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Original Research Article

A randomized prospective study comparing ultrasonic shears with electrocautery for post-operative morbidity in modified radical mastectomy

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ABSTRACT

Background: Modified radical mastectomy is commonly performed surgery for breast carcinoma. The present study was conducted to compare intra-operative and post-operative surgical outcomes by using monopolar electrocautery and ultrasonic shears in MRM.
Methods: A randomized prospective study was conducted with a sample size of 60 patients who were randomized into two groups. One group underwent MRM using ultrasonic shears (Group A) and the other one using monopolar electrocautery (Group B). Intra-and post-operative outcomes were compared.
Results: Group A had less intra-operative blood loss and it was statistically significant. Group A had less pain score on post op day 1 and it was statistically significant. However, Group A had less intra-operative time and less drain output but it was statistically insignificant. Group A had less post-operative complication (seroma formation, wound infection, hematoma formation and flap necrosis) compare to Group B and it was statistically significant. Group A, patient had early drain removal compare to Group B, and was statistically significantly.
Conclusions: Ultrasonic shears group had significantly lesser intra-operative bleeding, lesser post operative complications, post-operative early drain removal, less post operative pain score, when compared to electrocautery group. However, the two groups had no significant difference in post-operative drain output and operative time.

Key words: Modified radical mastectomy, Ultrasonic shears, Monopolar electrocautery, Intra and post operative outcomes

INTRODUCTION

Breast cancer is heading towards the leading cause of oncologic morbidity and mortality among woman worldwide. As a result of increased awareness about the disease, success of breast cancer screening program, revolutionary advancement in imaging in breast cancer have witnessed the insurgence in patients presenting with early breast cancer, for them breast conservative surgery (BCS) is the treatment of choice but still a large no of patients belonging to rural and low socioeconomic status present with the disease in the advance stage where BCS does not provide microscopic cancer clearance, thus modified radical mastectomy (MRM) remain the mainstay of treatment sometimes as a primary treatment and sometimes after neo-adjuvant chemotherapy to achieve tumor free margins. The main goal of cancer diagnosis and treatment are to cure or considerably prolong the life of

patient and to ensure the best possible quality of life to the survivor.[1] Traditionally Electrocautery and sharp dissection have been used in performing major breast cancer surgery along with hydro dissection, blunt and scissor dissection.[2] Electrocautery is the most common surgical instrument for dissection and hemostasis in MRM, with the advantage of reducing blood loss. Previous studies indicate that it may increase the postoperative complication, such as seroma formation, wound infection, flap necrosis, hematoma and prolonged drainage which led to the delay of adjuvant treatment after operation. However, in recent year harmonic dissection has emerged as an alternative tool for surgical dissection. The claimed advantage include less thermal damage to surrounding tissue, a more precise dissection, no surgical smoke, less eschar build up on the blade and reliable hemostasis thus, leading to a potential reduction in patient morbidity and improve operative efficiency.[3] Some studies show that Ultrasonic shears could shorten the dissection time, decrease blood loss, drainage volume, seroma formation and wound complication as compared to Electrocautery.[3,4-7] Despite the advantage of Ultrasonic shears, the inconsistent result of published trials invites more attention to its usages in MRM. There is lack of uniform consensus on depicting Ultrasonic shears as superior tool for dissection for modified radical mastectomy in Indian setting and insufficient literature based materials responsible to established superiority of the either instrument over each other. Hence the current study is endeavoured to investigate and compare the intra-operative and postoperative outcome in modified radical mastectomy using ultrasonic shears versus electrocautery. our study is an exercise whether ultrasonic shears can be recommended as a preferential surgical instrument in modified radical mastectomy.

METHODS

Institutional ethics committee approval was taken prior to the study commencement as it involved human participants. All patients were enrolled in the study after taking written informed consent.

Study design

A randomized prospective study was conducted in our tertiary care center (Lady Hardinge medical college and associated Smt. Sucheta Kriplani hospital) located in Delhi, India from January 2021 to June 2022. All female patients of age more than 18 years with operable breast carcinoma planned for modified radical mastectomy, were invited to participate in the study. 60 Patients were randomized into two groups equally by opaque sealed envelope method before surgery either to undergo MRM using ultrasonic shears (Group A) or using monopolar electrocautery (Group B). Intra-operative blood loss, operative time, post-operative drain output was monitored. Post-operative pain on day 1 was measured and monitored on visual analogue scale (VAS). Duration of drain and hospital stay of patients was monitored. Patients were followed up for a period of 30 days for any complications (hematoma formation, seroma formation, wound infection, flap necrosis) in the post-operative period.

Inclusion criteria

All female patients of age more than 18 years with FNAC /TRU-CUT proven carcinoma breast who were planned for modified radical mastectomy and consented to participate in the study were enrolled in the study.

Exclusion criteria

Recurrent breast carcinoma, previous radiation exposure to chest wall, patients with coagulation disorders, patients who have received treatment from outside before presenting to our hospital were excluded from study.

Management

All Patients underwent Auchincloss-modified radical mastectomy under general anaesthesia. Ultrasonic dissector (Hormonic Focus, Ethicon Inc, USA) was used for dissection in Group A. Monopolar electrocautery (Megadyne, Ethicon Inc, USA) was used for dissection in Group B. Skin incision was made with a scalpel and, superior and inferior flaps were dissected using ultrasonic shears in Group A and electrocautery in Group B. The breast tissue along with the underlying pectoralis fascia was dissected from the medial to lateral side and by dissecting the clavipectoral fascia, axilla was entered and axillary dissection performed. Scrub nurse was asked to make a separate count of mops used and collection in suction jar. Once a mop was fully soaked, it was discarded. All fat, fascia and level I and II axillary lymph nodes were removed in all cases with preservation of the long thoracic nerve and thoracodorsal pedicle. Thereafter, homeostasis was achieved. Two drains were placed, one in the axilla and the other beneath the flaps and were connected to one suction drains. Flaps were approximated using suture and compression dressing was applied. Operative time estimated. Patients received routine post-operative care. Drain output was monitored daily and were emptied once every 24 h till post op day 5 and suction was reapplied. Drains were removed when the output was <30 mL per day on two consecutive days. Post-operative pain was monitored using VAS on a scale from 0 to 10 on postoperative day (POD) 1. Patients were discharged usually on post operative day 2-5 as per unit protocol and both the drains were removed when no undue complications were present. All patients were followed up in the outpatient department for a period of 30 days. The outcomes studied were: Operative time (minutes), Intra-operative blood loss (ml), post-operative pain on day 1 score using VAS, daily drain volume till post op day 5 (ml), Duration of axillary drain (days), Post operative hospital stay (days) and Post-operative complications like seroma formation, wound infection, hematoma formation, flap necrosis till post op day 30.

Statistical analysis

Statistical analysis was performed by the SPSS program for Windows, freely available version (SPSS, Chicago, Illinois). Continuous variables were presented as mean±SD, and categorical variables were presented as absolute numbers and percentage. Data was checked for normality before statistical analysis. Normally distributed continuous variables were compared using the unpaired t test, whereas the Mann-Whitney U test was used for those variables that were not normally distributed. Categorical variables were analyzed using either the chi square test or Fisher's exact test. For all statistical test, $p<0.05$ was considered statistically significant.

RESULTS

In our study, all patients were female and married. Both groups were comparable in terms of number of patients in each group, mean age distribution, side of breast lump, duration of breast lump, body mass index, body surface area, educational status, TNM stage, hormonal receptor status, co-morbidities, neo adjuvant chemotherapy (Table 1).

Table 1: Preoperative data of the studied groups.

Variables	Ultrasonic group N (%)	Electrocautery group N (%)	P value
Age (years, means±SD)	50.53 (10.45)	50.0 7(10.02)	0.860
Side of lump			
Right	7 (23.3)	19 (63.3)	0.002
Left	23 (76.7)	11 (36.7)	
Duration of lump (years means±SD)	0.77 (0.55)	0.02 (0.54)	0.076
BMI (kg/m2), means±SD	25.50 (2.87)	25.50 (2.87)	1.000
BSA, means±SD	1.53 (0.24)	1.52 (0.23)	0.961
Morbidity			
DM	2	0	0.150
HTN	3	0	0.076
Hypothyroidism	1	0	0.313
Histological type, invasive ductal carcinoma	30	30	1.000
Receptor status			
ER	14/16	14/16	1.000
PR	14/16	14/16	1.000
HER2	12/18	4/26	0.020
Cycle of chemotherapy			
None	5	6	
3 cycles	7	12	
4 cycles	18	12	

Table 2: TNM staging in each group.

TNM staging		Number of cases		P value
		Ultrasonic shears group	Electrocautery group	
Tumor stage	T2	6	6	0.785
	T3	13	13	
	T4a	4	2	
	T4b	7	8	
	T4c	0	1	
Node stage	N0	4	12	0.031
	N1	23	17	
	N2	3	0	
	N3	0	1	
Mets stage	0	30	30	-

On comparing the TNM staging of two group, there was no significant difference between two regarding T staging as p=0.785 but nodal stage shows statistically significant difference as p=0.031 (Table 2). Mean operative time in

ultrasonic shears group was 140.17(±29.98) minutes and in electrocautery group was 147.67(±41.85) minutes with p=0.428. Although there were less time taken in ultrasonic shears group but this was statistically insignificant (Table 3). The amount of intra-op blood loss was less in ultrasonic shears group with mean blood loss 533.50(±198.14)ml on comparing with electrocautery group mean blood loss 681.67(±300.14)ml with p=0.028, this was statistically significant difference (Table 4). The mean pain score calculated using VAS score on scale of 1 to 10 on post operative day 1 in ultrasonic shears group was 2.63 (±0.67) and in electrocautery group was 3.27(±0.64). There was less pain in ultrasonic shears group patients and there was statistically significant difference (p=0.001) (Table 5).

There was less drain output till day 5 in ultrasonic shears group patient on comparing to electrocautery group but it was not statistically significant difference except on day 3 between two in our study (Table 6). All patients in both groups were followed till post-op day 30 and no patient in either group develop flap necrosis. In electrocautery group, 3 patients develop hematoma on 2nd, 4th, 5th day respectively and no patient in ultrasonic shears group develop hematoma and with p=0.075, this was statistically insignificant difference. In ultrasonic shears group, 2 patients develop seroma on day 13th and 15th day respectively and in electrocautery group 10 patients develop seroma formation ranging from day 13rd-19th with p value of 0.009, this was statistically significant difference.

Table 3: Duration of procedure.

Duration of procedure (mins)	Mean (SD)		P value
	Ultrasonic shears group	Electrocautery group	
	140.17 (29.98)	147.67 (41.85)	0.428

Table 4: Mean blood loss.

Blood loss (ml)	Mean (SD)		P value
	Ultrasonic shears group	Electrocautery group	
	533.50 (198.14)	681.67 (300.14)	0.028

Table 5: Post-operative pain.

Post-operative pain score	Mean (SD)		P value
	Ultrasonic shears group	Electrocautery group	
	2.63 (0.67)	3.27 (0.64)	0.001

Table 6: Mean daily drain output.

Post-operative drain output (ml)	Mean (SD)		P value
	Ultrasonic shears group	Electrocautery group	
Day 1	69.66 (29.76)	89.16 (54.07)	0.089
Day 2	57 (27.56)	75 (54.67)	0.113
Day 3	43.66 (18.28)	59.33 (38.05)	0.047
Day 4	39.33 (20.33)	46.66 (29.04)	0.262
Day 5	30.5 (20.73)	38.83 (26.57)	0.181

Table 7: Post-operative complications.

Parameters		Number of cases		P value
		Ultrasonic shears group	Electrocautery group	
Flap necrosis	Present	0	0	-
	Absent	30	30	
Hematoma formation	Present	0	3 (2^{nd}, 4^{th}, 5^{th} day)	0.075
	Absent	30	27	
Seroma formation	Present	2 (13, 15^{th} day)	10 (13-19^{th} day)	0.009
	Absent	28	20	
Wound infection	Present	0	1 (9^{th} day)	0.313
	Absent	30	29	

Table 8: Mean drain out days.

Drain out (day)	Mean (SD)		P value
	Ultrasonic shears group	Electrocautery group	
	8.17 (1.37)	9.60 (2.98)	0.020

In ultrasonic shears group, no patients develop wound infection and in electrocautery group one patient develop wound infection on post operative day 9 with p=0.313, this difference was statistically insignificant (Table 7). Mean hospital stay in ultrasonic shears group was 2.3 (±0.7) days and in electrocautery group was 2.53 (±0.57) days, there was less duration of post-op hospital stay in ultrasonic shears group on comparing with electrocautery group but with p value of 0.163, this was statistically insignificant difference as patients in both groups were discharged on post-op day 2-5th day as per unit discharge protocol. On comparing the mean post operative drain out, in ultrasonic shears group mean drain removal day was 8.17(±1.37) while in electrocautery group mean drain removal was 9.60(±2.98) days. With p value of 0.020, it was statistically significant difference. This showed that dissection with ultrasonic shears leads to lesser days of post operative drain (Table 8).

DISCUSSION

In our study operative time was less in ultrasonic shears group but it was not statistically significant (p=0.428). Meta-analysis by Huang et al and Currie et al also shows no significant difference in operative time in two groups.[4,9] However in study by Archana et al duration of surgery in ultrasonic shears and electrocautery group was 115.84 mins vs 151.38 mins respectively with p=0.001 there was less time taken in ultrasonic shears group and it was statistically significant.[8] The amount of blood loss in our study during dissection performed using ultrasonic shears was significantly (p=0.028) less when compared to electrocautery in our study. This finding was well proven in previous studies by Archana et al, Huang et al and Adwani et al.[3,4,8] In our study, ultrasonic shears group patients have lesser post operative pain on POD -1 compare to electrocautery group patient with p value =0.001 which was statistically significant. In a study by Archana et al the difference in the VAS score was significant only on POD 1 and not significant on POD 2-5.[8]

Our study shows that there was significantly (p=0.009) less seroma formation in ultrasonic shears group (2 patients on 13th and 15th post operative day) compare to electrocautery group (10 patients on post operative day 13-19th). Meta analysis by Huang et al also shows significantly less seroma formation in ultrasonic shears group. Study by Hoefer et al also show significantly less seroma formation in ultrasonic shears group comparing to electrocautery group.[4,10] In our study no patient develops flap necrosis in either group. Three patients develop hematoma formation on 2nd, 4th, 5th day in electrocautery group and no patient develop hematoma in ultrasonic shears group with (p=0.075) it was statistically not significant. One patient in electrocautery group develop wound infection and no patient in ultrasonic shears group develop wound infection but this was statistically not significant (p=0.313). In study by Khaled et al, Kiyingi et al, and Faisal et al, the incidence of post operative complication was comparable between both groups and was not statistically significant.[2,11,12]

Current study shows that in the ultrasonic shears group drain output till post op day 5 was lower than in the electrocautery group but it was not statistically significant except on day 3 where it was significantly (p=0.047) less in ultrasonic shears group.

Current study shows that mean number of days of drain was significantly (p=0.02) less in ultrasonic shears group compare to electrocautery group. Study by Archana et al and Memon et al also show early removal of drain in ultrasonic shears group compared to electrocautery group.[8,13] In our study mean days of hospital stays post operatively was not significant as patients in both group were discharged on post-op days 2-5 days as of unit discharge protocol. In a study by Kiyingi et al, there was also no difference between the median length of inpatient stay.[2]

Limitations

The main limitation of the study was its small sample size, which limits the wider application of the results of this study. As multiple surgical team operated the patients so there is scope for bias due to surgical technique in this study. As the study was performed in a single tertiary care centre, there may be centripetal bias. Studies on larger patient groups are required to validate the results of this study on larger populations.

CONCLUSION

In our study of comparison of the ultrasonic shears with electrocautery, there is significantly less amount of intra-op blood loss and less post-op pain on POD-1 with use of ultrasonic shears. There is no significant reduction in drain output post operatively till POD-5 except on POD -3 with use of ultrasonic shears. There is significantly less seroma formation with use of ultrasonic shears. There is significantly early removal of subcutaneous drain with use of ultrasonic shears. There is less operative time duration with use of ultrasonic shears compare to electrocautery but it is not significant. There is less hematoma formation with

use of ultrasonic shears compare to electrocautery but it is not significant.

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REFERENCES

1. Mittal P, Kumar A, Kaur S, Pandove PK, Singla RL, Singh J. A comparative study of the use of harmonic scalpel versus unipolar cautery in modified radical mastectomy. Niger J Surg. 2017;23:20-5.
2. Kiyingi AK, Macdonald LJ, Shugg S and Bollard RC. Ultrasonic shears dissection versus electrocautery in breast surgery in regional Victoria. Pract. 2006;60:562-64.
3. Adwani A, Ebbs S. Ultracision reduces acute blood loss but not seroma formation after mastectomy and axillary dissection: a pilot study. Int J Clin. 2017;23: 20-5.
4. Huang J, Yu Y, Wei C, Qin Q, Mo Q, Yang W. Harmonic scalpel versus electrocautery dissection in modified radical mastectomy for breast cancer: a meta-analysis. PLoS One. 2015;10:e0142271.
5. Budd DC, Cochran RC, Sturtz DL, Fouty WJ. Surgical morbidity after mastectomy operations. Am J Surg. 1978;135:218-20.
6. Tejler G, Aspegren K. Complications and hospital stay after surgery for breast cancer: a prospective study of 385 patients. Br J Surg. 1985;72:542-4.
7. Vitug AF, Newman IS. Complications in breast surgery. Surg Clin North Am. 2007;87:431-51.
8. Archana A, Sureshkumar S, Vijayakumar C. Comparing the ultrasonic shears with electrocautery in reducing post-operative flap necrosis and seroma formation after modified radical mastectomy in carcinoma breast patients: a double-blind prospective randomized control trail. Cureus. 2018;10:e2476.
9. Currie A, Chong K, Davies GL, Cummins RS. Ultrasonic dissection versus electrocautery in mastectomy for breast cancer–a meta-analysis. Eur J Surgi Oncol. 2012;38:897-901.
10. Hoefer RA, DuBois JJ, Ostrow LB, Silver LF. Wound complications following modified radical mastectomy: an analysis of perioperative factors. J Am Osteopath Assoc. 1990;90:47-53.
11. Khaled I, Saad I, Soliman H, Faisal M. Intraoperative and postoperative outcomes of Harmonic Focus versus monopolar electrocautery after neoadjuvant chemotherapy in breast conservative surgery: a comparative study. World J Surg Oncol. 2021;19: 325.
12. Faisal M, Fathy H, Shaban H, Abuelela ST, Marie A, Khaled I. A novel technique of harmonic tissue dissection reduces seroma formation after modified radical mastectomy compared to conventional electrocautery: a single-blind randomized controlled trial. Patient Saf Surg. 2018;12:1-2.
13. Memon F, Ahmed A, Parveen S, Iqbal S, Anwar A, Hashmi AA. Outcomes of harmonic scalpel and electrocautery in patients who underwent modified radical mastectomy. Cureus. 2020;12:e12311.

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