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ORIGINAL ARTICLE

Ultrasonic Shears Versus Electrocautery in Axillary Dissection for Breast Cancer—A Randomized Controlled Trial

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Abstract Theoretical advantages of use of Ultrasonic shears include less tissue damage and better sealing of lymphatic vessels. This may play a role in reducing prolonged drainage following axillary dissection for breast cancer. We conducted a prospective randomized controlled study to evaluate efficacy of ultrasonic shears over cautery for axillary dissection. Between April 2011 and April 2013, 92 patients were randomized to undergo axillary dissection with either ultrasonic shears (n=46) or electrocautery (n=46). Primary endpoints were time till drain removal and cumulative axillary drainage. Categorical data were compared by Pearson's chi-squared test. Continuous variables were compared by Independent t test or Mann Whitney U test. Data was analyzed using SPSS version 18.0. Both groups were comparable with respect to clinical and pathologic characteristics. Clinical characteristics of mean age, body mass index, side of tumor, neoadjuvant chemotherapy, and type of surgery (breast conservation or mastectomy) were similar. Pathologic variables (weight of specimen, number of lymph nodes harvested, pathologic T and N status, as well as grade of tumor) were also comparable among the two groups. There was no statistically significant difference in either primary endpoint of time till drain removal (15 vs. 14.5 days, p=0.73) or cumulative axillary drainage (1,260 vs. 1,086.5 ml, p=0.79). Patient and disease characteristics among the two groups were similar. But, there was no difference in either primary endpoint of cumulative axillary drainage or time to drain removal. We conclude that there is no advantage to use of ultrasonic shears over cautery in reducing drainage following axillary dissection for breast cancer.

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Introduction

Axillary dissection is a standard component of surgical therapy for breast cancer. Morbidity of axillary dissection includes prolonged lymphatic drainage necessitating drain placement [1, 2]. The presence of an axillary drain requires proper management, is uncomfortable for the patient, and causes pain and limited arm movements. Other complications of axillary dissection include seroma formation with a reported rate ranging from 3 to 60 %, arm numbness and upper limb lymphedema [3–5].

Axillary dissection can be performed with a variety of techniques, including use of cold knife, scissors, monopolar cautery or bipolar cautery. Ultrasonic shears (harmonic scalpel) are a relatively new addition to the surgical armamentarium. These use ultrasonic energy to cut and coagulate soft tissue simultaneously, sealing vessels up to 5 mm, as well as lymphatics. They also have minimal collateral thermal damage [6, 7]. This may play a role in reducing prolonged drainage following axillary dissection for breast cancer. We conducted a prospective randomized controlled study to evaluate whether ultrasonic shears are superior to electrocautery for reducing axillary drainage following surgery for breast cancer.

Methods

Between April 2011 and April 2013, 92 patients were randomized to undergo axillary dissection with either ultrasonic shears (n=46) or electrocautery (n=46). This number was calculated to give us 80 % power to find a mean difference of 85 ml with 5 % level of significance. Inclusion criteria

included all operable breast cancer, either primary surgery or following neo-adjuvant chemotherapy. Patients undergoing modified radical mastectomy as well as breast conservation were included. The only exclusion criterion was patients who were planned for immediate reconstruction following surgery.

Institutional ethical clearance was obtained. Informed consent was taken from all patients. The patients were counseled and pre-operatively taught to manage the surgical drain and to measure and record daily drain output. The technique of surgery using both electrocautery and ultrasonic shears was standardized. The surgical drain was removed once daily drain output was less than 30 ml for two consecutive days.

Primary endpoints were time till drain removal and cumulative axillary drainage. The time of drain removal was defined as the length of time (in days) the drain remained in place.

Statistical Techniques

Descriptive statistics were reported using mean and SD for continuous normally distributed variables else median and 25th, 75th percentiles. Categorical variables were reported using number and percentages. Continuous variables were compared by Independent *t* test or Mann Whitney *U* test, where appropriate. Categorical data were compared by Pearson's chi-squared test. A p value of <0.05 was taken to be significant. Analyses were conducted using the SPSS version 18.0.

Results

The clinical and pathologic characteristics of both groups were compared. Clinical variables that were studied included age, body mass index, side of tumor, neoadjuvant chemotherapy (whether received or not), and type of surgery (breast conservation or mastectomy) (Table 1). Pathologic variables evaluated included weight of specimen (measured in the operating room immediately after resection), number of lymph nodes harvested, pathologic TNM tumor (T) and nodal (N) status, as well as grade of tumor (Table 2)

Table 1 Clinical characteristics

		Cautery	Ultrasonic shear	P value
Age (yrs)		52.6±8.9	55.1±11.9	0.29
BMI		26.2±4.2	25.8±5.1	0.65
Side of tumor	Right	26 (54.2)	22 (45.8)	0.40
	Left	20 (45.5)	24 (54.5)	
Pre operative chemotherapy	Yes	6 (46.2)	7 (53.8)	0.76
	No	40 (50.6)	39 (49.4)	
Type of surgery	BCS	5 (41.7)	7 (58.3)	0.53
	MRM	41 (51.2)	39 (48.8)	

BMI body mass index, *BCS* breast conservation surgery, *MRM* modified radical mastectomy

Table 2 Pathologic characteristics

		Cautery	Ultrasonic shear	P value
Specimen weight (gms)		676.7±468.2 585 (342.5, 975.0)	726.0±429.7 720 (438.8, 938.8)	0.64
Nodes harvested (*n*)		16.7±5.6 16 (12.8, 22)	17.4±7.1 14.5 (12, 22.5)	0.86
Tumor size pT	pT1	9 (45.0)	11 (55.0)	0.87
	pT2	23 (51.1)	22 (48.9)	
	pT3	5 (55.6)	4 (44.4)	
	pTd	5 (62.5)	3 (37.5)	
	pTx	4 (40.0)	6 (60.0)	
Nodal status pN	N0	25 (59.5)	17 (40.5)	0.29
	N1	7 (46.7)	8 (53.3)	
	N2	10 (45.5)	12 (54.5)	
	N3	4 (30.8)	9 (69.2)	
Grade	G1	8 (53.3)	7 (46.7)	0.94
	G2	27 (50.0)	27 (50.0)	
	G3	11 (47.8)	12 (52.2)	

Mean age, tumor side, pre op chemotherapy status or type of surgery (BCS vs MRM) were similar among both groups. Average BMI was 26.2+/−4.2 in cautery group and 25.8+/−5.1 in ultrasonic shear group (p=0.65, not significant). Mean specimen weight was 585 g in cautery group and 720 g in ultrasonic shear group (p=0.64, not significant). Tumor size showed equal distribution except T4 and Tx lesions which showed a shift towards cautery group and ultrasonic shear group respectively, but this was not significant (p=0.87, not significant), Average16 nodes were harvested in cautery group and 14.5 nodes in ultrasonic shear group (p=0.86, not significant). There was more N3 disease in ultrasonic shear group but p=0.29 was not significant. Tumor grade was also evenly distributed among the two groups.

Thus, there was no statistical difference among the two groups with respect to either the clinical or pathologic variables studied.

When the two primary endpoints i.e. time till drain removal and cumulative axillary drainage were analyzed (Table 3), it

Table 3 Primary endpoints

	Cautery	Ultrasonic shear	P value
Cumulative drainage	1,524.5±1,426.1 1,086.5	1,422.3±1,027.3 1,260	0.79
	(652.5, 1,765.0)	(693.8, 1,721.8)	
Drain removal days	17.4±11.6 15	16.8±10.8 14.5	0.73
	(10, 19.3)	(10, 20.3)	

was found that the drain was removed at a mean of 15 days in cautery group and 14.5 days in ultrasonic shear group (p=0.73, not significant). Also cumulative drainage of cautery group was 1,086.5 ml and that of ultrasonic shear group was 1,260 ml (p=0.79, not significant).

Thus, although patient and disease characteristics among the two groups were similar, there was no difference in either primary endpoint of cumulative axillary drainage or time to drain removal.

Discussion

Previous authors have described various strategies in an attempt to reduce morbidity of axillary dissection, with limited success. These include closure of dead space [8, 9], use of thrombin [10], compression dressings [11, 12] aspiration alone instead of drainage [13], use of collagen tissue sealants [14, 15], and delaying postoperative shoulder exercises [16]. Use of ultrasonic shears for breast cancer surgery has been described as early as 2000 by Deo et al. [17], in which they showed the feasibility of modified radical mastectomy using ultrasonic shears. Subsequent they and several authors [18, 19] have published studies comparing use of ultrasonic shears and electrocautery for breast cancer surgery. Most of these studies are case series or retrospective reviews, and non-randomized [20, 21]. The few prospective studies have shown conflicting results regarding the efficacy of ultrasonic shears, although most claim benefit in some or all the parameters studied [22–24]. More recently, a prospective randomized study of a relatively small number of 25 patients (13 and 12 patients each in harmonic scalpel and electrocautery arm) was able to demonstrate statistically significant reduction in all the studied parameters of resection time, blood loss, duration of drain and postoperative seroma formation, when harmonic scalpel was used [25].

Based on previous studies for calculation [22], the present study was planned to have an 80 % power to find mean difference of 85 ml (Cumulative Drainage amount) between the two study groups with standard deviation of 136.1 in group1 and 153.4 in group 2, considering 5 % level of significance. Therefore, a total of 92 subjects were randomized in two arms of 46 subjects each. The primary endpoints (time till drain removal and cumulative axillary drainage) were both chosen because they were easily measurable and objective. On previously defined statistical analysis, it was found that, despite both groups being comparable in their clinical and pathologic variables, there was no significant difference in either primary endpoint of time till drain removal or cumulative axillary drainage.

Conclusion

We conclude that ultrasonic shears is **not** superior to electrocautery for reducing axillary drainage following surgery for breast cancer.

Conflict of interest The authors declare that they have no conflict of interest.

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