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COORDINATORE DEL CORSO: PROF. ANGELO FILIPPINI

**RECURRENT HEMORRHOIDAL DISEASE AFTER
STAPLED PROLASSECTOMY : HYPOTHESIS ON
PREDICTIVE FACTORS AND SURGICAL
MANAGEMENT**

**“La malattia emorroidaria recidiva post-prolassectomia:
ipotesi su fattori predittivi e strategia chirurgica”**

Relatore

Dottoranda

Prof. Domenico Mascagni

Dott.ssa Alessandra Panarese

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1. INTRODUCTION

The surgical procedure of stapled haemorrhoidopexy is now considered safe and its safety is improving with experience and technical upgrading. Compared to conventional procedures, stapled haemorrhoidopexy has the advantage - in the short term results - of less postoperative pain but the main disadvantage - in the long term follow-up- of possible recurrent prolapse.

This occurs between three months and one year after the operation and should be differentiated -for a more correct evaluation of the results- by the persistent prolapse, that is immediately evident after surgery or in the first two months. Both –persistent and recurrent prolapse- required treatment if symptomatic.

The percentage of symptomatic prolapse -persistent and recurrent- after stapled procedures varies widely in the several clinical trials described in the literature, ranging from a minimum of 2% to the worst results of 53.3% (8, 15, 26-32). The unsatisfactory results mainly depend on incorrect indications (IV grade haemorrhoids with predominant external, fibrous component), technical mistakes during surgical procedure and insufficient prolapse correction.

Avoiding or minimizing the possibility of a recurrent prolapse should be demanded to a well realized primary operation, calibrated on the effective amount of the prolapse (using single or double stapled technique, instruments with larger case, parachute technique, or with an immediate, intraoperative correction of the persistent prolapse or excision of a residual pile). A more precise, simple classification of the

different features of prolapse in which these different techniques should be applied, with a choice of surgery not more left to the surgeon's idea, could give experienced and correct guidelines thus reducing these unsatisfactory percentages of recurrent prolapse.

Nowadays, however, we are in the condition to face the patient, who has already undergone a stapled haemorrhoidopexy with a single “Procedure for Prolapse and Haemorrhoids” -PPH- or a double stapling “Procedure for Prolapse and Haemorrhoids” - DSPPH - , insufficiently corrected or, in any case, with a final recurrent prolapse.

The recurrent haemorrhoidal disease can take the appearance of single or multiple recurrent piles or of a true prolapse, partially or totally involving the anal circumference, mobile or fixed, symptomatic or not.

The literature is still debating on the different haemorrhoidal treatments, conventional, stapled or realized with different new devices; it is rich of recruitments of short and long term complications. We find less on how to minimize these undesirable effects of stapling procedures and there are no experiences describing and classifying the recurrences and the strategies to deal with them.

The aim of this work is to analyze the different features of recurrences after stapled haemorrhoidal operations and the procedures realized to treat them in order to lay down solid and firm starting points to focalize some guidelines of treatment of recurrences after stapled prolapsectomy

2. ANATOMY AND PHYSIOLOGY OF THE ANAL CANAL

The anal canal is the terminal portion of the large intestine, completely extraperitoneal, it extends from the anal verge and the rectum. According to surgery the demarcation between the rectum above and the anal canal below is the anorectal ring. According to anatomy, the rectum changes to the anal canal at the dentate line. The surgical anal canal is about 3-5 cm long. In its upper two thirds it is lined with columnar epithelium and in the lower third with squamous epithelium, which meets at the dentate line. Fig.1 (1). The junctional area between these two epithelial surfaces is called the transition zone. In the upper anal canal there are vascular cushions, which contain branches and tributaries of superior, middle and inferior rectal arteries and veins. They are three, one on the left and two on the right (3, 7, and 11 o'clock position in supine position). They allow the complete closure of the anal canal, providing continence together with the internal sphincter. Fig.1 (2), Fig.1 (3).

In front of the anal canal, there are the cervix and vagina in females, instead, the seminal vesicles, prostate, and urethra in males. Anterior to the anal canal is the rectovesical fascia (of Denonvilliers), and behind (posterior) is the presacral endopelvic fascia (of Waldeyer), under which lie a rich presacral plexus of veins. Posterior to the anal canal is the coccyx and the sacrum.

The involuntary internal anal sphincter is a thickening of the circular muscle layer of the rectum and it provides most of the continence. The voluntary external anal sphincter has 3 parts: subcutaneous, superficial, and deep, is innervated by the perineal branch of the fourth sacral nerve and by inferior hemorrhoidal nerves.

The superior rectal (hemorrhoidal) artery, which is the terminal branch of the inferior mesenteric artery, supplies the anal canal above the dentate line. The middle rectal artery (a branch of the internal iliac artery) and the inferior rectal artery (a branch of the internal pudendal artery) supply the lower anal canal. The internal hemorrhoidal plexus of veins, above dentate line, drains into the portal system of veins. The external hemorrhoidal plexus of veins, below the dentate line, drains into systemic veins (4).

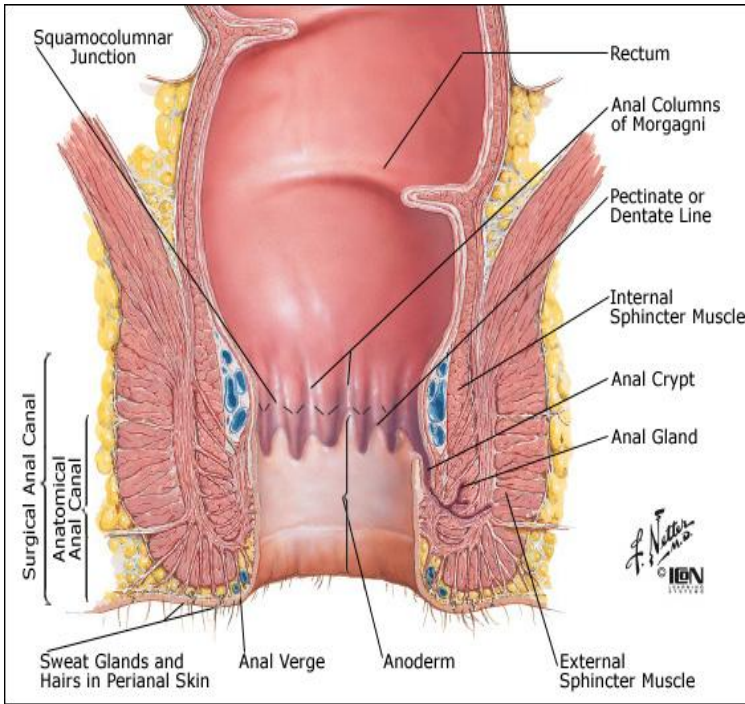


Fig.1 Anatomy of the anal canal

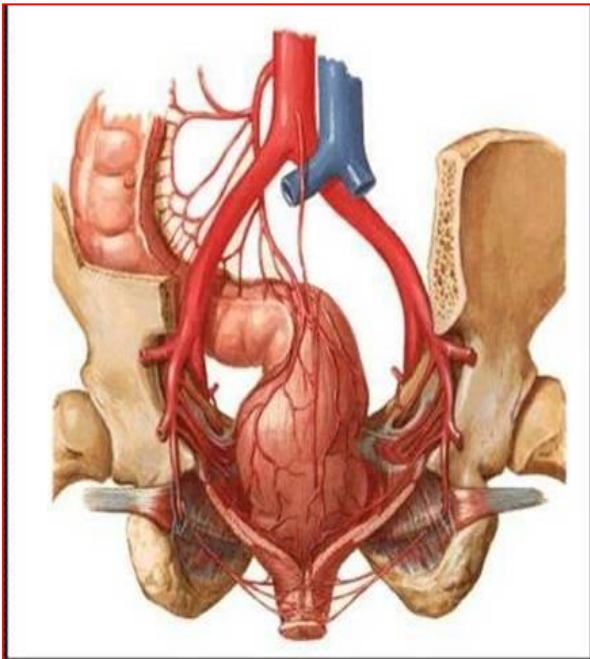


Fig.2 Arterial circulation

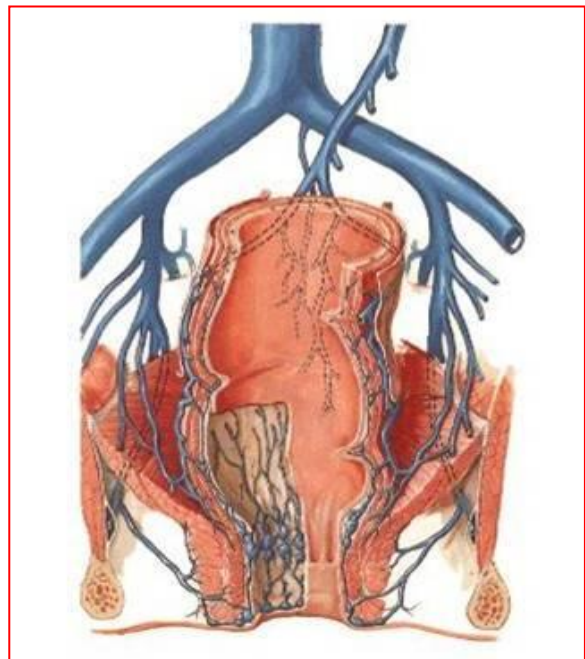


Fig.3 Venous circulation

3. HAEMORRHOIDAL DISEASE

Haemorrhoidal disease results from the hypertrophy of the haemorrhoidal plexus with the pathological changes in the anal cushions. It is one of the most common anorectal disorders affecting at least once in life of 50–70% of people living in industrialised countries with a frequency peak between the fourth and sixth decade (5). The word “hemorrhoids” is derived from the Greek, and means “the flow of blood”.

Most studies relate fibre intake, constipation, prolonged straining and hormonal changes to the pathogenesis (6,7). For patients who do not respond from conservative management or whose illness degree indicates a low probability of success by non-excisional intervention techniques, surgical treatment should be considered (8).

3.1 Classification of haemorrhoids

Haemorrhoidal disease is classified according to the degree of prolapse, although this not reflect the severity of patient’s symptoms. However, some form of classifications is helpful in assessing different therapies. There are four degree: - first degree, no prolapse; second degree, prolapse at straining but reducing spontaneously; third degree, prolapse at straining but reduced manually; fourth degree, irreducible and permanent prolapse.

3.2 Symptoms

Bleeding: is the most common symptoms. It results from the rupture of the capillaries of the lamina propria. The blood is bright red and is first noticed on the toilet paper after a bowel movement with firm faeces. Repeated trauma produces a chronic inflammation, which makes the mucosa more fragile and likely to bleed. In this way the bleeding may become important. There are often perianal pain, discomfort, mucous discharge and perianal itching or irritation as clinical presentation Prolapse may occur during defecation or physical effort. It can be reducible or non reducible.

4. TREATMENT OF HAEMORRHOIDAL DISEASE

4.1 Medical treatment

Patients with minor symptoms may benefit from a diet with more water and high-fiber intake. Some advices about defecatory habits may be useful. It's important to explain that excessive straining at stool and prolonged periods of sitting on the lavatory are bad habits, while the adoption of a squatting position is advantageous.

4.2.1. Surgical treatment for minor degrees (I-II) haemorrhoids

Injection sclerotherapy: the sclerosant agent used is 5% Phenol in oil or 5% Quinine and urea hydrochloride. Three or five millilitres are injected at the point where the reddish mucosa changes to the purplish mucosa, under the mucosa. Complications: pain, hemorrhage, prostatitis and pronounced inflammatory response.

Rubber Band and Ligation: a small rubber band or O ring is applied tightly around the mucosa, pulled into the barrel of an applicator in order to cause an ischemia sloughing of the mucosa. Complications: pain. If the pain is severe, the band must be removed.

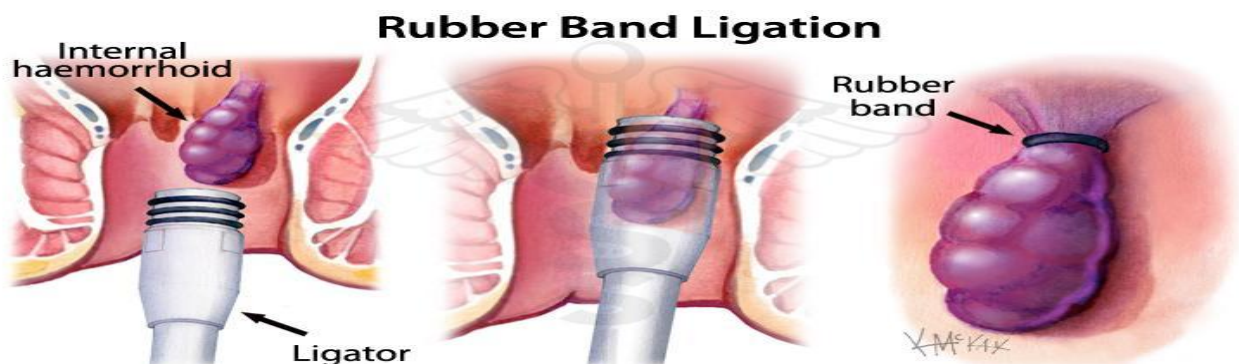


Fig. 4

Photocoagulation: Infrared coagulation is applied in pulses to the base of the haemorrhoidal cushions. It causes a circumscribed area of tissue destruction. Complications: there are only few complications because the depth of tissue destruction is limited to 3 mm. Pain is unusual and hemorrhage is negligible.

HeLP: In the hemorrhoidal laser procedure operation, a Doppler probe was inserted into the anal canal through a dedicated disposable proctoscope to identify the terminal branches of superior hemorrhoidal arteries approximately 3 cm above the dentate line. Five pulsed laser shots were delivered to each identified artery through the proctoscope to close the terminal branches. The procedure was repeated for each artery through clockwise rotation of the proctoscope. Absence of a Doppler signal after treatment confirmed arterial coagulation.

This technique was chosen in case of grade II or III hemorrhoids with incomplete mucosal prolapse.

Cryotherapy This technique has been abandoned because of the big pain and profuse discharge caused.

4.2.2. Haemorrhoidectomy

There are two varieties of haemorrhoidectomy, open and closed. The indication is III and IV degree of haemorrhoid.

Closed hemorrhoidectomy, which was popularized by Ferguson, has the aim to remove as much internal haemorrhoid as possible and to close the wound in order to avoid stenosis and minimize postoperative discharge.

Ferguson technique With the patient in lithotomy position, exposure is obtained by a Hill Ferguson retractor. Haemorrhoidal excision is performed with diathermy. The intraanal mucosal wound and skin are completely closed with an absorbable running suture of vicryl 3/0.

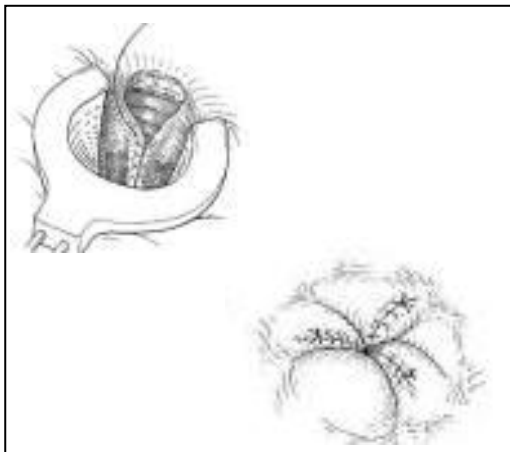


Fig. 5 (Ferguson, 1959)

Parks technique Parks described submucosal hemorrhoidectomy in 1956. A longitudinal incision is made along the mucosa over each haemorrhoid and the anodermon either sides to create flaps to expose the underlying hemorrhoidal tissue, which is then removed. At the apex of each wound the pedicle is ligated. The mucosa is closed.



Fig. 6 (Parks, 1956)

Open hemorrhoidectomy is based on the technique described by Milligan in 1937 and known as the Milligan Morgan operation.

Milligan and Morgan Technique In the M&M technique, the three major haemorrhoidal vessels are ligated and excised. In order to avoid stenosis, three pear-shaped incisions are left open, separated by skin and mucosa bridges.

Complications: Pain, hemorrhage, delayed healing, formation of abscess or anal fissure. (4)

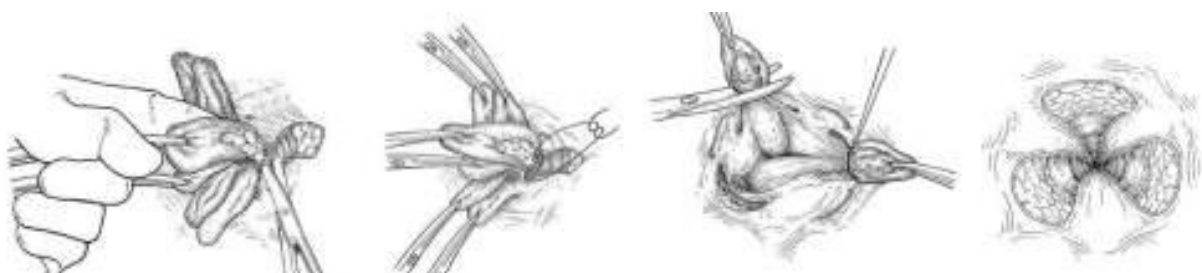


Fig. 7 Milligan & Morgan, 1937

4.2.3 Procedure for prolapse and haemorrhoids (PPH)

In 1998 A. Longo introduced a new surgical treatment for haemorrhoidal prolapse, based on a different therapeutic concept in respect to traditional surgery, such as Milligan Morgan or Ferguson technique. Infact the haemorrhoids are not removed and the aim of the operation is to restore the haemorrhoidal plexus to its original anatomic position, preserving the hemorrhoidal cushions, by the use of staplers.

PPH The Stapler Haemorrhoidectomy is performed according to the technique described by Longo (9). After an anal canal lubrication, the circular anal dilator, equipped with the obturator, is introduced with small circular movements, obtaining a reduction of the prolapse, anal skin and, partly, of the rectal mucosa. After obturator removal, the prolapsed mucous membrane falls into the dilator lumen. The next step is the purse-string suture anoscope introduction through the dilator. Rotating the anoscope, a purse-string suture with 2-0 polypropylene around the entire anal circumference, approximately 2 to 3 cm above the dentate line, is performed. It includes only the rectal mucous and the submucous membrane. The haemorrhoidal circular stapler is completely opened. Then, its head is introduced and positioned beyond the purse string, which is then tied with a closing knot. The ends of the suture are knotted externally. With traction on the purse string, the prolapsed mucous membrane is pulled into the casing of the circular stapling device. In female patients, the posterior vaginal wall is checked to avoid entrapment in the agraphes line. The

stapler is screwed on and fired to excise a ring of mucosa and submucosal and then examined by anoscopy. We usually put on the resection line additional absorbable sutures, in order to obtain an accurate haemostasis and an additional prolapse lifting.

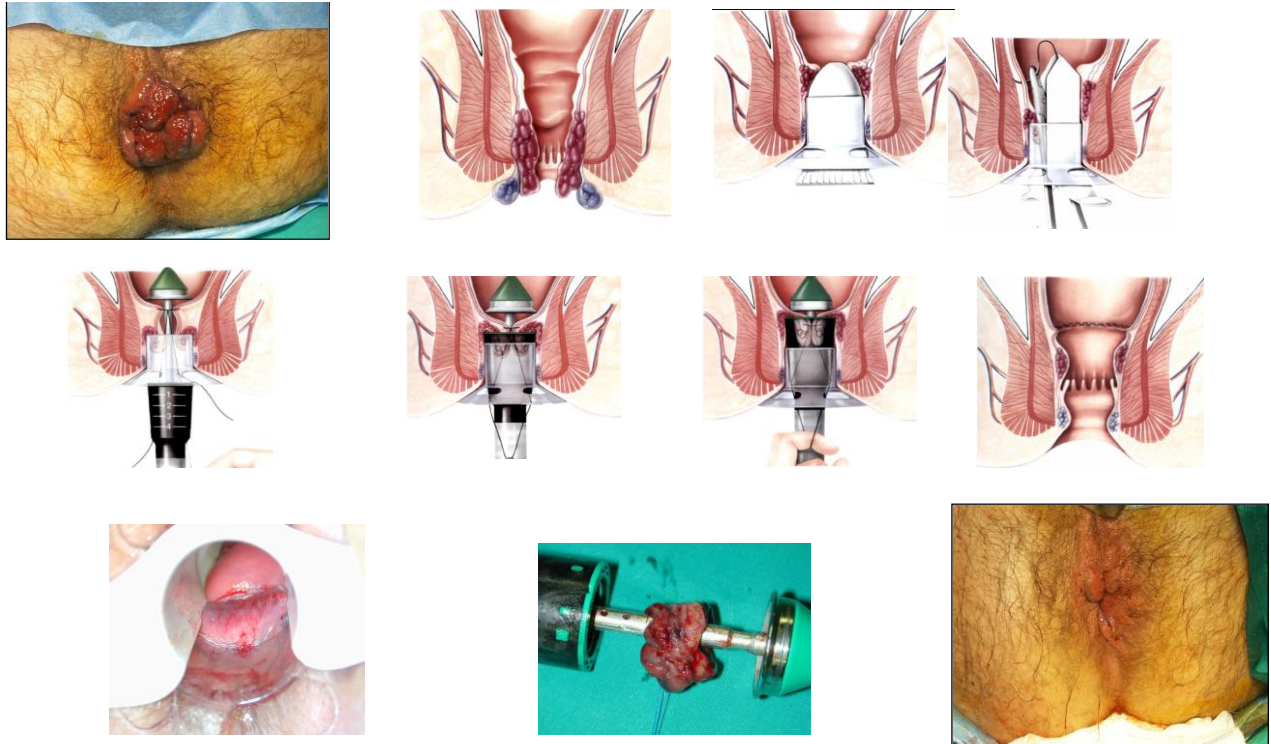


Fig. 8

DSPPH The procedure typically involves the sequential use of two conventional PPH circular staplers, such as those used during prolapse and haemorrhoidectomy procedures. An anterior and posterior full-thickness rectal wall resection is created, and the intended result is a circumferential transanal resection of the rectum.

Before the procedure, the patient is given an enema and begins antibiotic prophylaxis.

The patient is placed in the lithotomy position. An initial examination is undertaken

to confirm the presence and extent of the internal rectal prolapse and rectocele and also to confirm the absence of coexistent pathology. Circular anal dilator is inserted into the anal canal and maintained secured to the perianal skin with four radial stitches on the perianal skin (anterior, posterior, left and right).

Three 2-0 prolene purse-string sutures are placed at the apex of the prolapse at 10, 12, and 2 o'clock traversing the mucosa, submucosa, and rectal muscle wall over half the rectal circumference.

The first PPH-01 stapler is inserted, and the posterior rectal wall is protected with a spatula. The ends of sutures are delivered through the specific holes of the stapler, and tension is applied to prolapse into the stapler housing, making sure that the posterior vaginal wall had not been incorporated; the stapler is closed and fired. By the same procedure, two semi-circumferential purse-string sutures and a second PPH-01 stapler are performed on the posterior rectal wall. Hemostatic stitches with full-thickness 2-0 Vicryl stitches are used to control bleeding from staples line. All surgical specimens obtained from procedure are sent for histological examination.

4.2.4 New techniques and new devices

In case of a very large or asymmetrical prolapse we have been performing over the last two years the single stapler parachute technique (SSPT). The SSPT allows with the use of only one stapler a bigger resection of the prolapse in terms of weight, volume and length and, when required, an asymmetrical resection. It is possible, thanks to the application of traction stitches instead of a purse string.

In case of large prolapse a limit can be the discrepancy between the capacity of the case of the stapler and the amount of prolapse to be removed.

New circular staplers CPH (Circular Stapler for Prolapse and haemorrhoids), produced by Chex Healthcare and defined according to the size CPH 32 and 34, have been recently introduced.

They have some interesting features: the case of high capacity that allows to accommodate a greater amount of prolapse compared to the case of PPH; the presence of 4 longitudinal grooves instead of 2 for the passage of the puller wires of the prolapse; a higher number of agraphes that reduces incidence of dehiscence and bleeding. Two different CAD included in the kit, the classic circular and one with anterior and posterior wings, incomplete at the sides, suitable for narrow basins with close ischial tuberosities. wings on the knob that allow a more ergonomic screwing.

Another new stapler is the **COVIDIEN EEATM Haemorrhoid and Prolapse Stapler**: The set optimizes visibility of the subject's tissue and ease of placing the

pursestring with a proprietary Anoscope Kit, and enhanced consistency in tissue capture and visibility with the Detachable Anvil. The Detachable Anvil assembly provides new levels of tissue visibility and access. The surgeon can see and assess the tissues that will be resected before closing and firing the instrument. The three Anchor Points on the Center Rod eliminate the need to fish the pursestring sutures through the instrument and eliminate the concerns of variable finger tensioning. That depends on how much prolapse you want to resect. The Detachable Anvil design enables you to assess the amount of prolapse to be resected before it is captured in the instrument shell. After assessing the amount of prolapse necessary for resection, select the anchor point that would provide the right amount of tissue resection for the individual patient. The mucosal and submucosal tissues resected in a Hemorrhoidopexy are generally thin tissues where a 3.5mm staple may be more appropriate to create an optimal anastomosis. Covidien also offers a 4.8mm stapler for more extensive tissue resections where a 3.5mm staple would be insufficient. The gradients serve as a guide to enable the surgeon to judge approximately how deep the instrument is being inserted. The scale of the numbers is centimeters. The Dilator has been matched in size to the Anoscope and will dilate further into the rectal cavity for greater visibility of the underlying anatomy.

CSC33 of the SEDA SpA has similar features.


| | PPH 01 | PPH 03 |
|---|---|--|
| |  |  |
| NUMERO PUNTI | 28 | 28 |
| DIMENSIONE PUNTO | 5.5mm(GAMBA) 4.0mm(CORONA) | 4.0mm(GAMBA) 4.0mm(CORONA) |
| ALTEZZA PUNTO CHIUSO (RANGE DI CHIUSURA) | 1.0mm-2.5mm | 0.75mm-1.5mm |

Fig. 10



Fig.11



Fig.12

4.3 THD (Transanal hemorrhoidal dearterialization)

The THD is a minimally invasive procedure. It does not cut or remove any haemorrhoidal tissue, hence post-operative complications are significantly reduced compared to haemorrhoidectomy.

Methods: THD, an ambulatory procedure, employs a specially designed proctoscope coupled with a Doppler transducer to allow identification and suture ligation of the hemorrhoidal arteries.

During the THD procedure, the blood-supplying arteries of the haemorrhoid are precisely located with a fine, specially designed proctoscope coupled with a Doppler ultrasound probe.

Each of these arteries is then sutured through a small operating window of the same proctoscope. As the procedure is carried out in the area above the dentate line (an area without sensory nerves), the patient doesn't feel any stitches during or after the intervention. In case of prolapsed haemorrhoidal cushions (3rd and 4th degree haemorrhoids), a running suture with a few stitches is applied to the prolapsed piles.

The aim is a firmer adhesion of the mucosa to the deep layers of the rectal wall.

Complications: may be bleeding and urge to defecate but these symptoms gradually disappear.

4.4 DOPPLER-GUIDED HAEMORRHOID ARTERY LIGATION (HAL)

Doppler-Guided Haemorrhoid Artery Ligation (HAL) involves the use of a doppler to identify the arterial vascular pedicle, which is then tied off with a stitch. This reduces blood flow to the haemorrhoid, which over time shrinks the size of the haemorrhoid. It is suited for internal haemorrhoids and has the benefit of being minimally invasive (10).

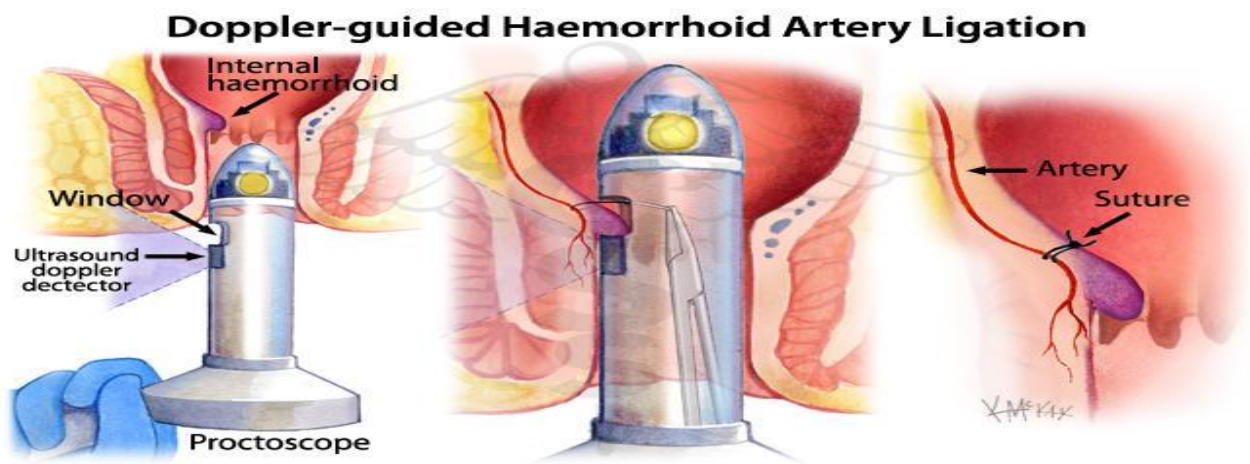


Figure 9. Doppler-Guided Haemorrhoid Artery Ligation (HAL)

5. HAEMORRHOIDAL DISEASE RECURRENCE AFTER STAPLED PROLAPSECTOMY: REVIEW OF THE LITERATURE

Before Longo proposed his pioneering technique in 1998 (9), the M&M was the most widely used and accepted procedure for haemorrhoidectomy. However, the SH introduction, which seemed to provide less postoperative pain, reduced hospital stay and faster return to work; numerous trials have been conducted to determine which of the two techniques was more effective. The comparison between the trials is not easy because some trials do not specify the degree of haemorrhoids treated, and only a few studies have a follow-up long enough to define significant results. Previous studies considered patients with second- and third-degree haemorrhoids (12), patients with third- and fourth-degree haemorrhoids (13-16), patients with second-, third- and fourth-degree haemorrhoids (17) and patients with fourth-degree haemorrhoids (13, 18, 19). Moreover, in two further studies (20,21), there is no reference to any specific degree of haemorrhoids. Mostly, in the short term, all trials showed that SH, if compared with the M&M, reduces the length of the hospital stay, thus providing a quicker recovery and less postoperative pain (12, 22). Most of the trials have a short follow-up (13, 19, 23,24). Those papers based on a longer follow-up highlighted that SH, again compared with conventional surgeries, is associated with a higher long-term risk of haemorrhoid recurrence, with a higher likelihood of longterm symptom recurrence and with the need for additional treatments (15, 25,26). Several studies have recently reported a higher percentage of haemorrhoid

recurrence after SH (until 10%), especially in patients with fourth degree Hs (8,26–32). Our surgical team has been adopting, since its early introduction in 1998, the Longo technique. At the beginning of our experience, we applied this technique for the treatment of Hs of second, third and fourth degree with good results in terms of less postoperative pain, faster return to work and shorter hospital stay. Nevertheless, the long-term evaluation of our results showed a higher rate of recurrence in patients with fourth-degree haemorrhoids. Therefore, we regard the SH as a safe and an effective treatment for Hs, although a rigorous selection of patients is recommended. Furthermore, we have to consider that by applying the SH technique, there is the risk of intraoperative and immediate postoperative complications, such as closing or perforation of the rectum, pelvic sepsis and mechanical circular suture dehiscence.

6. HYPOTHESIS ON PREDICTIVE FACTORS OF HAEMORRHOIDAL DISEASE RECURRENCE AFTER STAPLED PROLAPSECTOMY

To prevent recurrence is important to evaluate the predictors of recurrence. A possible risk factor is the use of PPH in case of irreducible prolapse. The long-term evaluation of our results showed a higher rate of recurrence in patients with fourth-degree haemorrhoids, treated by PPH. Therefore, we regard the SH as a safe and an effective treatment for Hs, although a rigorous selection of patients is recommended. According to our experience, the Longo technique is recommended for the treatment of Hs of second- and third degree. In second- and third degree, however, the M&M can also be applied with good results. We believe, however, that in case of irreducible prolapse the M&M is preferable. (8) .

In addition surgeon must be able to apply the proper technique to the appropriate and specific indications and to tailor the operative management to the individual patient's need. Commonly increased surgical experience is associated with a trend towards lower recurrence rates.

S. Festen, H. Molthof and al. (33) identify patient-related and perioperative predictors associated with persisting prolapse and prolapse recurrence after PPH. They noticed that a surgery duration ≥ 25 min was associated with persistence of prolapse, maybe because it may reflect a more complex surgical situation and thus lead to a poorer outcome after PPH. Another factor detected was the absence of

muscle tissue in the doughnut-shaped specimen. The presence of some muscle tissue along with mucosa, instead of only mucosa, means a more extensive resection.

On the contrary, Ohana et al. (34) observed no difference on the recurrence rate with respect to the presence or absence of muscle tissue in the resected specimen.

One more important factor that may be correlated with early failure is the height of the stapler line in relation to an anatomic marker, like the anal verge or dentate line.

If the positioning of the stapler line is too high above the apex of the haemorrhoidal complex, it will not lift the haemorrhoidal complex enough. On the other hand, if the stapler line is too close to the anoderm, can cause postoperative pain and possibly more faecal urgency.

A reason can be found in an insufficient mucosa removal, an incomplete mucosa lifting or in an asymmetry of the rectal prolapse, which the PPH may not completely correct (35,36).

7. MATERIALS AND METHODS

We performed a retrospective study on 69 patients, affected by recurrent or residual prolapse after a primary operation of stapled haemorrhoidopexy (58 patients treated with a single PPH -PPH- and 11 with a double stapling procedure -DSPPH-) and undergoing reoperative surgery for the treatment of recurrence (Table I). This cohort of patients was recruited between January 2005 and January 2011 in three Italian national reference centers for proctological surgery (Pisa, Rome and Pordenone) and was retrospectively analyzed.

Thirty-five patients were females and thirty-four were males. The mean age was 50 (range, 25–74) years. The clinical history of all of these patients was carefully studied and informations about proctological history were indicated.

In particular we investigated:

- The first clinical onset of haemorrhoidal disease, that called for the primary operation, reporting which symptoms were prevalent among hemorrhoidal crisis and/or bleeding and/or prolapse -degree according to the Goligher's classification-
- the first operation: PPH or DSPPH
- the well-being interval between the operation and the recurrence of the symptomatic prolapse
- the clinical onset of haemorrhoidal recurrence, reporting which symptoms were prevalent among hemorrhoidal crisis and/or bleeding and/or prolapse

- intraoperative findings, describing the prevalent anatomical pattern among: residual or recurring hemorrhoidal prolapse with single or multiple piles - ≤ 3 -, mobile or fixed circumferential prolapse
- second operation: PPH, DSPPH or excisional surgery- Milligan Morgan (MM), whatever performed-
- outcome: excellent, good, sufficient, poor.

After surgical treatment, complication symptoms and hospital stay were recorded.

The follow-up was performed by ambulatory visits after a week, 4 weeks and 6 months from the surgical treatment and then yearly.

The outcome of reintervention was defined respectively: - “positive”, when the patient was either cured or improved as far as the symptoms are concerned, together with either no abnormality or very minor lesions at the surgeon’s examination.

- “negative”, when symptoms and clinical findings either were only minimally improved, remained unchanged or worsened.

8. RESULTS

The symptoms of primary onset had been: haemorrhoidal crisis in 17 patients, bleeding in 5 patients, prolapse in 45 patients and finally both prolapse and bleeding in 2 patients. (Table 2)

58 out of 69 patients had undergone a PPH at the primary operation and 11 out of 69 a DSPPH.

In 23 patients (34%) primary surgery had been performed in other Hospitals.

Prolapse degree according to Goligher's classification was: II degree in 15 cases, III degree in 36 cases, IV degree in 18 cases (Table 3).

The mean time of recurrence was 18 months (range 2-42 months) in the 58 patients, who had undergone a PPH and 12 months (range 2-42 months) in those who had undergone a D-PPH (Table 4).

All operations were performed at least six months after the onset of the recurrence's symptoms. Only two patients underwent a reoperation after about two months for a haemorrhoidal thrombosis.

The clinical onset of recurrence appeared in the form of: haemorrhoidal crisis in 12 patients, bleeding in 8 patients, recurrent prolapse in 29 patients and residual prolapse in 20 patients (Table 5).

Intraoperative findings in the 58 patients, who had undergone a previous single PPH, were: 30 recurrent or residual prolapsed haemorrhoids with single or multiple piles- ≤ 3 - (17 residual and 13 recurrent), 4 congested haemorrhoids, 18 mobile prolapse, 6 mobile prolapse associated with thrombosed haemorrhoids.

In these cases the operations chosen were: 34 excisional surgery, 12 PPH, 6 DSPPH, 6 PPH plus excisional surgery.

Intraoperative findings in the 11 patients, who had undergone a previous DSPPH, were: 6 recurrent or residual prolapsed haemorrhoids with single or multiple piles- ≤ 3 - (3 residual and 3 recurrent), 2 congested haemorrhoids, 2 mobile prolapse, 1 mobile prolapse associated with thrombosed haemorrhoids.

In these cases the operations chosen were: 8 excisional surgery, 1 PPH, 1 DSPPH, 1 PPH plus excisional surgery.

Table 6 and 7 describe the intraoperative reports after a previous PPH and after a previous DSPPH and the operations applied.

The preoperative and postoperative management (use of painkillers drugs, antibiotics and laxatives), the kind of anaesthesia -general or local- of the patients undergoing reoperative surgery for recurring haemorrhoids was similar to that applied in the first operation.

The mean operative time was comparable to that of the primary surgery in patients treated with PPH or DSPPH or excisional surgery.

The hospital stay and return to full activity were similar to the primary operations.

Postoperative complications after a “stapled” operation (PPH, DSPPH) and after a “non stapled” operation are summarised in Table 8. They were comparable to those relative to primary surgery.

In the “stapled” group bleeding occurred in 3 patients.

In one case the bleeding was controlled by introducing a Foley catheter into the anorectum and by inflating its balloon at 30-40 cm³, one case was coped with a local application of a hemostatic device, one case required a surgical revision under anaesthesia.

In the “non stapled” group, instead, bleeding occurred in 1 patient and required a surgical revision.

2 patients in the “stapled” group and 2 patients in the “non stapler” group complained of urgency but this symptoms solved spontaneously one month after operation.

Postoperative pain was under control in both group thanks to the use of the routine FANS usually employed. However, there were 2 patients in the “stapled” group and 2 patients in the “non stapler” group, who reported persisting anal pain in the 2 weeks following operation and required further use of painkillers. After this time, the pain symptoms disappeared in these three patients and continued in the other one. The mean follow-up after reoperative surgery resulted in 40 months (range, 23-96)

No cases of second recurrence occurred in the treated patients.

The outcome assessed on the basis of the clinical examination, as well as at the opinion expressed by the patients was excellent in 34 patients, good in 23 patients, sufficient in 8 patients, poor in 4 patients because two considered their symptoms (bleeding and congested haemorrhoids) unchanged, one reported a worsening of constipation and another complained of persistent pain.

Table 9 summarises the outcome.

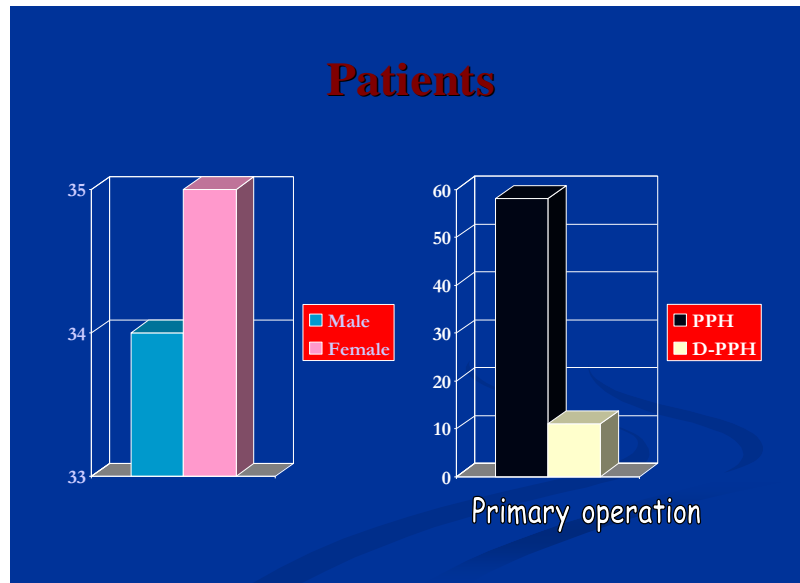


Table 1

| Symptoms of | primary onset |
|----------------------|----------------------|
| Haemorrhoidal crisis | 17 |
| Bleeding | 5 |
| Prolapse | 45 |
| Prolapse+Bleeding | 2 |
| Total | 69 |

Table 2

Goligher degree at the primary operation

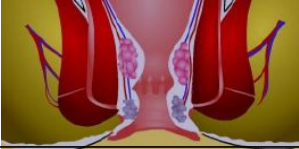
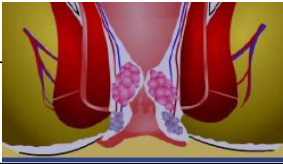
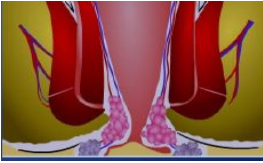
| Goligher degree | Number of patients | |
|-----------------|--------------------|---|
| I | 0 |  |
| II | 15 |  |
| III | 36 | |
| IV | 18 |  |

Table 3

Mean time of recurrence

| | Post PPH | Post DSPPH | TOT |
|---------------------|---|---|---------------|
| 0-3 months | 8 | 1 | 9 |
| 4-6 months | 7 | 3 | 10 |
| 7-12 months | 16 | 4 | 20 |
| 13-24 months | 13 | 2 | 15 |
| 2-5 years | 14 | 1 | 15 |
| Mean Time | 18 months (Range 2-42 months) | 12 months (Range 2-42 months) | 69 pts |

Table 4

Symptoms of recurrence

| | |
|----------------------|-----------|
| Haemorrhoidal crisis | 12 |
| Bleeding | 8 |
| Recurrent Prolapse | 29 |
| Residual Prolapse | 20 |
| Total | 69 |

Table 5

| INTRAOPERATIVE FINDINGS POST a previous single PPH | Patients 58 | | OPERATION APPLIED |
|---|----------------------------------|---|--------------------------|
| Prolapsed haemorrhoids with single or multiple piles ≤ 3 (Recurrent or residual) | 30 (17res. h.+ 13 rec. h.) | → | 30 Excisional surgery |
| Congested Haemorrhoids | 4 | → | 4 Excisional surgery |
| Mobile Prolapse | 18 | → | 12 PPH 6 DSPPH |
| Mobile Prolapse + Thrombosed Haemorrhoids | 6 | → | 6 PPH+excisional surgery |

Table 6

| INTRAOPERATIVE FINDINGS POST a previous DSPPH | Patients 11 | | OPERATION APPLIED | |
|---|--------------------------------------|---|------------------------------|--|
| Prolapsed haemorrhoids with single or multiple piles ≤ 3 (Recurrent or residual) | 6 (3res. h.+ 3 rec. h.) | → | 6 Excisional surgery | |
| Congested Haemorrhoids | 2 | → | 2 Excisional surgery | |
| Mobile Prolapse | 2 | → | 1PPH 1DSPPH | |
| Mobile Prolapse + Thrombosed Haemorrhoids | 1 | → | 1PPH+excisional surgery | |

Table 7

| Postoperative complications | “Stapled group” | “Non stapled group” |
|-----------------------------|-----------------|---------------------|
| Pain | 2 | 2 |
| Bleeding | 3 | 1 |
| Urgency | 2 | 2 |

Table 8

Outcome

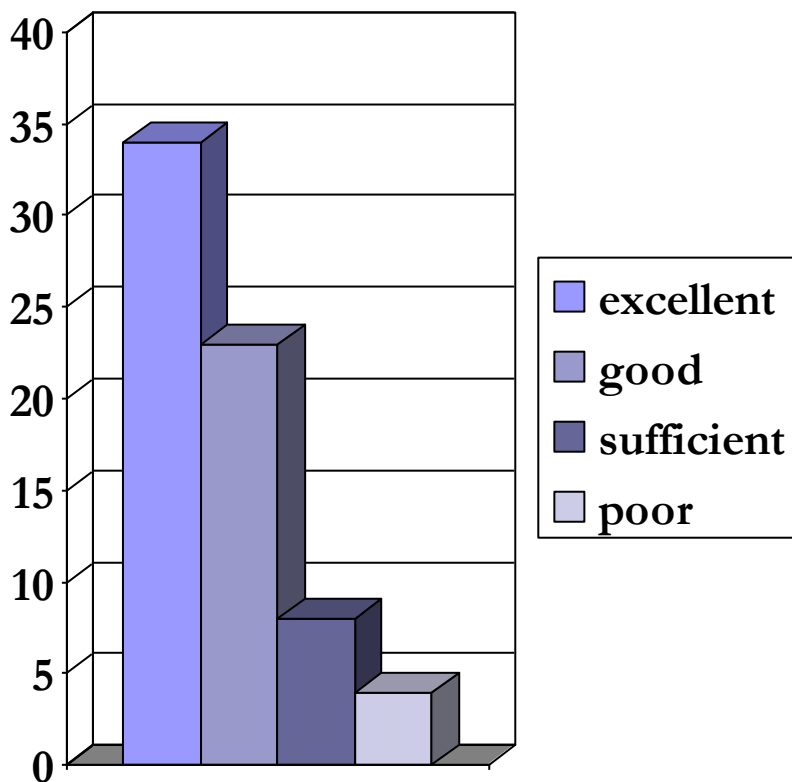


Table 9

9. DISCUSSION

The percentage of symptomatic prolapse -persistent and recurrent- after stapled procedures varies widely in the several clinical trials described in the literature, ranging from a minimum of 2% to the worst results of 53.3% (8, 15, 26-32).

Reoperation rates after PPH, whereas, have been reported between 7 and 14% (37-40, 42). Our attention is dedicated to the study of recurrence after stapled procedures. We examined the clinical history of patients with haemorrhoidal recurrence and focused on the possible common symptoms between the primary onset and the recurrence of prolapse. It was observed a correlation between the symptoms of primary onset and recurrence. I.e. patients who had been operated because of a haemorrhoidal crisis, experienced the recurrence with a haemorrhoidal crisis almost ever.

The disorders resulting from the “prolapse” (perineal heaviness, wet anus, itching, discomfort during defecation) were the most represented.

The presence of a residual or recurrent prolapse can be derived or from an incorrect indication to surgery or from an insufficient resective approach. Alternatively it may be due to an operation, which had been previously carried out incorrectly with an insufficient pull of the prolapsed tissue in the operative case. The assessment of the mobility of the prolapse allows to shed light on the reasons for the recurrence. If the prolapse is mobile, it is possible that the first operation was not properly performed or that the indication was uncorrect. If the prolapse is fixed, primary surgery was probably not the main cause of it.

In case of recurrence, symptoms guide to the decision of a reoperation and the surgical technique is determined according to the intraoperative report, that in almost equal percentage is divided between the mobility of the prolapse and the presence of recurrent and/or residual haemorrhoidal prolapsed piles.

In the case of a mobile prolapse the choice was a transrectal resection with stapler (PPH or DSPPH, depending on the amount of the prolapse that should be resected).

On the contrary, in the case of a fixed prolapse or single or multiple piles ≤ 3 , the choice should be a traditional surgery (Milligan Morgan, whatever performed). In case of multiple piles ≥ 3 the choice is a transrectal resection with stapler (PPH or DSPPH, depending on the amount of the prolapse that should be resected). A PPH combined with Milligan Morgan Haemorrhoidectomy is applied in case of a mobile prolapse with some residual pile.

Thus, intraoperative evaluation is crucial and so is the knowledge of all the surgical options, because they only allow the surgeon to suitably decide, without prejudices, between an excisional surgery and a restapled procedure.

A second excision surgery or a re-stapled haemorrhoidopexy have the same difficulties of a primary operation and are not more different from that one. The previous anastomosis (usually comprised in the second resection) is not an obstacle to the realization of the purse string for the second stapled procedures.

All operations were performed at least six months after the onset of the recurrence's symptoms. Only two patients underwent a reoperation after about two months for a

haemorrhoidal thrombosis. We have proved that after this six months' period a re-stapler procedure can be safely performed.

The results of this second operation were brilliant, with a limit of 40 months follow up.

Our study shows that the use of stapler in the treatment of recurrence is feasible, safe and has a good appreciation by the patient, with no more pain or longer hospital stay. No serious complications have been reported.

Festen S et al studied the feasibility and efficiency of a second PPH in case of persistent or recurrent prolapse and concluded that it has a high success rate with no more morbidity if compared to a primary PPH (41). On the contrary, White I et al assessed that a second PPH can be performed safely without risk of complications but it is associated with more pain and longer recovery time (42).

Starting from the analysis of recurrence, after determining the procedures for its treatment, it is appropriate to define the surgical strategy to avoid or minimize the risk of a new recurrence. The primary operation should be calibrated on the effective amount of the prolapse. So well and more in the second operation.

In the first decade after Longo proposed his technique only staplers, such as PPH 01 and PPH 03 produced by Ethicon, Johnson & Johnson, were available. A limit of these staplers can be the discrepancy between the capacity of the case and the amount of prolapse to be removed.

The double stapled technique was, later, introduced to get the possibility to remove more prolapse and obtain an excellent and definitive haemorrhoidopexy.

New circular staplers as CPH (Circular Stapler for Prolapse and haemorrhoids), produced by Chex Healthcare and defined according to the size CPH 32 and 34, EEATM Haemorrhoid and Prolapse Stapler by COVIDIEN and CSC 33 stapler by SEDA SpA have been recently introduced with the aim to realize a larger prolapsectomy with a large suture and a low risk of bleeding. They have two interesting features: the case of high capacity that allows to accommodate a greater amount of prolapse and a higher number of agraphes, that reduces the incidence of dehiscence and bleeding.

Furthermore, a new technique, called “single stapler parachute technique” (SSPT), can be applied, allowing, with the use of only one stapler, a bigger resection of the prolapse in terms of weight, volume and length and, when required, an asymmetrical resection, adapted to the actual amount and shape of the prolapse, with the application of traction stitches, usually six, instead of a purse string.

The foregoing statements demonstrate how these techniques are constantly evolving and thus require a periodic critical evaluation of the results.

10. CONCLUSIONS

Avoiding or minimizing the possibility of a recurrent prolapse should be demanded to a well realized primary operation, calibrated on the effective amount of the prolapse (using single or double stapled technique, instruments with larger case, parachute technique or with an immediate, intraoperative correction of persistent prolapse).

However a surgeon should be able to deal with the patient who has already a residual or recurrent disease.

A complete clinical study with a correct evaluation of the symptoms and a careful intraoperative assessment of the recurrence's features are of primary importance for the choice of the technique to be applied.

The aim of a reoperation is the resolution of the prolapse and of the symptoms, avoiding a second recurrence. Surgeon must evaluate all treatment options and know all kind of techniques.

Re-excisional surgery but also a re-stapled procedure can be safely and successfully realized with the same operating methods of a primary operation, with no more complications or difficulties.

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