Mucopexy-Recto Anal Lifting *(Mu-RAL)*: a standardized minimally invasive method of managing symptomatic hemorrhoids, with an innovative suturing technique and the HemorPex System®.

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Abstract

Background. Conservative surgery of hemorrhoidal disease is less painful than traditional hemorrhoidectomy, and mucopexy has less risk of serious postoperative complications than stapled hemorrhoidopexy. The aim of this study was to evaluate the safety and effectiveness of a standardized, modified hemorrhoidopexy with the HemorPex System in patients with symptomatic grade III and IV hemorrhoids.

Materials and methods. Patients were enrolled from May 2013 to Dec 2015 and operated on with the Mu-RAL (Mucopexy-Recto Anal Lifting) technique, based on arterial ligation and mucopexy at 6 locations, using a standardized clockwise/anti-clockwise rotation sequence of the HPS anoscope in the following sequence: 11 o'clock, 1 o'clock, 9 o'clock, 3 o'clock, 7 o'clock and 5 o'clock position.

Follow-up controls were carried out by independent surgeons, as follows: a digital exploration 21 days after the intervention, digital exploration and proctoscopy at 3 and 12 months and repeated at a 12 months interval. Patients who did not strictly follow the postoperative controls were excluded from the study. Primary outcome measurement was the recurrence rate, secondary measurements were: operative time, hospital stay, postoperative pain, postoperative symptoms and satisfaction score

Results.

We operated on 126 patients (72 males, mean age 53.9, range 29-83): 87 (69.6%) with III degree and 39 with IV degree hemorrhoids. Mean duration of follow up was 554 days (range 281-1219). Four patients were excluded from the study. One-year recurrence rate was 5.1%. The mean duration of the intervention was 29 minutes (range 23-60) and 92 patients (73%) were discharged during the same day of the operation. Pain VAS score was 3.9 (range 2-7), 2.5 (range 0 -6), and 1.9 (range 0 -5) in the first, second and third postoperative day, respectively. Twenty-two patients (18 %), all submitted to spinal anesthesia, had postoperative acute urinary retention. Fecal urgency, observed in 26 % of patients at the first control, resolved within one year after the operation. Mean time to return to normal activity was 8 days (range 5 - 10). The patients' satisfaction scores at one-year follow up were 29.6 % excellent, 58.7% good, 7.6% fairly good and 4.1% poor.

Discussion. In our experience the standardization of MuRAL operation, performed with HPS, turned out to be an effective minimally invasive approach in managing symptomatic grade III and IV hemorrhoids , without exposing patients to the risk of developing severe complications, with the possibility to perform a a redo MuRAL procedure in the event of recurrence. In our series up to 88% of the patients reported a satisfaction score good, or excellent. Further comparative randomized studies with longer follow-up period are mandatory.

Introduction

The “vexata quaestio” about the best surgical treatment of hemorrhoidal disease is still unresolved: the results of many randomized studies show that conservative operations, based on the ligation of terminal branches of superior hemorrhoidal artery and mucopexy, in comparison with operations based on excision of hemorrhoidal piles, have some advantages, particularly in the early postoperative period .[1,2]

Mucopexy - Recto Anal Lifting *(MuRAL)* is a minimally invasive procedure centered on an innovative suturing technique, carried out by following a standardized approach in performing mucohemorrhoidopexy, while simultaneously ligating the distal branches of the Superior Rectal Artery without Doppler guidance.

The HemorPex System® (HPS) is a rotating surgical proctoscope, specially designed to enable mucohemorrhoidopexy under direct vision and providing a quadrant based selective access to the mucohemorrhoidal prolapse above the dentate line. The anoscope introducer avoids the interference by the prolapsed tissue of the adjacent quadrants throughout the duration of the intervention. [Figure 1]

Various non-homogenous studies involving the HPS have been performed during the last years, unfortunately with non-comparable clinical results, mainly due to the lack of standardization.[3,4,5,6]

In the present study we investigated the safety and medium-term effectiveness of the *MuRAL* method, performed by following a standardized approach, taking the incidence of recurrence as the primary outcome and also evaluating operative time, hospital stay, postoperative pain, postoperative symptoms and satisfaction score as secondary outcomes.

Materials and Methods

The study has been approved by the Milan Area 1 - Ethics Committee – Decision number 017/55113.

Patients with grade III or IV hemorrhoids were enrolled and selected between May 2013 and December 2015. Upon receiving informed consent from all patients, all the MuRAL procedures were performed by the same two-surgeon team, following the personally standardized technique reported below. The presence of two surgeons was required by our accreditation system, but the procedure can be technically carried out by a single surgeon.

The intervention was performed under general, or spinal anesthesia. All patients were given Metronidazole 500mg intravenously, one hour before the intervention.

Technique

With the patient in lithotomy position, the HPS handle was anchored with stitches placed on the midline perineal skin. In order to prevent the dragging of the mucosa inside the device, when changing the quadrant for hemorrhoidopexy, we applied a standardized rotation sequence. Arterial ligation and mucopexy were performed at 6 locations, whereby we took advantage of the device's rotation feature to gain selective access to the prolapse through the operating window in the following order: 11 o'clock, 1 o'clock, 9 o'clock, 3 o'clock, 7 o'clock and 5 o'clock position. [Figure 2]

The device was introduced with the operating window of the proctoscope at 11 o'clock position and the first hemorrhoidopexy was performed, starting from the lower edge of the operating window and progressing upwards with a mucosa-submucosa whip stitch, continued with an ascending running suture every 2-4mm so that finally, when the two ends of the thread were tied up, the lifting effect was smoothing the prolapse. [Figure 3]

After inserting the introducer, the device's operating window was then rotated to the 3 o'clock position and back to 1 o'clock, where the second hemorrhoidopexy was performed. The hemorrhoidopexy at 9 o'clock position was performed after inserting the introducer and rotating the operating window to 7 o'clock position, anticlockwise, and then back to 9 o'clock position. Then we performed the hemorrhoidopexy at 3 o'clock position, after having rotated the proctoscope's operating window clockwise to 5 o'clock position. Since the 4 previous hemorrhoidopexies enabled us to reposition and anchor the mucosa at the above-mentioned locations, the two last hemorrhoidopexies at 7 o'clock and 5 o'clock positions were performed directly without a need to follow the clockwise-anticlockwise movement. Finally hemostasis was checked. No hemostatic sponges were left in place.

The lifting effect can only be obtained if the stitches involve mucosa and submucosa, whereby the resolution of the prolapse is left to the subsequent fibrosis [Figure 4]. In the aim to promote an inflammatory reaction leading to a significant fibrosis, we use a thick Polyglycolic Acid braided thread

0/0, with a 5/8 needle 26mm.

During hospitalization all patients were administered Acetaminophen 1gr intravenously every 8 hours. Ketorolac 30 mg i.v. was administered as a rescue drug, when NRS pain score was greater than 4. After the discharge the patients were advised to take Acetaminophen 1000mg by mouth, or ketoprefene 80mg , when needed, maximum t.i.d.

Follow-up controls were carried out by independent observers (two surgeons who had not been involved in performing the operation). Clinical examinations were performed as follows: a digital exploration 21 days after the intervention; Unless of evidence of early recurrence, proctoscopy was not performed in the early period, so as to avoid possible mechanical disruption of the mucopexy columns. Systematic controls were performed at 3 and 12 months and entailed digital exploration plus proctoscopy, which were repeated at a 12 months interval. Patients who did not strictly follow the postoperative controls were excluded from the study.

We considered as the primary outcome measure the rate of failure, defined as the presence of residual prolapsed rectal mucosa, and/or prolapsed haemorrhoids at clinical examination. Secondary outcome measures were: operative time, hospital stay, postoperative pain by the Visual Analog Scale (VAS), time of return to normal activity, postoperative symptoms. Patient Satisfaction was assessed at one-year control or at a same-period phone call by an independent trained nurse, using a 4-point scale (1=excellent, 2=good, 3=fairly good, 4 poor), expressing the overall perception of the patient.

Results

During the considered period, we treated 126 patients (72M, 54F), the mean age was 53.9 years (range

29-83). Eighty-seven (69 %) patients had symptomatic hemorrhoids grade III, of which 6 patients with a recurrence after a proctological operation carried out elsewhere (2 patients after stapled hemorrhoidopexy, 2 after a stapled hemorrhoidopexy and a subsequent rectoplasty for rectal stenosis, and 2 patients after Milligan-Morgan). Thirty-nine patients (30.9%) had symptomatic hemorrhoids grade IV, among which 7 patients already operated elsewhere (2 patients with a recurrence after THD, 2 patients with a recurrence after Milligan-Morgan hemorrhoidectomy and 3 patients with a recurrence after stapled hemorrhoidopexy). Fifteen patients (11 with grade III hemorrhoids and 4 with grade IV hemorrhoids) had concomitant grade II-III rectocele, and 1 patient had a concomitant anal fissure, treated with left lateral sphincterotomy at the end of the MuRAL intervention. (Table 1 and 2)

Four patients (2 with grade III and 2 with grade IV hemorrhoids) did not come to one of the postoperative controls and were excluded from the study.

Median duration of follow up was 554 days (range 281-1219).

Primary outcome measurement

Out of 122, 5 patients (4.1%) developed a recurrence: 3 cases were observed within 3 months after the intervention and 2 cases were observed 12 months after the intervention. Three patients with recurrence had preoperative symptomatic hemorrhoids grade III and two patients had symptomatic hemorrhoids grade IV. Two patients with recurrence were treated with a redo MuRAL, one with STARR, one with Milligan-Morgan and one patient refused further surgery.

One of the patients who had a redoMuRAL for an early recurrence after MuRAL, developed a second early recurrence and was finally cured with a Milligan-Morgan procedure and pelvic rehabilitation programme.

None of the cited 13 patients who underwent MuRAL as a revisional procedure after Milligan-Morgan, Stapled hemorrhoidopexy, and THD developed a recurrence.

Secondary outcome measurements

The overall mean duration of the intervention was 29.5 minutes (range 22-60) but was shorter among the Grade III Hemorrhoids Group (27.6 minutes – range 22-45) than among the Grade IV Group (33.8 minutes – range 25-60). The difference was statistically significant (p=0.008). Eighty-eight patients (72.1%) had one-day surgery, 31 patients (25.4) had same-day surgery and 3 old patients (2.4%), who lived alone far from our hospital, needed a two days hospitalization. Pain VAS score has been registered over 3 days following the surgery: on the first day mean VAS score was 3.9 (range 2-7) and 2.5 (range 0 -6) and 1.9 (range 0 -5) in the second and third days, respectively.

Twenty-two patients (18.0 %), all submitted to spinal anesthesia, had postoperative acute urinary

retention.

Regarding the postoperative symptoms, 32 patients (26.2%) suffered from rectal tenesmus, which disappeared within 3 days after the intervention; 3 patients (2.4 %) developed postoperatively an anal fissure, which healed with medical therapy. Mean time to resuming normal activity was 8 days (range 5 - 10).

At the three-week-post-operative check, 23 patients (18.8%) reported fecal urgency. At the control at 3 months after the intervention the incidence of fecal urgency was reduced to 4.9 % (6/122); no fecal urgency complaints have been reported by patients at the 12 months follow-up examination.

The break down of results regarding fecal urgency showed that 10 patients were among the grade III hemorrhoids group (10/85; 11.8%) and 13 among the Grade IV Group (13/37; 35%). The difference was statistically significant p=0.002). Among the 10 Grade III hemorrhoids patients with post-operative urgency, 2 had had a previous operation (2 Longo + rectoplasty) and 7 had concomitant Grade II o III rectocele. Among the 13 Grade IV hemorrhoid patients with post-op urgency, two had had a previous procedure (1 THD, 1 Longo), 4 had concomitant rectocele, and the remaining 7 patients only had hemorrhoids.

The satisfaction scores reported by the patients at one-year control were: 29.6 % excellent, 58.7% good, 7.6% fairly good and 4.1% poor.

Discussion

Our results demonstrated a very low (4.1%) rate of recurrence at one-year follow up, which is similar to the one obtained by Iachino *et al* in grade III hemorrhoids.[4] Basile *et al.* reported a higher (7.5 %) incidence of recurrence at 36 months in patients with grade III hemorrhoids.[6]

The results were less satisfactory in patients with grade IV hemorrhoids: Iachino *et al.* reported 37.5 % of recurrence and this poor result led the authors to conclude that HPS is contraindicated in patients with advanced grade hemorrhoids.[4] In our series the recurrence rate after MuRAL with HPS in grade IV patients was 5.4% (2/37 patients), even if this subset of patients is still limited in number and follow-up duration.

In our opinion, as also reported by Ratto *et al* for THD,[7] mucopexy, rather than arterial ligation, is key to achieve good results in prolapsed hemorrhoids.

In our series all recurrences occurred within one year from the intervention (3 cases during the early postoperative period and 2 cases within one year from the intervention). No other recurrence has been observed among the 75 patients, whose follow-up exceeded 24 months and we therefore could consider one year as a sufficient period to suggest conclusions.

As expected, patients submitted to the procedure for Grade IV hemorrhoids showed statistically significant longer operative time and greater post-operative pain.

Regarding early and late complications, the incidence of acute urinary retention, a typical complication related to spinal anesthesia, among our patients was lower than the 22% reported in the series of Basile *et al*,[6] but higher than the 4.5% in the series of Iachino *et al* ,in which 92 % of patients were operated on under local anesthesia.[4]

Incidence of fecal urgency was appreciably low in comparison with stapled hemorrhoidopexy and the symptom disappeared in few months.[8] However a statistically significant higher rate has been recorded in patients with Grade IV hemorrhoids than in grade III group. Patients with grade III hemorrhoids who developed transient fecal urgency all had had previous surgery or had concomitant rectocele.

None of the serious complications reported after stapled hemorrhoidopexy was observed in our series of patients submitted to MuRAL with HPS.[9,10,11]

Regarding the utility and effectiveness of Doppler guidance for arterial ligation, our data did not consent to draw any conclusion, nevertheless it is important to remember that two recent studies demonstrated a substantially equivalence of the results in patients operated on with, or without Doppler guidance: the intervention without Doppler was even shorter and less painful.[12,13]

The last question concerns the genesis of the lifting effect, obtained with Mu-RAL. The hypothesis that the 6 longitudinal scars, subsequent to the 6 mucopexies, observed at proctoscopy one year after the operation could facilitate the formation of a “fibrosis basket”, which should stabilize the vertical lifting effect and prevent recurrences, needs confirmation by experimental studies.

Conclusions

In our experience the standardization of Mucopexy – Recto Anal Lifting (Mu-RAL) method, performed with HPS, turned out to be a safe and effective minimally invasive approach in managing symptomatic hemorrhoids of grade III and IV, with low recurrence rate and without exposing patients to the risk of developing severe complications, and a redo MuRAL procedure could also be considered for treating recurrences. In our series up to 88% of the patients reported a satisfaction score good, or excellent. However, further comparative studies with longer follow-up periods are mandatory.

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Figure Legends

Figure 1: Gaining Selective Access to Prolapse Through the Device's Operating Window

Figure 2: Mucohemorrhoidopexy & Dearterialization

Figure 3: Quadrant Based Approach – Sequence Followed

Figure 4: Postoperative Status

Lifting effect mechanism.

The six longitudinal scars aim at facilitating the formation of a fibrosis basket, which should stabilize the vertical lifting effect and prevent the development of a possible recurrence.
NOTE: The schematic steps of the procedure have been drawn over the background of a basic anatomic illustration derived from https://en.wikipedia.org/wiki/Hemorrhoid