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Harmonic Scalpel® compared with *bipolar* electro-cautery hemorrhoidectomy: A randomized controlled trial

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ABSTRACT

Introduction: Surgical excision using Harmonic Scalpel® is a modern technique used for ablation of symptomatic third degree and all fourth-degree hemorrhoids. Compared with electrocautery, Harmonic Scalpel® causes minimal lateral thermal injury during tissue dissection. The resulting mucosal defect is then either left open or sutured (closed) depending on surgeon preference. The aim of this work was to evaluate the value of using Harmonic Scalpel® in reducing incidence of postoperative complications following Hemorrhoidectomy.

Patients & Methods: This is a single-blind randomized controlled trial done at Zagazig University hospital during the period from July 2007 to December 2008. Patients underwent surgical excision of complex grade III or grade IV hemorrhoids. They were divided into two groups: (A) Harmonic Scalpel® Hemorrhoidectomy group and (B) Bipolar Electro-cautery Hemorrhoidectomy group. Pain levels scoring and postoperative complications were analyzed.

Results: Postoperative pain in Group (A) was significantly less with less analgesic requirement. There was no significant difference between both groups regarding other postoperative complications.

Conclusion: This study demonstrates significantly reduced postoperative pain after Harmonic Scalpel® Hemorrhoidectomy compared with bipolar electro-cautery Hemorrhoidectomy. Most likely, this result came from the avoidance of excessive lateral thermal injury caused by bipolar electrocautery.

1. Introduction

Hemorrhoids (piles) arise from congestion of internal and/or external vascular plexuses around the anal canal. Depending on the severity, they are classified into 4 degrees. In many cases hemorrhoidal disease can be treated by dietary modifications, topical medications and soaking in warm water, which temporarily reduce symptoms of pain and swelling. Additionally, painless non-surgical methods of treatment are available to most patients as a viable alternative to a permanent hemorrhoid cure. In a certain percentage of cases, however, surgical procedures are necessary to provide satisfactory long-term relief.[1]

Surgical hemorrhoidectomy is a notoriously painful procedure. Considerable research over the last two decades has concentrated on reducing pain following these surgical procedures. Investigators have concentrated in three areas; analgesic delivery during the postoperative period, modification of the surgical technique and the use of a variety of surgical instruments in the hope of decreasing postoperative pain.[2]

Alternatives to traditional oral narcotic analgesics for postoperative pain have included subcutaneous morphine infusion,[3] transdermal fentanyl patch[4] and parenteral Toradol® (Roche, Nutley, NJ) administration.[5] Modifications of the surgical technique have included open, semiopen[2] and closed incisions,[1] routine performance of lateral internal sphincterotomy[6] and the use of stapling devices[7] (both linear and circular). None of these techniques has been demonstrated to be conclusively superior to the other techniques.[8–11]

Laser Hemorrhoidectomy gained wide-spread publicity but has not been consistently demonstrated to be superior to conventional Hemorrhoidectomy in reducing postoperative complications. In addition, the need for using a combination of Nd–YAG and CO_2 lasers to utilize the benefits of both to complete the procedure, makes it a cumbersome and an expensive one.[12]

The rationale for the use of Harmonic scalpel® in hemorrhoidectomy is relatively low temperature that divides the tissues through the high frequency ultrasonic energy that disrupts protein hydrogen bonds. The relatively low temperature (80 °C) yielded results in minimal lateral thermal injury (<1.5 mm). On the

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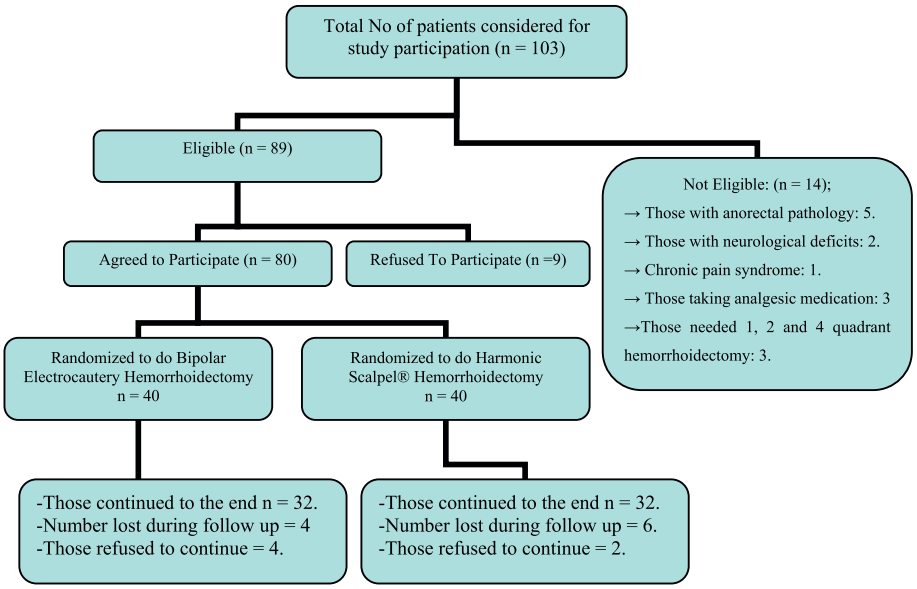

Fig. 1. Trial flow sheet showing progress through the phases of the trial.

contrary, both electrocautery and laser cause significant lateral thermal injury and burn several millimeters in depth. This difference causes less postoperative pain and decreases the need for narcotic use.[13] In this study we present our experience in using Harmonic scalpel® in hemorrhoidectomy and evaluating the postoperative complications in comparison to the use of bipolar electrocautery.

2. Patients and methods

A randomized single-blind controlled trial was performed. Sixty-four cases requiring surgical Hemorrhoidectomy were prospectively randomized into two groups; Group (A) in whom Harmonic scalpel® was used and Group (B) where bipolar electrocautery clamp was used. Indications for Hemorrhoidectomy (Inclusion criteria) were either; (1) Symptomatic Grade III internal hemorrhoids in association with large external components or (2) Prolapsed, thrombosed Grade IV hemorrhoids. Meanwhile exclusion criteria included; (1) Patients with other anorectal pathology as fissure or fistula-in-ano, (2) Patients with neurological deficit as paraplegia or previous cerebro-vascular accidents, (3) Patients with chronic pain syndromes, (4) Patients chronically taking narcotic analgesics and (5) Patients who were found to require one, two or four quadrant hemorrhoidectomy. The study had been previously approved by the Research Ethics Committee of the university. Informed consents were obtained from all patients. For details of trial profile, see the trial flow sheet (Fig. 1).

The technique used for surgical hemorrhoidectomy was standardized in all patients. The patient was placed in the prone jackknife position under spinal anesthesia. This was performed with a 27G needle, using 12 mg of 0.5% hyperbaric bupivacaine associated with morphine (70 μg). No vasoconstrictor was used routinely, apart from ephedrine (10 mg) if blood pressure decreased 20% from baseline values.

A modified Ferguson three quadrant hemorrhoidectomy was performed in all patients, using Harmonic scalpel® in 32 cases and bipolar electro-cautery clamp in the other 32. Technically, both are very similar but in Harmonic scalpel® we used the "scissor" configuration (Coagulating Shears® Model). Surgical incisions were left open in all cases.

Postoperative pain was evaluated by means of a visual analog scale that was explained to patients. Pain was evaluated by a score of 0 (no pain) to 10 (worst pain possible). Patients were asked to rate their pain both preoperatively (in the outpatient clinic) and on postoperative days 1, 3, 4, 7, 14 and 28. Postoperative analgesia was administered as a narcotic analgesic (Pethidine) up to the end of the third postoperative day and thereafter using NSAI'Ds (Diclofenac Sodium, DS). Required analgesic doses were recorded and analyzed as a marker for pain severity.

Mean pain scores for each day of follow up in both groups were compared using Wilcoxon's rank-sum test. Also, the amount needed of narcotic analgesics and NSAI'Ds were calculated for each group and compared using two-sample *t*-test.

3. Results

Demographics of the study population are summarized in Table 1. The two groups were comparable regarding the age and sex distribution. There was no significant difference between both groups in history of previous surgery, grade of hemorrhoids at time of surgery and degree of preoperative pain.

Postoperative pain was found to be significantly less in Group A in all days of postoperative follow up, as depicted in Fig. 2.

Table 1
Demographic data of the patients and other study variables.

Variable	Age/yrs (Mean ± SD.)	Sex		Previous Surgery		Grade		Preoperative Pain
		M	F	Yes	No	III	IV	
Group A (32 cases)	46 ± 3.2	20	12	4	28	26	6	3.2 ± 0.7
Group B (32 cases)	44 ± 2.1	18	14	5	27	28	4	2.8 ± 0.4
P-value	NS	NS		NS	NS	NS	NS	NS

NS = Non-significant, SD = Standard Déviation. Two-sample *t*-test was used to test ages between groups; Chi-squared test was used for sex; Fisher's exact test was used for grade and previous surgery and Wilcoxon's rank-sum test was used for preoperative pain.