

Grade 3 haemorrhoidal treatment: rubber band ligation or haemorrhoidectomy – a prospective study

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Abstract

Aim: There is some controversy over which treatment should be used for grade 3 haemorrhoids. With the aim of assessing the efficacy of rubber band ligation to treat grade 3 haemorrhoids this treatment was compared to Milligan/Morgan haemorrhoidectomy.

Methods: A prospective, analytical, observational and descriptive study was performed on all patients diagnosed with symptomatic grade 3 haemorrhoids between September 2007 and December 2008. Patients were assigned to each group according to whether or not they presented an external component. Treatment was by Milligan/Morgan haemorrhoidectomy or rubber band ligation respectively. Pain and analgesic requirements were assessed during the first 7 days post-operatively. The degree of resolution of the symptoms, the degree of

satisfaction and the days off work were recorded.

Results: Statistically significant differences were observed between the 2 groups as to post-operative pain and analgesic requirements. Both variables were greater in the group of patients treated by haemorrhoidectomy. There was a statistically significant difference between the 2 groups as to days off work.

Conclusion: The results show that rubber band ligation is effective for treating grade 3 haemorrhoids and the few complications and slight post-operative pain enable us to recommend it as the procedure of choice for the management of this condition as it is the safest treatment that enables the patient to recover quickly.

Keywords: Rubber band ligation; Haemorrhoidectomy; Haemorrhoids.

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Introduction

Haemorrhoid-related pathology frequently affects a broad group of the population and causes a variety of symptoms; notably pain, rectal bleeding and pruritus. A variety of techniques have been developed to treat the pathology according to the degree of haemorrhoid presentation. These include methods such as rubber band ligation, photo-coagulation, sclerotherapy, cryotherapy [1] and various haemorrhoidectomy and stapled haemorrhoidopexy techniques. Surgery is reserved for patients with grade 4 haemorrhoids and for patients in whom non-surgical treatment has failed or those who suffer from external symptoms such as external hemorrhoids or cutaneous flaps. Rubber band ligation has been shown to be the most effective method for treating grade 2 haemorrhoids. However, there is more controversy over the treatment of grade 3 haemorrhoids. Currently, less invasive, less painful procedures tend to be carried out and lead to quick recovery. With these aims, various scientific articles have been published in which rubber band ligation is applied to grade 3 haemorrhoids. [2,3] Because of this, we commenced treatment of grade 3 haemorrhoids with rubber band ligation in our department and we report the following study where we assessed its results by comparing this treatment with haemorrhoidectomy.

Material and Methods

We performed a prospective, analytical, observational, and descriptive study of 94 patients diagnosed with grade 3 haemorrhoids who were symptomatic between September 2007 and December 2008. Patients were diagnosed in the general surgery outpatient

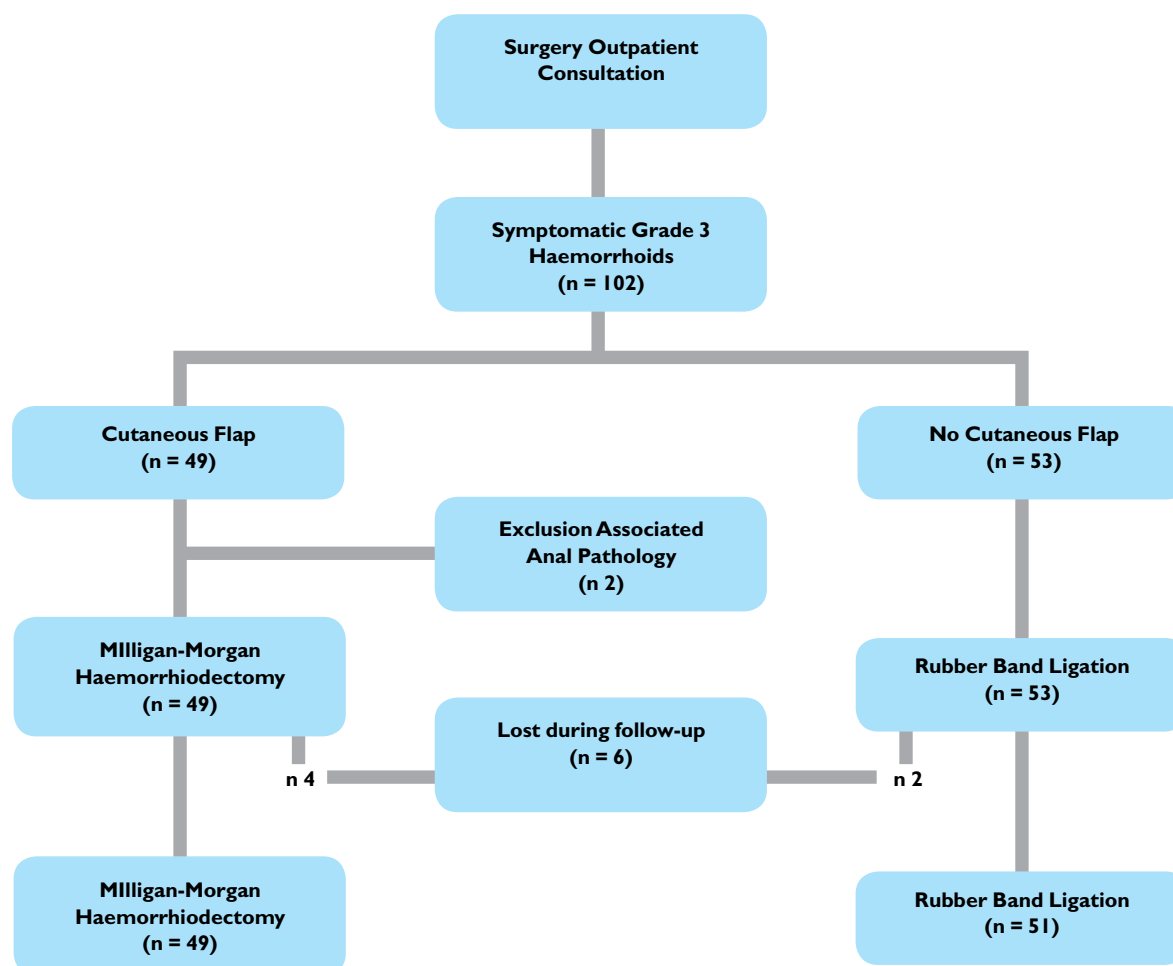
department where the procedure they were going to be subject to was explained and where they were issued with informed consent forms. Patients were divided into 2 groups—those treated by Milligan-Morgan haemorrhoidectomy and those treated by rubber band ligation. (Figure 1)

The technique performed was chosen depending on the presence of a cutaneous flap. Thus, we performed Milligan-Morgan haemorrhoidectomy with Ligasure Max® (Covidien®) for patients with an external component and rubber band ligation for the remainder. The first group required spinal anesthesia for the operation whereas the second group did not.

All patients were operated on in the same theatre in the outpatient major surgery department. The immediate post-operative period was monitored in the recovery area of the outpatient major surgery department. Upon discharge, all patients were issued a questionnaire to record pain levels during the first 7 post-operative days by means of an analog scale in addition to daily analgesia requirements. Patients who underwent Milligan-Morgan haemorrhoidectomy were administered endovenous analgesia during the first 48 hours post-operatively by means of an elastomeric pump. As of the second day post-operatively, the elastomeric pump was removed and oral analgesic was commenced. This consisted, just as with the group treated with rubber band ligation, of ketorolac every 8 hours and tramadol on demand. Patients treated with rubber band ligation only received oral analgesia on demand.

The questionnaire issued to patients covered the initial post-operative observation in the outpatient department one week following the operation. At this initial observation we administered a verbal survey

Figure 1 Patient Distribution.



which considered aspects such as control of symptoms, onset of complications, days off work, and the degree of patient satisfaction. This verbal survey, together with physical examination, was repeated in all successive observations for patients until full resolution of symptoms at a follow up time of one year. These data were recorded in a data collection sheet.

Patients who presented associated anal pathology and those who did not meet the criteria to be included in the major outpatient surgery programme were excluded from the study.

Statistical Analysis

We performed a statistical or descriptive analysis using mean and standard deviation for quantitative variables and absolute and relative frequencies for categorical variables. We used the Mann-Whitney U non-parametric test for quantitative variables and the λ^2 or exact Fisher test for categorical variables. To assess the variation in the time pain lasted and the analgesia that was required the two-way ANOVA test was used. Statistical significance was considered for $P < .05$. We performed a statistical analysis with the SPSS programme version 11.

Results

We excluded 8 patients from the study; 2 patients because they presented associated anal pathology and we lost 6 patients during follow-up. Of all 94 patients included in the study 51 were treated by rubber band ligation and 43 by Milligan-Morgan haemorrhoidectomy.

We observed a statistically significant difference in favour of women in the group treated by haemorrhoidectomy. The distribution of prior symptoms referred by patients was homogeneous in both groups.

We observed statistically significant differences as to post-operative pain reported by patients between the 2 groups. The pain reported by patients subjected to haemorrhoidectomy was clearly greater except on the day of the operation when differences were not statistically significant (Table 1).

Table 1 Post-procedure related pain.

Day	Rubber Band Ligation Pain		Haemorrhoidectomy Pain		Statistical Level
	Mean	SD	Mean	SD	
Day 0	3'69	2'27	4'06	3'04	0'7
Day 1	2'55	1'80	3'64	2'20	< 0'0001
Day 2	1'94	1'66	4'88	2'67	< 0'0001
Day 3	1'55	1'18	6'68	1'93	< 0'0001
Day 4	1'34	1'00	6'42	2'25	< 0'0001
Day 5	1'25	0'99	5'53	2'24	< 0'0001
Day 6	1'19	0'76	4'84	2'16	< 0'0001
Day 7	1'11	0'41	3'93	1'74	< 0'0001

The results obtained were virtually superimposable by assessing requirements for analgesia during the first week post-operatively and we observed statistically significant differences between the 2 groups. The analgesia required in the group of patients treated by haemorrhoidectomy, except during the day of the operation, was clearly greater (Table 2).

Table 2 Post-procedure required analgesia.

Day	Rubber Band Analgesia		Haemorrhoidectomy Analgesia		Statistical Level
	Mean	SD	Mean	SD	
Day 0	0'97	0'97	1'22	1'64	0'6
Day 1	0'75	1'27	2'15	2'26	≤ 0'0001
Day 2	0'46	1'21	3	2'07	≤ 0'0001
Day 3	0'30	0'90	3'46	2'04	≤ 0'0001
Day 4	0'21	0'79	3'40	2'40	≤ 0'0001
Day 5	0'15	0'60	3'15	2'49	≤ 0'0001
Day 6	0'13	0'58	2'60	2'04	≤ 0'0001
Day 7	0'11	0'41	1'75	1'78	≤ 0'0001

As for the onset of post-operative complications it is notable that 79% of patients did not report complications. The low percentage of complications observed was distributed homogeneously between the 2 groups; 7 patients reported rectal bleeding (3 in the rubber band ligation group and 4 of those treated by haemorrhoidectomy), 5 anal pain (3 in the rubber band ligation group and 2 in those treated by haemorrhoidectomy), 2 prolapse (in the rubber band ligation group), 1 acute retention of urine (post-haemorrhoidectomy), and 2 anal stenosis (in the group treated by haemorrhoidectomy).

We assessed monitoring of symptoms during post-operative follow up; 93.6% of patients referred full remission and significant improvement in symptoms. Among these, 58 patients (61.7%) reported full remission of symptoms of which 66.7% were in the rubber band ligation group and 55.8% in the haemorrhoidectomy group. It is notable that neither of the 2 groups reported no improvement in symptoms and that 11.8% of patients from the rubber band ligation group reported a relative improvement in symptoms. (Table 3)

Table 3 Systems improvement after analgesia.

Symptoms Control	Rubber Band Ligation	Milligan-Morgan Haemorrhoidectomy	Total
No Improvement	0	0	0
Relative Improvement	6 (11.8%)	0	6 (6.4%)
Significant Improvement	11 (21.6%)	19 (44.2%)	30 (31.9%)
Full Remission	34 (66.7%)	24 (55.8%)	58 (61.7%)
Total	51 (100%)	43 (100%)	94 (100%)

We observed statistically significant differences between the 2 groups as to days off work; this was 28.8 days in the group treated with haemorrhoidectomy and 1.3 days in the case of rubber band ligation.

We gave a survey on the degree of satisfaction to all patients with outpatient surgery consultations and we observed that 53 patients stated they were very satisfied with the treatment, of which 32 were patients treated by rubber band ligation and 21 treated by haemorrhoidectomy. The remaining 36 patients stated they were satisfied of which 15 belonged to the rubber band ligation group and 21 to the haemorrhoidectomy group. No patient stated they were not very satisfied or dissatisfied.

Discussion

The presence of various techniques to treat haemorrhoid-related pathology reveals that there is no technique which is better, in spite of the multiple randomized studies performed by comparing the various techniques.[4] Milligan-Morgan haemorrhoidectomy described in 1937 continues to be widely performed today with minor modifications and especially for advanced haemorrhoids due to the fact that it is an effective technique, although associated with intense post-operative pain and some latent complications. Rubber band ligation is also broadly disseminated as a treatment for lower grade haemorrhoids. It is safe, involves less post-operative pain, and entails a quick recovery. There is controversy over the recidivism of haemorrhoids post-ligation, especially grade 3 haemorrhoids with indices which vary from 4% to 80%, [5] although articles have recently been published which advocate the safety of rubber band ligation [3,6,7] based on both resolution of presenting symptoms, absence of repeat treatment, and also the satisfaction reported by patients and the time before returning to work.

Because haemorrhoid-related pathology is a benign disease, we believe we should always try the least aggressive and safest procedure which enables quick recovery of the patient. For this reason, we decided to perform rubber band ligation on patients with grade 3 haemorrhoids. The study was not randomized because patients with haemorrhoid-associated cutaneous flaps or external component requested their removal and we therefore performed Milligan-Morgan haemorrhoidectomy on these patients; it was possible to remove them within the same haemorrhoidectomy wound. Both procedures were performed without hospital admission, in the same theatre, with the aim of reducing inter-group differences and based on the fact that we have performed haemorrhoidectomy without admission since 1998 with replacement indices of 95%. With the same aim of maintaining as much homogeneity of the groups treated, only patients with grade 3 haemorrhoid pathology were included.

Just as for the latest studies by Shanmugam et al., and Forlini et al., we have chosen as evidence of the efficacy of the treatment the resolution of symptoms reported by patients as they are the reason for attending for consultation and is what alters their quality of life. [6,3] Therefore, we see in our study that there are no significant inter-group differences with regard to symptoms reported initially which enables us to ensure that they are groups comparable between themselves.

The efficacy of both treatments has been proven in this study by observing that only 2% of patients required repeat treatment and that 93.6% were symptom-free upon completion of treatment in both groups without statistically significant differences between them. The current literature describes a rate of 20% for second ligation sessions in the first month as correct. [8,9]

The most significant differences found were with regard to post-operative pain. We attribute similar figures for pain reported by

the 2 groups on the day of the operation to discomfort reported by patients and which are reduced in the haemorrhoidectomy group thanks to the endovenous analgesia pump. Forlini also described 46% of patients reporting pain during the first 24 to 48h post-ligation which is attenuated with sitz baths and analgesia. During the first post-operative day the differences in pain reported are statistically significant between the 2 groups in a more manifest way after 48 to 72h when endovenous analgesia was withdrawn from the haemorrhoidectomy patients; this frequently coincides with the first bowel movement.

Similar to figures observed for post-operative pain, statistically significant differences were detected for the ingestion of analgesia. It is notable that patients treated with rubber band ligation virtually did not require analgesics.

Performing a haemorrhoidectomy with Ligasure is a safe method which does not involve bleeding and is reported to cause less pain than other exeresis techniques.[10] In any case, in the light of these results and as observed in various comparative studies published, we consider that the existence of pain is more related to whether or not there is a surgical wound rather than different treatment instrumentation.

A highly appreciated factor in the wellbeing of the patient is time off work and in our study the result obtained was very notable; we observed that patients treated by haemorrhoidectomy required a mean of 30 days off work and patients treated with rubber band ligation could go back to work immediately.

The fact that the study was not randomized may be a limitation of the study. This is conditioned by the existence of patients with cutaneous external pathology who must undergo surgery; however, the clear homogeneity of the groups and the high statistical significance together with the broad value of the sample helps us to accept the results obtained.

Various publications have insisted that the possibility of recidivism is the main problem in the medium-long term after rubber band ligation.[11,12,13,14] For this reason we extended the follow-up of patients for a post-operative year even though they were healed before this. The latest publications describe groups in which 80% to 90% of patients are symptom-free after 2 years.[3,7,15,16] These figures coincide with what we observed in our study just as we emphasise that a broad ligation of the three haemorrhoidal packets is necessary.

The few complications observed indicate that both treatments are safe procedures to manage haemorrhoids.

In light of the results obtained together with the high degree of satisfaction revealed by patients we conclude that rubber band ligation is effective for the treatment of grade 3 haemorrhoids and the few complications and little post-operative pain enables us to recommend it as the procedure of choice for the management of this condition.

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Discussion

This study investigated the post-operative pain experienced by patients following oral surgery under day case general anaesthesia. We were disappointed to find 42.6% of patients experiencing moderate to severe pain at 6h after surgery and that this had reduced little at 24h. This finding was despite our prescription of ibuprofen, paracetamol and codeine according to the best research evidence and was no better than has been reported by other authors. Regardless of the quality of the intervention, pain following oral surgery may never be completely eliminated, but it should be minimised as much as possible. It has been suggested that the standard to strive for is for patients to experience post-operative pain that is not greater than mild in severity [10]. Other authors have reported similar results to us [22] or worse [23]. Our study recorded dispensed analgesics but made no attempt to check compliance of dosing. It may be that patients did not take the medication as recommended. Our verbal instructions are for patients to take analgesics regularly for 24h rather than on a "when necessary" basis. Patients may have taken medications only when necessary or not at all. Pain after the surgical removal of wisdom teeth is reported to peak at the first 12 h and therefore we were surprised that the severity of pain was diminished very little at 24h [24]. However, the patients in this study were undergoing procedures other than the surgical removal of wisdom teeth alone. Some patients reported no pain and this is likely to be because they were undergoing only simple surgery but required general anaesthesia because of their level of anxiety or lack of co-operation.

One study has investigated whether pre-packaged analgesics results in better compliance and improved post-operative pain relief. The authors found no significant difference in pain intensity between the group requiring analgesics at the discretion of the surgeon and those requiring the pre-packaged analgesics [25], although others have shown significant reduction in pain intensity using pre-packaging. This practice also has the advantage of reducing the risk of overdose [26].

It is often difficult to measure patient satisfaction. In this study, patients were asked about whether they were satisfied with the prescribed take home analgesic in managing their post-operative pain. In addition, they also gave an overall rating of satisfaction about their pain relief. Despite a large number of patients experiencing pain above the level of moderate pain, the majority were satisfied with the analgesics prescribed. The pattern and frequency of analgesic consumption varies depending on individual's pain threshold and most tend to consume analgesics only as required. Patient education may therefore be a requirement for improving the pain experience after surgery.

Overall, only 16% of patients required additional self-prescribed analgesics. This is much lower than the findings of McHugh and Thoms who found a high proportion of patients (43%) had to obtain additional analgesics to those prescribed following discharge from day case surgery [7]. In this study all patients were discharged with analgesics to take home but the choice of analgesic varied according to the surgeon's opinion of the anticipated patient post-operative pain. This may have been influenced by the complexity of surgery, time of surgery, and other factors such as knowledge, experience and attitudes. Improving patients' post-operative pain experience may therefore require staff education. The group who were prescribed ibuprofen only had the highest incidence of additional self-prescribed analgesic requirement. The results suggest that ibuprofen alone as take home analgesic may not be sufficient and patients would benefit from a broader spectrum of analgesic which include a combination of NSAID and a compound analgesic. We do have a departmental protocol for the type of analgesia to prescribe according to anticipated pain severity but protocol adherence may not have been ideal even if

anticipated pain appropriately determined. It was however good that most patients received a NSAID and a range of analgesics.

The overall rating of patient satisfaction with pain relief was high despite a large proportion reporting moderate to severe pain at 6h and 24h. This finding is similar to that of previous studies [7, 12, 27]. The discrepancy may be due to different dimensions of patient satisfaction being measured with patients reporting satisfaction with care by staff [28]. This paradoxical relationship between patient satisfaction and pain severity suggests that general satisfaction questions should not be used in isolation as they are unreliable [29].

Conclusion

Despite a departmental recommendation of prescribed systemic analgesia based on best research we found that an unacceptably large proportion of patients experienced moderate to severe pain after day case oral surgery under general anaesthesia at 6h and 24h. Strategies need to be considered to improve the patient experience. These may include patient and staff education, consideration of the routine use of a wider spectrum of analgesics and interventions to minimise onset of pain with pre-emptive or protective analgesia.

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