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Stapled haemorrhoidopexy vs. Milligan-Morgan haemorrhoidectomy for grade III haemorrhoids: a randomized clinical trial

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SUMMARY: **Stapled haemorrhoidopexy vs. Milligan-Morgan haemorrhoidectomy for grade III haemorrhoids: a randomized clinical trial.**

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The aim of this double blind randomized clinical trial was to compare the short-term and long-term outcomes of stapled haemorrhoidopexy (SH group) performed using a circular stapler with that of the Milligan-Morgan haemorrhoidectomy (MMH group). A total of 79 consecutive patients with grade III haemorrhoids were randomized into two groups treated with SH (n. 39) and MMH (n. 40). The outcomes of the procedures were evaluated postoperatively and over a follow-up period of minimum 2 years.

Patients undergoing the SH procedure showed greater short term advantages than MMH group with reduced pain, shorter length of hospital stay, earlier return to work and high patient satisfaction. Long-term follow-up has indicated more favourable results in MMH group in terms of resumption of symptoms with absence of residual prolapse and risk of recurrence of prolapse. At two years follow-up recurrent prolapse was confirmed in six patients of SH group (13%) whereas in none of the MMH group. At six months follow-up there weren't significant difference in the mean satisfaction score for the two groups. At two years the mean satisfaction score was higher in the MMH group vs SH group. Seven patients in the SH group needed a reoperation whereas none in MMH group.

From January 2009, in our Surgery Unit the patients are always informed about a higher recurrence rate of SH and we perform this technique only when the patient choices to accept this risk to take advantage of the short-term benefits of this procedure.

RIASSUNTO: **Emorroidopessi con suturatrice meccanica versus emorroidectomia sec. Milligan-Morgan nelle emorroidi di III grado: studio clinico randomizzato**.

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Lo scopo di questo studio clinico randomizzato in doppio cieco è stato quello di comparare i risultati a breve e lungo termine dell'emorroidopessi effettuata con suturatrice meccanica circolare (SH) versus l'emorroidectomia sec. Milligan-Morgan (MMH). 79 pazienti con emorroidi di terzo grado sono stati randomizzati in 2 gruppi trattati con SH (39 casi) e con MMH (40 casi). I risultati delle procedure sono stati valutati nel periodo postoperatorio con un follow-up di almeno 2 anni.

Nel breve periodo i pazienti operati con SH hanno mostrato dei maggiori vantaggi rispetto al gruppo MMH rappresentati da minor dolore, tempo di ricovero più breve, ritorno al lavoro più precoce ed un grado di soddisfazione maggiore. I risultati a lungo termine hanno mostrato migliori risultati nel gruppo MMH con risoluzione della sintomatologia, assenza di prolasso residuo e minore incidenza di recidiva del prolasso. Ad un follow-up di sei mesi non c'erano significative differenze tra i due gruppi. Ad un follow-up di due anni in sei pazienti si è avuta una recidiva del prolasso nel gruppo di SH (13%) mentre in nessuno dei pazienti del gruppo MMH. Dopo due anni dall'intervento 7 pazienti del gruppo SH necessitarono di un reintervento, nessuno del gruppo MMH.

Dal gennaio 2009, nella nostra UO i pazienti vengono sempre informati circa la più alta incidenza di recidive della SH e noi attuiamo questa tecnica solo se il paziente accetta tale rischio pur di avvantaggiarsi dei benefici a breve termine di tale procedura.

KEY WORDS: Stapled haemorroidopexy - Milligan-Morgan haemorrhoidectomy.
Emorroidopessi con suturatrice meccanica - Emorroidectomia sec. Milligan Morgan.

Introduction

Haemorrhoids are one of the most common anorectal disease affecting 5 percent of the general population (1). The Milligan-Morgan technique remains the most widely practiced procedure for the treatment of the symptomatic grade III or grade IV haemorrhoids. This tech-

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nique is not without complications, including bleeding (2) and late anal stricture (3). Stapled haemorrhoidopexy (SH) is a new procedure first described by Longo in 1998 (4) as alternative to conventional haemorrhoidectomy and has become increasingly popular in the last years as the treatment of choice for third- and fourth-degree piles.

SH offers several advantages over conventional techniques of haemorrhoidectomy, including reduced postoperative pain (5-8), reduced hospital stay, earlier recovery time and quick return to work (6, 9). This technique reduces the intra-operative time too. The effectiveness of the Longo procedure as a definitive cure of haemorrhoidal symptoms is still unclear.

The present double blind randomised clinical trial was designed to determine whether SH or conventional MMH is superior for the management of haemorrhoids in patients with grade III haemorrhoids followed for a period of minimum two years.

Patients and methods

The study was a double-blind, randomized clinical trial.

The protocol was approved by the Hospital ethical committee and patients gave written informed consent to participate in the study.

Between January 2005 and April 2007, we enrolled 80 consecutive patients with grade III haemorrhoids.

Demographic parameters, symptoms and bowel habits were similar between groups (Table 1). To improve comparability between the two techniques, only patients with symptomatic grade III haemorrhoids were recruited.

Patients with the following conditions were excluded: 1) acute thrombosed piles, 2) other concomitant anal disease (fissure, abscess, fistula, incontinence or inflammatory bowel disease), 3) previous anal surgery, 4) haematological disorder, 5) ongoing treatment with oral anticoagulants, 6) American Society of Anaesthesiologist (ASA) grade III or IV.

Patients over the age of 50 years underwent colonoscopy before haemorrhoidectomy.

Patients were admitted on the day of operation and were assigned randomly to one of two groups: 1) 40 stapled haemorrhoidopexy (SH) or 40 Milligan-Morgan haemorrhoidectomy (MMH). All the operations were performed by the same surgeon (C.A.). To avoid a learning curve effect, the surgeon had performed 100 SH before the trial. All the operations were performed without bowel preparation (only a enema was given three hours before the operation), under spinal anaesthesia and with patient in the lithotomic position. A short term prophylactic antibiotics was given two hours before the procedure.

The SH were performed with the PPH 01 stapling gun (Ethicon Endosurgery Johnson & Johnson Cincinnati OH) according to the technique described by Longo (4). Actively spurting vessels were suture-ligated (00 polyglactin). An anal tampon was left in the rectum at the end of the procedure for detect a possible haemorrhage and it was removed 4-5 hours after the procedure.

Conventional haemorrhoidectomy was performed according to Milligan-Morgan technique (10). The internal and external piles were dissected entirely up to the anorectal ring with scissors and the pedicle was interrupted after suture-ligation. Haemostatic dressing was left in the anal canal at the end of the procedure for 4-5 hours.

Normal diet was allowed and a bulk laxative was prescribed after surgery.

The patients undergone to MMH procedure were instructed to irrigate the anal wounds with antiseptic solution at least twice a day and after every bowel movement.

A 10-cm visual analog scale from 0 (no pain) to 10 (the worst pain imaginable) was given to every patients to evaluate the intensity of pain post-operatively. The pain score was recorded daily until the first follow-up visit (10 days after operation) and the number of intramuscular analgesic injections given during hospitalization and after hospital discharge was recorded.

Data were obtained through telephone interview after patient discharge from the hospital by an independent observer who was unaware of operation performed. Other information, including day of first bowel movement after surgery and the time it took to return to the job, was also recorded. The continence was scored on scale of 1 to 20 according to the incontinence score system of Jorge and Wexner (11).

After the first follow-up visit (ten days after operation), clinical evaluation was performed at 1 month, 6 months and then every year.

In addition, the patients were evaluated by use of a standardized questionnaire (12) (Fig. 1) at 6 months, one year and then every year after the procedure.

Finally, the physician at 6 months and then every year asked if the symptoms that the patient had before surgery were relieved, ameliorate, unchanged or worsened.

TABLE 1 - DEMOGRAPHIC DATA.

Parameter	SH	MMH
Patients, n.	40	40
Sex ratio	23/17	25/15
Median age, years (range)	45 (20-71)	48 (24-74)

Results

A total of 79 patients (SH procedure 39 and 40 MMH) completed randomization and returned for at least two years follow-up. The median follow-up was 35 months (range 24-51 months). There was significant difference between the two groups in terms of operating time, hospital stay, pain score, analgesic injections required in the first week after surgery and time for first bowel movement (Table 2).

The mean operating time was significantly shorter in the SH group (25 minutes; range 15-35 minutes) than in the MMH group (38 minutes; range 20-45 minutes).

The pain scores during the first ten days evaluated by VAS were significantly lower in the SH group (2.5; range 2-5) than in the MMH group (6.8; range 3-9).

The time of the first bowel movement was early in the SH group: 1.5 days (range 2-3) vs. 2.5 (range 3-4).

The pain score at the first bowel movement was significantly lower in the SH group at 2.7 (range 1-5) compared to 7.2 (range 1-10) for the MMH group.

The consumption of intramuscular analgesic injections and/or oral analgesic drug during first post-operative week was higher in the MMH group.

TABLE 2 - OUTCOMES.

	SH 39 Median/range	MMH 40 Median/range
Mean operating time, min (range)	25 (15-35)	38 (20-45)
Mean hospital stay, days (range)	1.3 (1-2)	2.5 (1-4)
VAS score (0-10) during the first 10 days, mean (range)	2.5 (2-5)	6.8 (3-9)
First bowel movement, mean days after surgery (range)	1.5 (2-3)	2.5 (3-4)
Mean VAS score at the first bowel movement (range)	2.7 (1-5)	7.2 (1-10)
Analgesic during the first 10 days, mean (range)	10 (4-17)	19 (7-28)
Return to work, mean days after surgery (range)	6 (4-13)	15 (7-23)

The duration of hospital stay was lower in the SH group at 1.3 days (range 1-2) compared to 2.5 days (range 1-4 days).

In the SH group haemostatic sutures were required in 31 patients (77.5%) to control minor staple line bleeding points.

Thirty-one complications occurred in twenty-four patients (Table 3).

Among early complications, post-operative bleeding was observed in 3 cases (7.5%) of the MMH group: two cases suffering from mild post-operative haemorrhage did not require surgical intervention but it was necessary to operate again one patient under spinal anaesthesia 6 hours after the procedure because of a copious bleeding.

It was never necessary to operate again any patient of the SH group for bleeding.

No patient had a residual prolapse immediately after the operation.

Seven male patients (17.5%) in the SH group developed transient urinary retention which was treated with catheterization vs. sixteen patients (40%) in the MMH group.

Four patients (10%) in the SH group had external haemorrhoidal thrombosis that responded to conservative measures.

We have analyzed the answers of the questionnaire at six months, one year and then every year. The Tables 4 and 5 show the clinical results respectively at six months and at two years after procedure.

At six months follow-up there were not significant differences of the outcomes between the two groups.

We draw attention to six patients (15%) in the MMH group with moderate pain during defecation and four patients (10%) in the SH group. Three patients in the MMH group (7.5%) suffered from flatus incontinence whereas only one (2.5%) in the SH group.

1. Do you have bleeding during defecation?
- Not present
- Light
- Moderate
- Severe

2. Do you have Haemorrhoidal Prolapse during defecation?
- Not present
- Light
- Moderate
- Severe

3. Do you have anal pain?
- Not present
- Light
- Moderate
- Severe

4. Do you have urgency?
- Not present
- Light
- Moderate
- Severe

5. Do you have tenesmus?
- Not present
- Light
- Moderate
- Severe

6. Do you have loss of feces?
- Not present
- Light
- Moderate
- Severe

7. Has haemorrhoidal thrombosis occurred since the operation?
- Yes
- No

8. Were the symptoms you had before the surgery
- worsened
- unchanged
- ameliorated
- relieved

Fig. 1 - Standardized Questionnaire modified from Guenin et al (12).

TABLE 3 - EARLY POST-OPERATIVE COMPLICATIONS.

	SH		MMH	
	40 pts	(%)	40 pts	(%)
Haemorrhage, n (%)	0		3	(7.5)
Urinary retention, n (%)	7	(17.5)	16	(40)
External haemorrhoidal thrombosis, n (%)	4	(10)	0	
Anal sepsis, n (%)	0		0	
Reoperation, n (%)	0		1	(2.5)

TABLE 4 - CLINICAL RESULTS SIX MONTHS AFTER PROCEDURE.

Symptoms	SH 39 pts		MMH 40 pts	
	pts	(%)	pts	(%)
Bleeding during defecation	3	(7.5)	2	(5%)
Prolapse during defecation	3	(7.5)	0	
Anal pain during defecation	4	(10)	6	(15%)
Urgency	4	(10)	0	
Tenesmus	2	(5)	5	(12.5%)
Flatus incontinence	1	(2.5)	3	(7.5)
Resurgery	0		0	
Mean satisfaction score (0-3)*	2.6		2.5	

** score based on symptoms after surgery*
0 worsened
1 unchanged
2 ameliorated
3 relieved

Four patients (10%) of the SH group had faecal urgency.

None of the patients complained of liquid or solid incontinence.

The bleeding during defecation was absent in most of the patients.

No patient needed a second procedure for recurrence within the first six months after the procedure although partial residual prolapse was detected in three patients (7.5%) of the SH group vs 0 patients of the MMH group.

After a follow-up of two years the answers of the questionnaire showed a higher rate of bleeding and prolapse in SH group with lesser mean satisfaction score (Table 5).

Seven patients (18%)in SH group complained of the bleeding whereas only one (2.5%) in MMH group. The bleeding was severe and continuous during every defecation in five of seven patients of SH group while was reported as light and sporadic only by patient of MMH group.

TABLE 5 - CLINICAL RESULTS TWO YEARS AFTER PROCEDURE.

Symptoms	SH 39 pts		MMH 39 pts	
		(%)		(%)
Bleeding during defecation	7	(18)	1	(2.5)
Prolapse during defecation	5	(13)	0	
Anal pain during defecation	0		0	
Urgency	0		0	
Tenesmus	0		0	
Flatus incontinence	0		0	
Resurgery	5	(13)	0	
Mean satisfaction score (0-3)*	2.06		2.8	

** score based on symptoms after surgery*
0 worsened
1 unchanged
2 ameliorated
3 relieved

Five patients (13%) of SH group complained haemorrhoidal prolapse during the defecation whereas none patients in MMH group.

Five patients (13%) in the SH group needed reoperation whereas none in MMH group.

Residual prolapse and/or bleeding were the most frequent causes of reoperation.

In three cases we performed repeated stapled reintervention because the patients chose this procedure while in four cases we performed haemorrhoidectomy for partial residual prolapse of the piles.

The mean satisfaction score (Table 5) at two years follow-up was higher in the MMH group vs SH group.

The main preoperative symptoms in SH and in the MMH group were respectively relieved in 66% vs 81%, ameliorate in 28% vs 17%, unchanged in 13% vs 2%; none patient between the two groups had worsening of the symptoms.

Discussion

Pain after conventional haemorrhoidectomy continues to be a major problem.

In the last years the interest of surgeons about the treatment of the haemorrhoids has renewed thanks to the SH described by Longo in 1998 (4). This procedure has been introduced as an alternative to conventional haemorroidectomy and has become increasingly common because it shows a better patient acceptance mainly because results in less pain.

However the effectiveness of SH as a definitive cure of haemorrhoidal disease is still uncertain.

Several randomized trials published have revealed that the results of the SH were less favourable than any type of haemorrhoidectomy in terms of bleeding recurrence (8, 13), residual prolapse (14), recurrent prolapse (6, 8, 13-17) with a high risk of reintervention (8, 14), both skin tags and bleeding (18) or the appearance of new symptoms such as urgency and pain (19).

The controversy is increased because there are other studies or articles based on systematic reviews (9, 13, 20-23) in which similar or better clinical results were obtained in patients treated with SH compared to MMH.

In this study we have evaluated the outcomes of the two procedures post-operatively and over a follow-up period of minimum two years (range 24-51 months).

Our experience has showed that SH is a safe treatment for grade III haemorrhoids with a good short-term patient's satisfaction mainly because it ensures lesser post-operating pain and total elimination of anal wound care. In SH the pain is lesser than MMH because the procedure does not damage the perianal skin and the sensi-

tive anoderm: a direct consequence of this was a significantly shorter length of hospital stay for the SH group and the need for less analgesic intake.

Nevertheless, this technique requires appropriate training to avoid possible severe complications like pelvic sepsis (24), rectovaginal fistulas (25, 26), rectal perforation (26-28) or stenosis (28).

We suggest that the SH should be performed by experienced colorectal surgeons who are familiar with the technique.

Our experience have showed a higher number of patients with post-operative adverse events for MMH group than SH.

Reoperation for early adverse events was required only in one patient (%) of MMH group for haemorrhage and in 0 patients having the SH procedure.

In 31 cases (75.5%) of SH group, it has been necessary to put some hemostatic stitches on the suture line as we are always very careful to treat hemostasis and that's why, to our knowledge, we have never come up with a post-surgery hemorrhagie that needed a reoperation. As well as no patient, from our series, referred persistent anal pain that we think is generally due to a procedural problem like too distal a suture in the anal canal. We have acknowledged it in some of our early patients during all of our skillfull learning.

In the present study 10 % of the patients from SH group complained of fecal urgency at the first follow-up (< six months) whereas none had this problem at subsequent follow-up despite the fact that examination of 92% of the cases showed that histological samples contained some smooth muscles.

In accordance with other Authors, we think that a certain degree of muscle incorporation is inevitable on most of the patients and might even be desiderable for a greater fixation in the anal canal of the suture (29). Erroneously SH is considered an expensive procedure because of the stapler cost that is approximately 400 euro in Italy.

If we consider the shorter hospital-stay and earlier return to work for the patients of the SH group, the economic saving seems to be considerably greater.

Nevertheless a correct analysis of the costs has to consider the outcomes at longer follow-up. The higher rate of recurrences of SH group and the necessity of a reintervention (13% in our series), with the consequent loss of working days, increases considerable the costs for the society at long term.

The SH has shown better results at the mid-short term follow-up while at one year after the procedure, the SH carries a significantly worst results like bleeding and/or prolapse during defecation and higher rate of thrombosis of external haemorrhoidal piles than MMH group.

At the minimum follow-up of two years our study has showed an increase in the recurrence of haemorrhoidal symptoms after SH and need of additional operation compared with MMH.

Finally, at 6 months follow-up when the physician asked if the symptoms that the patients had before surgery were relieved, ameliorate, unchanged or worsened, the answers were the same in both group while at longer follow-up the patient's satisfaction in the SH group decreased and at two years following it was lesser than MMH group.

Conclusion

SH offers greater short term benefits with reduced pain, shorter length of hospital stay, earlier return to work and high patient satisfaction but it is less effective than MMH as a definitive cure of grade III haemorrhoids.

The present randomized clinical trial has indicated more favourable results in terms of resumption of symptoms and risk of recurrence in long-term follow-up for the patients undergone to MMH procedure compared with SH. Therefore from January 2009, in our Surgery Unit the patients are always informed about a higher recurrence rate of SH and we perform this technique only when the patient choices to accept this risk for take advantage of the short-term benefits of this procedure.

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