ORIGINAL ARTICLE

COMPARISON OF AXILLARY DRAIN OUTPUT IN CONVENTIONAL AND ADVANCED COMPRESSIVE ENERGY SOURCE LIKE ULTRASONIC SCALPEL AND LIGASURE DISSECTION OF AXILLA IN BREAST CANCER SURGERY

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Background: Breast cancer is the most common malignancy worldwide. Surgical treatment of axilla is a part of treatment of locally advanced breast cancer. Conventional knot tying plus electrocautery and advanced compressive energy sources are used to reduce the continued axillary serous fluid discharge when drains are in place and seroma formation afterwards. **Methods:** This double-blind comparative study was carried out from April 2018 to October 2019. In total 180 patients undergoing axillary dissection for treatment of locally advanced breast cancer were recruited. Patients were divided into two groups (C and H) depending upon method of dissection used for axillary surgery. **Results:** For most participants, amount of axillary drain volume in Group C was between 400–700 ml (in 48.9% participants) and for Group H more than 700 ml (in 44.4% participants). This difference is not statistically significant (p=0.288). Duration of hospital stay (p=0.003) and duration of drain placement was significantly longer (p=0.019) for most participants in Group H. More hospital visits were required for the said group. There was statistically significant co-relation between immediate complications and haemostasis techniques (p=0.003) with more incidence of Seroma noticed in Group H than in Group C. **Conclusion:** Current study shows limited benefits of using ultrasonic scalpels in breast cancer surgeries. Variables such as BMI, Age and chemotherapy need to be controlled in order to derive a true comparison.

Keywords: Ultracision; Electrocautry; Axillary dissection; Seroma formation

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INTRODUCTION

Breast cancer is the most common malignancy in women worldwide.[1,2] The picture is gloomier in Pakistan where every ninth women is suffering from the disease and that too, in a comparatively younger age group. Surgical component of treatment comprises of treatment of primary pathology in breast and treatment of axillary disease. With time the treatment of primary disease has become more conservative with modified radical mastectomy reserved only for wide spread or advanced disease.[3,4] Axillary metastasis are also a matter of concern due to resulting lymphedema, lymphorroea and restriction of mobility, when addressed surgically. Therefore, sentinel lymph node biopsy, pre-operative axillary assessment and placement of clips and dye in the FNAC proven lymph nodes has been widely accepted among surgeons to avoid surgical treatment of axilla and thus avoiding resulting complications. However, in clinically positive axilla and cases where sentinel lymph node biopsy was never done, surgical treatment of axilla becomes inevitable. Adjuvant treatment is usually started within thirty days of surgery and needs complete recovery from the surgery.[5–8] Conventionally axillary dissection is performed with electrocautery and knot tying with absorbable sutures. The lymphatics in the axilla are disrupted in axillary dissection and similarly the raw area produces fluid including blood and interstitial fluid. These all contribute to the fluid in the axilla after surgery, thus prolonging the time of complete recovery and delaying the adjuvant treatments.[5–8] Axillary drains and compression dressings are done in an attempt to reduce this fluid.[9–12] The drain is a source of significant morbidity and discomfort. Presence of an axillary drain requires management by attendants at home, when kept for a longer time. It is uncomfortable for the patient, and causes painful restricted movements. The risk of fluid accumulation persists even after drain removal and seroma might occur. Seroma can further result in flap necrosis, wound dehiscence, and usually requires repeated needle aspirations. Sometimes a huge seroma cavity may need to be excised. All these may eventually fix the issue but at the expense of delay in the treatment in adjuvant settings.

Electrocautery is effectively used for dissection and haemostasis in breast surgery.[13–15] This reduces the overall blood loss, operative time consumed in knot tying of small vessels as well as the need of use of multiple instruments. However, the risk of seroma is increased due to local inflammatory reaction caused by thermal tissue damage in the skin flaps. The blood supply of skin flaps also becomes questionable due to dissipation of heat when raising flaps of the skin. There may be vascular plexus disruption, and incomplete lymphatic and vascular occlusion; these complications often contribute to a higher seroma rate.[16,17]

In comparison the use of advanced compressive energy source like ultrasonic scalpel, LigaSure and harmonic dissection outweigh the use of conventional methods.[16,17] The advantages, being less scar formation compared with blades, the narrow circumference of collateral thermal damage to encircling tissue, the lack of smoke (although there is a transient mist), the lack of injury or excitement to motor nerves in the axilla, and the ability to utilize the technique in patients with pacemakers .As the overall evidence is not sufficient because of wide variation in the results of different researches.[17–22] We present our experience with both, the conventional and advanced compressive energy source like ultrasonic scalpel, LigaSure and harmonic in surgical treatment of axilla in breast cancer.

MATERIAL AND METHODS

This double-blind comparative study was carried out in department of General Surgery, Pakistan Institute of Medical Sciences (PIMS) Islamabad, after obtaining approval from the Ethical review board of PIMS and Shaheed Zulfiqar Ali Bhutto Medical University Islamabad. Study took place over a period of18 months from April 2018 to October 2019. Sample size according to prevalence of Breast cancer in the region was calculated and written informed consent was taken from the participants undergoing Breast surgery with axillary dissection. Participants were randomly divided in two groups using double blind convenient probability sampling technique. Group H had axillary dissection with advanced compressive energy source like ultrasonic scalpel and LigaSure Group C had axillary dissection with conventional methods of combination of electrocautery and knot tying.

Each group consisted of 90 patients. Characteristics of patients including age, gender, BMI, tumour size, status of axilla, recipient of neo-adjuvant chemotherapy, was recorded. Patients with a previous ipsilateral axillary surgery for any reason, those on anticoagulants such as aspirin, warfarin, and those with bleeding diathesis were excluded from the study. Breast conserving surgery was performed in 80 cases and all the rest underwent modified radical mastectomy. In all patients, axillary dissection included the I, II levels. All procedures were performed by surgeons who had five years or more experience in breast surgery. At the end of each intervention a drain was inserted in the axilla. The two groups were compared in terms of: duration of surgery, immediate complications such as hematoma, drainage volume, duration of hospitalization, and duration of continued suction drainage, number of visits to the outpatient department, seroma formation after drain removal, number of aspirations, wound infections, and ultimately the day of fitness for further treatment

The Harmonic Scalpel (Ethicon, Somerville, NJ) is a system that allows cutting and haemostasis with maximum safety, precision and control without the application of electrical energy to the patient because it uses ultrasound technology to cut tissues while simultaneously sealing the edges of the cut. The scalpel surface itself cuts through tissue by vibrating in the range of 20,000 Hz to 60,000 Hz. The vibration cuts through the tissues and seals it using protein denaturation, rather than heat. The lateral thermal damage is also reduced.

An electrosurgical generator able to detect the characteristics of the tissues closed in the jaws of the instrument. It delivers the exact amount of energy needed to seal it permanently and the delivering time. The heat generated from bipolar energy determines the fusion of collagen and elastin in the walls of vessels with creation of permanent seal zone. An acoustic signal informs the surgeon when the vessel obliteration is complete and its division is possible. The seal one has a transparent appearance that is easy to recognize. Furthermore, this sealing system has minimal heat dissipation. It provides tissue sealing of up to 7mm vessels.

Cause haemostasis by slow heating of tissues in close contact, then fluid loss and bubbling, then steam release with cooling, then restarts the cycle of slow heating. Haemostasis is achieved by tissue desiccation. There is extensive lateral damage. Monopolar electrocautery has a small active electrode and a large indifferent plate. Widely used, easily available but not safe in patients with cardiac implants such as pacemakers and defibrillator.

Any hematoma formation during first three hours was recorded. 24 hrs volume and content of drain was noted. Patient was discharged next day after 24 hrs with drain in place. First postoperative visit was made between third and fifth day of surgery. Drain was removed when the drainage volume was found to be less than 30 ml in last 24 hours. Stitches were removed on tenth postoperative day. Any wound dehiscence and flap necrosis as well as infection were noted. Patient was on regular follow

up every fourth day for drain assessment and number of visits to outpatient department was also recorded.

Our primary end point was to compare the axillary drain output in both the groups and our secondary end point was to compare the time to get ready for adjuvant treatment. Demographic data collected included age, gender, body max index (BMI), tumour size, and status of axilla, neo-adjuvant chemotherapy and duration of surgery. Statistical analysis was conducted using SPSS 20.0. Results were expressed as average±standard deviation for continuous data and as number of patients and percentage for categorical data. Between-group comparisons were performed using chi-square for categorical data and Student's t-test for continuous data. Statistical significance was considered for *p*-value <0.05.

RESULTS

Overall, 180 patients were included in the study. There were 176 females and 4 males in the study. The average BMI of the recruited patients, was 23.5 (SD±3). The significant difference (p=0.05) was observed between two groups of patients with respect to age, tumour size, status of axilla and neoadjuvant chemotherapy treatment (Table-1). Mean age of participants in group 'C' was 53.3 years (SD±9.3) while that in group 'H' was47.4 years (SD±10.7). About 52.2% participants had size of tumour more than 5 cm followed by 2–5 cm in 36.7% of participants and 11.1% had tumour size less than 2 cm. Axillary status of the patients studied showed that 63.3% (n=114) were clinically and radiologically positive, 28.9% (n=52) were clinically negative but radiologically positive and only 14 cases (7.8%) were both clinically and radiologically negative. Most of the patients had received neo-adjuvant chemotherapy (63.3%; n=114), 20% had not taken any neoadjuvant chemotherapy and 16.7% had received less than 6 cycles of chemotherapy.

Duration of surgery for most of the cases (53.3%, n=96) was between 2–2:30 hours followed by 41.1% cases (n=74) having duration more than 2:30 hours and 5.6% (n=10) having surgery duration less than 2 hours. Mean duration of surgery for Group C was 2.21±0.265 hours and for Group H it was 2.25±0.276 hours.

For most participants amount of axillary drain volume in Group C was between 400–700 ml (in 48.9% participants) and for Group H more than 700 ml (in 44.4% participants) as shown in table-2 and figure-1.

Number of days drain was kept was 5–10 days in most of the patients in both groups (48.9% in Group C and 51.1% in Group H). In both groups participants were discharged 24 hours post-operatively but number was higher in Group H (64.4%) than in Group C (42.2%).

Seroma was the most common immediate complication observed in both groups, more in Group H (n=28; 31.1%) than in Group C (n=12; 13.3%) as presented in Graph 2. Bleeding was more commonly present in Group C (n=8; 8.9%) than in Group H (n=2; 2.2%). In Group C flap necrosis and wound dehiscence was observed in 4 (4.4%) participants each whereas no incidence of flap necrosis or wound dehiscence was reported in Group H (Figure-2).

On average 3–5 number of hospital visits were required by most participants in both groups with 44.4% in Group C and 55.6% in Group H. Aspiration of seroma was required in 11.1% of participants in Group C and 31.1% of participants in Group H.

80% of the participants from Group C completed their surgical treatment before 15th post-operative day whereas from Group H 86.7% participants finished their surgical treatment before 15th post-operative day.

Co-relations using Chi square test were calculated between method of haemostasis with axillary drain output, duration of surgery, duration of hospital stay, duration of drain placement, number of visits to hospital and immediate complications as shown in table-3.

There was no statistically significant co-relation found between conventional methods (Group C) and ultrasonic scalpels (Group H) for amount of drain volume (p=0.288) and duration of surgery (p=0.298). Duration of hospital stay was longer than 24 hours for most participants in Group H than in Group C, the difference being statistically significant (p=0.003). Duration of drain placement was more than 5 days for 78 participants in Group H and 64 participants in Group C showing significant co-relation (p=0.019). In Group H more than 3 number of hospital visits were required for 72 participants as compared to only 56 participants in Group C who visited hospital for more than 3 times after discharge (p=0.03) showing significant co-relation. There was statistically significant co-relation between immediate complications and haemostasis techniques (p=0.003) with more incidence of Seroma noticed in Group H than in Group C.

Effect of Age and BMI on immediate complications (e.g seroma) also came out to be statistically significant (p=0.00) with a rise in complications with increasing age and BMI.

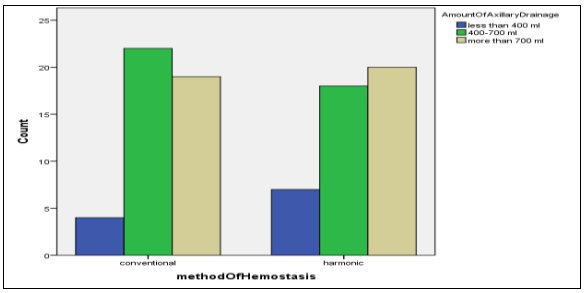

Figure-1: Amount of axillary drainage

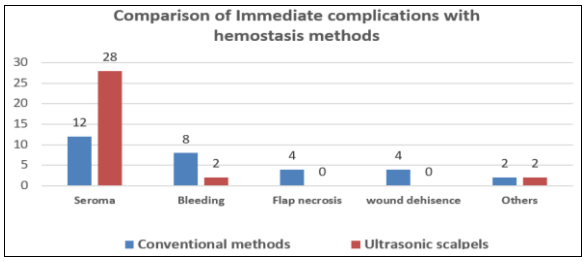

Figure-2: Comparison of immediate complications with haemostasis methods

Table-1: Demographic parameters in the two groups

		Method ff haemostasis		Asymp.sign. (2-sided)
		conventional	harmonic	
age Group	less than 30 years	2	14	
	31–50 years	32	44	
	above 50 years	56	32	.000*
gender	female	86	90	
	male	4	0	.043
BMI group	less than20	20	22	
	21–25	48	32	.036*
	above 25	22	36	
Tumour Size	less than 2 cm	6	14	
	2–5 cm	44	22	.002*
	more than 5cm	40	54	
Status Of Axilla	clinically and radiologically positive	48	66	
	clinically negative but radiologically positive	38	14	.000*
	both clinically and radiologically negative	4	10	
Neoadjuvant Chemotherapy	Received neoadjuvant chemotherapy	64	50	
	no neoadjuvant chemotherapy	8	28	.001*
	less than six cycles of chemotherapy	18	12	

*Statistically significant

Table-2: Comparison of axillary drain output in conventional and compressive methods

	Group C (Conventional method)	Group H (Compressive techniques)
Less than 400 ml	8.9% (n=8)	15.6% (n=14)
400-700 ml	48.9% (n=44)	40% (n=36)
More than 700ml	42.2% (n=38)	44.4% (n=40)

Table-3: Results in the two groups

		Method of Haemostasis		Asymp. sign. (2-Sided)
		conventional	harmonic	
Duration of surgery	less than two hours	6	4	
	2–2:30 hrs	52	44	.298
	more than 2:30 hours	32	42	
Amount of axillary drainage	less than 400 ml	8	14	
	400–700 ml	44	36	.288
	more than 700 ml	38	40	
Duration of drain placement in axilla	less than 5 days	26	12	
	5–10 days	44	46	.019
	more than 10 days	20	32	
Duration of stay in the hospital	discharged after 24 hours	58	38	
	discharged after 48 hours	22	26	
	more than 48 hours	10	26	.003
Immediate Complication	bleeding	8	2	
	flap necrosis	4	0	
	wound dehiscence	4	0	.003
	others	2	2	
	none	60	58	
	seroma	12	28	
No of visits to hospital	less than three visits	34	18	
	3–5 visits	40	50	.030
	more than five visits	16	22	
Intervention required to deal complication	aspirations	10	28	.
	surgical correction under local anaesthesia	8	0	
	surgical correction under general anaesthesia	2	0	.000
	not required	70	62	
Day of end of surgical treatment	before 15th postoperative day	72	78	.444
	15–20 postoperative days	16	10	
	more than 20 days	2	2	

DISCUSSION

Use of Ultrasonic scalpel devices (UD) has the advantage of decreased spread of thermal energy and less tissue destruction in the surrounding tissues as compared to use of conventional methods like electrocautery (EC) or surgical blade.

In our study we have observed that there was no statistically significant difference in drain output and duration of surgery in both groups. There was higher incidence of Seroma formation observed in participants where Ultrasonic scalpel devices were used. However, bleeding was significantly less in UD group as compared to EC group and no incidence of wound dehiscence and flap necrosis was reported with use of harmonic scalpels. Duration of hospital stay, number of hospital visits after discharge and duration of drain placement was more in UD group than EC group (statistically significant). Various authors have studied the effect of Ultrasonic devices on drain output, operation times and complications during Breast surgeries and compared it to conventional methods of dissection.

In a study conducted in Services hospital Lahore, authors found a decrease in total mean axillary drain output and decreased numbness in cases where UD were used as compared to EC.[23]

Deo *et al*[24] in a similar study reported decreased blood loss and drain volume using harmonic scalpels. The duration of drainage was also reduced however there was no statistically significant difference in duration of surgery. A prospective randomised control trial performed in Malaysia[25] also suggested that the use of UD decreased drain volume as well reduced number of days the drain was kept. No such trend was found in the current study.

A study conducted in Ohio concluded that there were no significant differences in duration of surgery, drain volume and postoperative pain between UD and EC groups in breast reduction surgeries. They also reported higher rate of complications (statistically insignificant) with the use of Ultrasonic scalpels.[26] These findings are consistent with those in the current research. Researchers in Chennai conducted a similar study during 2014–2016 and reported that in MRM the overall axillary drainage and early drain removal is not superior in UD than observed in EC group.[27] Yilmaz *et al* from Turkey reported higher seroma formation with use of electrocautery[28] and more bleeding and operation time using scalpel. However, no difference was observed in total drain volume, duration to keep drain, hematoma and surgical site infection.

CONCLUSION

Current study shows limited benefits of using ultrasonic scalpels in breast reducing surgeries. Variables such as BMI, Age and chemotherapy need to be controlled in order to derive a true comparison. The cost-benefit ratio of ultrasonic scalpels should be considered before its use is further propagated in breast surgeries. Further research is needed in this domain with increased sample size, homogeneity among compounding variables and longer follow up to study long term complications.

AUTHORS' CONTRIBUTION

SZ: Principle author, data collection, drafting the research paper, corresponding author. MAK: Refining the basic idea and objectives of the research. UR: Data collection. NM: IT and data assessment on SPSS

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