30(12): 1723-8.
 [http://dx.doi.org/10.1007/s00384-015-2314-7] [PMID:
 - 26208412]
- [14] Wang ZG, Zhang Y, Zeng XD, et al. Clinical observations on the treatment of prolapsing hemorrhoids with tissue selecting therapy. World J Gastroenterol 2015; 21(8): 2490-6.
- [http://dx.doi.org/10.3748/wjg.v21.i8.2490] [PMID: 25741159]
- Khubchandani IT. H.-C. Lin, D.-L. Ren, Q.-L. He, H. Peng, S.-K. Xie, D. Su, X.-X. Wang: Partial stapled hemorrhoidopexy versus circular stapled hemorrhoidopexy for grade III-IV prolapsing hemorrhoids: a two-year prospective controlled study. Tech Coloproctol 2012; 16(5): 345.
 [http://dx.doi.org/10.1007/s10151-012-0866-x] [PMID: 22936580]
- [16] Lin H-C, He Q-L, Ren D-L, et al. Partial stapled hemorrhoidopexy: a minimally invasive technique for hemorrhoids. Surg To-day 2012; 42(9): 868-75.
 [http://dx.doi.org/10.1007/s00595-011-0085-5] [PMID: 22160324]
- [17] Sturiale A, Fabiani B, Menconi C, *et al.* Long-term results after stapled hemorrhoidopexy: a survey study with mean follow-up of 12 years. Tech Coloproctol 2018; 22(9): 689-96.
 [http://dx.doi.org/10.1007/s10151-018-1860-8]
 [PMID: 30288629]
- [18] Naldini G, Martellucci J, Rea R, et al. Tailored prolapse surgery for the treatment of haemorrhoids and obstructed defecation syndrome with a new dedicated device: TST STARR Plus. Int J Colorectal Dis 2014; 29(5): 623-9. [http://dx.doi.org/10.1007/s00384-014-1845-7] [PMID: 24569943]
- [19] Gallo G, Martellucci J, Sturiale A, et al. Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of hemorrhoidal disease. Tech Coloproctol 2020; 24(2): 145-64.
 [http://dx.doi.org/10.1007/s10151-020-02149-1]
 [PMID: 31993837]
- [20] Reboa G, Gipponi M, Gallo M, et al. High-Volume Transanal Surgery with CPH34 HV for the Treatment of III-IV Degree Haemorrhoids: Final Short-Term Results of an Italian Multicenter Clinical Study. Surg Res Pract 2016; 20162906145 [http://dx.doi.org/10.1155/2016/2906145] [PMID: 26998510]
- [21] Porrett LJ, Porrett JK, Ho YH. Documented complications of staple hemorrhoidopexy: a systematic review. Int Surg 2015; 100(1):

44-57.

[http://dx.doi.org/10.9738/INTSURG-D-13-00173.1] [PMID: 25594639]

Menconi Č, Fabiani B, Giani I, Martellucci J, Toniolo G, Naldini G. Persistent anal and pelvic floor pain after PPH and STARR: surgical management of the fixed scar staple line. Int J Colorectal Dis 2016; 31(1): 41-4.
 [http://dx.doi.org/10.1007/s00384-015-2355-y]

26248794] De Santis G, Gola P, Lancione L, Sista F, Pietroletti R, Leardi S.

 [23] De Santis G, Gola P, Lancione L, Sista F, Pietroletti R, Leardi S. Sigmoid intramural hematoma and hemoperitoneum: an early severe complication after stapled hemorrhoidopexy. Tech Coloproctol 2012; 16(4): 315-7. [http://dx.doi.org/10.1007/s10151-011-0696-2] [PMID:

[24] Naldini G. Serious unconventional complications of surgery with stapler for haemorrhoidal prolapse and obstructed defaecation because of rectocoele and rectal intussusception. Colorectal Dis 2011; 13(3): 323-7.
 [http://dx.doi.org/10.1111/j.1463-1318.2009.02160.x] [PMID:

20002689]
[25] Grapsi A, Sturiale A, Fabiani B, Naldini G. Mucocele complicating stapled hemorrhoidopexy. Int J Surg Case Rep 2017; 33: 38-40.

[http://dx.doi.org/10.1016/j.ijscr.2017.02.020] [PMID: 28273604]

- Pescatori M, Spyrou M, Cobellis L, Bottini C, Tessera G. The rectal pocket syndrome after stapled mucosectomy. Colorectal Dis 2006; 8(9): 808-11.
 [http://dx.doi.org/10.1111/j.1463-1318.2006.00968.x] [PMID:
- [27] Na SK, Jung H-K, Shim K-N, Jung SA, Chung SS. Iatrogenic rectal diverticulum with pelvic-floor dysfunction in patients after a procedure for a prolapsed hemorrhoid. Ann Coloproctol 2014; 30(1): 50-3.

[http://dx.doi.org/10.3393/ac.2014.30.1.50] [PMID: 24639972]

- Blouhos K, Vasiliadis K, Tsalis K, Botsios D, Vrakas X. Uncontrollable intra-abdominal bleeding necessitating low anterior resection of the rectum after stapled hemorrhoidopexy: report of a case. Surg Today 2007; 37(3): 254-7.
 [http://dx.doi.org/10.1007/s00595-006-3363-x]
 [PMID: 17342370]
- [29] Ratto C. THD Doppler procedure for hemorrhoids: the surgical technique. Tech Coloproctol 2014; 18(3): 291-8.
 [http://dx.doi.org/10.1007/s10151-013-1062-3] [PMID: 24026315]
- [30] Elbetti C, Giani I, Novelli E, Martellucci J, Feroci F. Symptomatic pile tailored procedure. A new perspective for hemorrhoidal disease treatment. Ann Ital Chir 2017; 88: 348-51. [PMID: 29051401]

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