HARMONIC SCALPEL HAEMORRHOIDECTOMY VS CONVENTIONAL MILLIGAN AND MORGAN HAEMORRHOIDECTOMY: A PROSPECTIVE STUDY
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ABSTRACT: BACKGROUND: Haemorrhoids are one of the most frequent anorectal disorders encountered in the primary care setting. Haemorrhoidectomy is the procedure of choice. Harmonic scalpel had been advocated for performing bloodless Haemorrhoidectomy, in place of electric cautery and ligatures. AIM: The aim of this study is to compare Harmonic scalpel Haemorrhoidectomy with conventional M. M. Haemorrhoidectomy using electric cautery in the management of grade III and grade IV haemorrhoids with reference to certain characteristics like postoperative pain, complications, hospital stay, cost of surgery. METHODS AND MATERIALS: This is a randomized single blind control study with 50 patients divided into two groups. 25 patients underwent M. M. Haemorrhoidectomy (M. M. Group), and rest underwent Harmonic scalpel Haemorrhoidectomy (H. S. Group). Results were compared in relation to certain characteristics like perioperative bleeding, postoperative pain and complications, hospital stay, cost of surgery. RESULTS: Age and gender wise distribution in both groups is comparable. Intraoperative bleeding was more frequent in the MM group than in HS group (32% versus 16% respectively). Intraoperative bleeding was more frequent in the MM group than in HS group (32% versus 16% respectively). Hospital stay was prolonged in the MM group than HS group, as 44% in MM group were discharged at three days, when compared to 76% in HS group. CONCLUSION: Harmonic scalpel haemorrhoidectomy had better outcome in characteristics like postoperative pain, post-operative complications, hospital stay, but its more expensive than conventional M. M. Haemorrhoidectomy.

KEYWORDS: Harmonic scalpel, Haemorrhoidectomy, Milligan Morgan.

INTRODUCTION: Haemorrhoids are one of the commonest anorectal disorders encountered in general surgical practice. They are the most common cause of bleeding per rectum and responsible for considerable patient suffering and disability.[1] Haemorrhoidectomy is the treatment of choice for grade III and grade IV Haemorrhoids. Post-operative course after haemorrhoidectomy will be protracted and painful. Different surgical techniques and use of recent advancements in instrumentations like Harmonic scalpel, Ligature and circular stapler (PHI) had been advocated for better outcome and to minimize perioperative bleeding and post-operative pain.

Harmonic scalpel is an ultrasonically activated instrument, which vibrates at a rate of 55,000 HZ per second. It generates less temperature during tissue dissection and controls bleeding by coaptive coagulation at low temperatures ranging from 50°C to 100°C. Coagulation occurs by means of protein denaturation when the blade vibrating at 55000 HZ, couples with protein, denaturating it to form a coagulum that seals small coapted vessels. When the effect is prolonged, secondary heat is produced that seals larger vessels.

By contrast, electro surgery and lasers coagulate by burning (Obliterative coagulation) at higher temperatures (150°C to 400°C). Blood and tissue are desiccated and oxidized (Charred)
forming eschar that covers and seals the bleeding area. Rebleeding can occur, when blades are removed during electro surgery, stick to tissue and disrupt the eschar. The precision of cutting and coagulation is controlled by adjusting the power level, blade edge, tissue traction and blade pressure. The reduced postoperative pain after Harmonic Scalpel Haemorrhoidectomy compared with electrocautery controls, likely from the avoidance of lateral thermal injury.(2)

MATERIALS AND METHODS: This is a randomized single blind control study conducted in Osmania General Hospital, Hyderabad. A total number of 50 patients were involved in the study out of whom 25 underwent open M. M. Haemorrhoidectomy and rest of them underwent Harmonic scalpel Haemorrhoidectomy. This study conducted over a period of 20 months (November 2009 to July 2011). Approval of the local ethics committee had been obtained and patients were informed about the study and written consents were taken. All patients were admitted and investigated. Diagnosis was based on digital rectal examination (DRE) and proctoscopy. The patients were randomly selected for Open M. M. Haemorrhoidectomy or Harmonic scalpel haemorrhoidectomy.

Exclusion Criteria: Diabetic patients, Patients with bleeding tendencies, Patients with associated anorectal problems and Patients with history of anorectal operations were excluded.

Operative Technique: Surgery was done under spinal anaesthesia in lithotomy position for all patients. A senior surgeon was present at all surgeries to ensure that same technique was used. In M.M. Group, classical Milligan- Morgan haemorrhoidectomy technique was used.

H.S haemorrhoidectomy: Gordan and Nivatvongs (1999).3 summarized the technique as follows. Using the coagulating shears on power setting5 with the sharp side of the blade up, the dissection of the keratinized haemorrhoidal tissue is begun at the base, working towards the apex. Care is taken to avoid cutting the internal anal sphincter. Once the more friable haemorrhoidal tissue is reached, use the blunt side of the blade with power setting on 3.

The haemorrhoid is excised and haemostasis is well controlled.

Milligan and Morgan Haemorrhoidectomy technique.(4): After injecting dilute adrenaline (1:300000) into subcutaneous tissue between pile masses, artery forceps are applied to skin covering external component of piles and traction applied to reveal the internal component (Pedicle), which is also grasped by artery forceps. V-Cut is made through skin and subcutaneous fibres around the skin holding forceps using knife or cutting diathermy. With traction by operator and assistant, pile mass is carefully dissected off from underlying internal sphincter. Dissection proceeds up the anal canal, with the sides of the mucosal dissection converging towards the pile apex. A transfixation ligature of strong Vycryl is applied to the pedicle at that level and pile excised well distal to ligature. Haemostasis secured using diathermy. Each haemorrhoid is dealt with this in this manner, taking care to leave mucocutaneous bridges.

Operating time and intraoperative complications were observed. Patients were monitored postoperatively till discharge. Patients were asked to rate their pain preoperatively and postoperatively. Postoperative analgesia was administered as two doses of NSAID (Diclofenac) injection intramuscularly up to 2nd postoperative day and there after using oral form of NSAIDs. Depending on the requirement opioid analgesics were given. Persistent pain after 48 hrs. Were included under pain. Required analgesic doses were recorded and analyzed as a marker for pain severity. Accordingly patients were divided into four grades according to Yanagida et al. (2003).5
Grade 1: No pain (No analgesics were taken).
Grade 2: Mild pain (1 dose of NSAID IM in the first 24 hrs. postoperative).
Grade 3: Moderate pain (2 doses of NSAID IM in the first 24 hours postoperative).
Grade 4: Severe pain (Narcotic analgesics were added).

Lactulose 20 ml once daily for two weeks were given, starting on the night of surgery. All patients were advised to have sitz bath twice daily with betadine solution. Follow up was done for a period of three months. Data were analyzed by Epi Info version 3.5.3 using Chi Square test.

RESULTS: This study included 50 patients with III and IV degree haemorrhoids. A total of 25 patients were randomized to receive harmonic scalpel hemorrhoidectomy (HS) and 25 patients underwent the conventional Milligan and Morgan procedure:

1. Age and gender wise distribution in both groups is comparable as shown Tables 1 & 2 and graphs 1 & 2. Most of the patients belonged to age group of 41-50 years.
2. Operating time was initially longer in harmonic scalpel group but as experience was gained operating time was shorter than Milligan Morgan group as shown table 3 and graph 3. Chi square value 0.08, p value 1.00.
3. Intraoperative bleeding was more frequent in the MM group than in HS group (32% versus 16% respectively) as shown in table 4. This indicates that harmonic scalpel haemorrhoidectomy may be suitable for anaemic patients and patients with coagulation disorders. The degree of pain was higher in the MM group than that of the HS group. Urinary retention was more frequent in the MM group than in HS group within the first postoperative week. Urinary catheterization was not needed in any of the cases. The prevalence of postoperative discharge was higher in MM group 40% when compared to the HS group 12% as shown in table 5 and graph 5.
4. Duration of post-operative hospital stay was prolonged in the MM group than HS group, as only 44% in MM group were discharged at three days when compared to 76% in HS group.
5. Long term complications with 3 to 6 months postoperatively in both groups revealed the absence of anal stenosis, acute anal fissure, faecal incontinence and recurrence however, further follow up is needed.
6. While 76% of patients in HS group were discharged after 3 days only 44% were discharged in MM group, 48% of patients in MM group had to stay upto 6 days while only 24% of them stayed till 6 days and 8% of patients in MM group had to stay more than 6 days in the hospital.
7. Harmonic scalpel haemorrhoidectomy is more expensive than conventional Milligan and Morgan hemorrhoidectomy. Although the former operation had significant improved outcomes after surgery, it suggest less post-operative stay, thus providing significant financial benefits to justify the additional expenses.
Table 1: Age wise distribution of patients treated by Harmonic Scalpel Haemorrhoidectomy (HS) & Conventional Milligan & Morgan Haemorrhoidectomy (MM).

| Age Group  | Male | | Female | |
|------------|------|---|--------|---|
|            | Number | Percentage | Number | Percentage |
| 21-30 years| 02   | 8%   | 03     | 12%  |
| 31-40 years| 05   | 20%  | 05     | 20%  |
| 41-50 years| 12   | 48%  | 13     | 52%  |
| 51-60 years| 04   | 16%  | 03     | 12%  |
| 61-70 years| 02   | 8%   | 01     | 4%   |

Table 1

Graph 1: Most of the patients belong to 41-50 yrs group.

| Gender | HS | MM |
|--------|----|----|
|        | Number | Percentage | Number | Percentage |
| Male   | 21   | 84% | 20     | 80% |
| Female | 04   | 16% | 05     | 20% |

Table 2: Gender wise distribution in HS and MM groups

Graph 2: Gender wise Distribution in HS and MM Groups
Intraoperative bleeding

|        | Number | Percentage |
|--------|--------|------------|
| HS     | 04     | 16%        |
| MM     | 08     | 32%        |

Table 3: Intraoperative bleeding in patients treated by HS and MM

Graph. 3: Intraoperative bleeding in patients treated by HS and MM

Postoperative complications

|                  | HS          | MM          |
|------------------|-------------|-------------|
|                  | Number      | Percentage  | Number  | Percentage  |
| Pain             | 10          | 40%         | 15      | 60%         |
| Urinary Retention| 04          | 16%         | 07      | 28%         |
| Bleeding         | 03          | 12%         | 07      | 28%         |
| Discharge        | 03          | 12%         | 10      | 40%         |
| Infection        | 02          | 8%          | 04      | 16%         |

Table 4: Postoperative complications in patients treated by HS and MM

Chi square value 1.194, P value 0.87, degree of freedom 4
Table 5: Duration of postoperative hospital stay in patients treated by Harmonic Scalpel Haemorrhoidectomy (HS) and Conventional Milligan and Morgan Haemorrhoidectomy.

| Postoperative hospital stay (days) | HS   | MM  |
|-----------------------------------|------|-----|
| 1-3                               | 19   | 11  |
| 4-6                               | 6    | 12  |
| >6                                | -    | 2   |

Chi square value 6.13, P value 0.04, and degree of freedom 2.

**DISCUSSION:** Haemorrhoids are one of the most frequent anorectal disorders encountered in the primary care setting. They are the most common cause of bleeding per rectum, and are responsible for considerable patient suffering and disability.\(^{(1)}\) Bleeding from first and second hemorrhoids often improves with the addition of dietary fiber, stool softeners, increased fluid intake, and avoidance of straining. Persistent bleeding from first, second, and selected third-degree hemorrhoids may be treated by rubber band ligation. Surgical haemorrhoidectomy is generally indicated for grade three and four haemorrhoids.

The obvious disadvantage of surgical haemorrhoidectomy is the postoperative pain resulting from the surgical defect in the sensitive perianal skin and anoderm. Much of this pain may arise from the thermal injury from the use of electrocautery or laser.\(^{(2)}\)

The Harmonic Scalpel possesses the unique advantage of causing very little lateral thermal injury. The rationale for using the Harmonic Scalpel in performing surgical haemorrhoidectomy was the concept that a decreased lateral thermal injury (0-1.5mm deep) at the surgical site may translate into decreased post-operative pain. In contrast with electrocautery haemorrhoidectomy, the Harmonic Scalpel generates very little smoke. A local water vapor is generated, which is easily removed in adjacent suction and does not permeate as far as electrocautery smoke.
The present study demonstrated that intraoperative bleeding was less frequent in HS group (16%) than MM group (32%). Thus harmonic scalped haemorrhoidectomy may be suitable for severe anaemic patients as well as patients with coagulation disorders. Minor postoperative bleeding, that did not necessitate surgical interference although insignificant, was more in the MM group than HS group within 7 postoperative days (28% for HS group versus 12% for MM group).

An attractive feature of the Harmonic Scalpel haemorrhoidectomy is the excellent haemostasis during the procedure. Haemostasis is accomplished by coaptation of the vessels, which are sealed by denatured proteins. During haemorrhoidectomy, haemostasis was most readily established using the blunt edge of the blade and using the "variable" power mode. This combination was generally used for the internal haemorrhoidal component, this being the most vascular portion of the dissection.

The sharp edge of the blade and "full" power mode were generally used for the external components to afford optimum cutting ability through the thicker perianal skin. Because of the less vascular nature of the tissue, the coagulation mode was generally not necessary during the dissection of the external haemorrhoid. The excellent haemostasis offered by the Harmonic Scalpel permits an efficient excision of the haemorrhoidal tissue without the need to establish haemostasis from multiple bleeding sites.

During the course of the evaluation of our work, several distinct advantages and disadvantages of the Harmonic Scalpel became evident. One of the main advantages, as illustrated during the current study, was less postoperative pain after Harmonic Scalpel haemorrhoidectomy and the need for no postoperative narcotic analgesics. In this respect, the results of this study are in agreement with those reported by Armstrong et al., (2001), Ramadan et al., (2002) and Abo hashem et al., (2010). The later authors reported that pain at first defecation and at rest first and second week after surgery was significantly lower in HS group then MM group. Armstrong et al., (2001) reported that postoperative pain was significantly less in the HS group. Moreover, they found that the "net" postoperative pain scores were also significantly lower than in HS group on each of the postoperative days.

During the early stages of the evaluation, it soon became apparent that patients undergoing Harmonic Scalpel haemorrhoidectomy experienced less pain than their Conventional Haemorrhoidectomy counterparts. At the first night post-operatively, 90% of MM group had severe pain, which required narcotic analgesia, while no single case of HS group suffered from severe pain. All of the HS group were satisfied with NSAID injections first night post-operatively. A pilot study was conducted by Armstrong et al., (2001) to compare the Harmonic Scalpel haemorrhoidectomy with electrocautery, and the clinical impression was confirmed by the results of the pilot study. This also goes with the work of Ramadan et al., (2002) and Abo hashem et al., (2010) who report that the degree of pain was significantly higher in MM group.

The significant reductions in both the postoperative pain experienced by the Harmonic Scalpel patients and the analgesic requirements reflect an overall decrease in post-haemorrhoidectomy pain in the Harmonic Scalpel group. These results confirm the initial concept that the elimination of a lateral thermal injury does indeed translate into significantly less postoperative pain. An obvious comparison could be made between haemorrhoidectomy using harmonic scalpel or conventional haemorrhoidectomy and electrocautery. If bleeding sites are individually ligated (A time-consuming and infrequent surgical practice), no thermal injury whatsoever is imparted. Under these circumstances, post-haemorrhoidectomy pain would be
expected to compare to that in the Harmonic Scalpel group or even improve on it.

More often, however, supplemental electro-cautery is used to a greater or lesser extent during conventional haemorrhoidectomy to coagulate individual bleeders. In contrast, a hypothetical argument may be raised concerning the "painless" nature of deep (third-degree) burns resulting from the destruction of dermal pain fibres. The deep burn of electrocautery is sometimes invoked as a potentially beneficial feature, resulting in less pain than an equivalent "non-thermal" scalpel or scissor incision. However, this argument defies the everyday clinical experience of observing the discomfort, surrounding inflammation, and healing time of a "clean" surgical incision compared with that of a deep thermal burn.\(^{(2)}\)

The current study demonstrates that early complication occurred more frequently in the MM group. Urinary retention was more frequently in the MM group 28\% than the HS group 16\% within the first postoperative week. These results are in agreements with those reported by Ramadan et al., (2002) and Abo hashem et al., (2010). The prevalence of postoperative discharge was higher in the MM group than HS group.

Postoperative discharge was 40\% in the MM group compared to the HS group which had only 12\%. The infection rates were higher in the MM group 16\% when compared to the HS group 8\%. Duration of post-operative hospital stay was significantly lower in the HS group 76\% were discharged after three days while only 44\% were discharged in the MM group, 24\% in HS group were discharged between 4-6 days and 48\% in MM group. While 8\% in the MM group had to stay more than six days in the hospital adding to the expenditure of the procedure and late return to work.

Ramadan et al., (2002) reported that the duration of hospitalisation was significantly longer in MM group than HS group. Armstrong et al., (2001) Ramadan et al., (2002) and Abo hashem et al., (2010) reported that harmonic scalpel group showed quicker return to work than electrocautery group and MM group respectively. Approximately half of the harmonic scalpel group reported full time employment, 55\% of them in the first week, while 23\% in the electrocautery group. There was great variability in the time taken off work, ranging from one day to two months, 16\% of them more than three weeks in the HS group and three days to three months in the electrocautery group, 32\% of them more than three weeks in the electrocautery group (Armstrong et al., 2001).

Long-term complications within 3 to 6 months post-operatively in both groups revealed the absence of anal stenosis, acute anal fissure, fecal incontinence and recurrence. However long term follow up is needed. Ramadan et al., (2002), reported that re-operation was needed in 12\% of MM group versus 3.4\% in the HS group. One of the early drawbacks of Harmonic Scalpel haemorrhoidectomy was the presence of a definite learning curve for the procedure.

The Harmonic Scalpel takes slightly longer than electrocautery to divide the haemorrhoidal tissue. This calls for patience and the avoidance of undue traction on the surgical specimen, which is an almost instinctive reaction to the slower rate of cutting. Undue traction on the surgical end of the specimen inevitably results in bleeding from the lead point of the dissection.

The design of the earlier models of handsets for the Harmonic Scalpel proved clumsy and unwieldy during surgical haemorrhoidectomy with the patient in the prone jackknife position. The blades in these models were relatively thick and straight, obscuring the line of vision, especially during dissection of the internal haemorrhoid from the internal sphincter. Later designs of the Harmonic Scalpel with thinner and curved blades have eliminated this problem and provide better visualization of the surgical anatomy.\(^{(2)}\)

The significant disadvantage with the Harmonic Scalpel, as has been noted with all new
technologies, is the extra expense incurred. However, the current study demonstrates improved outcomes after surgery and suggests less time lost from work, thus providing significant financial benefits to justify the additional expense. In conclusion, harmonic scalpel haemorrhoidectomy provides a promising avenue for future research. These results must, however, be reproduced by other investigators before a definitive role for the Harmonic Scalpel can be established.

CONCLUSIONS: The study demonstrated that, Harmonic scalpel haemorrhoidectomy had better outcome in characteristics like postoperative pain, postoperative complications, hospital stay, and long-term complications, but it is more expensive than conventional M. M. haemorrhoidectomy.

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