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Original Research Article

A STUDY OF COMPLICATIONS IN USING HARMONIC SCALPEL VERSUS ELECTROCAUTERY IN POST MODIFIED RADICAL MASTECTOMY – A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Postoperative seroma and flap necrosis remain common morbidities after modified radical mastectomy (MRM), and optimizing the dissection technique (harmonic scalpel versus electrocautery) may reduce these complications and enhance recovery. The objective is to compare the postoperative complications in using harmonic scalpel versus electrocautery in post MRM. **Materials and Methods:** This single-centre, parallel-group, single-blinded randomized controlled trial enrolled 60 adults undergoing elective MRM and randomized (1:1) to harmonic scalpel (Group A) or electrocautery (Group B) dissection. **Result:** Among 60 participants (30 per arm), baseline characteristics were well balanced between Group A and Group B. Mean age (49.5±8.5 vs 49.2±10.1 years; p=0.923) and BMI (25.4±2.4 vs 25.8±2.6 kg/m²; p=0.625) were comparable, with similar urban residence (63.3% vs 60.0%) and menopausal status (premenopausal 53.3% vs 50.0%). Comorbidities were also similar (diabetes 30.0% vs 33.3%; hypertension 26.7% vs 30.0%). Tumour profile did not differ: neoadjuvant chemotherapy was received by 20.0% vs 23.3%, and most patients were AJCC stage II (56.7% vs 60.0%). Preoperative labs were comparable (Hb 12.1±1.2 vs 12.3±1.1 g/dL). Intraoperatively, Group A had shorter operative time (112.8±18.8 vs 128.7±21.8 min; p=0.004) and lower blood loss (170.7±58.4 vs 241.8±88.2 mL; p=0.001). Postoperatively, drain outputs and duration were lower, with earlier drain removal (≤POD7: 40.0% vs 10.0%). Seroma (16.7% vs 53.3%; p=0.007) and flap necrosis (6.7% vs 33.3%; p=0.024) were reduced in Group A. Early pain and analgesic use were lower, and hospital stay was shorter (4.8±0.9 vs 6.7±1.1 days; p<0.001) in Group A. **Conclusion:** Harmonic scalpel dissection in MRM significantly reduced seroma and flap necrosis and was associated with lower blood loss, improved drain outcomes, reduced early postoperative pain and analgesic use, and shorter hospital stay compared with electrocautery.

INTRODUCTION

Breast cancer continues to impose a substantial burden on health systems, particularly in low- and middle-income settings where late presentation is common.[1] Recent global estimates from the International Agency for Research on Cancer (IARC) indicate that breast cancer accounted for a major proportion of cancer incidence and mortality in 2022.[2] Surgical management is central to curative intent treatment, and although breast-conserving approaches are preferred when feasible, modified radical mastectomy (MRM) remains widely performed due to tumour size, multifocal disease, patient preference, resource constraints, and logistical barriers to radiotherapy access.[3] Despite improvements in oncologic safety and perioperative care, MRM is still associated with relevant postoperative morbidity. Common early complications include surgical site infection, hematoma, wound dehiscence, flap necrosis, and particularly seroma, which is among the most frequent and clinically troublesome sequelae of mastectomy with axillary dissection.[4] Seroma represents the accumulation of serous fluid in the dead space created by mastectomy flap elevation and axillary dissection, and it may contribute to patient discomfort, repeated aspirations, delayed drain

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removal, risk of infection, delayed wound healing, and postponement of adjuvant therapy.[5] Reported seroma rates vary widely (ranging from 3% to over 85%) depending on definitions, underscoring its multifactorial etiology and challenges in prevention.

The choice of surgical dissection and haemostatic technique is considered a modifiable contributor to postoperative drainage and seroma formation. Conventional electrocautery/electrosurgery achieves cutting and coagulation by delivering high-frequency alternating current through tissue, generating heat and causing protein denaturation, desiccation, and vessel sealing. While electrocautery is efficient, widely available, and economical, the higher temperatures and lateral thermal injury associated with electrosurgical dissection may exacerbate tissue inflammation, lymphatic disruption, and exudation, thereby influencing drainage volume and postoperative wound morbidity.[6] In MRM, where large skin flaps and extensive lymphovascular channels are transected, minimizing collateral thermal damage and improving lymphatic sealing are conceptually important for reducing seroma and flap-related complications.[7] Ultrasonic dissection systems, particularly the harmonic scalpel, have therefore gained attention as alternatives to electrocautery for mastectomy and axillary clearance. Harmonic devices use high-frequency ultrasonic mechanical vibration to divide tissue and achieve haemostasis through compression and protein denaturation, without current passing through the patient as in monopolar electrosurgery.[8] The harmonic scalpel has been described as operating at lower tissue temperatures (commonly cited around 50–100°C) compared with conventional electrocautery (often cited 150–400°C), potentially reducing smoke, charring, and lateral thermal spread.[9] This mechanistic profile provides a biological rationale that ultrasonic dissection might decrease postoperative inflammatory exudate, reduce drainage volume, and lower the incidence of seroma and flap necrosis after MRM.[10]

Given that postoperative seroma and flap necrosis directly affect patient comfort, wound healing, hospital stay, drain dependence, and timing of adjuvant therapy, evaluating energy modality in MRM has practical relevance. In this context, the aim of the present study was to compare the postoperative complications in using harmonic scalpel versus electrocautery in post MRM.

MATERIALS AND METHODS

This was a single-centre, hospital-based, experimental, parallel, single-blinded randomized controlled trial – conducted in the Department of General Surgery, Aarupadai Veedu Medical College and Hospital, Puducherry, India over a duration of 18 months. The study was approved by the Institutional Human Ethics Committee (IHEC) with reference number AV/IHEC/01/2024/055 dated 07/06/2024. The participants were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Eligible participants included adults aged >18 years with a clinical diagnosis of stage I–III breast carcinoma who underwent elective MRM in the study setting and provided written informed consent. Patients were excluded if they had a history of prior breast surgery, metastatic disease, breast ulcers/discharge or active wound infection, risk factors likely to impair wound healing (including anaemia), or if they were receiving anticoagulant or corticosteroid therapy.

Sample size for this trial (harmonic scalpel vs electrocautery; 1:1 allocation) was estimated using a two-sample comparison of means approach. Assuming a two-sided $\alpha=0.05$ and 90% power, the expected effect size was derived from Archana et al,[11] based on intraoperative blood loss (electrocautery 276.25±108.10 mL; harmonic scalpel 200.13±65.19 mL; $\Delta=76.12$ mL), yielding a minimum required sample size, rounded off to 30 per group (total N=60). Participants were recruited using nonprobability (convenience/purposive) sampling with complete enumeration of eligible patients. Baseline data were recorded in a predesigned proforma, including age, sex, body mass index, comorbidities (diabetes, hypertension), tumour stage (I–III), and relevant preoperative laboratory parameters required for anaesthetic fitness. Diagnosis of carcinoma breast was confirmed preoperatively by fine-needle aspiration cytology (FNAC) and/or trucut (core-needle) biopsy. Participants were allocated in a 1:1 ratio to one of two intervention arms: Group A (harmonic scalpel) and Group B (electrocautery). Randomization used computer-generated random sequence with allocation concealment through sequentially numbered, opaque, sealed envelopes opened in the operating room after patient enrolment. All patients underwent MRM with axillary lymph node dissection up to level II. Operative time was recorded in minutes from skin incision to completion of skin closure. Intraoperative blood loss was estimated using the gravimetric method (1 g = 1 mL).[12] Suction was not used during the procedure, and the final blood loss was documented in millilitres. At wound closure, negative-pressure closed suction drains were placed in both groups, with one drain positioned along the lower skin flap/pectoral region and a second drain placed in the axilla.[13] Postoperatively, drain output was measured and documented every 24 hours for each drain and as total daily output. Drain removal was performed when the total drain output in the preceding 24 hours fell to <30 mL.[14] Total duration of drainage (days) and total drain volume were recorded. Primary outcomes were assessed prospectively. Seroma was considered present if drain output remained >40 mL after postoperative day (POD) 7 or if a clinically evident fluid collection (fluctuation) developed beneath the skin flap during follow-up after discharge; seroma was confirmed by needle

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aspiration, and the number of aspirations required was documented.[15] Flap necrosis was evaluated by daily wound inspection during hospital stay and at subsequent follow-up visits and was documented as present when there was clinically evident partial- or full-thickness skin-flap devitalization (dusky discoloration progressing to black eschar/slough). SSI was considered when features consistent with CDC/NHSN definitions occurred within 30 days of surgery (purulent discharge, localized pain/tenderness, swelling, erythema, or wound opening with clinician diagnosis).[16] Secondary outcomes were recorded as follows. Postoperative pain was assessed using a validated visual analogue scale (VAS) each postoperative morning from POD1 to POD7 (0–10).[17] Length of postoperative hospital stay was calculated as the number of days from the date of surgery to the date of discharge. After drain removal, patients were followed up weekly for 12 weeks; at each visit, the wound and flap were examined for seroma, flap necrosis, and SSI, and any interventions (including aspirations) were recorded.

Statistical analysis: Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 27.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean ± standard deviation (SD). Categorical variables were expressed as frequency and percentage. Normality of distribution for continuous variables was assessed using visual inspection of histograms and the Shapiro–Wilk test. For comparisons between the two independent study groups, continuous outcomes were compared using the independent samples t-test when data were approximately normally distributed; when normality assumptions were not met, the Mann–Whitney U test was applied. Categorical variables were compared using the Chi-square test of independence; Fisher's exact test was used when expected cell counts were <5. All statistical tests were two-tailed, and a p value of <0.05 was considered statistically significant.

RESULTS

Of 74 patients assessed, 14 were excluded (9 ineligible, 5 declined), and the remaining 60 were randomized equally (30 per group), completed the assigned intervention with no loss to follow-up, and were all included in the final analysis. Baseline characteristics were comparable between Group A and Group B (all p>0.05). Mean age was similar (49.5±8.5 vs 49.2±10.1 years; p=0.923) as was BMI (25.4±2.4 vs 25.8±2.6 kg/m²; p=0.625). The distribution of residence (urban 63.3% vs 60.0%), menopausal status (premenopausal 53.3% vs 50.0%), diabetes (30.0% vs 33.3%), hypertension (26.7% vs 30.0%), and receipt of neoadjuvant chemotherapy (20.0% vs 23.3%) showed no significant difference (all p≥0.931). Tumour stage (AJCC I/II/III: 20.0/56.7/23.3% vs 16.7/60.0/23.3%) and laterality (right 53.3% vs 50.0%) were also similar (p=0.942). Intraoperatively, Group A had a significantly shorter operative time than Group B (112.8±18.8 vs 128.7±21.8 minutes; p=0.004) and lower estimated blood loss (170.7±58.4 vs 241.8±88.2 mL; p=0.001), while the ease-of-use score was higher in Group A (4.5±0.4 vs 4.1±0.6; p=0.001). Intraoperative complications were uncommon and comparable (6.7% vs 13.3%; p=0.671). Postoperatively, drain outputs were consistently lower in Group A. Total drain output was markedly reduced in Group A (554.5±140.2 vs 930.1±266.0 mL; p<0.001) and drainage duration was shorter (8.0±2.1 vs 10.2±2.1 days; p<0.001), with earlier drain removal in Group A (≤POD7: 40.0% vs 10.0%; >POD10: 10.0% vs 43.3%; p=0.003).

Table 1: Baseline demographic, clinical, tumour, and laboratory characteristics of participants by study group

		Group A N = 30	Group B N = 30	P value
Age (years), Mean ± SD		49.5 ± 8.5	49.2 ± 10.1	0.923
Body mass index (kg/m²), Mean ± SD		25.4 ± 2.4	25.8 ± 2.6	0.625
Residence, n (%)	Urban	19 (63.3)	18 (60.0)	0.956
	Rural	11 (36.7)	12 (40.0)	
Menopausal status, n (%)	Premenopausal	16 (53.3)	15 (50.0)	0.942
	Postmenopausal	14 (46.7)	15 (50.0)	
Diabetes mellitus, n (%)	Yes	9 (30.0)	10 (33.3)	0.972
	No	21 (70.0)	20 (66.7)	
Hypertension, n (%)	Yes	8 (26.7)	9 (30.0)	0.949
	No	22 (73.3)	21 (70.0)	
Neoadjuvant chemotherapy, n (%)	Yes	6 (20.0)	7 (23.3)	0.931
	No	24 (80.0)	23 (76.7)	
Tumour stage (AJCC), n (%)	I	6 (20.0)	5 (16.7)	0.942
	II	17 (56.7)	18 (60.0)	
	III	7 (23.3)	7 (23.3)	
Tumour laterality, n (%)	Right	16 (53.3)	15 (50.0)	0.942
	Left	14 (46.7)	15 (50.0)	
Haemoglobin (g/dL), Mean ± SD		12.1 ± 1.2	12.3 ± 1.1	0.497
Platelet count (×10³/µL), Mean ± SD		265.6 ± 68.3	246.8 ± 37.5	0.194
Random blood sugar (mg/dL), Mean ± SD		122.4 ± 26.7	131.1 ± 33.8	0.273
Blood urea (mg/dL), Mean ± SD		25.7 ± 5.5	26.8 ± 6.4	0.477
Serum creatinine (mg/dL), Mean ± SD		0.9 ± 0.2	0.8 ± 0.2	0.324
Serum sodium (mEq/L), Mean ± SD		139.0 ± 2.1	139.0 ± 2.0	1.000
Serum potassium (mEq/L), Mean ± SD		4.1 ± 0.4	4.1 ± 0.5	0.863

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*Statistically significant at p<0.05

Table 2: Comparison of intraoperative parameters and postoperative drain outcomes between study groups

		Group A N = 30	Group B N = 30	P value
Intraoperative details				
Operative time (minutes), Mean ± SD		112.8 ± 18.8	128.7 ± 21.8	0.004*
Estimated blood loss (mL), Mean ± SD		170.7 ± 58.4	241.8 ± 88.2	0.001*
Ease-of-use score (1–5), Mean ± SD		4.5 ± 0.4	4.1 ± 0.6	0.001*
Intraoperative complications, n (%)	Yes	2 (6.7)	4 (13.3)	0.671
	No	28 (93.3)	26 (86.7)	
Postoperative drain outcomes				
Drain output on POD1 (mL/24h), Mean ± SD		159.2 ± 41.4	202.7 ± 41.0	<0.001*
Drain output on POD3 (mL/24h), Mean ± SD		84.7 ± 23.3	133.1 ± 35.8	<0.001*
Drain output on POD5 (mL/24h), Mean ± SD		47.8 ± 22.9	79.0 ± 29.7	<0.001*
Drain output on POD7 (mL/24h), Mean ± SD		35.4 ± 27.9	57.5 ± 29.0	0.004*
Total drain output (mL), Mean ± SD		554.5 ± 140.2	930.1 ± 266.0	<0.001*
Duration of drainage (days), Mean ± SD		8.0 ± 2.1	10.2 ± 2.1	<0.001*
Day of drain removal, n (%)	≤POD7	12 (40.0)	3 (10.0)	0.003*
	POD8–10	15 (50.0)	14 (46.7)	
	>POD10	3 (10.0)	13 (43.3)	
*Statistically significant at p<0.05. SD, Standard deviation				

Table 3: Comparison of postoperative complications (seroma, flap necrosis, and other adverse events) and length of hospital stay between study groups

		Group A N = 30	Group B N = 30	P value
Postoperative seroma				
Postoperative seroma (overall), n (%)	Yes	5 (16.7)	16 (53.3)	0.007*
	No	25 (83.3)	14 (46.7)	
Seroma criterion/confirmation (among seroma cases), n (%)	Prolonged drainage (>40 mL after POD7)	3 (60.0)	10 (62.5)	1.000
	Clinically evident collection (aspiration-confirmed)	2 (40.0)	6 (37.5)	
No. of aspirations required (among seroma cases), Mean ± SD		1.8 ± 0.8	2.4 ± 1.0	0.233
Aspirations distribution (among seroma cases), n (%)	1	2 (40.0)	3 (18.8)	0.677
	2	2 (40.0)	6 (37.5)	
	3	1 (20.0)	5 (31.2)	
	≥4	0 (0.0)	2 (12.5)	
Flap necrosis				
Flap necrosis (overall), n (%)	Yes	2 (6.7)	10 (33.3)	0.024*
	No	28 (93.3)	20 (66.7)	
Extent of flap necrosis (among necrosis cases), n (%)	Partial-thickness	2 (100.0)	8 (80.0)	1.000
	Full-thickness	0 (0.0)	2 (20.0)	
Management of flap necrosis (among necrosis cases), n (%)	Conservative (dressings/antibiotics)	2 (100.0)	6 (60.0)	0.549
	Debridement + secondary suturing	0 (0.0)	2 (20.0)	
	Debridement + split-thickness skin graft	0 (0.0)	2 (20.0)	
Other complications				
Complications, n (%)	Surgical site infection	2 (6.7)	6 (20.0)	0.254
	Hematoma/bleeding	1 (3.3)	2 (6.7)	1.000
	Wound dehiscence	1 (3.3)	3 (10.0)	0.612
	Drain-site infection	1 (3.3)	2 (6.7)	1.000
	Readmission within 30 days	1 (3.3)	2 (6.7)	1.000
Hospital stay				
Postoperative hospital stay (days), Mean ± SD		4.8 ± 0.9	6.7 ± 1.1	<0.001*
Postoperative hospital stay (days), n (%)	≤5 days	24 (80.0)	4 (13.3)	<0.001*
	6–7 days	6 (20.0)	22 (73.3)	
	>7 days	0 (0.0)	4 (13.3)	
*Statistically significant at p<0.05				

Table 4: Analgesic requirement by study group (first 72 hours postoperatively; N = 60)

		Group A N = 30	Group B N = 30	P value
Diclofenac doses (75 mg) in first 72h, Mean ± SD		4.0 ± 1.1	5.1 ± 1.0	<0.001*
Rescue opioid required, n (%)	Yes	6 (20.0)	12 (40.0)	0.159
	No	24 (80.0)	18 (60.0)	
No. of rescue opioid doses (among those requiring rescue), Mean ± SD		1.3 ± 0.5	1.8 ± 0.8	0.277
Total tramadol equivalent (mg) in first 72h, Mean ± SD		13.3 ± 29.2	35.0 ± 49.4	0.066
Total analgesic doses (NSAID + rescue) in first 72h, Mean ± SD		4.2 ± 1.2	5.8 ± 1.5	<0.001*
*Statistically significant at p<0.05				

Postoperative seroma occurred significantly less often in Group A than Group B (16.7% vs 53.3%; p=0.007), and flap necrosis was also reduced (6.7% vs 33.3%; p=0.024). Among seroma cases, the basis

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for diagnosis was similar between groups, with most meeting the criterion of prolonged drainage >40 mL after POD7 (60.0% vs 62.5%), while aspiration-confirmed collections accounted for 40.0% vs 37.5% (p=1.000); the mean number of aspirations did not differ significantly (1.8±0.8 vs 2.4±1.0; p=0.233). Necrosis was predominantly partial-thickness in both groups (100% vs 80.0%), and management patterns were comparable (conservative care 100% vs 60.0%; p=0.549). Other postoperative complications such as surgical site infection (6.7% vs 20.0%), hematoma/bleeding (3.3% vs 6.7%), wound dehiscence (3.3% vs 10.0%), drain-site infection (3.3% vs 6.7%), and 30-day readmission (3.3% vs 6.7%) were not significantly different (all p>0.05). Postoperative hospital stay was significantly shorter in Group A (4.8±0.9 vs 6.7±1.1 days; p<0.001), with most Group A patients discharged within ≤5 days (80.0% vs 13.3%; p<0.001).

Postoperative pain scores (VAS) were generally lower in Group A during the early postoperative period, with significantly reduced VAS at 6 hours (5.0±0.7 vs 5.6±0.8; p=0.005) and 12 hours (4.7±0.5 vs 5.0±0.7; p=0.042), and again at 48 hours (2.6±0.6 vs 3.0±0.9; p=0.028) and 72 hours (2.2±0.7 vs 2.6±0.8; p=0.036), while scores were similar at 24 and 36 hours and by POD7 (1.1±0.7 vs 1.3±0.6; p=0.118). Analgesic requirements mirrored these findings: Group A received fewer diclofenac doses in the first 72 hours (4.0±1.1 vs 5.1±1.0; p<0.001) and had lower total analgesic doses (NSAID plus rescue) over 72 hours (4.2±1.2 vs 5.8±1.5; p<0.001). Rescue opioid use was numerically lower in Group A (20.0% vs 40.0%), with a lower mean tramadol equivalent consumption (13.3±29.2 vs 35.0±49.4 mg), though these differences were not statistically significant.

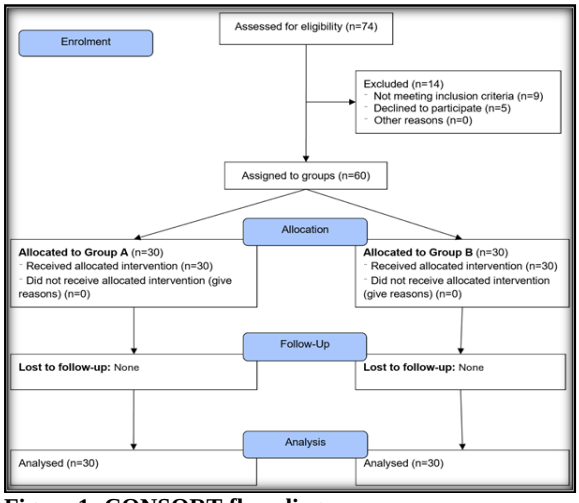

Figure 1: CONSORT flow diagram

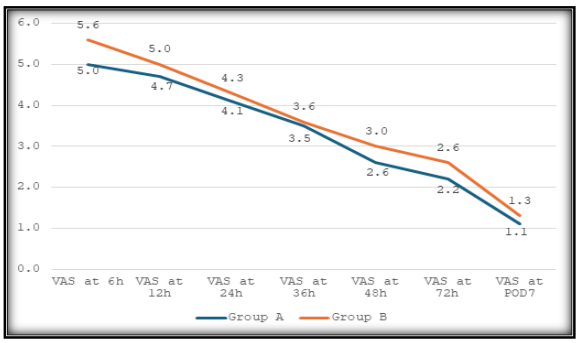

Figure 2: Comparison of postoperative pain (VAS) between groups at predefined time points (N = 60).

DISCUSSION

The present randomized controlled trial compared harmonic scalpel dissection (Group A) with conventional electrocautery (Group B) in patients undergoing MRM, focusing on postoperative seroma and flap necrosis as primary outcomes and operative time, blood loss, drainage profile, pain, and hospital stay as secondary outcomes. The results demonstrated that while baseline demographic, clinical, tumour-related, and laboratory parameters were comparable, harmonic scalpel use was associated with significantly improved intraoperative and postoperative outcomes, particularly with respect to blood loss, drain output, seroma incidence, flap necrosis, pain, and length of hospitalization.

In this study, the two arms were well balanced for age (49.5 ± 8.5 vs 49.2 ± 10.1 years), BMI (25.4 ± 2.4 vs 25.8 ± 2.6 kg/m²), residence, and menopausal status, suggesting effective randomization and minimizing selection bias. Balanced comorbidity distribution for diabetes and hypertension is important because these conditions are known to influence wound healing, infection risk, microvascular perfusion, and flap viability after mastectomy; as noted by Rifkin et al. (2019).[18] In corroboration, Memon et al. (2020) recognizes diabetes as a risk factor for impaired wound healing and postoperative infections due to microvascular disease and altered inflammatory responses.[19] Likewise, comparable tumour staging and neoadjuvant chemotherapy exposure between groups reduced confounding from disease extent or chemotherapy-related tissue changes, which may predispose to delayed healing and increased fluid collections, as noted by Słonimska et al. (2024) and Wuhrer et al. (2021).[20,21] Thus, observed differences in outcomes can reasonably be attributed to the dissection modality (harmonic vs electrocautery), rather than baseline patient or tumour factors. A key finding was significantly shorter operative time in the harmonic scalpel group, coupled with lower estimated blood loss. Reduced intraoperative blood loss is clinically relevant in breast surgery because hematoma and oozing can contribute to dead space, promote inflammatory exudation, increase postoperative drain output, and potentially elevate infection risk. Meta-analytic evidence from Huang et al. (2015) indicates that harmonic scalpel dissection significantly decreases blood loss in MRM compared

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to electrocautery, supporting this biological plausibility.[8] Mechanistically, harmonic scalpel technology achieves simultaneous cutting and coagulation through high-frequency ultrasonic vibration and protein denaturation, allowing effective sealing of small vessels and lymphatics with lower lateral thermal injury compared with conventional electrocautery; as noted by Dutta & Dutta (2016) and Pellegrino et al. (2008).[6,22] This reduced collateral tissue damage may limit microvascular disruption and inflammatory seepage, thereby decreasing blood loss. Electrocautery, by contrast, relies on resistive heating with higher tissue temperatures and potentially greater thermal spread, which may increase tissue necrosis, char formation, and oozing from disrupted lymphovascular channels.[19]

Surgeon-rated ease-of-use was higher with harmonic scalpel. This may reflect improved operative field visibility due to reduced smoke and charring, more controlled dissection planes, and less need for repeated coagulation for haemostasis. Such ergonomic and procedural efficiency can contribute to reduced operative time, an outcome that remains inconsistent across studies. For example, Huang et al.'s meta-analysis found no significant overall difference in operative time between harmonic and electrocautery, suggesting that time savings may depend on surgeon familiarity and institutional workflows.[8] However, Faisal et al. (2018) and Khan et al. (2014) have reported either longer or similar durations, illustrating heterogeneity in operative technique and experience.[23,24]

Postoperative drainage outcomes strongly favoured harmonic scalpel. Drain removal by POD7 was achieved in 40% of Group A compared to 10% in Group B, while >POD10 drainage was far less common in Group A (10% vs 43.3%). These findings align closely with prior controlled studies and meta-analysis evidence. In the meta-analysis by Huang et al. (11 studies, 702 patients), harmonic scalpel dissection significantly reduced total postoperative drainage (SMD -0.74), seroma development (OR 0.49), and wound complications (OR 0.38).[8] Khan et al. similarly reported lower drain volume and shorter drain duration with harmonic dissection in a randomized trial.[24] The pathophysiology of drain output after MRM is multifactorial, involving lymphatic leakage, inflammatory exudation from raw tissue surfaces, and dead space fluid accumulation, particularly after axillary dissection. The harmonic scalpel's improved lymphostasis likely reduces lymphatic leakage, which is a major component of post-axillary drainage. Faisal et al. (2018) noted that efficient sealing of lymphatic channels is considered a critical mechanism by which harmonic technology reduces drain output and seroma.[23]

A major strength of the study is that it demonstrated significant reductions in both primary outcomes. Seroma incidence was markedly lower in Group A than Group B (16.7% vs 53.3%; p=0.007). Seroma confirmation criteria were similar between arms (prolonged drainage vs aspiration-confirmed clinical collection), suggesting that the difference was not due to surveillance bias but reflected true outcome improvement. Although the mean number of aspirations among seroma cases did not differ significantly, repeated aspirations (≥4) occurred only in Group B, implying potentially more persistent seroma in electrocautery patients. These findings match the most consistent advantage of harmonic dissection reported in Huang et al. (2015).[8] Faisal et al. also reported significantly lower total drainage volume and reduced seroma after drain removal in harmonic dissection.[23] Flap necrosis was also significantly reduced in Group A. Importantly, all necrosis cases in Group A were partial-thickness and conservatively managed, whereas Group B had full-thickness necrosis (20% of necrosis cases) requiring surgical interventions including debridement with secondary suturing or split-thickness skin grafting. This reflects not only lower incidence but potentially reduced severity of flap compromise with harmonic dissection. The mechanism likely relates to reduced lateral thermal damage, as noted by Družijanić et al. (2012).[25] Excess thermal injury can cause microvascular thrombosis and devitalization of skin flaps, particularly in mastectomy where flap perfusion is marginal.[26] Morikawa et al. (2024) added that lower tissue temperatures and decreased thermal spread with harmonic energy may preserve subdermal plexus perfusion compared to electrocautery.[27] Clinical literature supports this direction; Cheng et al. reported reductions in necrosis (49%) and seroma (46%) and decreased postoperative drainage using harmonic technology across breast surgeries.[28]

Postoperative pain was significantly lower in the harmonic group at early time points (6h, 12h, 48h, 72h), with convergence by POD7. In corroboration, Group A required fewer diclofenac doses and fewer total analgesic doses in 72 hours. Pinho-Ribeiro et al. (2017) noted that reduced pain may relate to lower tissue inflammation and reduced thermal injury, which can decrease nociceptor activation and postoperative wound tenderness.[29] Khan et al. also reported lower postoperative pain with harmonic dissection and demonstrated lower risk of significant pain in multivariable analysis.[24] Although rescue opioid requirement was numerically lower in Group A (20% vs 40%), it was not statistically significant, likely reflecting sample size limitations for this endpoint. However, the overall reduction in NSAID dosing and total analgesic exposure suggests a meaningful analgesic-sparing effect.

Length of stay was significantly shorter in Group A (4.8 ± 0.9 vs 6.7 ± 1.1 days; p<0.001), with 80% discharged within ≤5 days compared with 13.3% in Group B. This reduction is clinically important in resource-limited settings where bed availability and cost containment matter. The shorter hospitalization is plausibly mediated by earlier drain removal, lower seroma incidence, reduced flap necrosis, and lower pain scores – all of which facilitate earlier discharge readiness. Cheng et al. similarly reported reduced

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length of stay (22%) with harmonic technology.[28] In contrast, some studies did not demonstrate reduced hospital stay because institutional protocols mandated discharge after drain removal or fixed postoperative discharge timelines. For example, Kozomara et al. reported no difference in length of stay due to standardized discharge practices despite drainage advantages.[30] Therefore, the present study's finding of reduced hospital stay suggests that discharge was clinically responsive and potentially linked to earlier recovery. Other complications (SSI, hematoma, wound dehiscence, drain-site infection, readmission) were numerically lower in the harmonic arm but not statistically significant. This pattern is consistent with meta-analysis evidence from Huang et al. (2015) showing reduced overall wound complications with harmonic dissection.[8] The lack of significance here may be due to relatively low event counts and the study's modest sample size. Nonetheless, the direction of effect supports the broader interpretation that improved tissue handling and reduced seroma/flap compromise may indirectly lower secondary morbidity.

Collectively, the findings suggest that harmonic scalpel dissection offers a clinically meaningful advantage over electrocautery in MRM, particularly through reductions in blood loss, postoperative drainage burden, seroma formation, flap necrosis, early postoperative pain, analgesic use, and hospital stay. However, the present study has certain limitations. First, it was conducted at a single centre with a relatively small sample size (N=60), which may limit generalizability and reduce power to detect differences in less frequent outcomes such as surgical site infection, hematoma, wound dehiscence, and readmissions. Second, although the trial was single-blinded, blinding of the operating surgeon was not feasible; this may have introduced performance bias (e.g., differences in intraoperative technique) and could have influenced subjective assessments such as the ease-of-use score. Third, some outcomes relied on clinical assessment and predefined criteria (e.g., seroma diagnosis and extent of flap necrosis) and were not uniformly confirmed with imaging such as ultrasound, which may have led to misclassification or under-detection of small fluid collections. Fourth, follow-up was limited to early postoperative and short-term surveillance, so longer-term outcomes such as chronic pain, shoulder dysfunction, lymphedema, late wound sequelae, cosmesis, and quality of life were not assessed. Finally, the study did not include an economic evaluation; given the higher device cost of harmonic technology, cost-effectiveness and budget impact in routine practice could not be determined.

CONCLUSION

In this randomized controlled trial of 60 patients undergoing elective modified radical mastectomy, harmonic scalpel dissection demonstrated superior perioperative outcomes compared with conventional electrocautery. Despite comparable baseline demographic, clinical, tumour-related, and laboratory profiles, the harmonic scalpel significantly reduced operative time and intraoperative blood loss, improved postoperative drainage parameters (lower daily and total drain output, shorter duration of drainage, and earlier drain removal), and markedly decreased the incidence of the two primary complications – postoperative seroma and flap necrosis. In addition, patients in the harmonic arm experienced lower early postoperative pain with reduced analgesic requirements and a significantly shorter postoperative hospital stay. Other complications such as surgical site infection, hematoma, wound dehiscence, drain-site infection, and readmission were numerically lower with harmonic dissection but did not differ statistically between groups. Overall, the findings suggest that the harmonic scalpel is a safe and effective alternative to electrocautery in MRM, offering meaningful reductions in key postoperative morbidities and facilitating earlier recovery and discharge.

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