



Harmonic Scalpel versus Electrocautery: An Experience of Modified Radical Mastectomy at Tertiary Care Teaching Hospital

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The harmonic scalpel, commonly used in laparoscopic surgery, now has promise for MRM dissection. The harmonic scalpel's high frequency mechanical vibrations cut and coagulate intraoperatively at the same time, generating less heat injury than electrocautery.

Objective: To compare the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery at tertiary care teaching hospital.

Methodology: The randomized controlled trial was conducted from 12th September 2018 11th March 2019 at Department of Surgery, Liaquat University of Medical and Health Science, Jamshoro. A total of 128 patients with infiltrating ductal carcinoma undergoing modified radical mastectomy, 20 to 50 years of age were included. Chronic Hepatitis, diabetes, and neo-adjuvant treatment patients were excluded. Modified radical mastectomy employing harmonic scalpel for Group A and electrocautery for Group B. Postoperative problems such as seroma development, postoperative hematoma, marginal necrosis, lymphedema, and wound infection were also observed.

Results: The mean age of women in group A was 39.81 ± 6.73 years and in group B was 39.45 ± 6.60 years. Mean duration of disease was 5.41 ± 1.91 months. The frequency of seroma formation

in harmonic scalpel group as 7.81% vs 26.56% in electrocautery group, $p=0.005$), frequency of pain is 53.13% vs 68.75% respectively, $p=0.070$, frequency of hematoma is 1.56% vs 17.19% respectively, $p=0.002$), frequency of marginal necrosis was 0.0% vs 7.81% respectively, $p=0.023$), lymphedema 3.13% vs 14.06% respectively, $p=0.027$) and wound infection 17.19% vs 35.94% respectively, $p=0.016$.

Conclusion: This research indicated that harmonic scalpel is superior to electrocautery in modified radical mastectomy.

Keywords: Modified radical mastectomy; harmonic scalpel and electrocautery.

1. INTRODUCTION

Breast cancer is the most frequent cancer in women, with a death rate of 21.9 per 100,000. Breast cancer incidence ranges from 9 to 32 per 100,000 women [1]. Annually, 130,000 new instances of breast cancer are recorded. One in every two women diagnosed with breast cancer dies. Globally, breast carcinoma is the second largest cause of cancer mortality among women. Breast cancer is a developed-world illness [2,3]. A mastectomy is a breast excision. Simple radical and modified radical mastectomy are two kinds of mastectomies.

The surgeon doing the mastectomy, the oncologist, and the plastic surgeon performing the reconstruction should all be involved in the decision-making process. Depending on the cancer's location and severity, certain procedures may be ineligible. The pectoralis major muscle is spared in a modified radical mastectomy. Historically, the main therapy for breast cancer was a modified radical mastectomy [4]. Breast conservation has gained popularity as a cancer therapy method. But mastectomy is still an option for people with breast cancer [5]. Common post-operative consequences include wound infection, dehiscence, seroma, hematoma, persistent pain, VTE, surgical dog ears, late sequel breast fibrosis, sensory loss, shoulder dysfunction, lymphedema, and recurring breast cellulitis (cellulitis). Seroma is the most dangerous [6,7].

Using electrocautery or a scalpel causes significant surgical morbidity in 35-50% of patients. This is due to the big post-mastectomy raw region, severed lymphatics, and electrocautery. It's a safe alternative to electrocautery [8]. The harmonic scalpel, commonly used in laparoscopic surgery, now has promise for MRM dissection. The harmonic scalpel's high frequency mechanical vibrations cut and coagulate intraoperatively at the same time, generating less heat injury than electrocautery [9].

The harmonic scalpel is a novel gadget brought into surgical practise in the past decade for dissection and hemostasis [10]. The harmonic scalpel has been widely utilised in minimally invasive surgery, but not in open surgery [11]. The Modified radical mastectomy with harmonic scalpel has not been shown to be effective in previous investigations [12,13]. The goal of this research was to compare the result of modified radical mastectomy utilising harmonic scalpel against electrocautery. There are past studies on this, but they are all foreign studies, and we discovered very little local literature on it, so further study is needed on the optimal method among them in complete modified radical mastectomy. Based on these findings, we may make practical suggestions in our normal practise guidelines for these patients to get more effective method with fewer post-operative morbidity.

2. PATIENTS AND METHODS

The six months randomized controlled trial was conducted in Department of Surgery, Liaquat University of Medical and Health Science, Jamshoro. The research included patients aged 20 to 50 years, female gender, pre- and postmenopausal women, nulliparous and multiparous women, and patients with infiltrating ductal cancer (as per-operational definition) while the exclusion criteria patients with chronic Hepatitis and diabetes diagnosed by blood tests, not agree to participate in the study, those patients who has had neo-adjuvant therapy, patients with stage III and IV of breast cancer, stage IIIA T0, N2, M0 or T1, N2, M0 or T2, N2, M0 or T3, N1, M0 or T3, N2, M0, Stage IIIB T4, N0, M0 or T4, N1, M0 or T4, N2, M0 g. Stage IIIC any T, N3, M0 and Stage IV any T, any N, M1. The presence of all of the following on FNAC was regarded positive for this study: cellular atypia (pleomorphism), mitotic activity, increase (>1:1) in nuclear cytoplasmic ratio (on microscopy). The outcome was appraised as follows: Pain: An unpleasant feeling occurring as a result after surgery labeled by Visual analogue

Scale (VAS) where score 0-3 was taken as no pain:

- No pain No pain
- Mild pain 1-3
- Moderate pain 4-6
- Severe pain 7-10

Hematoma: Define as building up of blood in a surgical wound usually within first 12 hour of MRM, assessed clinically by presence of swelling and bruising of skin/flap, confirmed by Needle Aspiration. Seroma: On the clinical examination pocket of clear serous fluid noted it was labeled as positive.

Infection: Defined as presence of (temperature >99°F), tenderness and purulent discharge from operative site on first dressing of third day than labeled as positive.

Lymphedema: Defined as the localized tissue swelling of the arm on the side of surgery sufficient enough to cause discomfort to patient labeled as positive. Marginal necrosis: Defined as when the margins of flap due to lack of blood and oxygen become partially blacked than was labeled as positive.

Hypertension: all known hypertensive (blood pressure >140/90 mmHg on 2 consecutive occasions) patients for last 2 years and taking medication with controlled blood pressure.

Diabetes mellitus: all known diabetic (FBS >110 mg/dl on 2 consecutive occasions) patients for last 2 years and taking medication with controlled serum sugar. The hypothesis was outcome is better after harmonic scalpel modified radical mastectomy as compared to electrocautery in modified radical mastectomy while the sample size was calculated as 128 by non-probability, consecutive sampling, i.e. 64 cases in each group, with 5% level of significance, 80% power of study and taking seroma formation in harmonic scalpel group as 8% and in diathermy group as 24% [11].

The research included patients who met the requirements. All participants signed a permission form. Patient evaluation included two groups. Modified radical mastectomy employing harmonic scalpel for Group A and electrocautery for Group B. Less than 5 years of experience performed both approaches. On the eighth post-operative day, all patients were returned for follow-up and stiches were removed. Postoperative problems such as seroma

development, postoperative hematoma, marginal necrosis, lymphedema, and wound infection were noted in both groups and entered in the predesigned Proforma.

All the data was entered and analyzed by using SPSS version 20.0. The quantitative variables like age, duration of disease and post-operative pain were presented as mean and standard deviation. The qualitative variables like parity (nulliparous/multiparous), menopausal status (pre-menopause/post-menopause), stage of carcinoma (I/II), diabetes mellitus (yes/no), hypertension (yes/no), outcome (post-operative pain, seroma formation, postoperative hematoma, marginal necrosis, lymphedema and wound infection) were presented as frequency and percentage. Chi square test was applied to compare the outcome (post-operative pain, seroma formation, postoperative hematoma, marginal necrosis, lymphedema and wound infection) in both groups and p-value ≤ 0.05 was taken as significant.

3. RESULTS

The age range in this study was from 20 to 50 years with mean age of 39.63 ± 6.62 years. The mean age of women in group A was 39.81 ± 6.73 years and in group B was 39.45 ± 6.60 years. Majority of the patients 101 (78.91%) were between 20 to 35 years of age while the Mean duration of disease was 5.41 ± 1.91 months. The age distribution for both groups is shown in Table 1 while the comparison of the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery, Stratification of post-operative pain with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension, stratification of seroma formation with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension, stratification of hematoma formation with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension, stratification of marginal necrosis with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension, stratification of lymphedema with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension and stratification of wound infection with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension are shown in Tables 2-8.

Table 1. Age distribution for both groups (n=128)

| Age (years) | Group A (n=64) | | Group B (n=64) | | Total (n=128) | |
|---------------|------------------|-------|------------------|-------|------------------|-------|
| | No. of patients | % age | No. of patients | % age | No. of patients | % age |
| 20-35 | 12 | 18.75 | 15 | 23.44 | 27 | 21.09 |
| 36-50 | 52 | 81.25 | 49 | 76.56 | 101 | 78.91 |
| Mean \pm SD | 39.81 \pm 6.73 | | 39.45 \pm 6.60 | | 39.63 \pm 6.62 | |

Table 2. Comparison of the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery

| Outcome | Group A (n=64) | | Group B (n=64) | | p-value |
|------------------|----------------|-------------|----------------|-------------|--------------|
| | Yes | No | Yes | No | |
| Pain | 34 (53.13%) | 30 (46.87%) | 44 (68.75%) | 20 (31.25%) | 0.070 |
| Seroma | 05 (7.81%) | 59 (92.19%) | 17 (26.56%) | 47 (73.44%) | 0.005 |
| Hematoma | 01 (1.56%) | 63 (98.44%) | 11 (17.19%) | 53 (82.81%) | 0.002 |
| Marginalnecrosis | 00 (0.0%) | 64 (100.0%) | 05 (7.81%) | 59 (92.19%) | 0.023 |
| Lymphedema | 02 (3.13%) | 62 (96.87%) | 09 (14.06%) | 55 (85.94%) | 0.027 |
| Infection | 11 (17.19%) | 53 (82.81%) | 23 (35.94%) | 41 (64.06%) | 0.016 |

Table 3. Stratification of post-operative pain with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | Group A (n=64) | | Group B (n=64) | | P-value |
|------------------|----------------|----------------|----|----------------|----|--------------|
| | | Pain | | Pain | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 05 | 07 | 10 | 05 | 0.194 |
| | 36-50 | 29 | 23 | 34 | 15 | 0.158 |
| Duration(months) | \leq 5 | 17 | 16 | 20 | 12 | 0.371 |
| | >5 | 17 | 14 | 24 | 08 | 0.093 |
| Parity | Nulliparous | 16 | 06 | 13 | 10 | 0.256 |
| | Multiparous | 18 | 24 | 31 | 10 | 0.002 |
| Menopause | Pre-menopause | 13 | 13 | 22 | 08 | 0.072 |
| | Post-menopause | 21 | 17 | 22 | 12 | 0.415 |
| Stageofcarcinoma | I | 18 | 15 | 26 | 05 | 0.011 |
| | II | 16 | 15 | 18 | 15 | 0.814 |
| Hypertension | Yes | 09 | 11 | 13 | 08 | 0.278 |
| | No | 25 | 19 | 31 | 12 | 0.137 |
| Diabetesmellitus | Yes | 15 | 12 | 21 | 08 | 0.188 |
| | No | 19 | 18 | 23 | 12 | 0.217 |

Table 4. Stratification of seroma formation with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | GroupA(n=64) | | GroupB(n=64) | | P-value |
|------------------|----------------|--------------|----|--------------|----|--------------|
| | | Seroma | | Seroma | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 01 | 11 | 04 | 11 | 0.223 |
| | 36-50 | 04 | 48 | 13 | 36 | 0.011 |
| Duration(months) | \leq 5 | 02 | 31 | 10 | 22 | 0.009 |
| | >5 | 03 | 28 | 07 | 25 | 0.185 |
| Parity | Nulliparous | 01 | 21 | 05 | 18 | 0.090 |
| | Multiparous | 04 | 38 | 12 | 29 | 0.023 |
| Menopause | Pre-menopause | 02 | 24 | 06 | 24 | 0.189 |
| | Post-menopause | 03 | 35 | 11 | 23 | 0.009 |

| | | GroupA(n=64) | | GroupB(n=64) | | P-value |
|-------------------|-----|--------------|----|--------------|----|--------------|
| | | Seroma | | Seroma | | |
| | | Yes | No | Yes | No | |
| Stageofcarcinoma | I | 03 | 30 | 07 | 24 | 0.137 |
| | II | 02 | 29 | 10 | 23 | 0.015 |
| Hypertension | Yes | 03 | 17 | 08 | 13 | 0.095 |
| | No | 02 | 42 | 09 | 34 | 0.021 |
| Diabetes mellitus | Yes | 01 | 26 | 10 | 19 | 0.004 |
| | No | 04 | 33 | 07 | 28 | 0.279 |

Table 5. Stratification of hematoma formation with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | Group A (n=64) | | Group B (n=64) | | P-value |
|------------------|----------------|----------------|----|----------------|----|--------------|
| | | Hematoma | | Hematoma | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 00 | 12 | 03 | 12 | 0.100 |
| | 36-50 | 01 | 51 | 08 | 41 | 0.011 |
| Duration(months) | ≤5 | 00 | 33 | 05 | 27 | 0.018 |
| | >5 | 01 | 30 | 06 | 26 | 0.050 |
| Parity | Nulliparous | 00 | 22 | 04 | 19 | 0.040 |
| | Multiparous | 01 | 41 | 07 | 34 | 0.023 |
| Menopause | Pre-menopause | 01 | 25 | 03 | 27 | 0.373 |
| | Post-menopause | 00 | 38 | 08 | 26 | 0.002 |
| Stageofcarcinoma | I | 01 | 32 | 05 | 26 | 0.072 |
| | II | 00 | 31 | 06 | 27 | 0.013 |
| Hypertension | Yes | 00 | 20 | 05 | 16 | 0.020 |
| | No | 01 | 43 | 06 | 37 | 0.045 |
| Diabetesmellitus | Yes | 01 | 26 | 07 | 22 | 0.029 |
| | No | 00 | 37 | 04 | 31 | 0.034 |

Table 6. Stratification of marginal necrosis with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | Group A (n=64) | | Group B (n=64) | | P-value |
|------------------|----------------|------------------|----|------------------|----|--------------|
| | | Marginalnecrosis | | Marginalnecrosis | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 00 | 12 | 02 | 13 | 0.189 |
| | 36-50 | 00 | 52 | 03 | 46 | 0.070 |
| Duration(months) | ≤5 | 00 | 33 | 02 | 30 | 0.145 |
| | >5 | 00 | 31 | 03 | 29 | 0.081 |
| Parity | Nulliparous | 00 | 22 | 04 | 19 | 0.040 |
| | Multiparous | 00 | 42 | 01 | 40 | 0.309 |
| Menopause | Pre-menopause | 00 | 26 | 03 | 27 | 0.097 |
| | Post-menopause | 00 | 38 | 02 | 32 | 0.129 |
| Stageofcarcinoma | I | 00 | 33 | 04 | 27 | 0.033 |
| | II | 00 | 31 | 01 | 32 | 0.329 |
| Hypertension | Yes | 00 | 20 | 03 | 18 | 0.079 |
| | No | 00 | 44 | 02 | 41 | 0.148 |
| Diabetesmellitus | Yes | 00 | 27 | 02 | 27 | 0.165 |
| | No | 00 | 37 | 03 | 32 | 0.069 |

Table 7. Stratification of lymphedema with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | Group A (n=64) | | Group B (n=64) | | P-value |
|-------------------|---------------|----------------|----|----------------|----|--------------|
| | | Lymphedema | | Lymphedema | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 00 | 12 | 03 | 12 | 0.100 |
| | 36-50 | 02 | 50 | 06 | 43 | 0.118 |
| Duration(months) | ≤5 | 00 | 33 | 02 | 30 | 0.145 |
| | >5 | 02 | 29 | 07 | 25 | 0.080 |
| Parity | Nulliparous | 01 | 21 | 03 | 20 | 0.317 |
| | Multiparous | 01 | 41 | 06 | 35 | 0.045 |
| Menopause | Pre-menopause | 01 | 25 | 06 | 24 | 0.068 |
| | Postmenopause | 01 | 37 | 03 | 21 | 0.123 |
| Stageofcarcinoma | I | 01 | 32 | 05 | 26 | 0.072 |
| | II | 01 | 30 | 04 | 29 | 0.185 |
| Hypertension | Yes | 01 | 19 | 04 | 17 | 0.169 |
| | No | 01 | 43 | 05 | 38 | 0.085 |
| Diabetes mellitus | Yes | 00 | 27 | 06 | 23 | 0.012 |
| | No | 02 | 35 | 03 | 32 | 0.597 |

Table 8. Stratification of wound infection with respect to age, duration of disease, parity, menopausal status, stage of carcinoma, diabetes mellitus and hypertension

| | | Group A (n=64) | | Group B (n=64) | | P-value |
|------------------|----------------|----------------|----|----------------|----|--------------|
| | | Infection | | Infection | | |
| | | Yes | No | Yes | No | |
| Age(years) | 20-35 | 03 | 09 | 05 | 10 | 0.637 |
| | 36-50 | 08 | 44 | 18 | 31 | 0.014 |
| Duration(months) | ≤5 | 07 | 26 | 11 | 29 | 0.535 |
| | >5 | 04 | 27 | 12 | 20 | 0.025 |
| Parity | Nulliparous | 03 | 19 | 10 | 13 | 0.027 |
| | Multiparous | 08 | 34 | 13 | 28 | 0.185 |
| Menopause | Pre-menopause | 03 | 23 | 11 | 19 | 0.030 |
| | Post-menopause | 08 | 30 | 12 | 22 | 0.178 |
| Stageofcarcinoma | I | 06 | 27 | 14 | 17 | 0.020 |
| | II | 05 | 26 | 09 | 24 | 0.281 |
| Hypertension | Yes | 03 | 17 | 06 | 15 | 0.294 |
| | No | 08 | 36 | 17 | 26 | 0.028 |
| Diabetesmellitus | Yes | 08 | 19 | 09 | 20 | 0.909 |
| | No | 03 | 34 | 14 | 21 | 0.001 |

4. DISCUSSION

Breast cancer is a very site-specific malignancy [14]. Late-presenting patients do not benefit from radical mastectomy in terms of survival or cure. The "mutilation" just increases morbidity and reduces quality of life. Earlier therapy with modified radical mastectomy is preferred [15]. To cure or significantly lengthen the lives of patients, and to offer the highest possible quality of life for survivors. Monopolar diathermy is now the most often utilised energy source in modified radical mastectomy. It works by heating a metal probe with an electric current to damage tissue [16,17]. Ultrasonic surgical instruments have been used

in clinical practise for almost a decade to reduce the hazards of older electrosurgical technologies, local peripheral energy damage, and potentially fatal monopolar energy problems [18]. The harmonic scalpel denatures protein by ultrasonic vibration at 55,500 Hz and 50-100 m [19]. This research compared the result of harmonic scalpel against electrocautery modified radical mastectomy. Age range in this study was from 20 to 50 years with mean age of 39.63 ± 6.62 years. The mean age of women in group A was 39.81 ± 6.73 years and in group B was 39.45 ± 6.60 years. Majority of the patients 101 (78.91%) were between 20 to 35 years of age. In our study, frequency of seroma formation in harmonic

scalpel group as 7.81% vs 26.56% in electrocautery group, $p=0.005$), frequency of pain is 53.13% vs 68.75% respectively, $p=0.070$, frequency of hematoma is 1.56% vs 17.19% respectively, $p=0.002$), frequency of marginal necrosis was 0.0% vs 7.81% respectively, $p=0.023$), lymphedema 3.13% vs 14.06% respectively, $p=0.027$) and wound infection 17.19% vs 35.94% respectively, $p=0.016$. In a study [11], frequency of seroma formation in harmonic scalpel group as 8% vs 24% in electrocautery group, $p=0.247$], frequency of hematoma is 0.0% vs 12% respectively, $p=0.235$], frequency of flap necrosis was 0.0% vs 4% respectively, $p=1.000$] and of lymphedema 4% vs 8% respectively, $p=1.000$]. There was no statistically significant difference noted in terms of postoperative pain i.e. 60% vs 76% respectively [11]. Another study has shown that there was no significant difference between the groups with regard to seroma (12% vs. 16%, $P = 0.684$), hematoma (4% vs. 4%, $P = 1.000$), wound infection (24% vs. 32%, $P = 0.529$), flap necrosis (8% vs. 28%, $P = 0.066$), pain intensity (measured on visual analog scale) (5.08 ± 1.29 vs. 5.20 ± 1.68 , $P = 0.778$), and lymphedema (4% vs. 8%, $P = 0.552$) [12]. The study findings are consistent with the study by Mittal P, et al. [20] Perveen S, et al. did a prospective study in modified radical mastectomy using harmonics and her results showed that MRM and axillary dissection using the harmonic scalpel was safe, feasible, and effective [21]. This device decreased operational time, peri-operative blood loss, drainage volume, and drainage duration. Seroma and lymphedema incidence were also decreased. The use of a harmonic scalpel in MRM reduced axillary dissection time, drainage volume and length, and hospital stay, according to a research by Galal [22]. Deo and Shukla used harmonic scalpel for dissection in MRM and reported encouraging results in terms of operative time, intra-operative blood loss, Lymphatic drainage and seroma formation [23,24]. However, the study by Galatius H & Okholm et al reported that there is no significant difference in the use of both the techniques in terms of operative time, peri-operative bleeding and wound complications [25]. Furthermore, they reported a high incidence of seroma formation in both the groups. Porter et al. [26] found that the use of electrocautery was significantly associated with increased seroma formation in a randomized controlled trial. On the other hand, Lumachi et al. [27] found that the use of ultrasonic shears has significantly reduced seroma formation in a randomized controlled trial, and also consistent

with former study [28]. A systematic review and meta-analysis [29] has shown that intraoperative blood loss, seroma and hematoma formation, drainage volume and time, necrosis, surgical duration and hospital stay are significantly different between the two groups. The harmonic scalpel is superior to traditional instruments in reducing intraoperative blood loss, seroma and hematoma development, drainage volume and time, necrosis prevalence, surgical length, and hospital stay [30]. In another meta-analysis [31], there was significant difference in total postoperative drainage, intraoperative blood loss, and wound complications between harmonic scalpel dissection and standard electrocautery in modified radical mastectomy for breast cancer. No difference was found as for operative time between harmonic scalpel dissection and standard electrocautery. Nagah et al. [31] compared Harmonic Scalpel with the Monopolar Electrocautery in Modified Radical Mastectomy and concluded that the the use of harmonic scalpel in MRM reduced operative time, blood loss, and drainage volume, reducing hospital stay.

5. CONCLUSION

This research revealed that harmonic scalpel modified radical mastectomy outperforms electrocautery in terms of result. To reduce post-operative discomfort, hematoma, seroma, and marginal necrosis, we propose harmonic for modified radical mastectomy in cancer breast.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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