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Original Research Paper

General Surgery

A STUDY OF HARMONIC SCALPEL ASSISTED HAEMORRHOIDECTOMY AT TERTIARY CARE CENTRE

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ABSTRACT

Background: Conventional haemorrhoidectomy is still considered as gold standard therapy for grade III & IV haemorrhoids. The conventional haemorrhoidectomy can be made easier with the help of harmonic scalpel with associated less post-operative complications. This study evaluated in a randomized prospective manner the differences in; duration of hospital stay, postoperative complications, symptomatic recurrence and cost effectiveness between conventional and harmonic scalpel assisted haemorrhoidectomy.

Methods: The prospective study was carried out in 60 patients of symptomatic grade III & IV haemorrhoids, presented during August 2015 to August 2017. Each group of 30 patients treated with harmonic scalpel assisted haemorrhoidectomy and conventional haemorrhoidectomy; followed up for 6 months for complications.

Results: In present study, the severity of pain was significantly more following conventional haemorrhoidectomy than harmonic scalpel assisted haemorrhoidectomy. Urinary retention was more common with conventional haemorrhoidectomy. Anal incontinence had similar incidence in both the groups of haemorrhoidectomy. Two patients had anal stenosis after conventional haemorrhoidectomy as compared to none in the harmonic scalpel group. No recurrence noted in both the groups. Cost effectiveness of the procedure is measured in form of hospital stay and return to daily activity and harmonic scalpel group have advantage over the conventional haemorrhoidectomy group in terms of less hospital stay and early return to daily activity.

Conclusion: Harmonic scalpel assisted haemorrhoidectomy appears to be a better procedure compared with conventional haemorrhoidectomy in terms of less post-operative complications and decreased hospital stay in symptomatic patients with grade III & IV haemorrhoids.

KEYWORDS : haemorrhoids, conventional haemorrhoidectomy, harmonic scalpel assisted haemorrhoidectomy

Introduction: Haemorrhoids, also known as piles, is one of the commonest ano rectal disorder observed in day today practice of general surgeons. Haemorrhoids arise from congestion of anal cushions and characteristically lie in the 3(left lateral), 7(right posterior) and 11(right anterior) o' clock positions. They are classified into internal and external haemorrhoids. A small subgroup of patients have external as well as internal haemorrhoids (internoexternal piles). The internal haemorrhoids arises above the dentate line while the external arises below the dentate line. The aetiological factors associated with formation of haemorrhoids are chronic constipation, prolonged straining, erect posture, pregnancy, ascites etc. The current theory suggests that shearing forces acting on the anus (for a variety of reasons) lead to caudal displacement of the anal cushions and mucosal trauma. With time, fragmentation of the supporting structures leads to loss of elasticity of the cushions they no longer retract following defaecation[1]. Symptoms may include painless per rectal bleeding, mucus discharge and prolapse. According to Goligher's classification they are classified into four grades based on their appearance and degree of prolapse. In first-degree haemorrhoids (grade I), anal cushions bleed but do not prolapse. In second-degree haemorrhoids (grade II) the anal cushions prolapse through the anus on straining but reduce spontaneously. In third-degree haemorrhoids (grade III), the anal cushions prolapse through the anus on straining or exertion and require manual replacement into the anal canal. In fourth degree haemorrhoids (grade IV), prolapse stay out at all times and is irreducible[2]. The treatment modalities depends upon the symptoms and grades of haemorrhoids. Grade I and early grade II piles can be managed conservatively with associated life style modifications. Grade II haemorrhoids have various treatment options like rubber band ligation and sclerotherapy. Surgical excision of haemorrhoids still remains gold standard treatment for symptomatic Grade III and IV haemorrhoids. The standard surgical procedures which are commonly used are the Milligan Morgan open haemorrhoidectomy and Fergusson's closed haemorrhoidectomy[3,4]. Harmonic Scalpel assisted Haemorrhoidectomy is one of the modification for the open haemorrhoidectomy technique; in which instead of using monopolar or bipolar diathermy, ultrasonic shears (harmonic scalpel) is used for the dissection purpose. This procedure seems to be safe and equally efficient[5]. Major complication associated with Milligan Morgan Haemorrhoidectomy is post-operative pain. Other complications are post-operative haemorrhage, urinary retention, soiling, stenosis and incontinence. Harmonic Scalpel is a new device introduced to surgery in last decade. It uses high frequency sound wave energy to cut and coagulate tissues at the same time at precise point of application. It denatures protein by using ultrasonic vibration to transfer mechanical energy sufficient to break tertiary hydrogen bonds at relatively low temperature compared to conventional diathermy. The blade vibrates at 55.5 kHz over a distance of 80 µm. Because ultrasound is the basis for Harmonic Scalpel® Technology, no electrical energy is conducted to the patient. Harmonic Scalpel assisted Haemorrhoidectomy has emerged to be a safe, rapid modality, with reduced blood loss and post-operative pain. **Ramadan et al** demonstrated decreased operation time, decreased post- operative pain and less use of analgesics in harmonic assisted haemorrhoidectomy compared to conventional surgery[6]. Multiple studies favour this technique. The rationale for evaluating the use of the Harmonic Scalpel for surgical haemorrhoidectomy lay in decreased lateral thermal damage with rapid coagulation of vascular cushions, resulting in reduced operating time and post-operative pain.

Patients and Methods

This prospective randomized controlled trial was conducted at tertiary care government hospital from August 2015 to August 2017. Total 60 symptomatic patients with grade III and grade IV Haemorrhoids were included in this study, and divided into Group 1 and group 2. Group 1 included 30 patients, in whom Harmonic

Scalpel assisted Haemorrhoidectomy was used as treatment. Group 2 – included 30 patients, in whom conventional Milligan Morgan Haemorrhoidectomy was used. All patients with Grade III, Grade IV were admitted through OPD on an elective basis. Both genders were aged 18 years and above, up to 70 years of age were included. Exclusions were presence of additional anorectal pathology (fistula in ano, anal fissures etc.), patients with neurological deficit, and patients with chronic pain syndrome, already on narcotics and those not fit for anaesthesia. Written valid informed consent for the surgery explained to the patients and relatives. Randomization was performed at the time of anaesthesia. Surgery was performed under general or spinal anaesthesia at the discretion of the anaesthetist. All procedures carried out in lithotomy position. Patients in Group 1 underwent Harmonic Scalpel assisted Haemorrhoidectomy. We used the "Focus "hand probe of the harmonic for this particular surgery. The power of the Harmonic Scalpel was set at level 3. The internal and external components of each haemorrhoidal complex grasped and elevated by a tooth forceps and the haemorrhoid bundle carefully dissected off the internal anal sphincter using the Harmonic shears. Control of the pedicle was achieved by coagulation using the same device. Homeostasis was obtained using the Harmonic Scalpel. Patients in Group 2 underwent Classical Milligan-Morgan procedure for haemorrhoidectomy. This technique used scissors alongwith diathermy to excise the three anal cushions leaving a mucosal bridge between each wound. The cranial aspect of the cushions was ligated using an absorbable suture (Vicryl 2-0) and the wounds were left open to heal by secondary intention. Surgery was standardized in each case by same team of surgeons. Mean operation time was documented, and post-operative pain was assessed using visual analogue scale (0-10). The patients were followed up upto 6 months. The data obtained was analysed using standard biostatistical tests like student's t-test, chi-square test

Results: Out of the 60 patients with symptomatic grade III and grade IV haemorrhoids, 38(63.33%) were males and 22(36.67%) were females. The age limit of the included patients had range from 23 years to 67 years. The mean ages of the participants were 43.28 years in the conventional method group and 39.84 years in the harmonic scalpel group (table 1).

group characteristics	Harmonic scalpel assisted group	Conventional haemorrhoidectomy group	Total
Males	18	20	38
Females	12	10	22
Mean age	39.84 years	43.28 years	

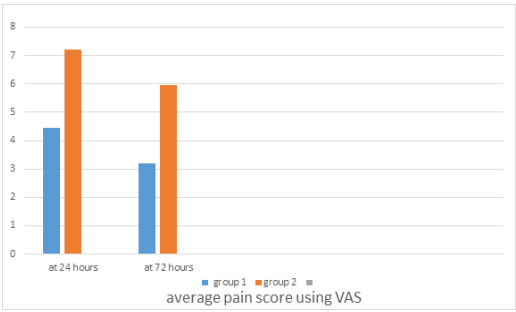
The mean operation times were 23.1 min in harmonic scalpel assisted and 33.2 min. for the conventional group respectively, and this difference was statistically significant with the operation time being significantly shorter in the ultrasonic scalpel group ($P < 0.05$). The mean hospital stays were 5.7 days in the conventional method group and 3.4 days in the ultrasonic scalpel group, this difference was also statistically significant ($p<0.05$).(table 2)

	Harmonic scalpel assisted group	Conventional haemorrhoidectomy group	P value
Mean operation time	23.1 min.	33.2 min.	0.025
Mean hospital stay	3.4 days	5.7 days	0.025

(*p value measured using student's t test)

The pain score measured using visual analogue scale at 24 hours and 72 hours after surgery. After 24 hours of surgery, on VAS the average severity of pain for the harmonic scalpel assisted group was 4.46 and for conventional group was 7.20 respectively. The difference is statistically significant ($p<0.050$). At 72 hours after surgery the results were 3.21 and 5.96 respectively (table3).

Pain score using visual analogue scale	Harmonic scalpel assisted group	Conventional haemorrhoidectomy group
At 24 hours of surgery	4.46	7.20
At 72 hours of surgery	3.21	5.96



Though the pain score was found to be less in harmonic scalpel assisted group, the average requirement of analgesics was not significantly less in that group in first 24 hours of surgery.

There was no major bleeding like complication in both the groups. In conventional surgery group, 1 patient having post-op urinary retention and 2 patient have anal stenosis compared to nil in the harmonic scalpel assisted group. The incidence of anal incontinence was similar both the groups i.e. 1 patient from both the group (table 4).

Other complications	Harmonic scalpel assisted group	Conventional haemorrhoidectomy group
Post-op urinary retention	0	1
Anal stenosis	0	2
Anal incontinence	1	1

Discussion: haemorrhoids is one of the commonest ano-rectal condition affecting mankind since ages. It is also thought that it is the curse of the vertical posture as this condition not found in other animals. The treatment of haemorrhoids depends upon the grade and symptoms of the patient. For grade III and grade IV haemorrhoids surgical excision of the haemorrhoids (open or closed haemorrhoidectomy) is still considered as gold standard therapy. But the Milligan Morgan haemorrhoidectomy is associated with many post-operative complications like pain, bleeding, urinary retention and anal stenosis etc. Because of such list of complications; the variety of modifications to the conventional surgery came out. Harmonic scalpel assisted surgery is one of these modifications. As harmonic scalpel causes less thermal damage, the possible complication rate get reduced. So in the present study we have tried to evaluate the role of harmonic scalpel assisted haemorrhoidectomy and its outcomes in comparison with the conventional surgery.

In our study the average age of the patients is around 40 years which is comparable with studies of Philipose et.al.[7] In the present study there is slight male preponderance as far as the incidence of the piles is concerned and it's similar with the studies of Saxena et al[8].

The mean operating time for ultrasonic groups is 23.1 min. and for conventional group is 33.8 min. There is statistically significant difference in both the groups. The reason behind this is the harmonic probe (Focus) has the ability to dissect as well as coagulate simultaneously. The operating time is slightly higher compared with other studies[9,10]. It may be because the majority of the patients in this study have all the three columns of the haemorrhoids present.

The average hospital stay is significantly less in harmonic assisted group and it's comparable with majority of the other studies[9,11] except the one study from Korea where its quiet high[10]. Because of the decreased post-op hospital stay, there is efficient use of infrastructure as well as manpower and thus helps in average cost reduction for the hospital. This is one of the important advantage of this procedure as ours is tertiary care government hospital where patient load is always high. The earlier return to work also helps the patients as there is significantly decreased loss of their daily wages.

The post-operative pain is one of the major factor in the assessment of this study. The post-operative pain is significantly less in harmonic scalpel assisted group as is comparable with most of the studies[9].

The reason behind this is related with the property of harmonic scalpel. The harmonic scalpel causes less thermal damage and having better precision; because of these reasons, there is less post-operative pain.

The other complications like urinary retention and post procedure anal stenosis are also less frequently observed in the harmonic scalpel assisted group. The post-operative anal incontinence is observed in one patient from both the groups but it is most likely related with pre procedure anal dilatation as a part of surgery. But all these complications are managed conservatively and doesn't required any major surgical interventions.

Conclusion: According to the results of the present study, the harmonic scalpel assisted haemorrhoidectomy is safe and effective modification of conventional haemorrhoidectomy. The results of harmonic assisted surgery are significantly better in terms of decreased post-operative pain and less hospital stay compared with conventional surgery. Thus the harmonic scalpel assisted surgery is better and cost effect alternative to conventional haemorrhoidectomy in management of grade III and grade IV haemorrhoids.

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