

A Randomized Controlled Trial Comparing Harmonic Scalpel and Electrocautery Dissection in Modified Radical Mastectomy

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ABSTRACT

Background: Modified radical mastectomy (MRM) remains the most commonly performed operative procedure for breast cancer today. Conventional MRM using electrocautery or scalpel is associated with a moderate degree of operative morbidity. Ultrasonic dissection using the harmonic scalpel has recently emerged as a safe alternative to electrocautery. **Aim:** To test the hypothesis that the use of a harmonic scalpel results in less estimated blood loss, postoperative pain, drainage volume, and duration of surgery, as well as fewer complications, such as flap necrosis, seroma, and surgical site infection, than conventional electrocautery without prolonging the operative time. **Methods:** A prospective randomized single blinded controlled study in which the operative and postoperative details of twenty breast cancer patients who underwent modified radical mastectomy for pathologically proven breast cancer using the harmonic scalpel (group A) were compared with twenty matched controls operated with electrocautery (group B) in Ain shams university hospitals between April 2014 and march 2016. **Results:** There was no significant difference in the operating time between the harmonic scalpel and electrocautery group (108 and 112.5 mins, p 0.924). The blood loss (100-170 ml) as compared to electrocautery group (250-350 ml) and drainage volume (300-450 ml) in group A versus (600-800 ml) in group B; were significantly lower ($p < 0.001$) in the harmonic scalpel group. Also, statistically significant lower postoperative pain in the harmonic group was documented. There was a significant reduction of drain days in harmonic scalpel group (average 4 vs 8.5 days). There was no significant difference in the wound complications rate between two groups. **Conclusion:** Modified radical mastectomy using harmonic scalpel is feasible and significantly reduces the blood loss and duration of drainage as compared to electrocautery.

INTRODUCTION

Breast surgeons are continuously challenged by morbidities associated with wound hematoma, wound infection, seroma, and axillary numbness. The conventional method of breast cancer surgery is typically performed using a monopolar electrocautery and a clamp-and-tie technique for vessel ligation. The clamp-and-tie technique is considered safe and effective, but it is a time-consuming procedure. Electrocautery was originally used to reduce acute blood loss on expense of increased lateral thermal damage that resulted in increased seroma formation. The development of the technology of ultrasonic waves that seal blood vessels less than five millimeters in a coagulation mode with the capability of dissecting and creating flaps with minimal lateral thermal damage that does not exceed one and half millimeters made this

instrument preferred by many surgeons. The harmonic scalpel was introduced as an alternative for hemostasis in surgical procedures about 2 decades ago. This instrument is used for cutting and coagulating tissues by producing high-frequency vibrations within the harmonic frequency range. This device generates a lower temperature elevation and reduces the spread of heat into the adjacent tissues as compared to electrocautery. Its use during laparoscopic procedures was very attractive resulting in nearly bloodless and clipless procedures with the advantage of time and effort saving that made surgeons more satisfied. In open surgery its use was limited because of its cost, however some reports showed that it may be cost effective in view of reducing the operative time, blood loss and postoperative pain sensation. Despite the emergence of breast conservation surgery, modified radical mastectomy (MRM) remains the most commonly performed operative procedure

for breast cancer today. Conventional MRM using electrocautery or scalpel is associated with a moderate degree of operative morbidity in 35 - 50% of patients. Much of this morbidity has been attributed to the large post mastectomy raw area, cut lymphatics and use of electrocautery. Some studies showed that the harmonic scalpel could shorten the dissection time and decrease blood loss, drainage volume, seroma development and wound complications as compared to electrocautery, while other papers indicated that neither clinical advantages nor disadvantages of the ultrasound dissection technique were found.

PATIENTS AND METHODS

This study was designed and evaluated in Ain Shams university hospitals between April 2014 and March 2016. The study included forty female patients suffering from pathologically proven breast cancer who were candidate for modified radical mastectomy. Patients were enrolled into two groups by random selection; the first group (group A) included 20 females who underwent modified radical mastectomy using the Harmonic scalpel (Harmonic Ultracision Shears, Ethicon Endo-Surgery, Inc.) and the second group (group B) was a control of a 20 females who underwent modified radical mastectomy using the conventional electrocautery.

Inclusion criteria were female patients aged 20-60 years, patients had unilateral pathologically diagnosed invasive duct carcinoma of the breast (stage T2N1M0 or less according to TNM classification of breast cancer), American Society of Anesthesiology Scores 1 and 2 Patients and signed informed consent.

Exclusion criteria were history of previous breast surgeries, those on neo-adjuvant therapy, blood dyscrasia, collagen diseases and pregnancy, infections (mammary or axillary) and ulcerated tumors and patients refused to participate in the protocol.

Surgical technique:

The skin over the involved area was inspected for signs of infection. A single preoperative dose of parenteral 3rd generation cephalosporin was administered on anesthesia induction.

General anesthesia was given via an endotracheal tube. The patient was positioned nearest the margin of the operating table on the side of the surgeon with The arm of the affected

side was abducted and placed upon a support at right angles to the patient. The skin was prepared with topical antiseptics as usual.

A transverse elliptical incision including the nipple and areola and an appropriate distance of 5 to 7.5 cm beyond the limits of the tumor whenever possible was made with a short extension laterally up toward the axilla for the axillary dissection and a more cosmetically acceptable closure.



Fig. 1: MRM performed via conventional electrocautery, flap elevation.



Fig. 2: MRM performed via conventional electrocautery, post-excision hemostasis.



Fig. 3: MRM performed via Harmonic scalpel, flap elevation.



Fig. 4: MRM performed via Harmonic scalpel, axillary dissection.

The flaps were elevated (figure 1) to the level of the clavicle superiorly, to the edge of the sternum medially, to the rectus sheath and costal margin inferiorly, and then laterally to the edge of the latissimus dorsi muscle. In group A, Flaps were raised using the harmonic scalpel with no suture material or electrocautery (figure 3) used for hemostasis while in group B, this was performed in a standard fashion using electrocautery (figure 2) or silk ties as appropriate.

Dissection was carried past the edge of pectoralis major muscle. Retraction of the pectoralis major medially exposes the pectoralis minor and the clavicular fascia. Incision into the clavicular fascia allows entry into the axillary fat and the contained nodes. Dissection was carried superiorly along the edge of the pectoralis minor to reach the inferior edge of the axillary vein (figure 4). The axillary contents were then separated from the lateral thoracic wall thus exposing the long thoracic nerve which was identified and preserved. Ligation and division of the smaller tributaries of the axillary vein as they enter the axilla allowed visualization and identification of the subscapular vessels and thoracodorsal nerve as they reach the subscapular and latissimus dorsi muscles posteriorly.

The axillary fat and nodal tissue between the long thoracic nerve and the subscapular vascular bundle was carefully dissected. Often, this is performed en bloc with the specimen.

The surgical incision was closed with subcuticular sutures of 3/0 proline. In all of the operations, a closed suction drain was used with two limbs, one were placed in the surgical bed of mastectomy and the other was placed in the bed of axillary clearance.

Blood loss was estimated by weighing the dry sponges pre-operatively and subtracting the weight from the weight of the used sponges and by calculating the amount of blood in the suction apparatus if used. Operative time was calculated (in minutes) for all the cases.

Follow up:

Postoperative pain recording was done in both the groups using visual analogue scale over the first 24 hours after surgery.

All patients were followed up with recording of the total amount of drainage fluid till drain removal, days till the drain removal (drains were removed when the output was less than 50 milliliters per twenty four hours),

The local postoperative complications (necrosis of the breast skin flap, seroma, hematoma and infection of the surgical wound) were evaluated at two time-points: on the 7th and 14th postoperative days. On the 14th post-operative day, all of the stitches were removed.

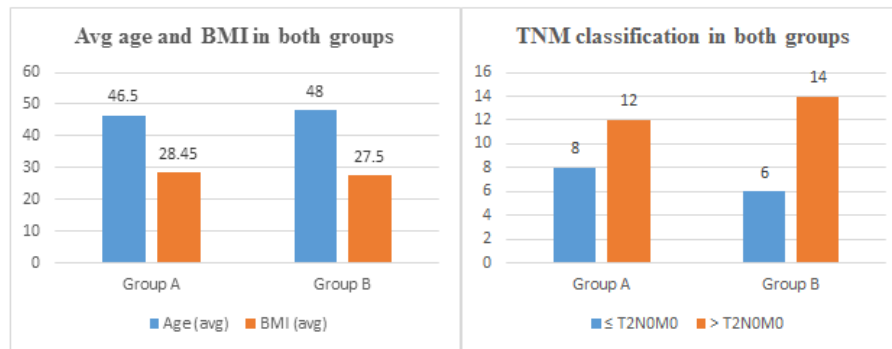
Data were analyzed using Fisher's and chi-square test. All tests are considered significant if ($p \leq 0.05$).

RESULTS

This study included 40 female patients aged 28-66 years (average 47 years) who were subdivided into two groups (A & B) who were candidate for modified radical mastectomy for pathologically proven breast cancer. Each group included 20 females. In the first group, ultracision harmonic scalpel was used for doing mastectomy while in the second group conventional electrocautery was used. Both groups were matched for age, body mass index and TNM stage as shown in table 1.

Table 1: Patients' characteristics. BMI: body mass index. NS: non-significant.

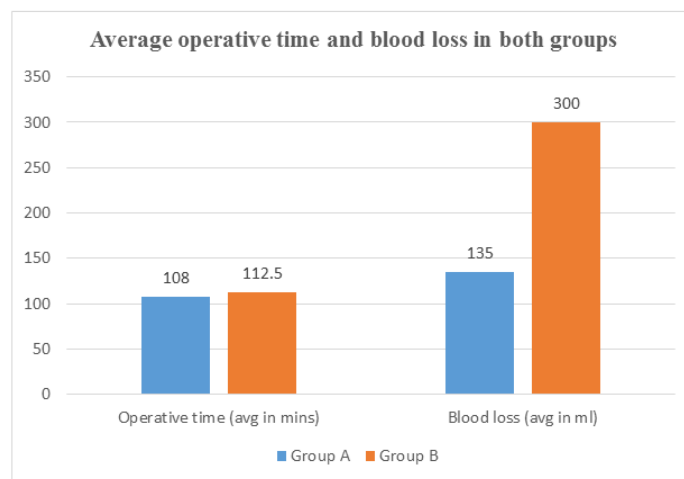
	<i>Group A</i>		<i>Group B</i>		<i>P value</i>
	No.	average	No.	average	
Number:	20		20		
Age (years):	28-65	46.5	30-66	48	0.185(NS)
BMI (Kg/m ²):	20.2-36.7	28.45	19.9-35.1	27.5	0.543(NS)
TNM stage:					
• ≤ T2N0M0	8		6		
• > T2N0M0	12		14		

**Intra-operative data:**

There were no statistically significant differences noted in the two groups in terms of operative time. In group A the operative time was 95-121 minutes (average 108 minutes) while in group B it was 100-125 minutes (average 112.5 minutes) (P value 0.924). The blood loss was significantly lower in the harmonic scalpel group (100-170 ml) as compared to electrocautery group (250-350 ml) (p<0.001).

Table 2: Intra-operative data analysis. NS: non-significant. S: significant.

	<i>Group A</i>		<i>Group B</i>		<i>P value</i>
	NO.	average	NO.	average	
Operative time (minutes):	95-121	108	100-125	112.5	0.924(NS)
Blood loss (ml):	100-170	135	250-350	300	<0.001(S)



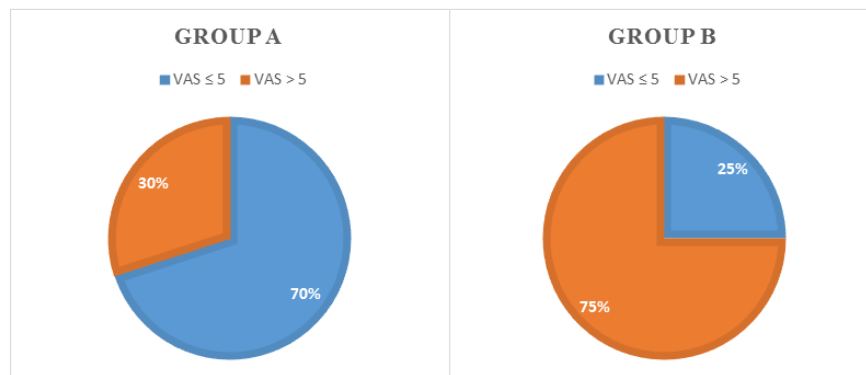
Post-operative data:

There was no mortality noted in the two groups. In the immediate post-operative 24 hours, there was statistically significant difference noted in terms of postoperative pain which was measured on the VAS scale which is further subdivided into two major subgroups ;the first included scores ≤ 5 and the second included scores >5 . 14 cases of modified radical

mastectomy with harmonic scalpel out of twenty (70%) were in the first group while only 5 cases out of twenty (25%) done by electrocautery were in the first group with $P < 0.001$ (highly significant) indicating statistically significant lower pain in the harmonic group both subjectively by VAS and objectively by correlating it with the patient need for parenteral analgesia required to relieve the pain (table 3).

Table 3: Results according to Visual Analogue Score (VAS) of Pain.

	Group A		Group B		P value
	No.	%	No.	%	
VAS ≤ 5 :	14	70%	5	25%	<0.001
VAS > 5 :	6	30%	15	75%	<0.001

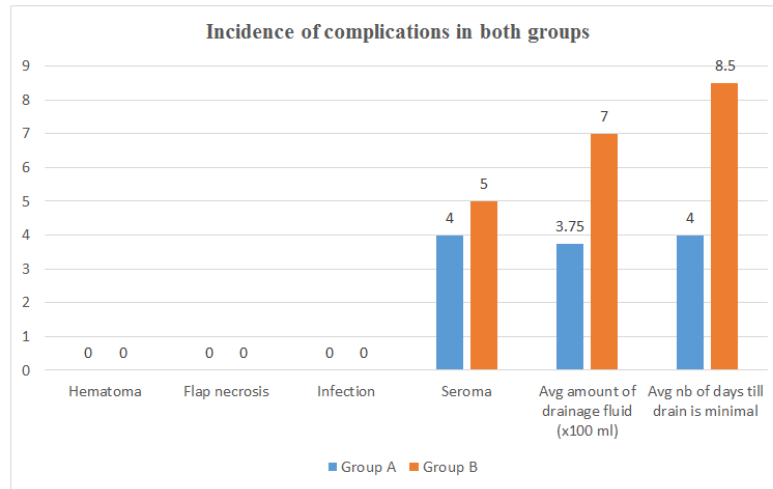


As regard major local wound complications, no cases of wound infection, hematoma or flap necrosis were reported in our study. Four patients in the harmonic scalpel group developed seromas (from skin and subcutaneous dissection) compared to five patients in the electrocautery group which was not statistically significant (p value 0.05). the only highly significant statistical difference ($P < 0.001$) between the two groups was the average total amount of drainage fluid all the period before drain removal (300-450 ml) in group A (average 375 ml) versus (600-800 ml) in group B (average 700 ml)), the average number of days till the drain fluid per day was less than 50 ml (3-5 days in group A (average 4 days) versus 7-10 days in group B (average 8.5 days)). Table 4 summarized those major postoperative morbidities.

Table 4: Post-operative morbidity data analysis and follow-up.

	Group A		Group B		P value
	No.	average	No.	average	
Hematoma:	0		0		
Flap necrosis:	0		0		
Infection:	0		0		
Seroma:	4		5		0.05(NS)
total amount of drainage fluid:	300-450 ml	375 ml	600-800 ml	700 ml	<0.001(S)
number of days till the drain is minimal:	3-5 days	4 days	7-10 days	8.5 days	<0.001(S)

NS: non-significant. S: significant.



DISCUSSION

The harmonic scalpel is an innovative device that vibrates at 55.5 kHz and causes three synergistic effects: cavitation, coagulation, and cutting to achieve effective hemostasis⁽⁶⁾ and tissue dissection at a precise point. With its advantage of reduced thermal spread that lowers the incidence of adjacent tissue destruction, this instrument has been approved by the U.S. Food and Drug Administration (FDA)^(11,12) for ligation of vessels up to 5 mm in diameter. The safety and advantages of the harmonic scalpel have been reported for surgeries in several anatomical regions. Although it has been extensively used in laparoscopic surgery, experience with the harmonic scalpel in “open” surgery is limited. The harmonic scalpel has recently been used in thyroid surgery⁽¹⁴⁾ and found to be associated with lower operating time and blood loss.

Many reports had investigated the use of the harmonic shears in modified radical mastectomy^(1,3,4) as a single instrument that carries safety, easiness and enjoyment of surgeons in making all the work by a single instrument that dissect skin flaps with minimal blood loss, seals the internal mammary perforators, seals the axillary vein tributaries efficiently without need for the use of clamps or ligatures.

With respect to intraoperative blood loss, a previous meta-analysis study conducted by Currie A et al⁽¹⁾ found a reduction in the mean intraoperative blood loss (236 vs.365 mls) after mastectomy, but the difference was not

statistically significant between using harmonic scalpel and electrocautery. However, our study revealed that a statistically significant reduction (135 vs 300 ml) ($p < 0.001$) was found in intraoperative blood loss for patients undergoing MRM with the use of harmonic scalpel dissection when compared to electrocautery. This is in agreement with most of literatures as reported by Deo et al^(3,4) and Adwani and Ebbs⁽⁵⁾. The harmonic scalpel has been thought to lower thermal injury to lateral tissues with the vibrating property and make the hemostasis more sufficient and the dissection more precise. Meanwhile, in the same meta-analysis it did not prolong operating time compared to electrocautery dissection which was comparable with our study.

As regards the rate of wound complications and postoperative drainage, the pooled results showed that the use of harmonic scalpel can significantly reduce the total postoperative drainage and seroma development as shown by Lumachi et al^(7,8), Kontos et al⁽²⁾, Deo and Shukla^(3,4) and Sanguinetti et al⁽⁹⁾. This agreed with our study results.

Postoperative pain was not a point of discussion in most of studies related to MRM performed with harmonic scalpel vs electrocautery. Our study reported significantly lowered postoperative pain score in the harmonic scalpel group which may be due to the minimal lateral thermal damage.

In conclusion, Harmonic scalpel can be recommended as a preferential surgical instrument in MRM but till now it is still not cost

effective in many hospitals in our country preventing the wide use of this beneficial tool.

CONCLUSION

Compared to standard electrocautery, harmonic scalpel dissection presents significant advantages in decreasing postoperative drainage, intraoperative blood loss and postoperative pain in modified radical mastectomy for breast cancer, without increasing operative time. Harmonic scalpel can be recommended as a preferential surgical instrument in modified radical mastectomy.

Disclosure:

This article is not sponsored by any company, so the authors have no competing interests as defined by Nature Publishing Group, or other interests that might be perceived to influence the results and/or discussion reported in this article.

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