Introduction: The surgical treatment of the breast cancer has shifted dramatically from radical operation to the breast conserving surgical technique. The most common complications of the conventional modified radical mastectomy with axillary dissection, electrocautery (diathermy) & the suture ligation are seroma, lymphodema with the incidence of 11% to 85% and 2% to 50% respectively

Objective: This study was conducted to evaluate the feasibility, safety & efficacy of modified radical mastectomy with axillary dissection using the harmonic scalpel in terms of operative time, lymph vessel sealing, haemostasis and post operative complications.

Design: Prospective observational study.

Setting and duration: This study was carried out in Ward–26 (Surgical unit III), Jinnah Postgraduate Medical Centre, Karachi, from December 2008 to June 2010.

Methodology: A total of 60 patients underwent Modified Radical Mastectomy and Axillary Clearance during this period. Patients with indications of modified radical mastectomy and ASA (American society of anaesthesia) score 1 and 2 were included in the study. Patients with early breast cancers (T1), previous breast surgery, neo-adjuvant therapy, patient with diabetes and other co-morbid were excluded from the study group.

Results: All the data was entered and analyzed in SPSS version 17. Descriptive statistics was used to summarize the continuous variables and presented as mean ± S.D and categorical variables in frequencies and percentages because this is observational study no statistical test and p-value is required. The mean intraoperative blood loss was 45 ± 12 ml and the mean operative time was 90 ± 7 minutes. No postoperative bleeding or haematoma occurred. But on the other hand, seroma (2), lymphodema (1) and wound infection (1) occurred. The mean drainage volume of flap drain and axillary drain was 20 ± 8 ml and 155 ± 35 ml respectively and mean drainage duration was 1.3 ± 0.2 and 2.7 ± 0.5 days respectively. The mean hospital stay was 3.7 ± 0.6 days. Among 60 patients, 19 (31.6%) patients had positive axillary nodes, out of which 6 patients (10%) had 1-2 positive lymph nodes and 13 patients (21.6%) had four or more positive nodes.

Conclusion: The Modified Radical Mastectomy & Axillary Dissection using the harmonic scalpel was safe, feasible, effective. This device simplifies the surgical procedure, reduces the operative time, peri-operative blood loss, drainage volume and duration of drainage. Furthermore the incidence of seroma and lymphodema was also reduced.

Keywords: Modified radical mastectomy, Harmonic scalpel, Seroma

Introduction: The harmonic scalpel is recently emerging as an alternative surgical tool for the dissection and Haemostasis. It has extensively been used in field of Minimally Invasive Surgery. Despite of the emergence of the breast conservation technique (surgery) modified Radical Mastectomy still remains the most commonly performed surgery for Breast Cancer’s today.
Electrocautery is associated with a moderate degree of operative morbidity in 35% to 50% patients. Much of this morbidity has been largely attributed to large postmastectomy raw area, cut lymphatic’s and use of electrocautery.

Lymph vessel sealing and hemostasis are usually performed using clips, suture ligation, or electrocautery. However, suture ligation is time-consuming and carries the risk of knot slipping, while clips may become dislodged. Moreover, electrocautery produces thermal spread to adjacent tissues and is considered a risk factor for seroma and other wound complications after mastectomy. Recently, modified radical mastectomy and axillary dissection using the harmonic scalpel have been described.

The electrothermal bipolar vessel sealing system, a novel hemostatic device, has been used in general surgery with safety and efficacy regarding hemostasis, complications, and reduction in operative time. The objectives of this study were to evaluate the feasibility, safety, and efficacy of modified radical mastectomy with axillary dissection using the harmonic scalpel in terms of lymph vessels sealing hemostasis and peri-operative complications.

Methodology:
This prospective observational study was conducted in ward-26, surgical Unit-III, J.P.M.C from Dec 2008 to June 2010.

A total of 60 patients underwent modified radical mastectomy. Patients of unilateral Breast disease, with all indications for the modified radical mastectomy with American Society of Anesthesiology Score 1 & 2 were included in the study.

Patients with early breast Cancer (T1), with history of previous breast surgeries, on Neo-adjuvant therapy and those with Diabetes & other co-morbidities were excluded from the study group.

The informed consent was taken from all patients before surgery and the operation was performed by same group of surgeons.

In all the cases, the entire procedure of modified radical mastectomy with axillary dissection was performed using harmonic scalpel. Lymph vessel sealing and hemostasis was also achieved, no clips, sutures or electrocautery was used. (Figure 1-2)

Two drains were placed, one under the flap and second in axilla. The drains were removed if the volume was less than 30 ml in 24 hours. All the patients were discharged from the hospital after the removal of drains, followed weekly for 4 weeks and then every 2 monthly. Postoperative complication i.e. bleeding, seroma, skin burn, hematoma, lymphedema, wound infection & flap necrosis were evaluated during the hospital stay & followed-up in outpatient clinics.

Collected data were age, hospital stay, intraoperative blood loss, operative time (from skin incision to skin closure), postoperative flap and axillary drainage volume and duration, and postoperative complications such as bleeding, seroma, skin burn, hematoma, lymphedema, pneumothorax, and wound infection or skin necrosis.
Modified radical mastectomy with axillary clearance using harmonic scalpel

Results:
The data was entered and analyzed in SPSS version 17. Descriptive statistics was used to summarize the continuous variables and presented as mean ± S.D and categorical variables in frequencies and percentages because this is observational study no statistical test and p-value is required. (Table 1)

During one and half year sixty (60) patients were operated by the same team of surgeon and the lymph vessels sealing and haemostasis were achieved using the harmonic scalpel in all the cases. No clips, sutures or diathermy (electrocautery) were used.

The mean intra-operative blood loss was 45 ± 12 ml and mean operative time was 90 ± 7 minutes. No postoperative bleeding, hematoma, flap necrosis or pneumothorax occurred. While two patient (3.33%) had seroma, one (1.66%) had lymphodema and one (1.66%) patient had wound infection.

The mean drainage volume of flap drain and axillary drain was 20 ± 8 ml and 155 ± 35 ml respectively and mean drainage duration was 1.3 ± 0.2 and 2.7 ± 0.5 days respectively. The mean hospital stay was 3.7 ± 0.6 days.

Among 60 patients, 19 (31.6%) patients had positive Axillary nodes: out of which 6 (10%) patients had 1-2 positive nodes and 13 (21.6%) had four or more axillary nodes positive.

Discussion:
The harmonic scalpel is an innovative device designed as an alternative to conventional vessel sealing technique. It has emerged as an alternative surgical tool for the dissection and hemostasis. It has extensively been used in field of minimally invasive surgery and open surgeries as well like in thyroid and breast.

The ultrasonic energy generated by the harmonic scalpel causes break down of hydrogen bonds and the formation of denatured protein coagulum which seal's off the vessels and lymphatics thus decreasing blood loss and lymphatic drainage.4

The conventional MRM with axillary dissection using electrocutry, clamp and tie technique are associated with moderate degree of morbidity in terms of Blood loss, hematoma, flap necrosis, seroma and prolong axillary drainage.3

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.5,6

However, the study by Galatius H & Okholm et.al reported that there is no significant difference in the use of both the techniques in terms of operative time, peri-operative bleeding and wound complications.7 Furthermore, they reported a high incidence of seroma formation in both the groups.

One of the important issue regarding the use of harmonic scalpel is extent of lateral thermal injury spread and associated tissue injury. Several experimental studies show that this extent of lateral thermal injury spread is limited to 2-3 mm.8

Our results of using the harmonic scalpel technique in MRM are encouraging. The device is handy, easy to use, safe and reliable. We experienced no technical difficulty with its use. No significant peri or post operative complication occurred and the estimated blood loss was much less as compared to other reported studies. Not only this, two (2) patients in our study experi-

Table 1: Clinical and postoperative complication data among 60 patients

<table>
<thead>
<tr>
<th>Variables/Mean, SD &amp; Range</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years</td>
<td>48.5</td>
<td>6.3</td>
<td>28-75</td>
</tr>
<tr>
<td>Number of Axillary nodes removed</td>
<td>19</td>
<td>5.4</td>
<td>13-38</td>
</tr>
<tr>
<td>Intra-operative blood loss in ml</td>
<td>45</td>
<td>12</td>
<td>25-70</td>
</tr>
<tr>
<td>Operative time in minutes</td>
<td>90</td>
<td>07</td>
<td>80-120</td>
</tr>
<tr>
<td>Flap drainage volume in ml</td>
<td>20</td>
<td>08</td>
<td>05-40</td>
</tr>
<tr>
<td>Duration of flap drain in days</td>
<td>1.3</td>
<td>0.2</td>
<td>1-2</td>
</tr>
<tr>
<td>Axillary drainage volume in ml</td>
<td>155</td>
<td>35</td>
<td>90-265</td>
</tr>
<tr>
<td>Duration of axillary drain in days</td>
<td>2.7</td>
<td>0.5</td>
<td>2-4</td>
</tr>
<tr>
<td>Stay in Hospital in days</td>
<td>3.7</td>
<td>0.6</td>
<td>3-6</td>
</tr>
</tbody>
</table>

Data are given as the mean (SD) and range or as the number and percentage of patients.
ence seroma formation unlike other literatures with reported incidences ranging from 11% to 85%. Secondly, the mean drainage volume is comparatively less than other studies.\textsuperscript{8,9,10}

None of our patients had skin burn or flap necrosis in contrast to the rate of the complication of 18% reported in some studies.\textsuperscript{11–13}

Furthermore only one (1) case of upper limb lymphedema have been observed in our study. However, this result should be carefully evaluated as lymphoedema take longer interval to develop after surgery. The follow up period should be at least four years or more to evaluate the frequency of lymphedema. Our study was limited because of shorter period of follow-up so we can not comment on the frequency of lymphedema.

Though, the harmonic scalpel is expensive than conventional technique but the benefits and the potential reduction of complications have made this device cost effective. Although there was no control group in our study, a comparison of our results with data from other studies in the literature suggests that there may be substantial benefit from the use of this device in breast surgery. (Table 2).

Table 2: Postoperative complications

<table>
<thead>
<tr>
<th>Postoperative complications</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative bleeding</td>
<td>0</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0</td>
</tr>
<tr>
<td>Seroma</td>
<td>2</td>
</tr>
<tr>
<td>Upper limb lymphedema</td>
<td>1</td>
</tr>
<tr>
<td>Wound infection</td>
<td>1</td>
</tr>
<tr>
<td>Wound necrosis</td>
<td>0</td>
</tr>
<tr>
<td>Skin burn</td>
<td>0</td>
</tr>
<tr>
<td>Pneumothorax</td>
<td>0</td>
</tr>
</tbody>
</table>


Conclusion:
To recapitulate modified radical mastectomy with axillary clearance using harmonic scalpel is feasible, safe and effective. The major advantage of this technique is that it simplifies the surgical procedure and eliminates the need of clips, ligatures and diathermy (electrocautery) together with achieving effective lymph vessel sealing and hemostasis. Thus, reducing the morbidity in the patients.

References: