Surgical management of haemorrhoids: an Italian survey of over 32 000 patients over 17 years

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Abstract

Aim The management of haemorrhoids has changed significantly in the last two decades as a result of new insights into their pathophysiology and the availability of new surgical devices. The aim of this survey was to evaluate changes in the management of haemorrhoids in Italy over the last 17 years.

Method An electronic database which recorded details of management relating to the severity of haemorrhoids between 2000 and 2016 was obtained from 18 of 34 colorectal surgeons who were invited to participate.

Results A total of 32 458 patients were treated for haemorrhoids by 18 expert coloproctologists during a 17-year period. Patients were classified as Grade II (7542, 23.2%), Grade III(15 360, 47.3%) and Grade IV (9556, 29.4%). Grade II haemorrhoids were treated with rubber band ligation in over 90% of the cases, and patients with Grade IV had a Milligan–Morgan (MM) haemorrhoidectomy in over 90% of the cases. In Grade III, the use of stapled haemorrhoidopexy progressively decreased from 30% to 35% (between 2000 and 2007) to 5% of the cases. Meanwhile, commencing from 2006 the use of Doppler-guided haemorrhoid artery ligation (DGHAL) with mucopexy

Introduction

Haemorrhoidal disease is common in the western worlds, and therefore their management has

increased progressively from 6% to 24%. Over the years, the percentage of MM haemorrhoidectomy remained consistent at between 65% and 70% of the cases.

Conclusion Relevant changes in the surgical choice of haemorrhoid treatment have occurred in Italy over the last 17 years. MM haemorrhoidectomy remains the most frequently performed procedure for Grade III haemorrhoids. Stapled haemorrhoidopexy has become much less popular in contrast to DGHAL with mucopexy which is being performed much more frequently.

Keywords haemorrhoids, Milligan–Morgan, Dopplerguided haemorrhoid artery ligation, PPH, stapled haemorrhoidopexy

What does this paper add to the literature?

The treatment of haemorrhoids have changed significantly in the last decades searcing for a less invasive and painful treatment. However there are no information about the changes of the pattern of treatment which have occurred over the time in the different grades of haemorrhoids. This paper shows how most of the Italian coloproctologist have changed their surgical approach to haemorrhoids in the last 17 years.

considerable resource implications [1]. The traditional surgical management of haemorrhoids by Milligan– Morgan (MM) haemorrhoidectomy has been dreaded by patients because of severe and prolonged postoperative pain and potential complications. In the last 20 years, new insights into the pathophysiology of haemorrhoids have led to the development of several minimally invasive and painless procedures including stapled haemorrhoid artery ligation (DGHAL) [4,5]

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¹The Italian Haemorrhoid Survey Group, see Appendix S1.

with mucopexy. Support from industry has encouraged the rapid and widespread adoption of these new techniques, before their superiority over traditional haemorrhoidectomy was confirmed by randomized clinical trials. Some of these new procedures have been validated and included in national and international guidelines on the management of haemorrhoids [6–9]. Nevertheless, analysis of the long-term outcome (in terms of recurrence rates) [10,11] and of the potential occurrence of life-threatening complications [12,13] has promoted a reconsideration of the traditional haemorrhoidectomy in several tertiary referral coloproctological units.

Italian colorectal surgeons have been very responsive in this field; in fact, most of the new techniques were invented or substantially revised by Italians [3,14–16] who have published more the 250 papers in PubMed in the last 20 years.

The aim of this survey was to record changes in the surgical management of haemorrhoids over the last 17 years and to determine whether current management accords with recent guidelines.

Methods

A total of 34 expert coloproctologists belonging to both the Italian societies of coloproctology [the Italian Society of Colorectal Surgery (SICCR) and United Italian Society of Coloproctology (SIUCP)] were invited to take part in this survey. They were selected on the basis of their scientific publications on the management of haemorrhoids and/or of their reputation in this field. There were 24 colorectal surgeons belonging to the SICCR and 10 to the SIUCP. Each surgeon was asked to fill an Excel spreadsheet including the number and type of procedures for haemorrhoids performed each year during the last 17 years. All the data were retrospectively obtained in a prospectively maintained database. The database was completed according to the degree of haemorrhoids (graded following Goligher's classification [17], which was adopted by all the colorectal surgeons during the period considered). We selected the time period 2000-2016 as most of the changes in the management of haemorrhoids have occurred after the introduction of the PPH procedure and the DGHAL and mucopexy during this time. Furthermore, in the same time period, several national and international guidelines have been published [6-9].

For each grade of haemorrhoids (except for Grade I), the procedures considered were rubber band ligation (RBL), MM haemorrhoidectomy, Ferguson operation, PPH, stapled transanal rectal resection (STARR),

DGHAL with mucopexy and non-DGHAL mucopexy. Infrared coagulation and injection sclerotherapy were not practised by any of the centres involved. Other rarely adopted procedures (such as the Whitehead operation, laser haemorrhoidectomy, Parks' haemorrhoidectomy etc.) were not considered. The MM and Ferguson operations, even if performed by diathermy, radiofrequency or ultrasound devices, were grouped together, as the technique of haemorrhoidectomy is very similar. Likewise, stapled haemorrhoidopexy performed with a PPH 01/03 (Ethicon EndoSurgery, Cincinnati, Ohio, USA) or other new high-volume stapling device such as an EEA stapler (Covidien-Medtronic©, Mansfield, Massachusetts, USA), ChexTM CPH34HV (Frankenman International Ltd, Sheung Wan, Hong Kong) or TST STARR+ (Touchstone. International Medical Science Co. Ltd, Suzhou, China) were considered together.

Statistical analysis

Data were reviewed and summarized in terms of percentages. Trends over the study period were analysed. Comparisons between multiple groups of procedures and their association with time were performed with univariate multinomial logistic regression models, separately for each grade of haemorrhoids. The results are presented as ORs with corresponding 95% CIs. The predicted probabilities calculated from the models are also reported in specific graphs. All the analyses were performed using the Statistical Analysis System (SAS) Package, Release 9.4 (SAS Institute, Cary, North Carolina, USA).

Results

Eighteen (53%) of the 34 centres invited (16 SICCR and 2 SIUCP) provided data. There was an equal geographical distribution of centres across Italy: five in the south, seven in central and six in the north of Italy. Among the nonresponding centres, three had no access to their data because the colorectal surgeon had moved from his previous hospital, three did not use a database for collecting data, four did not reply and six agreed to participate but did not send their data before the dead-line.

A total of 32 458 patients were treated for haemorrhoids in 18 centres during the 17-year period. Among them, 7542 (23.2%) patients were affected by Grade II haemorrhoids, 15 360 (47.3%) by Grade III and 9556 (29.4%) by Grade IV haemorrhoids. The mean number of patients treated in each centre was 1803 (range 295– 7502).



Figure 1 Distribution of the percentages of different types of surgery for Grade II haemorrhoids in the time frame.

The most frequently adopted treatment for symptomatic Grade II haemorrhoids was RBL (76.9%) followed by MM (8.7%), DGHAL and mucopexy (6.9%), PPH (5.8%) and non-DGHAL with mucopexy (1.7%). The percentage of Grade II haemorrhoids treated by RBL decreased slightly from 85% of cases in 2000 -70% in 2016. This seems to be related to the introduction of other minimally invasive techniques such as DGHAL and mucopexy (from 5% in 2008 to 12% in 2016) and non-DGHAL with mucopexy (from 1.7% to 4.5%). The adoption of MM haemorrhoidectomy, which is not recommended for this type of haemorrhoids by most international guidelines, remained consistently under 10% of the cases, substantially unchanged over the study period. The PPH procedure was used in 5%-9% of the cases until 2010 and decreased to 4% in the last 3 years (Fig. 1).

Adopting the multinomial model, the OR of performing DGHAL or non-DGHAL with mucopexy rather than RBL has moderately but significantly increased, to 1.18 (95% CI 1.15–1.20) and 1.28 (95% CI 1.21–1.34) respectively. These results underline a growing trend towards the adoption of these new technologies (Fig. 2).

As a consequence, the probability curve shows a small decrease over time because of the growing introduction of new technologies (Fig. 3).

In the case of Grade III haemorrhoids, the most frequently adopted treatment was MM haemorrhoidectomy followed by PPH, DGHAL with mucopexy, STARR and non-DGHAL with mucopexy. The frequency with which MM haemorrhoidectomy was performed was consistent at about 65% for many years but fell in 2005 to 50%. Between 2008 and 2016 the use of this operation has climbed back to 70%.

After 8 years during which the PPH trend accounted for 30%–35% of cases, it progressively decreased to 5% of the cases. Conversely, starting from 2006 the use of DGHAL with mucopexy has gradually grown from 6% to 24%, indicating that this technique and MM haemorrhoidectomy have progressively replaced the PPH procedure (Fig. 4). Our results demonstrate that non-DGHAL with mucopexy has begun to be adopted in the last 5 years (2.5%). In patients with Grade III haemorrhoids, the STARR operation was performed in about 5% of the cases between 2007 and 2013, but very rarely in the last 3 years.

Based on the multinomial model, the OR of using DGHAL or non-DGHAL instead of the MM operation



Figure 2 Odds ratio with 95% confidence intervals of performing different types of surgery for Grade II haemorrhoids against rubber band ligation.



Figure 3 Distribution of the probability of performing different types of surgery for Grade II haemorrhoids in the time frame.



Figure 4 Distribution of the percentages of different types of surgery for Grade III haemorrhoids in the time frame.

The use of PPH ranged from 6% to 13% until 2010 and then declined to 0%. Some of these patients were also treated by the STARR procedure, particularly between 2008 and 2013 (3%–5% of the cases), after which it was not used anymore. Interestingly, in the last 3 years both techniques have been abandoned for Grade IV degree haemorrhoids (only 24 in 8645 cases). Finally, a minor percentage of cases (between 3% and 6%) have been treated by DGHAL with mucopexy after 2008. This percentage has declined in the last few years to 2.4% (Fig. 7).

In the multinomial model only, the OR of using DGHAL with mucopexy instead of MM

has moderately increased [1.23 (95% CI 1.21–1.25) and 1.28 (95% CI 1.21–1.34), respectively] (Fig. 5).

Therefore, according to the predicted probabilities, the MM operation has shown a moderate decrease and the DGHAL a significant increase, while the probability of using the PPH technique in Grade III haemorrhoids is much less frequent. The predicted probability of the other techniques considered shows no significant changes (Fig. 6).

The treatment of choice for Grade IV haemorrhoids was MM in over 90% of the cases. This percentage fell slightly to about 80% in 2009–2010 concurrent with an increase in the use of PPH. It returned to 93% in the last 3 years.

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Figure 5 Odds ratio with 95% confidence intervals of performing different types of surgery for Grade III haemorrhoids against Milligan–Morgan haemorrhoidectomy in the time frame.

guidelines for the treatment of haemorrhoids, their management varies widely according to their grade and severity, personal experience and surgeon preferences, availability of new devices, and, perhaps, companies' influences.

The study clearly demonstrates that in Italy Grade II haemorrhoids are managed conservatively by RBL that is the only ambulatory method widely practiced in all the centers involved in the study. This option of treatment remained stable over the time while there is a small percentage of patients with Grade II haemorrhoids still requiring more aggressive treatment such as DGHAL, PPH or MM. In particular, starting from 2009, there is a slow but progressive increase in the use of DGHAL or non-DGHAL with mucopexy. This suggests that some surgeons prefer to manage II-degree haemorrhoids with a single operation instead of repeated minor procedures.



Figure 6 Distribution of the probability of performing different types of surgery for Grade III haemorrhoids in the time frame (MM, Milligan–Morgan; PPH, stapled haemorrhoidopexy).

haemorrhoidectomy has moderately increased (1.21, 95% CI 1.16–1.25) (Fig. 8).

The curve of predicted probability for using MM haemorrhoidectomy in patients with Grade IV haemorrhoids has been stable over the study period (Fig. 9).

Discussion

There is paucity of published data on the changes in surgical techniques employed to treat haemorrhoidal disease particularly Europe or United States. This survey gives an overall picture of the evolution of the surgical choice in haemorrhoids treatment in Italy. The survey shows that, despite the indication of national and international This trend is confirmed by the predicted probability model where the OR of performing DGHAL or non-DGHAL instead of RBL has moderately but significantly increased. These data are in disagreement with the conclusions of a recent RCT that compares RBL to DGHAL [11] and shows that, at 1 year of follow-up, haemorrhoid recurrence after DGHAL was similar to repeated RBL. Furthermore, in this trial, patients had more postoperative pain after DGHAL which was also more expensive and less cost-effective.

For Grade III haemorrhoids, which represent the most frequent indication for surgery, substantial changes in surgeon preferences have occurred in the time frame considered. The traditional haemorrhoidectomy remains





Figure 8 Odds ratio with 95% confidence intervals of performing different types of surgery for Grade IV haemorrhoids against Milligan-Morgan haemorrhoidectomy in the time frame.

definitively the most frequent procedure adopted in Italy. However, its frequency of use fell from about 70% to less than 60% in the period between 2006–2010, and then returned to 70% after 2010.

The evolution of PPH for Grade III haemorrhoids is interesting. This technique was firstly presented in 1998 by Longo [3]. He used circular staplers available in the market for other colorectal surgery, but in 2000 the Ethicon EndoSurgery produced and made widely accessible a dedicated stapler (PPH 01) [18]. For about 10 years after the introduction of this new device, stapler haemorrhoidopexy has been the second most practiced surgical technique to treat III-degree haemorrhoids in Italy (32% of patients evaluated in this 10-years survey). After that period, its use fell relates to an increased

Figure 7 Distribution of the percentages of different types of surgery for Grade IV haemorrhoids in the time frame.

awareness of the long-term recurrence rate of the procedure as described in recent publications [10,11,19].

Furthermore, the occurrence of serious complications such as rectovaginal fistulas, rectourethral fistulas, prostatic abscess, pelvic sepsis, persistent pain may have played a role in discouraging this technique [12,13]. As a consequence, some colorectal surgeons returned to the choice of traditional haemorrhoidectomy, and other modified the stapling technique using, for example the STARR technique with 2 PPH01 [20] or, more recently, the new high-volume circular staplers available in the market [21-22]. Others have adopted minimally invasive techniques such as DGHAL with mucopexy. This haemorrhoids-preserving procedure, which aims to reduce the arterial hyper flow to haemorrhoidal piles (by the haemorrhoidal arteries ligation) and mucosal prolapse (by rectal mucopexy), is becoming more popular partly as a result of published low morbidity rates and good outcomes [23].

These factors have all influenced the current preferences for the choice of procedure for Grade III haemorrhoids. In Italy, 68% of the cases had MM operation, 23.5% had DGHAL+ mucopexy, about 5% had PPH procedure, 2.5% non-DGHAL and mucopexy, while STARR was abandoned. The choice of treating haemorrhoids by means of low rectum resection (i.e. the STARR procedure) was not included in any international guidelines. The predicted probability model for Grade III haemorrhoids highlights a moderate increase in the probability to be operated by DGHAL or non-DGHAL with mucopexy instead of MM over time.

As regards Grade IV haemorrhoids, our results indicate that these cases amount to 30% of all patients. This



Figure 9 Distribution of the probability of performing different types of surgery for Grade IV haemorrhoids in the time frame.

is in contrast to the reported incidence of this grade of haemorrhoids which is about 5% as defined by Goligher *et al.*: "haemorrhoids...became so large and develop such considerable skin-covered component that they cannot be properly returned into the anal canal, but, instead, remain as a permanent projection of anal mucosa. These completely irreducible piles are haemorrhoids of the fourth degree" [17].The increased incidence in our series may be related to the fact that hemorrhoids may sometimes exteriorize spontaneously after their reposition into the anus [24].

The surgical choice for Grade IV haemorrhoids is still the MM operation, while use of PPH and STARR has been abandoned. DGHAL is being increasingly used in Grade III haemorrhoids.

We recognize some limitation of this study. There is possible variation in the classification of the severity of haemorrhoids, and some experts declined to participate in the survey. Nonetheless, this survey has documented relevant changes in the surgical choice of haemorrhoids treatment in Italy over the last 17 years. Grade II haemorrhoids are managed conservatively with RBL in over 90% of the cases, and Grade IV haemorrhoids are treated by MM in more than 93% of the cases. For Grade III haemorrhoids, the enthusiasm for the introduction of new procedures like PPH operation, claiming less postoperative pain, has dampened because of unsatisfactory long-term results and possible occurrence of rare but severe complications. These findings have recently been re-affirmed by the eTHOS trial [25], the larger randomized trial comparing stapled haemorrhoidopexy with traditional haemorrhoidectomy. On the other hand, new less invasive procedures, like DGHAL with

mucopexy [4,5] or the less expensive non-DGHAL with mucopexy, free of severe complication, have become available and are increasingly used. Nevertheless, their long-term outcome needs to be confirmed by further studies. In fact, the reported long-term outcome in terms of recurrences after these operations widely varies from 9.5% in large case series [26] to 30% in RCT [11]. The results of this survey indicate that today haemorrhoids management in Italy is aligned to the recently published Italian position paper²⁷ and to most of the international guidelines [6-9,27]. However, the pattern of surgical choice for haemorrhoid Grade III in Italy differs substantially from the one recently reported in a Dutch survey [28], where traditional haemorrhoidectomy was performed in 31% of the cases (instead of 70%), non DGHAL with mucopexy in 24% of the cases (instead of 2.5%), DGHAL with mucopexy in 9% of the cases (instead of 24%) and PPH in 19% of the cases (instead of 5%). These discrepancies could reflect different health care systems, surgical preferences and companies influences strongly suggesting the urgent need for European guidelines on haemorrhoids.

Conflict of interest

The authors declare no conflict of interest.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. The Italian haemorrhoid Survey group.