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***Retrospective Study***

**A 10-year Multicentric Retrospective Analysis Regarding Postoperative Complications and Impact of Comorbidities in Hemorrhoidal Surgery with Literature Review**

Postoperative Complications in Hemorrhoidal Surgery

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## **Abstract**

### **BACKGROUND**

Hemorrhoidal disease (HD) is considered a low-severity pathology by both general population and physicians, but the lengthy conservative therapy and postoperative complications suggest otherwise.

### **AIM**

Our study aimed to assess the effectiveness of different treatment options, both conservative and surgical, in contrast with some preexisting comorbidities.

### **METHODS**

We conducted a retrospective, 10-yearlong study between January 2011 and December 2021 in two surgical centers, a private and a state-owned hospital. We compared the efficacy and safety of several treatment options, such as open hemorrhoidectomy (OH), stapled hemorrhoidopexy (SH), rubber band ligation (RBL) and infrared coagulation (IRC) in terms of complication rates and types and their correlation with different preexisting comorbidities such as inflammatory bowel disease (IBD), use of anticoagulant medication (AM) and liver cirrhosis (LC). We also conducted a 20-years long PubMed research (1.263 articles) for relevant comparisons.

### **RESULTS**

Our study recorded 10.940 patients with HD, 10.241 with conservative and 699 with surgical treatment. Out of these, the male-to-female ratio of 1.3, and a peak in age distribution between 59 and 68 years old (32% of patients). For the entire study, we recorded a 90% incidence of immediate pain, immediate bleeding in 1.5% (11 cases), delayed bleeding in 1.0% (7 cases), and 0.6% surgical site infections. Urinary retention was also present, with 0.2% of patients, anal stricture in 1% and fecal incontinence for 0.5% of patients (4 cases). We recorded no severe complications such as Fournier's gangrene or rectovaginal perforations. IBD accounted for 6% of the patients, with

ulcerative colitis (UC) in 12% and Chron's disease (CD) in 10.5%. 6.6% of the patients had AM, determining 4% immediate and 2% delayed bleeding, in surgically treated patients.

## CONCLUSION

Our study determined that most common complications (pain, urinary retention, bleeding, and stricture) are correlated with each surgical technique and pre-existing comorbidities.

**Key Words:** Retrospective; Hemorrhoidal; Postoperative; Complications; Comorbidities

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**Core Tip:** We compared the efficacy and safety for the most widely used surgical and non-surgical solutions for hemorrhoidal pathology treatment, such as hemorrhoidectomy, stapled hemorrhoidectomy (SH), rubber band ligation (RBL), sclerotherapy (SCL), and infrared coagulation (IRC) in terms of complication rates, types of complications and implication of different preexisting comorbidities such as inflammatory bowel disease, use of anticoagulant medication and liver cirrhosis. We determined that even if RBL, RBL and IRC or IRC alone usually only require a one-day admission model, the classic or modified Milligan-Morgan technique still provides better overall long-term results, despite initially determining a higher level of pain and bleeding.

## INTRODUCTION

Although hemorrhoidal disease (HD) has been described many centuries ago (documented evidence in Mesopotamian literature as old as 1500 BC<sup>[1]</sup>, a worldwide study to address the overall incidence and prevalence across different races, cultures, and socio-economic levels has not yet been published. While in USA, hemorrhoidal pathology seems to be ranking forth amongst all gastrointestinal diseases that drive the patients to hospitals, especially to day-care clinics, determining more than 3 million admissions per year (according to a review by Everhart *et al* in 2009<sup>[2]</sup>, in other parts of the world, such as Eastern and Central Europe, the prevalence rate is close to 11%, as the Parvez *et al* online web-based survey shows<sup>[3]</sup>.

Even though many studies concur that the bulk of the patients have low-severity stages of hemorrhoidal disease<sup>[4, 5]</sup> during the first clinical presentation, if we factor in its high prevalence rate<sup>[3]</sup>, of more than 10% of the entire adult population, the rather long time for the conservative medication-based therapy to produce clinically significant results<sup>[6]</sup> and the severity of complications after surgery, it becomes clear that this pathology has a great overall impact on patients<sup>[7]</sup>.

## **MATERIALS AND METHODS**

Our study is a bi-centric, 10-year-long retrospective analysis, conducted both in a private clinic as well as in a state-owned hospital. The Colorectal Department of MedLife Hospital S.A., (Clinic A), is the private clinic, a one-day-surgery type of medical practice, the state-owned one is Witting Clinical Hospital, Department of General Surgery, a university multidisciplinary unit (Clinic B), that is focused more on a multi-day admission setting for patients, including HD.

Between January 2011 and December 2021, a total of 10.940 patients from both clinics with the diagnosis of HD on various degrees, that needed conservative or surgical treatment were selected, according to inclusion criteria.

Inclusion criterion consisted in patients diagnosed with primary hemorrhoidal disease with indication for treatment, regardless of their age, sex, comorbidities, and

length of hospitalization; comply with at least one of the scheduled postoperative follow-ups, at 7 days, 14 days and 30 days, respectively.

Exclusion criteria consisted in patients consulted in the outpatient care that needed no treatment at all, patients with secondary hemorrhoidal pathology as the primary diagnosis as a direct expression of portal syndrome with origins other than liver cirrhosis (LC) and with important collateral venous drainage, patients skipping at least one of the scheduled follow ups and patients that had corrective procedures in other medical facilities after the initial surgery in our clinics.

For clinical diagnosis of HD, we used the standard 4 stage Goligher's classification that also served as a tool to differentiate the choice of treatment options.

The study recorded details such as age, sex, urban or rural environment, classification of hemorrhoidal pathology before surgery, comorbidities with impact on HD, type and length (in minutes) of surgical procedure, duration of hospitalization (HT), return to work time (RTW), type of complications developed and their time of onset, in respect to the initial procedure.

Types of procedures recorded were open hemorrhoidectomy with a modified Milligan Morgan technique (MOH), stapled hemorrhoidopexy (SH) and rubber band ligation (RBL) with infrared coagulation (IRC). For comparison purposes we also described our experience with open hemorrhoidectomy by Ligasure and Doppler guided hemorrhoidectomy (DH-HAL). We had no cases operated with any of the closed hemorrhoidectomy techniques (CH).

Regarding the postoperative complications, our study recorded the most significant ones, such as pain, bleeding, infections of the surgical site (such as perianal abscesses and pelvic abscesses), mechanical complications (such as rectal or vaginal perforations), anal stricture, fecal incontinence, and urinary retention.

To assess the pain intensity, we used the standard Visual Analogue Scale (VAS) with 0 points for no pain and 10 points for extremely severe pain. Immediate postoperative pain was evaluated every 4 h, 8 h, and 24 h respectively and for the

delayed postoperative pain we used the 7 days, 14 days and 30 days markers respectively. Follow-up visits were scheduled according to these markers.

Bleeding was evaluated in a qualitative manner, with number of sponges/gauzes need to achieve hemostasis, both during the surgical procedure as well as in the postoperative stage, at 1 day and 7 days respectively (for delayed hemorrhage).

As for comorbidities, the study focused just on those with documented relation and impact for HD that can be managed in non-emergency centers, such as inflammatory bowel disease (IBD), anticoagulant medication (AM), and liver cirrhosis (LC).

Inflammatory bowel disease recorded both Crohn's disease (CD) as well as ulcerative colitis (UC), being the most met in medical practice. In this category we merged both chronic evolving IBD as well as newly discovered pathology.

The classes of anticoagulant medication recorded were antithrombotic (AT), such as Clopidogrel (Plavix), and anticoagulants (AC), including all classes of novel oral anticoagulant medication (NOAC) such as rivaroxaban (Xarelto), dabigatran (Pradaxa) and apixaban (Eliquis).

LC was recorded solely as a preexisting, documented diagnosis and in no connection to the ethiopathogenic mechanism (viral, medication-induced, toxic, or alcoholic, *etc.*). As such we did not differentiate between primary biliary cirrhosis (PBC) or alcohol and medication-induced LC.

For results comparing, a narrative literature review was carried out of all significant scientific papers published in PubMed database during the last twenty years (2002-2022). These results then served as a comparison with our study, and key differences were highlighted.

All details were integrated into an Excel database. Standard statistical reports have been created using the Excel included tools. For advanced statistical analysis we used IBM's SPSS, Statistics Campus Editions version (SPSS Inc., Chicago, IL, USA) with university account (<https://www.ibm.com/products/spss-statistics-campus-editions>).

Kolmogorov-Smirnov and Shapiro-Wilks test were used for determining the homogeneity of the variances with Levene test for normality distribution evaluation.

For continuous variables we used the t test for 2 group mean comparisons with the paired t test for dependent 2 group mean comparisons. In addition, the Mann-Whitney U test was chosen for independent groups comparisons with Wilcoxon signed rank test for dependent groups. For comparing more than 2 groups of normally distributed data we run the ANOVA test and for non-normally distributed data the Kruskal-Wallis test was used. Statistical significance value was set for  $p < 0.05$ .

## **RESULTS**

Between January 2011 and December 2021, both clinics recorded a total of 10.940 patients diagnosed with HD. From those, 8.144 patients (74%) received conservative, medication-based treatment and 2.796 have been treated either with or minimally invasive procedures (2.097 patients) or with invasive techniques (699 patients). This lot of 2.796 patients will be further discussed during this study. The complete distribution of patients, according to clinics and types of procedures is in Table 1.

**Table 1.** Distribution of patients according to clinics and procedure types.

Literature review consisted in a custom interrogation of PubMed and PubMedCentral for the terms “hemorrhoid” and “postoperative” and “complications”, for the past 20 years (2002-2022), selecting clinical trials (CT), meta-analysis (MA), randomized control trials (RCT), reviews (RW), and systematic reviews (SR) as scientific sources, resulting in a list of 1.263 articles. From those, CT accounted for 611, MT for 204, RCT for 423, RW for 529 and SR for 212. The list was sorted by newer articles first, then by SR, RW and MA with RCT and CT being last; also, only English redacted papers have been reviewed. From this pool of articles, we further refined the search by using pair of terms for each topic of our study, such as “hemorrhoidectomy” and “inflammatory bowel disease” that rendered a total of 9 results, “hemorrhoidectomy” and “anticoagulant medication” 2 results, and “hemorrhoidectomy” and “cirrhosis” 5 results, within the same timeframe.

The demographic analysis shows 1620 male patients and 1176 female patients (1.3 M/F ratio), the peak number of cases per age group being in the range of 39-48 years,



with 340 cases (29%). The complete demographic characteristics of the lot is displayed in Table 2. There was no difference between the groups in terms of demographic data ( $p>0.05$ ).

**Table 2.** Complete demographic details of the recorded lot.

As stated, the standard 4-grade Goligher's classification of HD was selected for diagnosis, by both clinics. However, the indication for treatment was guided by the actual clinical status of each individual patient, as many presented with a combination of HD grades (Table 3).

**Table 3.** Classification of cases, according to grades of HD

Therefore, the complete distribution of treatment options according to the grading of HD is as follows: all grade I patients, 8.144 (74 %) received conservative therapy (diosmine-based medication, sitz baths, topic agents with galenic medication, *etc.*); all patients with grade II HD and all patients with grade II that also had at least one grade III hemorrhoidal dilation plus all grade III patients received non-surgical treatment with RBL and IRC (2.097 cases, 19%). All patients with grade III HD that also had at least one grade IV dilation, and all fully grade IV patients were automatically assigned for surgical treatment consisting of OH, SH or OH with Ligasure (Valleylab, Boulder, Colorado, USA) (699 cases, 6%).

The range of surgical procedures was different amongst the clinics. Both clinics performed open hemorrhoidectomy (OH), stapled hemorrhoidopexy (SH) and rubber band ligation (RBL) with infrared coagulation (IRC) in the same surgical session, the latter two being always performed in conjunction and never as a stand-alone procedure. However, in Clinic B, we also had the option to use hemorrhoidectomy by means of high-energy auto-sealing electrocautery devices, such as Ligasure (for the first 5 years in

the study, using only the Atlas platform, as the newer FX and LS were not available at that time).

The OH technique used in both clinics is a modified Milligan-Morgan procedure that makes use of an electrocautery scalpel with blended current setting (35 W of peak power) for streamlining each hemorrhoidal dilation prior to a transfixing ligation with poly-filament 2/0 thread, round tip needle, followed by resection with at least 5 mm safe margin from ligation.

Doppler-Guided Hemorrhoidal Artery Ligation (DG-HAL) became available in the private clinic, only in the last 4 mo of our study, totaling 34 patients that were not included in this lot. The initial clinical results, although being particularly good and promising, due to the substantial number of discrepancies in relationship with other treatment options discussed, were discarded for comparison. This gap could not have been levelled out with statistical procedures, even by using statistical bootstrapping techniques.

Analysis of operating times (OT), hospitalization times (HT) and return to work times (RTW), compared to all types of procedures, including minimally invasive and invasive ones, is available in Table 4.

**Table 4.** Comparison between OT, HT and RTW across all types of procedures.

A median value of number of cushions per HD grade has been used as comparison for operating times.

As such, the longest operating times recorded for SH, the shortest for RBL+IRC. HT were shortest amongst RBL+IRC, with 1 days, and so were the RTW times, with 1 days. There is a statistical relevant difference of OT, HT and RTW when compared across all types of treatment options.

All surgical procedures (OH, SH, and OH with Ligasure) from both clinics, were performed under spinal anesthesia, with Marcaine™ (Bupivacaine, 0.5%, 4 mL). The

typical surgical setup included lithotomy position with the operating table 5 degrees tilted in Trendelenburg. For RBL with IRC local topic anesthesia (lidocaine-based) was always used.

The overall complications of the patients that received non-conservative treatment, according to the surgical technique used, are displayed in Table 5. As the aim of the study was not to compare different complication rates between the clinics, these have been reported globally, across all patients in both clinics.

**Table 5.** Complete demographic details of the recorded lot.

### *3.1. Postoperative complications analysis*

The overall complications panel for all 2796 patients treated with different methods, ranging from minimally invasive to invasive solutions, is displayed in Table 6.

**Table 6.** Overall complications in our study.

#### **3.1.1. Pain**

In our study, the immediate postoperative pain was present in 90.0% of all patients undergoing different procedures, minimally invasive or otherwise. For the same group, the delayed postoperative pain was present in 28% (783 cases).

For assessing the pain levels, we linked VAS with the need of analgesic medication, reported in mg/24h, of IV Paracetamol. Results are shown in Table 7.

**Table 7.** Comparison of VAS score and the amount of Paracetamol IV.

Reviewing the literature<sup>[8-11]</sup>, the physio pathological background for the pain seems to be the reflex contraction of the internal anal sphincter, regarding the surgical trauma, a contraction that outlasts the pain-free interval that spinal anesthesia offers. Therefore, the use of long-lasting local anesthetics (LA), such as Bupivacaine or Tetracaine, is highly recommended by some authors<sup>[10, 12, 13]</sup>. However, our experience differs, as in our study, where surgeries were performed under SA with Marcaine (0.5% Bupivacaine), since the standard OH can be done in a 30–40-minute timeframe, administering a long-lasting LA at the end of the procedure would overlap the pain free

interval by almost 90% of the SA, leaving just about 30 minutes, on average, of supplementary protection against pain. As such, our conclusion is that LA should be used only in procedures that extent to the limit of spinal anesthesia. Perhaps the local use of an LA combined with a vasoconstrictor agent, such as 4% Prilocaine and Epinephrine in 1:200.000 ratio, would yield better results in terms of controlling the immediate postoperative pain, but the use of LA and vasoconstrictor agents is not common in general surgery, and we do not recommend it either.

In our study we achieved good postoperative pain control by Paracetamol, IV, after the effects of SA have passed. We never had the need to administer opioid medication and, considering the complications it involves, it should be avoided and kept as a last resort, especially in one-day surgery centers.

### 3.1.2. Bleeding

Out of all postoperative complications, bleeding is the most feared one by patients and surgeons alike. In our study, the overall immediate postoperative bleeding was recorded in 1.5 % of the cases (42 patients) but required no secondary surgery, just monitoring the patient and wound dressing changing. We should mention that we made use of hemostatic cylinder-shaped plugs on a routine basis, in both clinics, if bleeding in the postoperative stage was highly deemed as probable by the surgeon.

Delayed bleeding (in a timeframe of up to 2 wk postoperative) was present in 1% of the cases (28 patients) mostly in patients with LC, and did not require any surgical revision, in contrast with other studies,<sup>[14]</sup> that indicate as often the need to achieve secondary surgical hemostasis, most likely form an active source, most probable after ligation undoing or a diffuse bleeding that requires hemostatic packings.

Comparing bleeding across all types of treatment options, OH had an overall of 2.0% bleeding, with 1.5% immediate and 0.5% delayed, SH had 4.0% immediate bleeding and RBL+IRC had 1.0% (21 patients) immediate bleeding situations.

Bleeding after OH with Ligasure was lower, both immediate and delayed, with an overall 1.0% complication rate, proving once again the usefulness of this type of high-energy vessel sealing technique.

### 3.1.3. Surgical site infections

From the pool of postoperative surgical site infections, in HD treatment, perianal abscesses are amongst the most commonly met, either in conjunction with an intersphincter collection or as stand alone. Most of the studies will place them in the range of 1.0% to 8.24% of operated patients<sup>[12, 15]</sup> and they develop most likely as a result of local determinants, involving a higher bacterial virulence in rectum and anal canal, especially of *Escherichia coli* and gut-specific *Bacteroides* strains<sup>[16]</sup>, a lack of proper mucosa defending factors such as Immunoglobulin A deficiency, abnormal integrity of the extracellular matrix (ECM) and epithelial-to-mesenchymal transition (EMT) or improper bowel preparation prior to surgery<sup>[17]</sup>.

Our study revealed an overall surgical site infection rate of 0.6% (17 patients), 14 patients with perianal abscesses and 3 with a pelvic abscess, as a result of delayed presentation and late reporting of developing symptoms. All three required reinterventions under SA for surgical drainage and debridement, with a good overall clinical outcome. Severe infectious complications, such as Fournier's gangrene or even sepsis, have never been recorded in our study, however some publications point out a worrisome percentage of 0.1%<sup>[12, 18]</sup>.

### 3.1.4. Anal stricture

Anal stricture is one of the most feared long-term complications in HD, and every step is required to mitigate this type of complication, as it seriously impacts the quality of life of the patient.

The underlying problem with this type of complication is the strong fibrotic shrinkage phenomenon that occurs after multiple diagonally disposed sites of hemorrhoids have been excised, especially using high energy electrocautery devices<sup>[19]</sup>. However, the time taken for this complication to fully develop is usually months and even years, and, in rare cases, as much as 20 years. Surgical options to correct this complication range from simple procedures, such as anal pneumatic or instrumental

dilatation, to extremely complicated ones, especially if this coexists with other major diagnosis, such as rectal cancer, that requires robotic surgery for an effective low reach<sup>[20]</sup>.

The overall cited incidence is around 1.0% of operated cases<sup>[12, 15, 21]</sup>. Our study recorded 0.7% (20 cases) overall rate in the entire lot, most of them form the pool of OH (13 cases) and to a lesser extent form SH (7 cases). RBL and IRC did not determine any anal strictures, as expected. However, the incidence rate of anal stricture was higher than expected when using OH with Ligasure, of 8.3%, compared with 1.8% in our modified OH technique or 1.0% for SH.

### 3.1.5. Fecal incontinence

This type of complication usually appears as a direct damage of the circular muscle fibers of the internal anal sphincter, usually during different types of surgical procedures for perianal fistula repair when it is performed as a stand-alone procedure<sup>[22, 23]</sup> or as a complementary procedure, such as lateral internal sphincterotomy (LIS) after hemorrhoidectomy with the intention of relieving pain by reducing the postoperative tonicity of the sphincter<sup>[24-27]</sup>. Damaging the external sphincter muscle fibers is uncommon during these types of procedures. The overall reported incidence of fecal incontinence is in the range of 2.0% to 10.0%, according to most studies<sup>[12, 15, 28, 29]</sup>.

Our study returned a rate of 0.5% of fecal incontinence (14 cases), mainly because we never associate LIS with any of the surgical procedures for HD, open or otherwise. Moreso, a careful evaluation of the internal and external sphincter muscle fibers condition is mandatory in both clinics for preserving the full function of the sphincter. We prefer to deal with the postoperative pain, sometimes triggered by an increased sphincter tonicity, by means of medication, rather than performing LIS. Those 14 cases in our study, 11 of them from OH and 3 from SH, perhaps come as a result of hemorrhoids acting as pneumatic barriers against a lower sphincter tonus, prior to surgery, leaving the incontinent sphincter exposed after hemorrhoidectomy. This

problem can be successfully avoided by means of intraoperative manometric sphincter tonus determination, a tool that we did not have at our disposal. Again, RBL and IRC did not determine any fecal incontinence.

#### 3.1.6. Urinary retention

The ethiopathogenic explanation for this type of complication would be a combination of a reactive situation to the local trigger of surgical-site pain and as a direct consequence of SA. Many studies<sup>[12, 30-32]</sup> underline that SA is a major contributing factor and perhaps resorting to epidural anesthesia (EA) can reduce this risk<sup>[33]</sup>.

Our study recorded just 6 cases (0.2%), all males, of immediate postoperative urinary retention, and this comes in large contrast with different studies<sup>[12, 30-32, 34]</sup> that place this type of complication in a range of 0.9% to as much as 30.0%.

However, we should mention that all patients in our study, undergoing invasive procedures for HD (OH, SH, OH with Ligasure), had a urinary catheter installed after full installment of SA. In our clinics this is the standard procedure to follow, as we believe this offers the best postoperative comfort for the patients, lowers the risk of urinary retention with little to no side-effects. The catheter is held in place for 12h after surgery and removed prior to the evening sleep. Although urinary infections associated with catheterization are a serious medical problem that may further complicate the postoperative outcome of any patient, including the ones in postoperative HD<sup>[35-38]</sup>, the 12h timeframe of the catheterization does not pose such a high risk of infection, provided that all antiseptic procedures have been respected, and proved successful in eliminating the risk of retention. All 6 male patients that had this complication could not have had the catheter installed, due to an ongoing large prostatic adenoma and the other 2 with post *Chlamydia* infection-induced strictures that could not have been resolved either by a Foley probe nor with a Nelaton-type catheter.

#### 3.1.7. Mechanical complications

These mechanical complications stand out as a major type of postoperative development, which includes rectal and/or vaginal perforation, in female patients. Fortunately, rectal perforation is rated at 0.1% of patients<sup>[12, 18, 39, 40]</sup> and is attributed to SH, mainly, as surgical procedure. Contributing factors are the improper positioning of the stapler during the procedure, preexisting undiagnosed rectal pathology, such as ulcerative recto-colitis (RC) or CD and even vaginal prolapse. Further complications can include pneumoperitoneum or retro-pneumoperitoneum, intra-abdominal bleeding leading, in some of the cases, to severe hypovolemic hemorrhagic shock, and peritonitis<sup>[39, 41-43]</sup>.

Our study did not determine any of these types of complications, mainly because we perform colonoscopy on a routine level, so RC or CD is well known in patients scheduled for surgery and we double check the final position of the device prior to firing it.

### *3.2. Complications rates comparison according to procedure types*

#### *3.2.1. Cold scalpel OH vs high-energy auto-seal hemorrhoidectomy*

<sup>4</sup> A direct comparison between OH and CH is not available in our study, as we did not resort to any of the many CH techniques, such as Ferguson`s. However, numerous studies have tried to pinpoint the differences between these procedures, with mixed results. Some major meta-analysis and RTCs<sup>[44-48]</sup> clearly demonstrate the superiority of CH, as a surgical option with focus on Ferguson`s technique, in particular, over OH, with Milligan-Morgan procedure as main representative. These comparisons were made on all major aspects of HD, such as postoperative pain, risk of postoperative bleeding, time of healing, surgical site infections, long-term anal incontinence, and patient satisfaction. On the other hand, some smaller studies<sup>[17, 49]</sup> with less than 1.000 patients enrolled, show no statistical differences in any key-factors of postoperative evolution of patients with HD, except the time for local healing that seems to be in favor of CH techniques.



In terms of comparing OH performed with cold-scalpel techniques *vs* hemorrhoidectomy with high-energy auto-seal devices, studies show a better overall response for Ligasure, in terms of intraoperative blood loss, immediate pain management, postoperative complications and patient satisfaction<sup>[50-54]</sup>.

In contrast with these reports, our experience with the LigaSure platform shows that anal stricture, as a long-term complication, has higher incidence than OH, even if we apply the Ligasure hand piece directly at the base of the hemorrhoidal dilation or after a previous cold scalpel mucous incision and hemorrhoidal pedicle diameter reduction by blunt dissection. By using Ligasure we had an anal stricture incidence of 8.3% compared to our modified OH technique, that itself uses standard electrocautery for hemorrhoid stump preparation, indicating that, over long-time, the local perianal tissue response towards Ligasure might trigger scar tissue formation with a higher rate, thus leading to a higher rate of anal stricture incidence. For this reason, we stopped using Ligasure in any of our procedures, 5 years ago.

Although our modified Milligan-Morgan technique makes use of conventional electrocautery, it cannot be classified as a standard diathermic procedure, since we also secure the hemorrhoidal stump with a transfixing suture. However, several literature reviews<sup>[55-57]</sup> that did this type of comparison, between Ligasure and standard diathermy, point out a better outcome of Ligasure and recommend it for one-day surgery clinics.

### 3.2.2. Stapled Hemorrhoidopexy *vs* Open Hemorrhoidectomy

The introduction of SH was a major advancement in surgical options for HD, introducing smaller operating times and less intraoperative bleedings, amongst several other advantages over standard OH. Therefore, the initial clinical response was very good, with many studies and RTCs pointing out less immediate and delayed pain, shorter hospitalization, and better patient work reintegration<sup>[58]</sup>. However, as complications after this type of procedure can be severe <sup>[39, 59]</sup> several other studies, RTC and meta-analysis were performed to reevaluate, on the long term, the safety, efficacy,

and advantages in terms of cost effectiveness of this method over conventional OH. These studies pointed out that recurrence rates, different surgical postoperative complications and overall quality of life after surgery favored OH, with a particular accent on OH being cheaper and with a better cost-to-clinical results ratio<sup>[60, 61]</sup>. Some of the more recent studies suggest that SH is still to be considered as a procedure under evaluation for routine surgical use in the global management of HD, despite its advantages in terms of reduced immediate and delayed postoperative pain, less intraoperative bleeding and shorter hospital stay<sup>[61]</sup>.

Our experience with SH has been a very positive one, with less immediate and delayed postoperative pain (4.8% *vs* 95%), less anal stricture (1.0% *vs* 1.8%) but higher immediate and delayed bleeding (4.0% *vs* 2.0%). Also, from the pool of immediate postoperative complications, SH generated 1 case (0.1%) of perianal abscess that required reintervention, and 0.3% of urinary retention (3 cases) *vs* 0.4% (4 cases). Long term complications recorded 3 cases of fecal incontinence (0.5) but no other severe outcomes, such as Fournier's gangrene or recto-vaginal perforations.

### 3.2.3. DG-HAL *vs* OH and SH

Doppler-guided hemorrhoidal artery ligation and mucopexy (DG-HAL) was first introduced back in 1995, by Morinaga *et al*<sup>[62]</sup> and further perfected over the years<sup>[63]</sup> to provide a safe and modern approach targeted towards one of main pathological triggers of HD: high arterial inflow into hemorrhoidal cushions. Because of its initial excellent results in terms of pain control, intraoperative and postoperative bleeding and anal stricture<sup>[64-67]</sup>, many studies tried to assess its effectiveness and efficacy in different degrees of HD. For grade II and III it seems to provide promising results, however, in patients with grade III and IV HD we can expect overall postoperative relapses ranging from 24% and up to as much as 67%<sup>[68-71]</sup>. DG-HAL also has some drawbacks, in terms of high costs and rather long-learning curve needed for a good evaluation of the mucopexy above the dentate line, one of the main reasons attributed to the high recurrence rates<sup>[67]</sup>.

When compared to OH, DG-HAL seems to have better overall results, in terms of lower postoperative pain and less intraoperative bleeding, with the same long-term outcomes, regarding anal stricture in particular, at least for grade II and III HD<sup>[12, 72, 73]</sup>. The same study recommends a careful evaluation when it comes to grade IV HD though, indicating fewer effective results. Several meta-analyses comparing DG-HAL with SH draw the same conclusions, that DG-HAL is superior in terms of postoperative pain, immediate or delayed, bleeding and surgical site infection rates<sup>[12]</sup>. A few studies did not, however, find any significant differences between DG-HAL and SH<sup>[74, 75]</sup>.

As previously stated, this technique has not yet been adopted in either of our clinics as a routinely procedure, but the proposal for routine clinical usage is currently under revision in Clinic A. Our study has recorded just 34 cases operated with DG-HAL, for Grade III HD, in the last 4 mo, with very promising results: no intraoperative or immediate postoperative bleeding, less than 5% of patients with a VAS pain score of 3, no fecal incontinence and no local site infections. Also, none of the life-threatening complications were present. However, operating times were 15% longer than a standard OH (for the same number of hemorrhoidal cushions per grade of HD) perhaps this being a result of our limited experience with this technique. Given the very short time that we had with DG-HAL, we can draw no conclusions for any of the long-term complications, such as anal stricture.

#### 3.2.4. RBL + IRC *vs* OH

Many studies point out that OH has overall more complication rates, both immediate and long-term, than RBL<sup>[76-79]</sup> with only a few studies point out that the difference, in terms of postoperative complication rates, is not significant<sup>[80]</sup>. However, OH has fewer recurrences than RBL, being regarded as a one-time surgical solution by many patients, especially those that present several sites of hemorrhoidal cushions. As such, OH can be effective in the range of up to 51% of cases while RBL may need in as much as 34% of the cases, a second intervention<sup>[80]</sup>. Several studies concur that OH

should be reserved for grade III HD and above, as well as for recurrences of HD after previous RBL procedures<sup>[77]</sup>.

From our experience we found that IRC alone has virtually no impact on the evolution of HD, especially in high grades (III or above). For this reason, we always perform IRC as an associated procedure with RBL. Our study recorded immediate postoperative pain in 2.0% cases (42 cases) and immediate bleeding in 1.9% of the cases (40 patients), that needed no surgical hemostasis, however. Also, operating times were much shorter than OH, in terms of effective surgery and especially in time spend in the operating room, since RBL + IRC does not require SA (median 32.5 minutes for OH *vs* median 5.5 minutes for RBL+IRC).

### *3.3. Comparison of preexisting comorbidities and their impact on postoperative evolution of HD*

#### *3.3.1. Concomitant colorectal pathology associated with HD*

All patients in our study, which received indication for RBL + IRC or surgical treatment (2.796 patients), from both clinics, had preoperative total colonoscopy (TC) performed, even though the clinical examination had no doubts regarding the positive diagnosis of HD. This comes as a way of screening patients for other coexisting pathologies that might have the same clinical behavior, mainly hemorrhage.

In our study 87 patients (3.1 %) had concurrent malignant tumors, mainly located in sigmoid but also in the descendant colon. These patients followed the colorectal cancer protocol and have not been included in this research. Also, our study recorded a total of 995 (35.6%) patients with diverticula (the precise location was not recorded by the study) and 23% polyps (643 patients).

#### *3.3.2. Impact of IBD*

Although hemorrhoidal pathology is not the main comorbidity in patients with IBD, large studies show that IBD prevalence in HD can still reach as much as 7%<sup>[81]</sup>, from which <sup>5</sup> Crohn's disease (CD) and ulcerative colitis (UC) are the main representatives. Moreso, there seems to be a difference in newly discovered patients

with IBD *vs* patients with chronic evolving pathology, the former displaying a higher overall complication rate than the latter<sup>[82]</sup>. In general, most studies and meta-analysis agree that both IBDs present some impact on the postoperative course of HD, starting from a general, non-specific level,<sup>[12]</sup> and down to individual types of complications<sup>[83]</sup>. The overall complication rates can go as high as 40%<sup>[84]</sup> with immediate postoperative bleeding being the most significant, and local site infections coming in second place with about 12%.

Our study recorded 168 patients with IBD from the entire lot of treated patients (2.796 patients), with a 1.14 ratio of UC to CD and 6% (42 patients) with IBD from the pool of operated cases (699 cases). The entire distribution of complications and the types of procedures involved in patients with IBD is displayed in table 7.

**Table 7.** Distribution of IBD types in our study

As it can be seen, UC delivered less complications, in both types of treatment option, invasive or conservative procedures.

### 3.3.3. Impact of AC and AT medication

Numerous studies tried to establish a consensus regarding the definitive risk of actual bleeding in patients with or without ongoing AC or AT medication at the time of HD treatment. However, it seems that we still have contradictive results. Some studies<sup>[85]</sup> suggest that bleeding was not statistically different for patients with or without AT treatment when undergoing surgical procedures, such as OH or DG-HAL<sup>[86]</sup>. However, larger studies<sup>[87, 88]</sup> pointed out that delayed bleeding was as high as 4.6% with more than 85% requiring reintervention for secondary hemostasis and even 36% blood transfusion. Some of the studies, focusing on both AT and AC medication<sup>[88]</sup>, came within the same observations, that this class of medication presents significant risks of peri-operative bleeding.

Although there is still a strong debate whether the patients undergoing invasive HD surgery should or should not interrupt the administration of AT with several days prior to surgery, our study could not test this theory as all cases selected for invasive procedures have been asked to stop the current AT medication for 3 days prior to surgery, since all of them required spinal anesthesia. Even if novel studies in the field of different types of anesthesia and AT therapy, published by European Journal of Anesthesiology (EJA)<sup>[89, 90]</sup>, suggest that low dosage of AT, under 200 mg per day and especially in regard to Aspirin, should not be stopped prior to SA as it does not provide a higher risk of peri-procedural bleeding, our anesthesiologist team still follows this protocol. Therefore, all 70 cases (2.5% of the treated patients) that developed immediate or delayed bleeding were outside the effects of this type of medication (AT and AC, including NOAC) at the time of surgery.

The same goes for patients with NOACS that underwent conversion protocol to subcutaneous low molecular heparin prior to surgery. For the patients treated with RBL+IRC (2.097) we did not interrupt the ongoing AC or NOAC medication prior to their treatment. From those, 713 patients had AT treatment (34%) based on Clopidogrel (Plavix) and 5% presented significant bleedings (36 patients) that required anal plugging with hemostatic material with 16% insignificant postprocedural bleedings (114 patients) that required simple external compression with wound dressings.

#### 3.3.4. Impact of LC

There are few studies that focus just on LC and how this type of important comorbidity may impact the outcomes of surgery in HD, mainly because these patients will certainly receive major surgical treatment for the underlying pathology – liver transplantation, abdominal tumor resection, vascular procedures for portal vein thrombosis, *etc.* There are few patients requiring dedicated surgery for bleeding hemorrhoidal dilations in this clinical setup.

Even though these studies are scarce, they point out the severity and serious impact of LC over the general complications rates, especially bleeding. However, there is some

contradictory data. Some studies would imply that sclerotherapy (SCL) would be the better choice of minimally invasive treatment, after the conservative one failed, against RBL that seems to provide a higher rate of bleeding<sup>[91-93]</sup>. On the other hand, some other studies could even correlate Child`s score of LC with prognosis and point out that the best course for treatment would be RBL as it provides the lowest recurrence rate for rebleeding, the better patient satisfaction scores and lower need for analgetic medication, compared to SCL <sup>[93, 94]</sup>.

## **DISCUSSION**

Even though the Goligher`s classification draws much criticism from some important surgical associations (such as Association of Colon and Rectal Surgeons of India), many other major surgical schools still use it for its simplicity and direct connection with the anatomical evidence<sup>[95]</sup>, therefore our study adhered to this reporting system as well. However, we acknowledge the need for changing the way we classify and report the HD, as this classification does not allow for a standardized surgical approach, does not take into account key factors of HD ethiopathogeny and it is not considering the associated symptomatology nor the dynamic evolution, such as the newly proposed classification system of Rubbini M. *et al*<sup>[96]</sup> does.

The need for mandatory colonoscopy as a complementary investigation or as a definitive one needed for positive diagnosis of HD is still under debate, especially in private owned clinics where a rapid diagnosis is preferable to shorten the time needed for diagnosis and thus shortening the overall patient hospitalization. However, given that many studies show a high rate of incidental diagnosis of other pathologies, concurrent with HD, such as uncomplicated diverticula <sup>[97, 98]</sup>, diverticulitis with a silent development<sup>[99]</sup> polyps<sup>[100, 101]</sup> and, of course, malignant tumors located above the reach of the standard rectal examination<sup>[101-105]</sup>, we believe this type of clinical investigation should be mandatory in all clinics, as a mean of screening. In our study, both clinics performed colonoscopy routinely for all grade II and above HD.

Out of all types of hemorrhoidectomies, both clinics in our study rely on a modified Milligan-Morgan, as a surgical solution from the pool of open type procedures. Ferguson, Parks and other closed techniques have never been used. The modification brought to the standard Milligan-Morgan technique brings the advantages of using a standard electrocautery in hemorrhoid surgery, such as faster local coagulation times, better intraoperative bleeding control, but combines them with the advantages of transfixing ligations, such as better control over postoperative bleeding. By bridging these advantages, we believe that we managed to lower the overall complication rates linked with OH techniques.

Our study did not encounter any of the severe local or systemic postoperative complications of HD, such as Fournier's gangrene or sepsis. Although there is documented evidence that sepsis can have, as a point of origin, a surgical site for hemorrhoidectomy<sup>[18, 106]</sup> as many of the triggering mechanisms of sepsis are met in the per-operative timeframe<sup>[107]</sup>, we had no such complications, perhaps due to using the monopolar cautery for the modified Milligan-Morgan procedure, careful hemostasis and use of hemostatic plugs, whenever required and the intraoperative administration of a single antibiotic dose. However, we cannot substantiate these findings with statistical analysis.

Our study revealed an incidence of 6% of IBDs but we did not record separately the newly diagnosed and chronic patients. We could theorize about the helpful role of chronic consumption of mesalazine (and its derivatives) in these patient's treatment plan that may offer a better postoperative tissue plasticity and provide a slightly better local regeneration. Perhaps this is the explanation behind the findings of some studies, such as Cracco *et al*<sup>[82]</sup>.

Even though studies that directly compare the efficacy and efficiency of Ligasure *vs* harmonic devices are scarce<sup>[108]</sup>, perhaps because both belong to the same group of high-energy vessel auto-sealing solutions, they still point out that both have similar outcomes in terms of postoperative pain, wound healing time and overall recovery. However, we believe that the slightly lower temperatures of harmonic devices<sup>[109]</sup> might



determine a better long-term tissue response and perhaps a lower anal stricture complication rate. Still, this conclusion is derived from our experience with Harmonic in open or laparoscopic general surgery procedures and has not yet been documented for HD. Since harmonic technology was not available in either of our clinics, LigaSure being the only type of high-energy bipolar device, further studies are required to draw any conclusions from our part, including the need to perform histological determinations to assess the amount of thermal damage of both types of devices.

Even so, we believe that the use of high energy devices should be limited at best or better yet not used at all as they still have a higher anal stricture complication rate in comparison to standard hemorrhoidectomy, even though all other aspects are in favor of vessel sealing platform, such as shorter operating time, and lower intra-operative bleeding<sup>[108, 110, 111]</sup>.

Some studies<sup>[112]</sup> show that immediate postoperative pain can be greatly reduced if hemorrhoidectomy, or any invasive procedure for HD, is performed under pudendal nerve block, using long-acting LA such as Bupivacaine or Prilocaine, eliminating the need of a combined SA and LA for the same type of procedures<sup>[113]</sup> and being superior to just SA. However, in our study, where all patients had SA with Bupivacaine, the immediate postoperative pain was lower than comparative studies, without the need of supplementing with any other LA, perhaps because OH or SH fit well within the 180 min SA duration, with operating times of just 30-40 min. This provides a long-time reserve until SA wears out, allowing for local inflammation to resorb and thus leading to lower levels of immediate pain.

We successfully managed to avoid urinary retention by routinely deploying urinary catheters in all patients undergoing invasive procedures, such as OH, SH or OH with Ligasure under SA. We did not record any urinary infectious complications in any of the patients with urinary catheters. We believe that, if proper antiseptic procedures are respected, and the probe does not stay in place for more than 12 h, the risk is minimally, as the data in our study shows. Also, the routine IV administration of ceftriaxone (Cefort<sup>TM</sup>), a 3<sup>rd</sup> generation cephalosporin, single intraoperative dose of 2 g, might have

helped achieving these results, even though this class of antibiotic is not the first line of choice in urinary tract infections.

### **Limitations of the current study**

Although careful intraoperative and postoperative evaluations were performed, none of our patients received pre- and postoperative manometric sphincter determinations to assess the level of remnant tonicity in comparison with the preoperative one, as neither of the two clinics have access to such investigation. This would, perhaps, have served better the patients with long term complications, such as anal stricture, allowing us to have a superior control over the rates for this type of postoperative complication.

Although HIV-induced immunodeficiency is a documented risk factor that increases the chances of anorectal infections and may delay surgical site regeneration after coloproctological procedures, no matter the type, whether classic hemorrhoidectomy<sup>[114]</sup> sclerotherapy<sup>[115]</sup> or RBL<sup>[116]</sup>, this study did not focus on this particular comorbidity, as patients are not routinely checked for HIV infections and many are reluctant to declare such pathology, during initial evaluation.

### **CONCLUSION**

Treatment of hemorrhoidal disease should benefit from a very tailored treatment plan, after a careful grade assessment of the patient. As such, we think grade I HD benefits most after conservative, medication-based and dietary treatments; an all-grade II HD patients or patients with a mixture of grade II and grade III HD or patients with all-grade III HD will benefit best from rubber band ligation with infrared coagulation as this provides the best balance in terms of safety, cost effectiveness and low complication rates. Patients with at least one hemorrhoidal cushion in grade IV, disregarding the predominant number of cushions with lower grades, should automatically benefit from either open hemorrhoidectomy or stapled hemorrhoidopexy, as neither RBL with IRC nor Ligasure could provide the same overall satisfactory results. We propose our

modified Milligan Morgan OH technique that has many advantages, even though marginal, over the standard OH because it provides less intraoperative and postoperative bleeding, reduces the risk of reinterventions for bleeding control and has an overall lesser chance of developing anal stricture, even though it induces higher immediate and delayed postoperative pain levels compared to SH. We believe stapled hemorrhoidopexy should be carefully considered carefully as it can be responsible for severe postoperative complications, especially in patients with IBD, such as Chron's disease.

Open hemorrhoidectomy by high-energy vessel-sealing platforms, such as Ligasure, may cause significant anal stricture and should be avoided, even though they can provide a better intraoperative bleeding control and overall shorter operating times.

We did not find any evidence suggesting the need of a supplementary local anesthetic in the perianal area, in patients operated with spinal anesthesia; immediate postoperative pain control in these patients could be successfully achieved with standard IV analgesics, such as Paracetamol.

Stopping the antithrombotic medication, especially Clopidogrel, is not mandatory from a surgical point of view, but advisable, especially in patients with a predominant grade IV hemorrhoidal disease as it can provide better intraoperative bleeding control and reduces the chances of reintervention.

Routinely placement of a urinary catheter for 12 h postoperative will significantly reduce the chances of urinary retention without significantly increasing urinary infection rate.

Using anal plugs, either in the form of simple gauze, for 12 h postoperative, or as a rectal expandable hemostatic foam will significantly reduce the immediate postoperative bleeding without with little to no discomfort for the patient, if correctly applied.

## **ARTICLE HIGHLIGHTS**

### ***Research background***

For many years hemorrhoidal disease (HD) has been perceived by society as a low-severity pathology, this perception being adopted even by physicians, albeit not gastroenterologists or surgeons. However, if we add the very high prevalence rate, of more than 10% of the adult population, the overall long length of conservative medication-based therapy and the severity of complications after surgery, it becomes clear that this is truly a disease that should change the perspective.

### ***Research motivation***

The main motivation of this study was to provide clinicians, both gastroenterologist and colorectal surgeons, the proper tools to better outlay the treatment options factoring in patients' comorbidities, chronic medication and the severity of hemorrhoidal disease.

### ***Research objectives***

We compared the overall clinical results of different surgical techniques on patients with grade II and above of HD and different comorbidities with documented impact in the development and evolution of HD.

### ***Research methods***

We developed a multicentric retrospective study that covers 10 years of treating patients with hemorrhoidal pathology, in two major clinics, a private-based medical facility and a state-owned hospital. Between January 2011 and December 2021, a total of 10.940 patients have been enrolled and treated for hemorrhoidal disease, in various stages and with different methods, ranging from medical options to surgical ones. The study also recorded full demographic details, classification of hemorrhoidal pathology before surgery as well as a comprehensive comorbidities panel, including inflammatory bowel disease (IBD), anticoagulant medication (AM), and liver cirrhosis (LC), all medical conditions with documented impact with impact on HD. Other important details such as length (in minutes) of surgical procedure, duration of hospitalization, return to work time, type of complications developed and their time of onset, in respect

to the initial procedure have been recorded. Regarding the surgical procedures we noted open hemorrhoidectomy with a modified Milligan Morgan technique (MOH), stapled hemorrhoidopexy (SH) and rubber band ligation (RBL) with infrared coagulation (IRC). For comparison purposes we constasted our data with the ones in international literature by performing a review consisting in a custom interrogation of PubMed and PubMedCentral for the terms “hemorrhoid” and “postoperative” and “complications”, for the past 20 years (2002-2022) and selecting clinical trials (CT), meta-analysis (MA), randomized control trials (RCT), reviews (RW), and systematic reviews (SR) as scientific sources, resulting in a list of 1.263 articles.

### ***Research results***

Our study recorded a total of 10.940 patients diagnosed with HD, 8.144 patients (74%) receiving conservative, medication-based treatment and 2.796 being treated with minimally invasive procedures (2.097 patients) or with invasive techniques (699 patients). Regarding the treatment, patients with grade I pathology (74 %) received conservative therapy. Non-surgical treatment with RBL and IRC was applied to patients with grade II HD and all patients with grade II that also had at least one grade III hemorrhoidal dilation plus all grade III (19%). Surgical treatment consisting of OH, SH or OH with Ligasure, 6% of cases, was reserved for patients with grade III HD that also had at least one grade IV dilation, and patients with fully grade IV pathology.

### ***Research conclusions***

We strongly believe that a complete and efficient treatment of hemorrhoidal disease should be a highly tailored one, based on a very good clinical assessment of the patient. Reviewing our lot of patients and procedures, we think that open hemorrhoidectomy by high-energy vessel-sealing platforms may induce significant anal stricture and should be avoided, even though they provide a better intraoperative bleeding control and overall shorter operating times.

As demonstrated by clinical data obtained in this study, we believe that our modified Milligan Morgan OH technique has many advantages, even though arguably marginal, over the standard OH, but more than enough to possibly make it a routine procedure in patients with grade IV HD.

### *Research perspectives*

Further study that includes patients with HD and HIV-induced immunodeficiency is in order, since this is a documented risk factor that increases the chances of anorectal infections therefore the postoperative development can be very unpredictable and may render different results than the ones in our study. Also, a full manometric evaluation, both prior and in the postoperative state can give us a more detailed information regarding the actual impact of different surgical techniques and tools, especially in regard to high-energy platforms.

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