ORIGINAL ARTICLE

Ultracision Versus Electrocautery In Performing Modified Radical Mastectomy And Axillary Lymph Node Dissection For Breast Cancer: A Prospective Randomized Control Trial

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SUMMARY

Background: Treatment for breast cancer has improved dramatically over the decades. Nevertheless, modified radical mastectomy with axillary dissection remains the standard treatment for most patients, especially those with big tumours. The conventional technology is to use diathermy to cut and coagulate blood vessels. The Ultracision dissector has been widely used in laparoscopic surgery and is documented to be safe and fast for cutting and coagulating tissue. The aim of this study is to compare ultracision to electrocautery, looking in terms of amount of post operative drainage, duration of drain days, seroma formation and other complications.

Methodology: This study was a prospective randomized control trial of modified radical mastectomy performed for breast cancer in Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM) between 1st June 2007 to 31st December 2008. Patients were randomized in two groups: group A (n = 20) underwent modified radical mastectomy using ultracision (UC) and group B (n = 20) with the conventional electrocautery (EC) method. Main outcome measures were amount of drainage and duration of drain days. An unpaired 2-tailed Student's t test and the $\chi 2$ test to compare the groups.

Results: A total of 40 patients were involved in this study. The majority of patients were Malay (55%) followed by Chinese (35%), Indian (5%) and others (5%). The mean volume of drainage from the axilla in the EC group was significantly higher than UC group [489.5 versus 188.1 mls ($p < 0.001$)]. The mean volume of drainage from the breast and the total drainage from both the breast and axilla was also significantly higher in the EC group compared to UC [169.3 versus 58.8 mls ($p = 0.004$) and 663.7 versus 247.0 mls ($p < 0.002$) respectively]. The drainage consequently showed significant reduction in terms of drain days in the axilla [6 days versus 3 days ($p < 0.002$)] and the breast [3 days versus 2 days ($p < 0.002$)] in the UC compared to the EC. There was no significant complication in both arms. In conclusion, the use of ultracision able to reduce the amount of drainage and the number of drain days after performing modified radical mastectomy. In doing so, the use of this technology enable us to discharge patients earlier without significant morbidities.

KEY WORDS:
Modified radical mastectomy, ultracision, electrocautery, breast cancer, surgery

INTRODUCTION

Breast cancer is the commonest cancer as well as the leading cause of cancer death in women world-wide. Surgery, when possible remains the mainstay of treatment. It is important that complications of surgery are kept at a minimal in order to prevent undue delay in the adjuvant treatment. Modified radical mastectomy is considered the commonest operative procedure performed for breast cancer in Malaysia. Traditionally, raising the skin flaps, shaving off the breast from the pectoral wall and axillary lymph node dissection has been performed by either scalpel (sharp dissection) or by electrocautery. Early complications in breast cancer surgery has always been attributed to excessive post-operative drainage , prolonged hospital stay, seroma formation, blood loss, haematoma formation, skin necrosis and nerve injury. Drains are kept till the drainage is less than 30mls/24 hours to reduce seroma formation but are removed on the 7th post operative day regardless of the amount drained the previous day to reduce the risk of ascending infection. Up till now there has been no clear pathophysiological explanation for seroma formation. Many studies have been published to analyze the risk factors. Ultracision uses ultrasonic technology that produces a balanced sinusoidal (or harmonic) ultrasonic wave. This is coupled to the metallic rod of the device and the wave motion is converted into high-frequency mechanical motion at the tip of a blade located at the end of the rod. The blade is then able to cut and coagulate tissue in a precise and controlled manner and results with minimal lateral thermal damage. The coagulation is provided by generation of high temperature at probe tip resulting in necrosis and even charring. According to Lumachi *et al*[1] in an analysis to assess the risk factors of seroma formation and evaluate the role of ultracision in performing ALND in patients with primary

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breast cancer undergoing MRM and breast conservative surgery , he found that the seroma rate to be 30.4% (28 out of 92 patients). Multivariate analysis using a logistic regression model showed that surgical procedure, size of tumour and total amount of drainage independently correlated with seroma formation. The use of ultracision may reduce the risk of seroma formation. Burak *et al*[2] concluded that the significant risk factors of seroma formation were an increased age, patient weight, initial 72 hours wound drainage and performing axillary dissection. In this study we postulate that the superior haemostatic and coagulating properties of ultracision will result in less drainage and subsequent seroma formation without increasing the morbidity.

MATERIALS AND METHODS

This study was a prospective randomized controlled study conducted by the Breast and Endocrine Unit, department of surgery, Hospital Universiti Kebangsaan Malaysia between 1st June 2007 to 31st December 2008. The study criteria were all patients with confirmed diagnosis of an infiltrating ductal carcinoma and planned for modified radical mastectomy (which entails axillary lymph node dissection as well). Patients with advance breast cancer, prior neoadjuvant chemotherapy and those who did not consent were excluded from the study. The sample size calculation was made by comparing the post-operative volume drainage using the two different methods3, giving rise to 22 patients in each arm. All the study participants were randomized to one of the two arms using the automated computer generated hospital registration number. The odd number went to the UC group with the even number to the EC group. All the study patients agreed to participate and the study protocol was approved by the UKM Animal and Ethics Committee.

Operative Technique

After the patient was cleaned and draped, an elliptical incision incorporating the tumour and nipple was made in the usual manner and the dermis was incised using electrocautery on cutting mode. In the UC arm, the skin flaps were raised and the breast was shaved off the pectoral fascia using the ultrasonic dissector by Ethicon Endo Surgery® by Johnson and Johnson. The instrument was also used to perform axillary dissection. Only those vessels larger than 5mm in diameter were ligated with suture tie or in the event deemed necessary by the surgeon. In the electrocautery arm, the whole procedure was performed using Valley Lab diathermy (power of 25 watt) for both cutting (pure mode) and coagulation (fulguration mode) for the whole procedure except for ligation of blood vessels bigger than 5mm or deemed necessary by the surgery. Electrocautery was also avoided around areas in close proximity to nerves during axillary dissection. All vessels that needed ligation, 3-0 linen sutures were used. Post operatively, two J-Vac suction drains size 12 French were placed in the axilla and chest wall respectively. The operative time and the weight of the breast and axilla were recorded.

Post-operative management

Patients were given oral analgesia (tablet Etoricoxib 120 mg OD) for pain relief. Daily drainage was recorded separately for both drains. The drains were removed when the drainage amount less than 30mls/24 hours or at the 7th day post surgery regardless of the amount of drainage. Wound was inspected on day 2 post surgery. It is the policy of the hospital to keep the patient until the drain is removed and the patient will be reviewed two weeks after the surgery.

Statistical Analysis

All patients were evaluated for the development of haematoma, seroma, wound infection, flap necrosis, lymphoedema, numbness and tingling sensation post surgery at 2 weeks or earlier if necessary. Statistical significant differences were analysed using the unpaired 2-tailed Student's t test and the χ^2 test. The p values of less than 0.05 were considered significant. Statistical software SPSS® for windows version 13.0 (SPSS Inc, Chicago, USA) was used for the above analyses.

RESULTS

From 1st June 2007 to 31st December 2008, a total of 40 patients with carcinoma of the breast were randomized in this study to either the ultracision group (n = 20) or the electrocautery group (n = 20). All patients were female. The majority of patients were Malays 22 (55%), followed by Chinese 14 (35%), Indian 2 (5%) and others 2 (5%). Surgery was performed faster using electrocautery (116 ± 21 minutes) as there was still a learning curve compared to ultracision (154 ± 31 minutes) (p value < 0.001). The operative time taken in the first 10 cases of ultracision compared to the operative time taken in the last 10 cases noted a significant reduction in time of 167.80 ± 37.26 minutes vs. 139.50 ±15.31 minutes. (p= 0.046). The clinical and post-operative complication data were as in Table I. Both group of patients had seroma complication which was managed by repeated aspiration.

DISCUSSION

From the introduction of breast surgery until recently, there has been a change from the more radical approach proposed by Halsted to the current modified approach. As a result, there has been a significant reduction in mortality and morbidities. In the recent years, we are still fraught by a significant percentage of morbidities. Seroma formation is one of the most important complications as it is associated with more serious complication such as infection, lymphoedema, delayed wound healing, prolonged hospital stay and frequent post-operative visits. There has been various methods introduced to prevent such morbidities notably seroma formation. Unfortunately, none has been consistent enough to prevent such complication. The pathophysiology of fluid accumulation in the breast and axillary space post operatively and seroma still remains debatable. It is still uncertain whether this fluid accumulation is due to lymph like fluid or an exudate. In such circumstances an efficient lymph vessel sealing instrument with minimal tissue injury would theoretically reduce the amount of fluid accumulation post operatively and provide adequate haemostasis to avoid intra-operative haemorrhage.

Table I: Clinical and post-operative complication data in both the electrocautery and ultracision arm

Variables	Electrocautery	Ultracision
Age (year)	53 ± 9	53 ± 7
Weight (kg)	58.8 ± 5.9	57.6 ± 4.6
Height (m)	153.5 ± 6.3	152.9 ± 7.9
Tumour size (mm)	37.9 ± 33.8	46.5 ± 41.1
Weight of axilla (gm)	70.3 ± 32.9	72.2 ± 28.1
Weight of breast (gm)	427.6 ± 107.9	464.9 ± 88.2
Mean tumour size (mm)	37.9 ± 33.8	46.5 ± 41.1
Post-operative complication		
Seroma	5	3
Wound infection	1	2
Skin edge necrosis	1	0
Tumour grading		
Grade I	3	2
Grade II	13	7
Grade III	4	11
Tumour histology		
Infiltrating Ductal Carcinoma (Non-specific)	18	18
IDC & DCIS	1	1
Mucinous Carcinoma	0	1
Papillary Carcinoma	1	0
Co-morbid illness		
Hypertension	5	4
Diabetes mellitus	1	1
Asthma	1	1

Table II: Detailed data on drainage volume and hospital stay

	Electrocautery	Ultracision	P value
Breast drainage			
Volume (mls)	169.3 ± 151.4	58.8 ± 27.9	P=0.004
Duration (days)	3 ± 2	2 ± 1	p< 0.002
Axilla drainage			
Volume (mls)	489.5 ± 155.2	188.1 ± 133.4	p< 0.001
Duration (days)	6 ± 1	3 ± 1	p< 0.002
Total drain (mls)	663.7 ± 229.6	247.0 ± 142.0	p< 0.002
Hospital Stay (days)	6 ± 1	3 ± 1	p< 0.002

The ultracision or harmonic scalpel uses a combination of mechanical pressure and high current low voltage energy. The high current low voltage energy denatures collagen and elastin fibers and the pressure approximates the vessel wall, allowing the proteins to form as a seal. The whole process will obliterate the lumen of the blood and lymph vessels permanently and completely. It has been proven to be safe and effective regarding haemostasis and other complications in abdominal and laparoscopic general surgical procedures[4-7].

Many studies on breast surgery have attempted to address the use of ultrasonic dissection with various results[1,2,3,7]. All of these studies showed that this instrument is safe. However, not all of them agreed that it was beneficial in terms of reducing the amount of drainage and seroma formation. One study by Lumachi *et al.*[1] that compared the rate of seroma formation in axillary dissection. The rate of seroma was lower (20%) with the use of ultracision compared to 40% without the use of ultracision. Hanne Galatius *et al.*[9] compared the use of ultracision versus electrocautery and scissor dissection but did not find any significant difference in terms of preoperative bleeding, drainage volume, and seroma formation. In a randomized control trial performed by SVS Deo *et al.*[3] there was no significant difference in the rate of seroma formation but significant reduction in the total drain volume and mean drain days in the ultracision arm. The operating time was similar in both arms. Similarly, Kozomora *et al*[10] found that ultracision significantly reduced the total operational drain secretion but the duration of hospital, post-operative pain and significant complication were similar compared to monopolar electrocautery. In contrast, Sanguinetti *et al*[11] showed that the significant reduction in blood loss and drainage volume led to significant reduction of draining days and also less seroma formation in the ultrasonic scissor.

The sample number calculated for this study was 22 in each arm but unfortunately we were able to recruit only 20 in each arm due to constraint of time. Nevertheless, our results using this technology are encouraging. The volume of drainage from the breast bed, axilla and the total drainage were significantly lower in the ultracision group. As a result, the drains in the ultracision group were removed earlier than the electrocautery arm and patients were discharged home earlier.

The average operative time for performing modified radical mastectomy with axillary lymph node dissection was significantly longer using ultracision (154 minutes vs 116 minutes; p <0.001). This could be explained by the lack of

experience in using the ultracision dissector and scissor as the technology was just introduced to the study centre. This can be avoided by exposing the surgeons to the new technology prior to the study. D. Bohm *et al*[12] conducted similar study and exposed the surgeon to the technique for 5 months prior to the study. With the short learning curve, they managed to show no significant difference in operating time between ultrasonic surgery and conventional device. This was seen in other studies by SVS Deo *et al.*[3], Lumachi et al.[1] and Hanne Galatius. *et al.*[9] which did not show statistically significant difference in duration of surgery. The analysis of the operative time taken in the first ten cases of ultracision were compared to the operative time taken in the last ten cases and there was a significant reduction in time of 167.80 ± 37.26 minutes vs 139.50 ±15.31 minutes. (p= 0.046). This explained the fast learning curve of using the ultracision dissector.

Finally, the major disadvantage is the cost of the device which is more expensive compared to the conventional electrocautery. However, there is a potential cost saving if the additional cost of hospital stay and the potential benefit of reducing morbidity is taken into account. A properly conducted cost-analysis study might be able to answer this issue.

CONCLUSION

An ultracision is a useful adjunct to mastectomy and axillary dissection in breast surgery. The benefit of this instrument is obvious in reducing the amount of drainage and the number of drain days from both the breast and axilla when performing modified radical mastectomy. Indirectly, the patients can be discharged home earlier. The instrument is safe and does not result in significant morbidity compared to the conventional technique.

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