Original Research Article

OUTCOME OF MODIFIED RADICAL MASTECTOMY USING HARMONIC SCALPEL VERSUS ELECTROCAUTERY

Abstract

BACKGROUND: The harmonic scalpel, which is widely used in laparoscopic surgery, nowadays presents an encouraging prospect for dissection in MRM. The high frequency mechanical vibrations of harmonic scalpel make intraoperative cutting and coagulation take place at the same time, with a relatively low temperature causing fewer thermal injuries than electrocautery.

OBJECTIVE: To compare the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery.

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. Patients with chronic Hepatitis and diabetes, patients who has had neo-adjuvant therapy were excluded. Patients of group A were undergone Modified radical mastectomy using harmonic scalpel and patients of Group B were undergone Modified radical mastectomy using electrocautery. Outcome was assessed as postoperative pain according to visual analog scale (VAS) and postoperative complications in the form of seroma

formation, postoperative hematoma, marginal necrosis, lymphedema and wound infection was recorded.

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. In my 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.

CONCLUSION: This study concluded that outcome is better after harmonic scalpel in modified radical mastectomy as compared to electrocautery in modified radical mastectomy.

KEYWORDS: modified radical mastectomy, harmonic scalpel, seroma.

Comment [D1]: Our study

INTRODUCTION: Breast cancer is the most common cancer among women worldwide with an incidence of 120.9 per 100,000 new cancer cases with a mortality of 21.9 per 100,000 women. The age standardized incidence rate of breast cancer varies from 9 to 32 per 100,000 women [1] . Around 130,000 fresh cases of breast cancer are reported annually. Out of every 2 women diagnosed with breast cancer one dies because of it. Breast carcinoma has remained the second leading cause of cancer death among women worldwide for the last 3 decades. Breast cancer is a disease of the developed world.[2,3]A mastectomy is the surgical removal of a breast. There are several types of mastectomies, simple radical and modified radical mastectomy. The decision of what type of mastectomy should be done should be made with the assistance of the surgeon performing the mastectomy, the oncologist and the plastic surgeon performing the reconstruction. Some techniques may not be able to be considered, depending on the location and severity of the cancer. A modified radical mastectomy is a procedure in which the entire breast is removed, including the skin, areola, nipple, and most axillary lymph nodes; the pectoralis major muscle is spared. Historically, a modified radical mastectomy was the primary method of treatment of breast cancer.[4] As the treatment of breast cancer evolved, breast conservation has become more widely used. However, mastectomy still remains a viable option for women with breast cancer.[5] In general; complications following breast surgeries include wound infection, wound dehiscence, seroma, hematoma, chronic pain, venous thromboembolism VTE, surgical dog ear, late sequel breast fibrosis, sensory loss, shoulder dysfunction, lymphedema and chronic/recurrent breast cellulitis. Of these, seroma poses a major threat.[6,7] Conventional MRM using electrocautery or scalpel is associated with a moderate degree of operative morbidity in 35-50% of patients. Much of this morbidity has been attributed to the large post mastectomy raw area, cut lymphatics and use of electrocautery. Ultrasonic dissection using the harmonic scalpel

has recently emerged as a safe alternative to electrocautery.[8]The harmonic scalpel, which is widely used in laparoscopic surgery, nowadays presents an encouraging prospect for dissection in MRM. The high frequency mechanical vibrations of harmonic scalpel make intraoperative cutting and coagulation take place at the same time, with a relatively low temperature causing fewer thermal injuries than electrocautery.[9] Previous data is variant regarding per-operative blood loss in patients treated with Harmonic Scalpel v/s electrocautery in Modified Radical Mastectomy.[10] In a study11, 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% repectively.[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 harmonic scalpel is a new device that has been introduced into surgical practice during the last decade as an alternative surgical tool for the dissection and hemostasis. It has been extensively used in the field of minimally invasive surgery but experience of harmonic scalpel in open surgery is limited.[11] Many other studies reported that no such efficacy finalized of Modified radical mastectomy with harmonic scalpel and more research is needed.[13] As post-operative morbidity following modified radical mastectomy is of main concern which affects the patients physically and socially, so the purpose of this study was to compare the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery. Although, previously studies are available on this but all

these are international studies and locally, we have found very limited literature on this, so there must be need of more research on the better technique among these in total modified radical mastectomy. Then on the basis of these results, some practical recommendations can be made in our routine practice guidelines for these particular patients to be provided with more effective technique which is associated with less post-operative morbidity.

Comment [D2]: To be tailored

PATIENTS AND METHODS: The six months randomized controlled trial was Department of Surgery, Liaquat University of Medical and Health Science, Jamshoro. The inclusion criteria of the study were all patients with age between 20 – 50 years, female gender both pre and post-menopausal women assessed by menstrual history, both nulliparous and multiparous women assessed by history, patients with infiltrating ductal carcinoma (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. Infiltrating ductal carcinoma was categorized in 4 stages, only stage I and II was labeled as positive for this study and presence of all of the following on FNAC was considered as positive; cellular atypia (pleomorphism), mitotic activity, increase (>1:1) in nuclear cytoplasmic ratio (on microscopy). Outcome was assessed in term of following:

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^{o}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]

Patients those fulfilling the inclusion criteria was selected for the study. Written consent was taken from all the participants. All patients were assessed in two groups. Patients of group A were undergone Modified radical mastectomy using harmonic scalpel and patients of Group B were undergone Modified radical mastectomy using electrocautery. Both techniques were performed by senior surgeons experience more than 5 years. The patient was discharged after surgery on stable condition and all cases were recalled for follow-up on 8th post-operative day and stiches were removed. Outcome was assessed as postoperative pain according to visual analog scale (VAS) and postoperative complications in the form of seroma formation, postoperative hematoma, marginal necrosis, lymphedema and wound infection was recorded in both groups and recorded 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 (pot-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.

Effect modifiers like age, duration of disease, parity (nulliparous/multiparous), menopausal status (pre-menopause/post-menopause), stage of carcinoma (I/II), diabetes mellitus (yes/no) and hypertension (yes/no) were controlled through stratification and post-stratification chi square test was used to see their effect on outcome. P-value ≤ 0.05 was considered as significant.

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 ± 6.73years 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 I 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 Table II-VIII.

Table-I: 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 ± SD	**39.81 ± 6.73**		**39.45 ± 6.60**		**39.63 ± 6.62**	

Table-II: 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**
Marginal necrosis	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 III: 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)	**≤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**
Stage of carcinoma	**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**
Diabetes mellitus	**Yes**	15	12	21	08	**0.188**
	No	19	18	23	12	**0.217**

Table IV: Stratification of seroma 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
		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)	**≤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**
Stage of carcinoma	**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 V: 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**
Stage of carcinoma	**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**
Diabetes mellitus	**Yes**	01	26	07	22	**0.029**
	No	00	37	04	31	**0.034**

Table VI: 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
		marginal necrosis		marginal necrosis		
		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**
Stage of carcinoma	**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**
Diabetes mellitus	**Yes**	00	27	02	27	**0.165**
	No	00	37	03	32	**0.069**

Table VII: 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**
Stage of carcinoma	**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 VIII: 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**
Stage of carcinoma	**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**
Diabetes mellitus	**Yes**	08	19	09	20	**0.909**
	No	03	34	14	21	**0.001**

DISCUSSION: Breast cancer is the most site-specific cancer in women.[14]For patients who present late, radical mastectomy does not offer any advantage in terms of survival or cure. It only increases morbidity and decreases quality of life (because of "mutilation"). For patients who present early, modified radical mastectomy is the treatment of choice.[15]The main goals of cancer diagnosis and treatment are (i) to cure or considerably prolong the life of patients and (ii) to ensure the best possible quality of life to the survivors. Nowadays, the most commonly used form of energy in modified radical mastectomy for raising flaps is monopolar diathermy. It is used to destroy tissue using conduction from a metal probe heated by electric current.[16,17] The ultrasonic surgical instrumentation was introduced into clinical practice nearly a decade ago in an effort to minimize the risks of traditional electrosurgical technologies, local peripheral energy damage, and potentially devastating complications associated with monopolar energy.[18]The harmonic scalpel denatures protein by ultrasonic vibration at a frequency of 55,500 Hz with a vibratory excursion of 50-100 μm.[19] We have conducted this study to compare the outcome of modified radical mastectomy using harmonic scalpel versus electrocautery. 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 yearsand 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 my 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 study11, 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% repectively.[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] In another study,[20] the mean operative time was significantly longer with harmonic scalpel when compared to that with electrocautery (140.40 ± 29.96 vs. 99.80 ± 24.00 min, P < 0.001). The smaller amount of drainage content (431.60 ± 145.94 vs. 594.20 ± 278.63, P = 0.013) and intraoperative blood loss (426.00 ± 76.54 vs. 502.00 ± 104.56, P = 0.005) in the group operated with the ultrasound harmonic scalpel was statistically significant. There was no significant difference between the groups with regard to drain duration (5.24 ± 0.97, P = 0.127), 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).[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 simplified the surgical procedure, reduced the operative time, peri-operative blood loss, drainage volume and duration of drainage. Furthermore, the incidence of seroma and lymphedema was also reduced.[21]Galal did a comparative study between the use of harmonic and electrocautery in MRM and concluded that the use of harmonic scalpel in MRM had shortened the axillary dissection time and decreased the drainage volume and duration, as well as hospital

stay.[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 differance 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. In another randomized controlled trial[28], women undergoing modified radical mastectomy were randomly allocated to either harmonic dissection (n = 76) or electrocautery (n = 76). Both the groups were comparable for baseline variables with age of 50.5 ± 12.2 and 48.5 ± 14.5 years in the harmonic and electrocautery groups, respectively. Harmonic dissection yielded better outcomes compared to electrocautery with lower estimated blood loss (100 ± 62 vs. 182 ± 92, $p < 0.001$), less drain volume (631 ± 275 ml vs. 1035 ± 413 ml, $p < 0.001$), fewer drain days (12 ± 3 vs. 17 ± 4, $p < 0.001$), less seroma formation (21.3 vs. 33.3 %, $p = 0.071$), and less postoperative pain [median (interquartile range) 2 (2-2) vs. 3 (3-4), $p <0.001$], whereas mean operative time (191 ± 44 vs. 187 ± 36 min, $p = 0.49$) and SSI (0 vs. 4 %, $p = 0.122$) did not differ. On multivariable Cox regression analysis, harmonic dissection was associated with lower risk of significant postoperative pain [adjusted relative risk 0.028 (95 % confidence interval (CI) 0.004-0.2)] and overall complications [adjusted relative risk 0.47, (95 % CI 0.26-0.86)]. On multiple linear regression, duration of drains in the harmonic dissection group was 4.5 days less than electrocautery ($r^2 = 0.28$, $\beta = 11.8$, $p < 0.001$).[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. Harmonic scalpel is superior to conventional tools in terms of decreasing intraoperative blood loss, seroma and hematoma formation, drainage volume and time, necrosis prevalence, surgical duration, and hospital stay, which should be strongly recommended in the surgery for breast cancer.[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 use of harmonic scalpel in MRM shortened the axillary dissection time and caused significant decrease in blood loss and drainage volume and thus lessened overall hospital stay.

CONCLUSION: This study concluded that outcome is better after harmonic scalpel modified radical mastectomy as compared to electrocautery in modified radical mastectomy. So, we recommend that harmonic should be used for modified radical mastectomy in carcinoma breast for reducing the mean operative pain, hematoma formation seroma formation and marginal necrosis which will in turn improve their quality of life by reducing post-operative morbidity.

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