COMPARATIVE STUDY OF SEROMA FORMATION IN HARMONIC SCALPEL VERSUS ELECTROCAUTERY IN POST MODIFIED RADICAL MASTECTOMY

Muhammad Farooq Shahid, Taseer Ibrahim*, Muhammad Ali Muazzam, Hummaira Chaudhry, Usman Shah Bukhari, Ghufran Ahmed

Combined Military Hospital Quetta/National University of Medical Sciences (NUMS) Pakistan, *Mega Medical Hospital, Rawalpindi Pakistan

ABSTRACT

Objective: To compare the frequency of seroma formation in harmonic scalpel vsunipolar electrocautery in post modified radical mastectomy (MRM).

Study Design: Quasi experimental study.

Place and Duration of Study: General Surgery Department, Pak Emirates Military Hospital Rawalpindi, from Jul to Dec 2017.

Methodology: Eighty women with breast carcinoma planned for modified radical mastectomy were included in the study with inclusion and exclusion criteria and divided in equal group A (Harmonic) and group B (Unipolar cautery). Randomization was performed by lottery method for both groups. A standard level III clearance was performed. All patients were followed up on weekly basis and seroma formation was evaluated in both groups.

Results: Mean age in group A and B was 51.36 ± 11.04 years vs 52 ± 11.19 years (p>0.05). Mean duration of complain in group A and B was 1.675 ± 0.47 months vs 1.775 ± 0.42 (p>0.05). Mean time of procedure in group A and B was 110.00 ± 4.71 mins vs 100.875 ± 5.14 (p>0.05). Mean body mass index in group A and B was 30.217 ± 4.99 kg/m^2 vs 30.210 ± 5.31 kg/m^2 (p>0.05). Seroma formation in group A and group B patients were found to be 5 (12.5%) vs 10 (25%) with (p>0.05).

Conclusion: Frequency of seroma formation in harmonic scalpel is lower than electrocautery in post modified radical mastectomy, so it can be safely performed along with harmonic scalpel with reduced duration of drainage and seroma formation.

Keywords: Harmonic scalpel, Modified radical mastectomy, Unipolar cautery.

INTRODUCTION

Breast carcinoma is awidespreadtumor and a major reason of carcinoma related mortality with 23% incidence of new cases and 14% of total deaths globally[1]. The incidence rate of breast cancer is highest in Pakistan among Asian countries with 51.7/100,000 as compare to GLOBOCAN incidence rate of 50.3/ 100,000[2]. The mortality rate of breast cancer for Pakistan (GLOBOCAN) was 25.2/100,000 highest among South Asian countries due to lack of awareness and delay clinical presentation[3]. There are two main types of breast carcinoma ductal and lobular classified into four stages, initial two confined to breast with axillary lymph node involvement while remaining two associated with chest wall fixity and metastases. Breast conservation operations (wide local excision, lumpectomy quadrantectomy) are for stage I patients while modified radical mastectomy (MRM) are for stage I & II. A simple mastectomy removes the breast tissue, nipple, areola and skin but not all the lymph nodes. A modified radical mastectomy removes the entire breast - including the breast tissue, skin, areola and nipple - and most of the underarm (axillary) lymph nodes[4].

Simple surgical blades are traditionally used for breast surgery, however in the past two decades, electrocautery which performs its action via an electrical current that produces heat has replaced surgical blades, in terms of reduced blood loss and less operating time. However, the increased incidence of seroma formation is still a concern for many surgeons[5].

With the advent of harmonic scalpel,a decade ago which uses ultrasound technology to create high-frequency mechanical vibrations to cut and coagulate at the same time, sealing vessels at lower temperatures than electro-surgery[6-9], making a major breakthrough in the field of surgery; however, its use in modified radical mastectomy (MRM) is still limitedwhich include cost and availability limitations[10].

There are only a few studies comparing the harmonic scalpel and electrocautery in MRM, and they mainly compare intra operative parameters seroma formation with electrocautery and harmonic. Therefore, this study was done to determine if the harmonic scalpel offers any advantages in reducing post-operative seroma formation in patients under-going MRM when compared with electrocautery so that we can select the right method in MRM to reduce the post-operative complication in term of seroma formation in our general population.

Correspondence: Dr Muhammad Ali Muazzam, Dept of Surgery, Combined Military Hospital Quetta Pakistan

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METHODOLOGY

This quasi experimental study was conducted in General Surgery department, Pak Emirates Military Hospital (PEMH) Rawalpindi, from July to December 2017. Sample size was calculated using Open Epi version 2.3 Software with the following assumptions {confidence level 95%, power 80%, p1= 8%[11-13], and p2 =33.3%[14], alpha=5%, (where p1 was expected proportion (seroma) in population 1 and p2 was the expected proportion (seroma) in population 2} sample size was 80.

After approval from Ethical Review Committee, a total of 80 female patients with Fine-needle aspiration cytology (FNAC)/biopsy-proven operable breast carcinoma (primary or post-neoadjuvant chemotherapy), female patients of all age groups, with tumour size >4cm, patients who were not candidate for breast conservation surgery, positive margin after breast conservation surgery were included. Those whom didn't give consent, with ASA grade IIIand IV, history of previous breast surgeries, history of Diabetes, ulcers, discharge, or active wound infections in the breast or anywhere in the body and with inoperable advanced breast malignancy were excluded. The study also excluded patients with risk factors that could affect wound healing like on anticoagulant or corticosteroid therapy. We followed all provisions of the Declaration of Helsinki in this study.

All the eligible patients fulfilling inclusion criteria admitted through outpatient department (OPD) with informed consent, completing full workup for surgery and anaesthetic fitness.Diagnosis was confirmed by FNAC or trucut biopsy. Basic demographics data was noted like age, duration of complain and BMI.

Patients were assigned randomly into two groups, 40 sample size for harmonic scalpel group i.e. group A and 40 sample size for electrocautery group i.e. group B. Randomization was performed by Lottery method for both groups. The group assignments were put into sealed envelopes, which was opened when the women were admitted for procedure. All the patients had undergone MRM by a single classified surgical specialist having experience of atleast 8 months of using both harmonic and diathermy. Both the groups underwent standard modified radical mas-tectomy with lymph node dissection up to level III.

With negative pressure closed suction drainswere kept in both the groups, with one tube along the lower skin flap and another tube in axilla. In post-operative period, drain quantity was noted every 24hr for both groups. Postoperatively our criteria for drain removal was when drain quantity in the last 24 hours had fallen to <30ml. Development of seroma as a complication was defined when drain quantity continued to be >40ml after postoperative day 7 or if there was clinically evident fluid collection beneath the skin flap during follow-up of patients after discharge from hospital. After removal of drain, we kept follow-up for the next 12 weeks, skin flaps were examined regularly to see any fluid collection noticing fluctuation, and seroma was confirmed with aspiration of fluid.

All patients were followed up on weekly basis and during each post-operative visit, the presence of seroma was assessed clinically, and the number of aspirations required for the seroma was also documented on especially designed proforma.

Data was analysed with IBM-SPSS-22. Comparison of proportion of group A and group B was done. Frequency and percentage weregenerated for qualitative variables such asseroma formation. Mean ± SD was generated for quantitative variables like duration of complain, age, duration of procedure and BMI. Chi-square test was applied to compare seroma formation in both groups considering $p \leq 0.05$ as significant.

RESULTS

A total number of 80patients were included in study, of whom 40 patients (50%) underwent MRM by harmonic scalpel and 40 (50%) by electrocautery.

Mean age in group A and B was 51.36 ± 11.04 years vs 52 ± 11.19 years (*p*-value 0.281). Mean duration of complain in group A and B was 1.675 ± 0.47 months vs 1.775 ± 0.42 (*p*-value 0.506). Mean time of procedure in group A and B was 110.00 ± 4.71 mins vs 100.875 ± 5.14 (*p*-value 0.307). Mean BMI in group A and B was 30.217 ± 4.99 kg/m^2 vs 30.210 ± 5.31 kg/m^2

Table: Comparison of seroma formation & drain parameters in both groups.

S. No.	Parameters	Group A Harmonic Scalpel (n=40)	Group B Electrocautery (n=40)	*p*-value
1.	Mean drain days(days)	6 ± 2	7 ± 2.5	0.001
2.	Mean drain volume (ml)	400 ± 50	600 ± 55	0.002
3.	Seroma formation(patients)	5 (12.5%)	10 (25%)	0.152

(*p*-value 0.103). Seroma formation and drain parameters in both groups are compare in table.

DISCUSSION

Success of any surgery depend upon its safety, efficiency, complications, recurrences and acceptance from patient. Hence our study regarding the use of harmonic vs electrocautery for Post MRM outcomes has been discussed taking into account of these factors.

In this study, the mean age of patients was 51.68 years, which was in concordance with some earlier studies[13]. The mean operative time in our study was longer using harmonic scalpel (110.00 ± 4.71 vs 100.875 ± 5.14 min $p>0.05$). Our study showed seroma formation in 5 (12.5%) patients in harmonic scalpel group as compare to 10 (25%) patients in electrocautery group, ($p>0.05$) results of our study are comparable with Damani *et al* who found in a study that frequency of seroma formation was 8% in harmonic scalpel ver-sus 20% in electrocautery ($p>0.05$) in post modified radical mastectomy[13]. However difference was statis-tically non-significant.

Khan *et al* reported frequency of seroma formation was 21.3% in harmonic scalpel versus 33.3% in electrocautery ($p=0.071$) in post modified radical mastectomy[14].

Deo *et al* concluded also that use of harmonic scalpel (16%) lower seroma formation as compare to cautery (22%)[9].

Galatius *et al* observed no significant difference among harmonic scalpel and electrocautery,[seroma formation in harmonic 50 (0-580) ml vs electrocautery 105 (0-3775) ml] in aspects of surgery duration and complications including seroma[15].

Researches by Kontos *et al* also exhibited positive outcomes of harmonic scalpel[16].

Adwani *et al* observed similar encouraging outcomes supporting our observation[11]. Lumachi *et al* also showed benefits of harmonic scalpel over conventional scalpel[17,18].

CONCLUSION

This study has concluded that frequency of seroma formation in harmonic scalpel is lower than electrocautery in post MRM, so it can be safely performed along with harmonic scalpel with reduced duration of drainage and seroma formation.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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