Mastectomy without Drain at Pectoral Area : A Randomized Controlled Trial

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Abstract

Objectives : Mastectomy is still one of the standard alternative procedures for the management of female breast cancer. Axillary node dissection is also performed to establish the accurate staging. After operation, the axilla must be drained because of lymphatic leakage. Whether the raw surface at the pectoral area should be drained or not is an interesting controversial point. The authors conducted a randomized controlled trial to compare outcomes after modified radical mastectomy (MRM) with and without drainage at the pectoral area.

Methods : Sixty patients who agreed to be treated with MRM and had given their consent were enrolled. Mastectomy was performed to remove the breast tissue proper by scalpel in order to minimize tissue injury. The axillary contents were removed by sharp instrument. After bleeding had stopped, patients were randomly allocated to one or other of 2 groups: group I (n = 30): only 1 drain was inserted at the axilla area; group II (n = 30): 2 conventional drains were inserted into the pectoral area and axilla area. The size of tube drain and negative suction pressure were constant in all cases. Volume of contents was recorded daily. Subcutaneous seroma or hematoma were carefully observed and confirmed by ultrasonography 3-5 days after operation. Overall drainage contents and complications were compared.

Results : The mean weight of breast tissue of group I was 632.1 g and group II 654.0 g ($p = 0.81$). Total drainage contents (median) from the two groups were 250 cm^3 and 231 cm^3 respectively ($p = 0.796$). Complications occurred in 1 case in group I and 2 cases in group II ($p = 0.35$). None of the above differences were statistically significant.

Conclusion : Mastectomy by scalpel can be performed without drainage at the pectoral area. Overall complications in the conventional group and the group without drain did not differ significantly.

Key word : Mastectomy, Sharp Dissection

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Even though the trend in surgical management of female breast cancer is towards more conservative surgery, mastectomy is still an alternative standard procedure[1,2]. Modified radial mastectomy (MRM) is an attempt to remove the breast tissue proper together with lymph nodes at the axilla for complete staging. Because of the increasing use of conservative breast surgery, more intensive care and closer follow-up after radiation of the breast must be performed. MRM is still accepted in occasional groups of patients who are concerned about the long-term outcome after conservative surgery.

After removal of breast tissue and axilla contents, there are large raw surfaces of tissue. Drainage of the surgical area is indicated to remove serum oozing from this area. The drain is inserted in order to shorten the recovery period and reduce the incidence of seroma[3-6]. The leakage from lymphatics following removal of axillary tissue is an indication for drainage of this area. Drainage contents of less than 30 cm^3/day is an indication for drain removal[7]. Several groups of surgeons have introduced seroma aspiration after operation as an alternative to drainage [7-11]. The prevention of seroma complication at the pectoral area was advocated by suturing with subcutaneous stitches[3,12].

Dissection of breast tissue from the surrounding area by electric cauterization has been reported to be a cause of serum leakage due to thermal injuries [4,11]. Sharp cutting by the scalpel has been advocated to minimize tissue injury. After the authors gained experience with this technique, a trial of mastectomy without a drain at the pectoral area was planned. The study was designed to compare the results between the two groups of patients in whom MRM was done by sharp dissection and the skin flap was either drained or not drained. The volume of serum drainage and overall complication rate were determined in each group.

PATIENTS AND METHOD

Between July 1999 and June 2001, 60 consecutive women with primary breast cancer underwent modified radical mastectomy who consented to be enrolled in this trial. The protocol was approved by the ethics committee board of Faculty of Medicine, Prince of Songkla University. The inclusion and exclusion criteria are shown in Table 1. The operative technique was performed in a uniform fashion in all patients by the same group of surgeons. The subcutaneous plane was injected with 100 cm^3 of normal saline solution. If there was no contraindication, adrenaline was combined at 1 : 200,000 concentration. The scalpel was used for the entire procedure except the dissection of the axillary area which was done by using dissecting scissors. Individual points of bleeding

Table 1. Inclusion and exclusion criteria.

Inclusion criteria
- Female, age 35-70 years.
- Accept to be enrolled in the protocol of modified radical mastectomy.
Exclusion criteria
- IDDM
- Hypertension
- History of anticoagulant or steroid therapy
- Pre-operative radiation or chemotherapy
- Tumor invaded skin (T4)

Table 2. Staging of breast cancer in the two groups.

Staging	Number of patients	
	Group I	Group II
T1 N1 MO	5	4
T2 NO MO	12	12
T2 N1 MO	10	9
T3 NO MO	0	2
T3 N1 MO	3	3
Total	30	30

at the pectoral area were stopped by electric cautery. Ligation by silk at the axilla was performed in all cases.

When the bleeding had completely stopped, patients were randomly allocated using a sealed envelope into one of two groups, 30 patients per group. In group I, only 1 drain was inserted at the axillary area, whereas in group II, 2 conventional drains were placed one each at the pectoral and axillary areas. The surgeon was not informed of the result of random allocation until starting to insert the drain. Polyethylene tube, no. 14 F, was used as the standard drain in this trial. Operating time and operative blood loss were recorded. Operating time was recorded from the start of MRM until completion of the last skin stitch. Intra-operative blood loss was estimated by the weight of gauze. Resected breast tissue specimen and axillary content were weighed (g). A continuous negative suction pressure of 40 cm H_2O was applied to the drain tube. Each day, drainage output was recorded and the retrograde pushing of a small amount of air to prevent clot formation was done. The drain was left in place for at least 2 days. Removal of the drain was indicated when the content was less than 0.5 cm^3/kg/d. The wound dressing was opened to detect skin flap necrosis and other complications on day 3. Ultrasonography was done to confirm the detection of seroma. If there was no seroma, the drain was removed.

The complications were recorded. Flap necrosis was classified as superficial necrosis or total flap necrosis. The volume of seroma from aspiration was recorded. The results of pathological staging were also assessed for TNM staging and cancer stage. Statistical analysis was used to test the significance of differences between the groups using Fisher Exact test, Student's *t*-test and Mann-Whitney test.

The pathological staging in both groups was mainly stage II. All patients were treated according to the treatment protocol of our department guidelines.

RESULTS

The pathological staging of breast cancer in these groups of patients is shown in Table 2. The majority of patients in this study were T2 lesion. The mean ± standard deviation of age of the patients in groups I and II were 46.7 ± 11.1 and 45.0 ± 8.7 years respectively. Mean volume of intra-operative bleeding in the two groups was 315.7 cm^3 and 361.7 cm^3 respectively. The mean operating time and standard deviation were 106.1 ± 23.1 min and 116.2 ± 38.7 min. The mean weights of breast tissue and axillary tissue are shown in Table 3. There were no statistical differences in the breast tissue and axillary tissue weight.

After operation, the drain in both groups received standard care and control using the same criteria. As shown in Table 4, the duration of drain insertion in the two groups was similar, 5.0 ± 2.7 and 4.8 ± 1.7 days respectively ($p = 0.66$). The median total volume of drainage contents in group I was 250 cm^3 and in group II 231 cm^3. Although the drainage

Table 3. Results of operation. Values are given as mean ± SD.

	Group I	Group II
Breast tissue (g)	632.1 ± 477.4	654.0 ± 277.6
Axillary tissue (g)	104.1 ± 189.3	64.5 ± 27.2
Operating time (min.)	106.1 ± 23.1	116.2 ± 38.7
Intra-operative blood loss (cm^3)	315.7 ± 182.6	361.7 ± 157.4

Table 4. Results of drain. Value of duration of drainage (days) is given as mean ± SD and value of volume from drain is given as median.

	Group I	Group II	P-value
Time of drainage (days)	5.0 ± 2.7	4.76 ± 1.7	0.66
Total volume from drain (cm^3)	250	231	0.796

Table 5. Results of seroma. Values numbers of patients or mean ± SD.

	Group I	Group II	P-value
Seroma at pectoral by US (n)	5	1	0.097
Seroma at axilla (n)	11	6	0.25
Volume of seroma (cm^3) at axilla	108.4 ± 40.2	156.2 ± 58.5	0.50

Table 6. Details of complications.

Complication (n)	Group I	%	Group II	%
Hematoma	1	3.3	1	3.3
Wound infection	-	-	1	3.3
Total (p = 0.35)	1		2	

volume in group I seems to be greater than in group II, there was no statistical difference between the groups (p = 0.796).

The number of patients with complications and seroma detection and the volume of the aspirated content are shown in Table 5, and the type of complication in Table 6. Seroma was the most common complication. The number of patients with complication and seroma detection was not statistically different between the two groups. Seroma collection at the axillary area frequently occurred after the axillary drain was removed. Mean volume of seroma aspiration from axillary area among patients with seroma in group I was 108.4 ± 40.2 cm^3 and 156.2 ± 58.5 cm^3 in group II. These were not statistically significantly different. The seromas at the pectoral area, which were detected by ultrasonography, were thin film seroma and almost all of them were absorbed without aspiration.

DISCUSSION

Pathological staging and mass of breast tissue and of axillary tissue removed were similar in the two groups. After operation the drains were given strict care of the same standard in all patients. The mean time of drain insertion did not differ significantly in the two groups (Table 4). The total volume of serum drained from the raw surfaces of the pectoral area and axilla area was 347.8 ± 409.2 cm^3 in group I, 271.7 ± 197.3 cm^3 in group II. The volumes were not significantly different (p = 0.36).

During the follow-up period, a number of patients had loculation of serum in the axillary area and aspiration was mandatory to improve the healing process. The proportion of patients developing seroma in the axillary area and the mean volume of seroma aspiration from these patients were not significantly different in the two groups. Because the space from the pectoral area was confluent with the cavity in the

axillary area, the small amount of serum after scalpel dissection could be reabsorbed or spread to the axillary space.

Tejler reported the results after MRM in 385 patients[13]. The most common complication was seroma, 36.5 per cent and hematoma 4.3 per cent. In the present study there were 2 cases who developed hematoma, one in each group. Both patients recovered well after conservative treatment without any surgical clot removal. Other complications were superficial skin flap necrosis in 3 cases in group I and in 2 cases in group II. The necrosis area was located at the skin edge, and no surgical debridement was needed for these patients. Wound infection occurred in 1 case in group II. Mastectomy by scalpel technique can shorten the operative time as seen in these groups of breast cancer. The average time of operation in the two groups was 106.1 and 116.2 minutes respectively. The control of bleeding by gauze packing and individual cauterization at the pectoral area were time-saving procedures. Sharp dissection with ligation stitches at the axillary space can minimize lymphatic leakage from nodal dissection. In general, these problems can be detected by clinical observation without the need for ultrasonography. However, in the present study the authors confirmed the clinical result of detection of hematoma and seroma by ultrasonography. The size and location of seroma were used as a guide for aspiration. Mastectomy by scalpel can also shorten the period of drainage tube retention, because of the minimized tissue injury when compared to the cauterization technique[11,14-16]. However, mastectomy by electric cauterization has been reported to be superior to scalpel technique in the control of bleeding during surgery[17]. In the present study there was only one case, in group I, who required packed red cell replacement. The overall result after mastectomy without drain at the pectoral area was not different from the drainage group. Drainage at the axilla is still important because it can reduce the incidence of seroma and its complications. Jeffrey et al[8] reported an incidence of 42 per cent seroma aspiration when axillary node dissection was done without drain.

SUMMARY

The results after MRM in the groups of patients with or without drainage tube at the pectoral area were not significantly different with respect to seroma or other complications. The total amount of drainage content and duration of drain insertion were not significantly different in the group of patients with or without drain at the pectoral area.

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การผ่าตัดเอาเต้านมออกโดยไม่ใส่ท่อระบายบริเวณหน้ากล้ามเนื้อเพคตอรัล : การศึกษาเปรียบเทียบแบบควบคุม

พุฒิศักดิ์ พุทธวิบูลย์, พบ, บูรภัทร์ สังข์ทอง, พบ*, ธนพล ไหมแพง, พบ*, ศรีลา สำเภา, พบ*, พรรณเพ็ญ อุตตมะกุล, พบ**, นวลตา อาภาคัพภะกุล, วทม (พยาบาล)****

วัตถุประสงค์ : การผ่าตัดเอาเต้านมออกยังถือเป็นการผ่าตัดมาตรฐานชนิดหนึ่งของการผ่าตัดมะเร็งเต้านม การผ่าตัดนี้ร่วมกับการเลาะต่อมน้ำเหลืองที่รักแร้ช่วยให้การวินิจฉัยระยะของการแพร่กระจายของโรคถูกต้องและแม่นยำ หลังผ่าตัดจะใส่ท่อระบายน้ำเหลืองจากรักแร้เนื่องจากมีการกระทบกระเทือนต่อท่อน้ำเหลืองบริเวณนั้น แต่สำหรับบริเวณหน้ากล้ามเนื้อเพคตอรัลที่เต้านมเคยวางอยู่นั้นภายหลังจากตัดเอาเต้านมออกแล้วอาจจะไม่จำเป็นต้องใส่ท่อระบาย ผู้รายงานจึงทำการศึกษาเปรียบเทียบระหว่างการใส่และไม่ใส่ท่อระบายบริเวณที่เต้านมถูกตัดออก

วิธีการศึกษา : ผู้ป่วยสตรีจำนวน 60 รายที่ได้รับการวินิจฉัยว่าเป็นมะเร็งเต้านมและเข้ารับการผ่าตัดเอาเต้านมออกชนิดโมดิฟายด์ แรดดิคัล โดยใช้มีดผ่าตัดและกรรไกรเลาะเนื้อเต้านมแทนการใช้เครื่องจี้ไฟฟ้า ผู้ป่วยจะถูกแบ่งออกเป็น 2 กลุ่ม กลุ่มละ 30 ราย กลุ่มที่ 1 จะได้รับการใส่ท่อระบายเส้นเดียวที่ตำแหน่งรักแร้ กลุ่มที่ 2 จะได้รับการใส่ท่อระบาย 2 เส้นคือที่รักแร้ 1 เส้น และที่บริเวณหน้ากล้ามเนื้อเพคตอรัลอีก 1 เส้น ขนาดท่อระบายและการดูแลท่อระบายทั้ง 2 กลุ่มจะเหมือนกัน ปริมาณของสารที่ดูดออกจากท่อระบายจะถูกบันทึก และช่องขังน้ำเหลือง (ซีโรมา) หรือก้อนเลือดที่อาจจะเกิดขึ้นจะถูกตรวจโดยการใช้คลื่นเสียงความถี่สูง วันที่ 3–5 หลังผ่าตัด ปริมาณของเหลวที่ออกจากท่อระบายและภาวะแทรกซ้อนที่บันทึกไว้จะนำมาเปรียบเทียบกันระหว่างกลุ่มผู้ป่วยทั้ง 2 กลุ่ม

ผลการรักษา : น้ำหนักของเต้านมเฉลี่ยของกลุ่มที่ 1 คือ 632.1 กรัม กลุ่มที่ 2 เท่ากับ 654.0 กรัม ($p = 0.81$) จำนวนของเหลวที่ออกจากท่อระบายของกลุ่มที่ 1 เท่ากับ 250 ลูกบาศก์เซนติเมตร และกลุ่มที่ 2 เท่ากับ 231 ลูกบาศก์เซนติเมตร ($p = 0.796$) ภาวะแทรกซ้อนทั้งหมดที่เกิดขึ้นพบ 1 รายในกลุ่มที่ 1 และ 2 รายในกลุ่มที่ 2 ($p = 0.35$) ซึ่งทั้งหมดไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ

สรุป : การตัดเต้านมออกโดยใช้มีดผ่าตัดและไม่ใส่ท่อระบายบริเวณหน้ากล้ามเนื้อเพคตอรัล ไม่พบผลการทดลองหรือภาวะแทรกซ้อนที่แตกต่างกับการใส่ท่อระบายบริเวณนั้น

คำสำคัญ : มะเร็งเต้านม, การใส่ท่อระบายบริเวณหน้ากล้ามเนื้อเพคตอรัล

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