## **ORIGINAL ARTICLE**

# Radiofrequency Ablation for Treatment of Haemorrhoids. Pilot Study

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## ABSTRACT

Haemorrhoids represent a common condition with the vast majority of patients responding to conservative management. A certain proportion of patients require intervention. The aim of this study was to evaluate the outcomes of a novel, minimally invasive technique employing radiofrequency ablation (RFA) energy (RAFAELO) to treat haemorrhoidal disease.

**Methods:** This was a prospective study involving 13 patients. All procedures were performed under deep sedation and local anaesthetic using a HPR45I probe. Patient demographics and outcomes were recorded. The Haemorrhoidal Severity Score (HSS) was administered pre-operatively and at a two-month interval. All patients in the study had failed banding and their main symptom was bleeding.

**Results:** The median age was 34 (range 20-70). There were eight males and five females. There were no immediate postoperative complications. There was one secondary haemorrhage nine days following surgery, which settled conservatively. HSS improved from 6.84 (SD1.8) before the procedure to 1.9 (SD1.2) after the procedure. The mean return to normal activities was 2 days.

**Conclusion:** RFA is a safe and effective treatment for symptomatic haemorrhoids. It allows a quick return to normal activities. Further studies are required to establish long term efficacy.

Keywords: Radio-frequency, Ablation, Haemorrhoids, RFA, RAFAELO

### INTRODUCTION

Approximately 50% to 66% of people have problems with haemorrhoids at some point in their lives<sup>1,2</sup>. As a condition, they are known to be difficult to treat and even when treatment is considered effective the side effects can be intolerable. Over the years many techniques have been developed with varying rates of success. Because of this haemorrhoid treatment has long posed a problem for clinicians. There is very low evidence about the management of grade 1 to 3 haemorrhoids regarding different treatment options in term of pain, recurrence of symptoms ,patient satisfaction. Haemorrhoidal disease (HD) is a common colorectal condition that often requires surgical treatment. Less invasive procedures are usually more acceptable to patients. The aim of this study was to report the outcome of a novel and minimally invasive technique employing a radiofrequency ablation (RFA) energy (Rafaelo<sup>®</sup>) to treat HD.

**Epidemiology:** As we have previously stated, haemorrhoidal disease is very common, although the exact incidence of haemorrhoids is difficult to quantify. This is because despite approximations of 50-66% of adults suffering with haemorrhoids at some point in their lives, only a small percentage (approx. 30%) of the population actively seek medical attention<sup>1,2</sup>. Unfortunately, this can lead to delayed presentations; leading to more advanced disease and added complications.

The gender epidemiology of haemorrhoids shows that both males and females are affected with about equal frequency<sup>1</sup>, with our study showing slight bias towards men, who make up 61.5% of our study. In regard to age. This shows that in general co morbidity is often not a limiting factor when deciding upon treatment modality. Interestingly, there does seem to be both racial and socio-economic factors associated with haemorrhoids, with a higher prevalence found in Caucasians and those coming from a wealthier background<sup>2</sup>. This would conflict with the epidemiological findings in regard to constipation, which showed a dramatic rise in those aged 65 and above, more common in afro-Caribbean's and from a low socio economic status<sup>2</sup>. This finding is interesting as one would think to associate hard, difficult to pass stools placing increased pressure on the anal cushions and therefore an increase in haemorrhoidal disease, and is a reason why improving dietary intake of fibre and fluid intake are key components of nonoperative treatments of haemorrhoids to prevent worsening symptoms<sup>2</sup>.

**Ánal cushions:** The 'normal, healthy' anal cushions, where the pathogenesis of haemorrhoids originates from, form part of the anal canal. They are made up of a combination of vascular

connective tissue, elastic fibres and collagen, and are lined by cylindrical epithelium<sup>3</sup>. The locations of the major anal cushions are generally found in three positions within the anal canal: right anterior; right posterior-lateral; left lateral, which can be characterised using a clock face as the 11, 7 and 3 o'clock positions respectively. Accompanying these 3 cushions are various numbers of minor cushions lying between them<sup>4</sup>. Although it is not fully understood the natural benefit anal cushions provide, it is postulated that they play a key role in a number of functions. These include but are not limited to: facilitating the human continence mechanism; sensing pressure from rectal contents; Assist in closing the anal canal; providing a role in preventing the anal sphincter from sustaining injury<sup>5,6</sup>. Therefore, successful effective treatment of haemorrhoids not only should focus on reducing/eliminating the symptoms that patients present with, but also focus on maintaining the important functions that the anal cushions provide.

The sliding theory, popularized by Thomson<sup>3</sup> and widely accepted, proposes that haemorrhoids form when the tissues that support the anal cushions disintegrate, resulting in a sliding, or displacement, of the mucosa which lines the anal cushions. This theory has since been built on by Lierse7, who showed that collagen and elastic fibres form a lattice-like structure around haemorrhoid vessels. When the extracellular matrixes (ECM) of these fibres disintegrate, the likelihood of haemorrhoids increases. Willis et al<sup>8</sup> has further added weight to this by being able to illustrate that there is a clear link between haemorrhoids and a reduced amount of collagen, leading to an increase in laxity. Several enzymes or mediators involved in the disintegration of these fibres have been analysed. One in particular appears to have a significant effect on breaking down the ECM, Matrix metalloproteinase (MMP), a zinc-dependent proteinase. A study conducted by Han et al9 concluded that the destructive nature of MMP-9 on elastic fibres within the anal cushions has a significant effect on the pathogenesis of haemorrhoids. MMP-9 was found to be over-expressed in patients with haemorrhoids, compared to those with normal anal cushion tissue.

#### Management modalities

**Non-surgical:** There are numerous approaches to the management of haemorrhoids, with the usual stepwise approach of conservative, non-surgical and finally surgical interventions, dependent on the degree of severity and the impact that symptoms are having on patients. The first port of call for managing haemorrhoids focuses on lifestyle changes to diet, and simple

topical treatments to ease symptoms. The mainstays of lifestyle adaptations involve increasing oral fluid intake, decreasing fat consumption, avoiding straining and increasing the amount of fibre consumed daily<sup>3</sup>. The focus on increasing dietary fibre centres around reducing the hardness of stool, which when passing via the anal canal could have shearing effects on the haemorrhoids present. A meta-analysis carried out by Alonso-Coello et al<sup>10</sup> found that increasing fibre intake had beneficial effects on bleeding by 50%, however did not show improvement in pain or prolapse. The study mainly focused on grades I+II haemorrhoids, whereas our study has focused more on grade III-IV, however, increasing fibre intake and other lifestyle adaptations should still form adjunct interventions for more advanced stages of haemorrhoids.

Once diet and lifestyle adaptations have been explored, the next steps focus on non-surgical interventions. Currently, rubber band ligation is the most popular choice of treatment for grade I and II haemorrhoids in the out-patient setting<sup>17</sup>. This involves, as the name suggests, using a rubber band to ligate haemorrhoidal tissue, causing the tissue to become ischaemic, necrose and scar. This eventually leads to the connective tissue fixating to the rectal wall. Iyer et al<sup>11</sup> found in their study of over 800 patients that rubber band ligation had a success rate of 80%.

But despite being a popular choice for haemorrhoids management, rubber band ligation does not come without risks and problems. One issue with rubber band ligation is the proximity of haemorrhoid tissue to the dentate line. If the rubber band is needed to be placed close to the dentate line, due to somatic nerve afferents being located close to the dentate line, there is a significant increase in the risk of causing severe pain. Also, the success rate for eliminating symptoms from haemorrhoids decreases as the number of rubber bands needed to ligate increases, which is more pronounced when four rubber bands is exceeded. Furthermore, despite being effective for Grades I and II haemorrhoids, for more advanced haemorrhoids, for example prolapsed haemorrhoids, rubber band ligation is much less effective than surgical options<sup>12</sup>, which we have explored in our study.

Surgical options: If the above treatments are unsuccessful or are not suitable for treating advanced haemorrhoid disease (grade IIIsurgical intervention is IV) then required. Open haemorrhoidectomy, characterised as the Milligan Morgan haemorrhoidectomy is widely used in the management of Grade IV haemorrhoids, and is classed as the most effective treatment for this category of haemorrhoids. Both the internal and external parts of the haemorrhoid are excised whilst maintaining enough skin is left to avoid anal stenosis<sup>13</sup>. It involves making an incision at the base of the haemorrhoid, before excising the haemorrhoid<sup>4</sup>. This can be done in a variety of ways, using scissors, diathermy or a vascular sealing device<sup>13</sup>. It has historically been the treatment of choice for more advanced haemorrhoids (grade III-IV). Recurrence rates in those undergoing haemorrhoidectomies are around 2%<sup>15</sup>, with longer term prolapse recurrence in one 7-year study being around 10%.

However, despite being the favoured choice in advand haemorrhoids, the major drawback of haemorrhoidectomy is post-operative pain. Again, as with rubber band ligation, this is linked to the proximity, or in some cases being below, the dentate line. Bleeding and infection are uncommon. One additional negative complication from haemorrhoidectomy that is documented in the literature is urinary retention, with varying figures. One study found up to 34% of patients undergoing haemorrhoidectomy developing the complication, however a more recent study puts this figure at  $5\%^{16}$ . It is postulated that this is caused by pelvic floor spasm and over using IV fluids post op.

**THD with Mucopexy:** As the main complication from haemorrhoidectomy is post-op pain, numerous ideas have been put forth and tested to see if the same efficacy as haemorrhoidectomy can be created, with a reduction in the debilitating complications it generates. THD, as it does not involve incisions or removal of any haemorrhoidal tissue, can be described

as minimally invasive surgery. The technique was first developed by Morinaga et al in 199517. It involves identifying the haemorrhoidal arteries, from the point of origin at the superior rectal artery, by using a doppler transducer with a specialist anoscope. Once the arteries feeding from the superior rectal artery are identified, they are ligated using an absorbable suture, which acts to decrease blood flow to the area much like rubber band ligation.

Various studies have been carried out focusing on THD as a stand-alone intervention. Giordiano et al<sup>18</sup> found that due to its nature as minimally invasive surgery, THD resulted in a much quicker return to work/normal functioning. Felice<sup>34</sup> from a cohort of patients found that THD provided 68 а 97% resolution/improvement to prolapse symptoms, and a 98% (56 patients suffering with bleeding pre-op) improvement from bleeding. In regards of recurrence, Ratto et al<sup>19</sup> found that from a cohort of 1000 patients ((8.2%) grade 2, (83.5%) grade 3, (8.3%) as grade 4), recurrence rate was 9.5% with a mean of 44 months follow-up. The breakdown of recurrence is as follows: 12 complaining of bleeding; 46 with prolapse; 37 with a combination of the two. At final follow-up, more than 95% from the 1000 patients had no current signs of haemorrhoidal disease on examination. In regard to a more likely negative outcome, they concluded the following had negative effects on outcomes: Grade IV haemorrhoids; younger age; higher artery ligation.

This initial technique (THD) has since been modified further, by introducing a recto anal repair, or mucopexy, in order to secure any prolapse caused by haemorrhoidal tissue. As the suture line from the mucopexy is above the dentate line, the theory is that this will reduce the amount of post op pain compared to other procedures. De Nardi et al<sup>20</sup> found that when compared with haemorrhoidectomy, Mucopexy had similar outcomes on postoperative pain and morbidity. Infantino et al in 2010<sup>8</sup>, when looking at grade II and grade III haemorrhoids found that THD with mucopexy was highly effective and a relatively pain free procedure, with those involved in the study suffering with post-op pain being managed with simple analgesics for a few days. Recurrence rate was 6.25%. A literature review carried out by Figuieredo<sup>21</sup> showed that reported prolapse rates are guite varied study to study, with a range between 3%-21%. The focus of surgical interventions is more aimed at grade III and grade IV haemorrhoids, which Dal Monte focussed on in comparing THD plus mucopexy with THD. They found that relapse rates were almost half in the mucopexy group (3.7%) compared to THD on its own (6%) in grade III haemorrhoids. Multiple other studies<sup>22, 23</sup> place recurrence of prolapse at around the 10% mark.

#### RAFAELO

#### Rafaelo Procedure (latest)

Over the years there are different surgical techniques from starting from injection ,banding to excisional surgery to treat haemorrhoids. Till today there is not single perfect surgical technique to treat haemorrhoids. Radiofrequency is safe and reliable technology. Rafaelo is recent invention for the treatment of all grade of haemorrhoids. The procedure is done under the local anaesthesia with or without sedation. After the insertion of anoscope, the local anaesthetic is administered at the base of haemorrhoidal tissue between the haemorrhoidal tissue and muscle layer. The probe HPR45i is inserted to the haemorrhoidal tissue base and radiofrequency ablation energy is given to the haemorrhoidal tissue. Two to three cycles given depending upon Instrument that provide degree of haemorrhoids. the radiofrequency in the form of heat to the blood vessels that lead to haemorrhoidal tissue shrinkage and later on the haemorrhoidal tissue shed away. The procedure normally done as day case and duration of procedure is in minutes. The advantage of the procedure is minimal pain during and after the procedure. Latest evidence is that it is effective in 90% of cases.

As all the surgical procedures carry some risks. This procedure can lead to postoperative pain, some bleeding and in

very few cases lead to incontinence. The Benefit for patients after the procedure is quick relief of symptoms, minimal bleeding, local anaesthesia and faster recovery. Benefits for surgeon is that it's easy and quick procedure with high patient satisfaction. In this paper we are going to describe the newly invented probe that provide radiofrequency ablation energy by F care system, Belgium. Our main goal is to check the safety and success of the procedure.



Fig 1. Rafaelo procedure

#### MATERIALS AND METHODS

We prospectively analysed 13 patients who underwent Rafaelo procedure. The collected data included demographic parameters (Table 1), details on the procedure, postoperative outcomes, selfreported pain, HSS score and recurrence rates. All patients were included according to the coded procedure carried out (RAFAELO). These procedures were performed between September 2019 until February 2020 by one senior colorectal surgeon Mr Eddie Myers. All patients were referred from a primary care facility with haemorrhoids either prior to or following initial diagnosis of haemorrhoids +/- treatment from a general practitioner. These patients were seen in a general surgical clinic, reassessed and counselled on the available treatments for their hemorrhoidal disease. All the patients previously had failed banding or injection sclerotherapy. All patients included agreed to undergo Rafaelo and were fully aware of the procedure technique and the potential risks/adverse problems possible.

Males (n, %)	8	61.5%
Females (n, %)	5	38.4%
Age (median)	22-70(median 34)	
ASA (n, %)	1 =	92%
	2 =	7.6%
	3 =	0

Table 1. Patient Demographics and ASA grade

Outcome measures: The primary outcome measure was the impact of Rafaelo on reduction of HSS score which is shown in

Table 2, self-reported pain and post-operative complications. Secondary outcome was Recurrence that was determined by follow up in surgical clinic in 2 months time combined with retrospective analysis of patient records to identify patients that recurrence following discharge from clinic. The patients were planned for one follow up which was at 2 months. Table 2: HSS Score

Itching
Bleeding
Faecal Soiling
Reduction By hand
Pain

Score 0. never. Score 1. Less than once a week Score 2. 1-6 times weekly Score 3. Every day

**Statistical analysis:** The mean, median and Standard deviation (SD) was calculated with SPSS software version 19.

#### RESULTS

There were total 13 patients, 8(61.5%) patients were male. The median age was 34(22-70) and 92% of the patients were ASA grade 1. The HSS score was calculated in all 13 patients preoperatively and 2 months after the RAFAELO procedure. There was substantial improvement in all components of HSS Score. Itching was improved from HSS score of 23 to. 11, Bleeding 27 to 0, faecal soiling 12 to 5, Manual reduction from 5 to 0 and pain from 22 to 12. Individual patient HSS score preoperative and postoperative shown in table 4. The mean HSS score calculated preoperatively was 6.84 (SD1.8) which was improved to 1.9(SD1.2) shown in Table 3and Fig 2. 1(7.7%) out of 13 patients had secondary hemorrage at 9th day which settled conservatively without any intervention. None of the patients showed recurrence after 2 months. All patients were return to normal activity after 48 hours.

**Itching:** HSS score was calculated to be 23 preoperatively in 13 patients and the HSS score was reduce to 11 aftert 12 months which showed substantial reduction in itching after the procedure **Bleeding:** Bleeding was the main symptom that was calculated highest on the HSS score preoperatively.

The score was 27 and after the follow up in 2 months the HSS score was zero. This showed that all the patient didn't have bleeding after 2 months.

**Faecal Soiling:** The symptom of faecal soiling was scored 12 that was reduce to 5 postoperatively at 2 months.

**Reduction by Hands:** Manual reduction of haemorrhoids by hands score 5 before procedure. The score was reduce to 0. none of the patient complain of manual reduction after 2 months.

**Pain:** Pain was the second important component in our study that our patient complaint of before the procedure. HSS score was calculated to be 23 and reduce to 12 after 2 months. The results showed significant reduction in the pain after the procedure.



Fig 2. This shows the mean of HSS score preoperatively and postoperatively by plotting whisker box plot.

Table 3.HSS Score

	Preoperative	Post operative	
Itching	23	11	
Bleeding	27	0	
Faecal soiling	12	5	
Reduction by hand	5	0	
pain	22	12	
Table 4. Individual Patient HSS Score preoperative and postoperative after 2			
months.			

Patient	Pre-op HSS score	Post-op HSS score (after 2months)
1	7	3
2	4	0
3	5	1
4	6	2
5	7	2
6	11	3
7	6	2
8	10	3
9	7	2
10	5	1
11	6	1
12	8	3
13	7	2

#### DISCUSSION

In our study we found that RFA results in improvement of HSS score with good quality of life. There were no major complications and no complain of incontinence. Our patients mainly complained of bleeding that was setelled after the procedure. Gupta and colleagues were the pioneers who demonstrate the better outcome after the RFA<sup>24</sup>. They also compare the RFA with rubber band ligation for grade 2 haemorrhoids. their results showed the better prognosis for RFA. Even their results were better, but they found increase in incidence of bleeding and change in degree of haemorrhoid to 3 or 4 as compare to rubber band ligation<sup>25</sup>. Their results showed that return to work was 2 days. RFA was initially design for grade 1 and 2 haemorroids<sup>26</sup>. Latest evidence showed that it can be used for grade 3 and grade 4 haemorrhoids. It is first novel study of Ireland we limit our procedure to grade 1 and grade 2 haemorrhoids. Our treatment was given to the patients who had failed rubber band ligation and injection sclerotherapy for haemorrhoids. Our experience confirm that RFA can be offered to all patients with grade 1 and 2 haemorrhoids as primary therapy, but patient proper counselling is required as RFA can only deal with internal haemorrhoids as for external haemorrhoids patient may need excision.

The fear for surgeon after haemorrhoidectomy that the patient will get pain, anal stenosis and incontinence lead to surgeon to consider new techniques that are less painful with decrease risk of faecal incontinence. Various mode of medical treatment like antibiotics ,various type of analgesia have been used with little success. RFA for haemorrhoids consider safe procedure with less complication as compare to conventional haemorrhoidectomy. Gupta et all in 2003 first surgeon who did RFA for haemorrhoids on 50 patients from April 2001 to March 2002 and followed up the patient for 12 months. Their result showed that 14 percent of the patient has bleeding during the first 4 weeks and all the patients had some amount of pain. They followed up the patient at 12 weeks and 12 months showed that post op symptoms got better during the follow up. None of the patients got complications like anal stenosis, stricture or faecal incontinence and postoperative pain.

The other techniques like stapled haemorrhoidopexy and Doppler guided haemorrhoidal artery ligation also been used for treating haemorrhoid disease. There is low evidence but still they are associated with less pain and early return to work<sup>27</sup>. SH that involve the removal of circumferential rectal mucosa leading the prolapse haemorrhoids back to normal position it is believe that that blood supply to haemorrhoids is also disrupted while excision of the rectal mucosa. Kolbert et al did the Doppler on the patient after the SH and showed that 80 percent of the blood supply

remain to the haemorrhoidal tissue. The complications associated with SH ranges 6-31%<sup>28</sup>. This lead most of the surgeon to abandon this procedure. The complications are comparable to conventional haemorrhoidectomy and reported as pelvic sepsis ,rectal anastomotic leak,thrombosis<sup>29</sup> rectal perforation ,and fornier gangrene<sup>29</sup>.

By comparing RFA to SH surgeon has peace of mind that these complications cannot be encountered.

Doppler guided haemorrhoidal artery ligation was started by moringa. they claim that this procedure is associated with less pain. They believe that by ligating the haemorrhoidal vessel will lead to haemorrhoids shrinkage by using Doppler. The problem with the procedure is that it is not possible to ligate all the haemorrhoidal branches that lead to surgeons to think about the completion of procedure<sup>49</sup> this procedure cannot be done without anaesthesia This procedure is not successful in treating the prolapse haemorrhoids<sup>30</sup>. DHAL has the success rate 62%-88% in one year follow up<sup>31</sup>. The both procedure SH and DHAL partly treat the haemorrhoidal disease.

Gupta at al in did RFA and fixation of haemorrhoids on 2376 patients between 1998-2005. They concluded that RFA with fixation of haemorrhoids lead to less post-operative pain, shorter hospital stays and early return to work. They concluded that the recurrence rate is less than 1.5% and complication rate is 3.5% that include post-operative bleeding, pain and perianal thrombosis 45. Eddama et al in a study between 2016 to 2018 who did RFA for haemorridal disease in 27 patients. All the procedure was performed under the local anaesthesia and deep anaesthesia. They also calculated the HSS score before and after the procedure. Their results showed that the improvement the HSS score from 7.6 to 1.6 after the procedure. The patient been follow up to 2 months. One (4%) patient reported the post op bleeding after the RFA. A total number of 27 patients who had RFA for the treatment of HD were recruited to this study. The procedure was performed under deep sedation and local anesthesia. Patients' demographics; hemorrhoids severity score (HSS); quality of life; pain and satisfaction scores; and recurrence rate were recorded.

The very important issue is the cost of the RFA that we did not address. The cost for the treatment including HPr45i probe which Is disposable being 300 pounds approximately. Affordability is issue but private sector can afford well. Our study positive points that we complete our patient follow up even in the Covid 19 crisis. The consultant colorectal surgeon performs all the cases by himself and the questioning about the HSS score was done by the team member involve in the study. The limitations of our study that we did not include grade 3 and 4 haemorrhoids. We did not compare the RFA with different treatment modalities available. As we have low sample size, we are not sure that improvement in HSS score can be applied to all population.

#### CONCLUSIONS

Our results concluded that RFA is safe an d effective treatment for hemorrhoids. There is low postoperative pain and bleeding after the procedure with higher patient satisfaction.

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