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ORIGINAL ARTICLE

HARMONIC SCALPEL AS A SINGLE INSTRUMENT IN MODIFIED RADICAL MASTECTOMY. IS IT MORE COST EFFECTIVE THAN ELECTROCAUTERY AND LIGATURE?

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Abstract

Aim: Electrocautery is proved to be associated with increased seroma during mastectomy. This study aimed at comparing mastectomy using harmonic scalpel versus electrocautery and whether the harmonic scalpel is cost effective or not؟

Methods: This study included sixty females undergoing modified radical mastectomy .Thirty were operated with harmonic scalpel and thirty with electrocautery .We compared operative time, blood loss, total drainage volume and days, pain score, total dose of nalbuphine and incidence of sermoa, hematoma and flap necrosis.

Results: There was no statistical difference between two groups as regard operative time (P=0.12), seroma (P=0.2), hematoma (P=0.7) and flap necrosis (P=1). There was a highly significant difference (P<0.001) regarding blood loss, total drainage volume and days, pain score and the total dose of nalbuphine. Hospital stay was not shortened because all patients were routinely discharged after three days.

Conclusion: Harmonic scalpel in mastectomy significantly reduces blood loss, postoperative pain, total drainage volume and days but does not lower operative time, seroma, total hospital stay and till now cannot be considered cost effective.

Keywords: Ultrasonic scissors, breast, diathermy.

INTRODUCTION

Many authors attacked the use of electrocautery for flap elevation during modified radical mastectomy as it was associated with increased risk of seroma formation.[1,2] Electrocautery was originally used to reduce acute blood loss on expense of increased lateral thermal damage which resulted in increased seroma formation.[3] 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.[4] 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.[5,6] 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. Actually most of these

reports were cases of thyroidectomy.[4,7] Many reports investigated the use of the harmonic shears in modified radical mastectomy 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.[8] All this was reported with the theoretical benefit of sealing lymphatics with minimal lateral thermal damage that minimizes postoperative lymphorrhea and enables earlier drain removal with less incidence of seroma formation.[11] We tried in this study to investigate the use of the harmonic shear in modified radical mastectomy in comparison with the traditional use of electrocautery and if is it cost effective or not?

PATIENTS AND METHODS

This prospective study was carried out in the period from January 2009 to august 2009.The study included sixty 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 included thirty females who underwent modified radical mastectomy using the Harmonic scalpel (Harmonic Ultracision Shears, Ethicon Endo-Surgery, Inc.) and the second group was a control of a thirty females who underwent modified radical mastectomy using the conventional electrocautery (Force FX™ Valleylab) both groups were matched for age, body surface area and tumor stage. Both groups were operated by the same surgeon (A.K). On doing mastectomy using the harmonic shear; we used both blades of the shear in a coaptive manner at level III that coagulates then cut to elevate both upper and lower flaps (Fig. 1), dissect breast from the pectoral muscle with division of the internal mammary perforators (Fig. 2), then dissect the axilla with division of the axillary vein tributaries without need for ligatures (Fig. 3), followed by insertion of suction drain and wound closure in the usual manner .Patients of the second group underwent mastectomy using electrocautery in the classic way. Operative time was calculated for all cases. Intraoperative blood loss was estimated by calculating the amount of blood in the suction apparatus. All patients were followed up with recording of the following parameters: the total amount of drainage fluid till drain removal, days till drain removal (drains were removed when the outcome was less than thirty milliliters per twenty four hours), postoperative hematoma, seroma, flap necrosis or wound sepsis. There was special attention for postoperative pain recording in both groups. This item was rarely investigated in the literature in correlation with the use of electrocautery .Both subjective and objective recording was done using visual analogue scale (VAS) by the end of the first twenty four hours and by calculating the total dose of nalbuphine required by the end of the first thirty six hours. Finally the added cost of the harmonic scalpel was weighted against benefits such as reduction of the operative time, reduction of the hospital stay, reduction of the postoperative morbidity. For descriptive statistics of qualitative variables the Frequency distribution procedure was run with calculation of the number of cases and percentages. For descriptive statistics of quantitative variables the Mean, Range and Standard Deviation were used to describe central tendency and dispersion. For analysis of the differences in proportions, Chi square test was used, Fishers exact test was used if the assumptions of Chi square were violated. Independent samples t-test was used to compare the level of quantitative variables between the two study groups. Data were analyzed on a personal computer running SPSS© for windows (Statistical Package for Social Scientists) Release 15. All tests are considered significant if ($p \leq 0.05$), all the tests were two sided tests.

RESULTS

This study included two groups of female patients who were candidate for modified radical mastectomy for pathologically proven breast cancer .Each group included thirty females. In the first group, harmonic scalpel was used for doing mastectomy while in the second electrocautery was used. Both groups were matched for age, body surface area and TNM stage Table 1. No immediate postoperative mortality was encountered in this study. There was no statistical difference between the two groups as regard the operative time (101.60 minutes ± 5.90 (SD) versus 104.30 minutes ± 7.40 With P = 0.12) , incidence of seroma (6/30 cases (20%) versus 10/30 cases (33%) with P=0.2), incidence of hematoma (5/30 cases (17%) versus 6/30 cases (20%) with P=0.7), and incidence of flap necrosis was 3/30 cases in each group with P =1 Tables 1,2. There was a highly significant statistical difference (P<0.001) between the two groups as regard the mean amount of blood loss (78.17 milliliters ± 9.78 (SD) versus 208.00 milliliters ± 20.24), the mean total amount of drainage fluid all the period before drain removal (446.00 milliliters ±70.64 (SD) versus 773.50 milliliters ± 159.82), the mean number of days till removal of the drain (5.90 days ±0.85 (SD) versus 13.37 days ± 0.93), The mean dose of nalbuphine required by the end of the first thirty six hours (22.80 milligram ±2.44 (SD) versus 35.20 milligram ± 2.07) Table 1. By subclassifying VAS into two major subgroups ;the first included scores from 4 to 6 and the second included scores 7 and 8 Table 3, twenty four cases of modified radical mastectomy with harmonic scalpel out of thirty (80%) were in the first group while only eight cases out of thirty (27%) 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 calculating the total dose of nalbuphine required by the end of the first thirty six hours.

Fig 1. Opening of skin and creation of the upper flap with the harmonic shear.

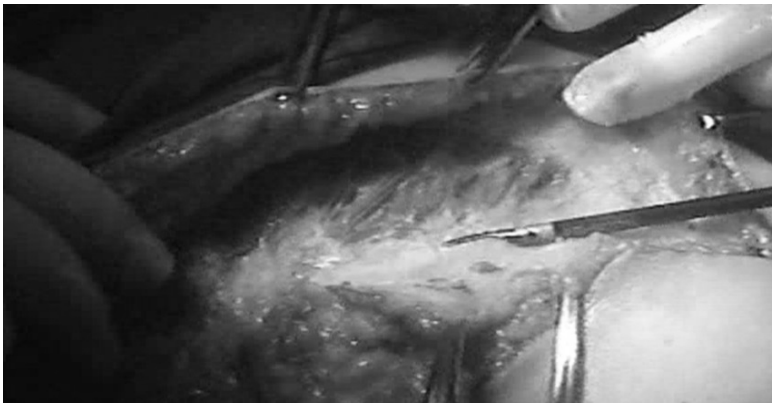

Fig 2. Nearly bloodless field with division of internal mammary perforators and dissection of the breast from pectoralis. major.

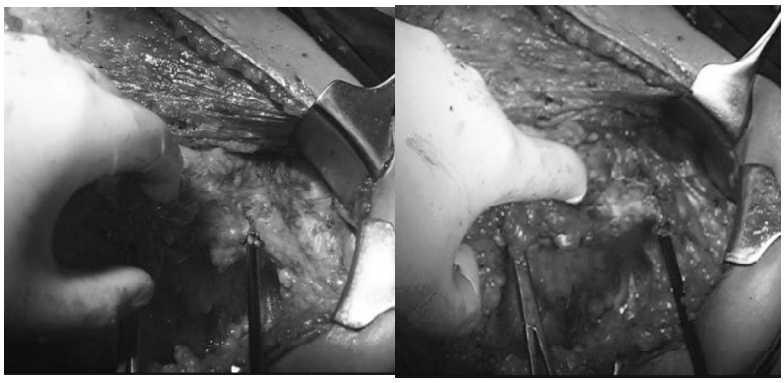

Fig 3. Axillary dissection using the harmonic shear.

Table 1. Patients' operative records.

Patient record	Harmonic group (No.=30) mean ± (SD)	Electrocautery group (No.=30) mean ± (SD)	P-value*
Age (years)	54.47 ±7.57	56.27 ± 9.05	0.41 (NS)
BSA(sq mts)	1.87 ± 0.16	1.87 ± 0.18	0.94 (NS)
Stage II	20	21	
Stage III	10	9	
Operative time (minutes)	101.60 ± 5.90	104.30 ± 7.40	0.12
Blood loss (ml)	78.17 ± 9.78	208.00 ± 20.24	<0.001(S)
Total drainage vol.(ml)	446.00 ± 70.64	773.50 ± 159.82	<0.001(S)
Drainage days	5.90 ± 0.85	13.37± 0.93	<0.001(S)
Dose of nalbuphine at the end of first 36 hours	22.80 ± 2.44	35.20 ± 2.07	<0.001(S)

*(independent samples t- test) (BSA= body surface area, sq mts= square meters, NS = non significant, S = significant, ml: milliliters)

Table 2. Incidence of seroma, hematoma, and flap necrosis.

Wound complication	Harmonic group	Electrocautery group	P-value †
Seroma	6 out of 30(20%)	10 out of 30(33%)	0.2 (NS)
Hematoma	5 out of 30(17%)	6 out of 30(20%)	0.7 (NS)
Flap necrosis	3 out of 30(10%)	3 out of 30(10%)	1 (NS)

† Chi-square test

Table 3. Visual analogue scale (VAS) ‡.

Score	4	5	6	7	8	Total
Harmonic group	21	2	1	4	2	30
Electrocautery group	2	2	4	18	4	30

‡ Patients were subclassified into two subgroups; the first includes scores from 4 to 6 and the second includes scores 7 and 8. 24cases of the harmonic group were score from 4 to 6 (80%) while only while only eight cases out of thirty (27%) done by electrocautery were in the first group with a p-value was <0.001(highly significant).

DISCUSSION

The first successful usage of the harmonic scalpel was in the field of endoscopic and laparoscopic surgery.[5] It was a great tool that facilitated dissection and homeostasis without need for clips and therefore blood loss and operative time were minimized.[6] In the field of open surgery many reports showed that harmonic scalpel was a useful tool for thyroidectomy as it minimized the operative time by avoiding the use of clamping and ligatures that may save around thirty minutes.[4] Moreover some reports showed that postoperative pain was less in the harmonic scalpel group as compared with the traditional technique. Those reports also concluded that harmonic scalpel may be cost effective in doing thyroidectomy.[7] In the field of modified radical mastectomy, our study revealed that the use of the harmonic scalpel efficiently reduces acute intraoperative blood loss without prolongation of the operative time. This is in agreement with most of literatures as reported by Deo et al[8] and Adwani and Ebbs.[9] Moreover it reduced the total amount of drainage fluid and drainage days .This agrees with most of reports[8] Unfortunately the incidence of seroma formation was not decreased by use of the harmonic scalpel. Also this agrees with most of reports.[8,10]

However Lumachi et al reported decrease of seroma with use of the harmonic scalpel.[11] The mechanism of seroma formation still not fully understood and need further work to reveal its exact mechanism.[12,13] Although drainage days were reduced with the use of harmonic scalpel, hospital stay was not reduced as most of our patients are discharged after three days with instructions to care of the drain at home and followed up at short postoperative visits. An important point is the lowered postoperative pain score and significantly less dose of nalbuphine used in the harmonic scalpel group. Of course this is be due to the minimal lateral thermal damage observed with the harmonic scalpel in comparison with electrocautery and this results in less irritation to pain nerve endings. This - to my knowledge - is rarely discussed with modified radical mastectomy but in my opinion it is very important issue to be considered as increased postoperative pain especially in elder patients suffering from cardiac disorders may be very dangerous event. In my opinion the use of the harmonic shear in doing modified radical mastectomy is still not cost effective as it does not lower the total operative time, does not lower the incidence of seroma formation; does not lower the hospital stay and still costly (in Egypt it costs around eight hundreds U.S dollars per case).The main advantages of its use are the perfect hemostasis, comfort of the surgeon with easier manipulation, less postoperative pain .All this cannot withstand -till now- against its cost.

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