Original Article

Comparison of Traditional Electrosurgery System versus Low Thermal Tissue Dissection System for Total Mastectomy: A Prospective Randomized Controlled Trial

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Objective: This study aimed to compare total drainage volume between patients underwent total mastectomy using traditional electrosurgery and low thermal tissue dissection system.

Materials and Methods: This is randomized controlled trial included total 50 patients who underwent mastectomy at Division of Head Neck Breast Surgery Siriraj Hospital. Twenty-five patients received traditional electrosurgery system during mastectomy whereas twenty-five patients received low thermal tissue dissection system (PEAK Plasmablade®). Total seroma volume, drainage duration, estimated blood loss, operative time, post-operative hospital stay, pain score, number of aspiration post tube drain removal and other post-operative complications were recorded and were compared between two group using SPSS Statistics for Mac version 21.

Results: Average age in the traditional electrosurgery (control) group was 59.32±2.09 years and was 60.44±2.09 years in the low thermal dissection (experimental) group. Overall, both groups had similar types of operation. Median drainage volume was 590 ml in the traditional electrosurgery group and 790 ml in the low thermal dissection group. The median drainage duration in the traditional electrosurgery group was 4 days which were similar to the low thermal dissection group.

Conclusion: The low thermal tissue dissection system demonstrated no superior advantages compared with the traditional electrosurgery system in mastectomy patients.

Keywords: Low thermal tissue dissection, Mastectomy, Traditional electrosurgery, Seroma

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Breast cancer is one of the most common cancers among Thai women[1]. Treatments of breast cancer are multidisciplinary; including surgery, chemotherapy, hormonal therapy and recent targeted therapy. In early breast cancer, surgery remains a major role in curative treatment of breast cancer. Among various types of surgery, mastectomy is still an effective surgical option.

However, mastectomy may result in some unexpected complications; including post operative bleeding, post operative infection and seroma which is one of the most common complications[2]. Seroma may cause pain or infection and that might lead to deterioration of patient's quality of life and more serious situation where further systemic chemotherapy may be delayed. There were many previous studies aiming to identify factors related to seroma production[3]. One factor mentioned was thermal damage from electrocautery, which leads to improvement and creation of new surgical electrocautery devices.

Various novel surgical equipments have been used in breast surgery to reduce the post-operative seroma. Low thermal tissue dissection system (PEAK Plasmablade®) is a recent instrument helping in control bleeding effectively during surgery with low thermal damage[4,5]. The device uses brief and precise radiofrequency (RF) energy pulses to cut and coagulate soft tissue. RF energy, combined with a proprietary insulation technology, enables the device dissect with the precision of a scalpel, and the bleeding control of traditional electrosurgery, while producing minimal thermal damage to surrounding tissue, thus may result in less tissue damage and less seroma production[6,7].

However, significant benefit of the device from previous studies was controversial, but previous studies were from Europe and USA. Therefore, this study is designed to demonstrate the benefit of this system in Asian population where breast volume may affect the result of seroma formation.

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The primary objective is to compare total drainage volume between patients underwent total mastectomy using traditional electrosurgery and low thermal tissue dissection system.

The secondary objectives were to compare the following parameters between two groups: drainage duration, estimated blood loss, operative time, post-operative hospital stay, pain score, number of aspiration post tube drain removal and other post-operative complications.

Materials and Methods

This study is a prospective randomized controlled trial, conducted at Siriraj Hospital from February 2017 to November 2017. Sample size was calculated from estimating drainage volume from samples of population who previously underwent total mastectomy in Siriraj Hospital.

A total of 50 patients who were scheduled for mastectomy (with or without axillary dissection) were randomized into 2 groups; traditional electrosurgery group (TE) and the low thermal tissue dissection group (PB). Patients underwent surgery performed by specialized breast surgeons, and were then followed-up at the Breast Clinic Siriraj hospital.

Inclusion criteria were patients aged ≥18 years old, who were scheduled for either total mastectomy (TM) with sentinel lymph node biopsy (SLNB) or with axillary lymph node dissection (ALND).

Enrolled patients were randomized into two groups. The study group include 25 patients who received low thermal tissue dissection machine (PEAK Plasmablade®, Medtronic Co., Ltd., Minessota, USA) during mastectomy. The control group include 25 patients who received traditional thermal dissection system (Force FX®, Medtronic Co., Ltd., Minessota, USA). The study was approved by the Siriraj Institutional Review Board (SIRB) (621/2559(EC1).

Total seroma volume, drainage duration, estimated blood loss, operative time, post-operative hospital stay, pain score, number of aspiration post tube drain removal and other post-operative complications were recorded. The results in this study were analyzed using IBM SPSS Statistics for Mac version 21. The statistics used to compare studied parameters were tested using Mann-Whitney U test for nonparametric data, Two-tail independent t-test for normal distributed parametric data, Chi-square test for categorical data.

Results

This study included 50 female patients with average age of 59.32±2.09 in the traditional electrosurgery group and 60.44±2.09 years in the low thermal dissection group. Average BMI in the traditional electrosurgery group was 26.20±1.09 and in low thermal dissection group was 25.00±0.89. Both groups showed no statistical difference in patients' BMI and breast weight. There was no significant difference in patient characteristics between the two groups (Table 1).

Overall in traditional electrosurgery group there were 18 patients who received only sentinel lymph node biopsy and 7 patients who received axillary lymph node dissection. In low thermal group there were 14 patients who received sentinel lymph node biopsy and 11 patients who received axillary lymph node dissection.

Median drainage volume was 590 ml in the traditional electrosurgery group and was 790 ml in the low thermal dissection group. The median drainage duration in the traditional electrosurgery group was 4 days which was no significant difference from the low thermal dissection group. Median operative time was 75 minutes in the traditional electrosurgery group and was 70 minutes in the low thermal group. Median estimated blood loss was 30 ml in both groups. Median hospital stay after operation was 3 days in traditional electrosurgery group and 4 days in low thermal dissection group. Median post-operative aspiration of seroma was 2 times in traditional electrosurgery group and 4 times in low thermal dissection group. There was no statistical significance between either groups in operative time, estimated blood loss, total post-operative seroma production, post-operative stay, drainage tube duration, post-operative aspiration attempts and post-operative complications. There was one patient who had post-operative bleeding in the low thermal

Table 1. Patient characteristics and clinical data, comparing between two groups

	Traditional electrosurgery (n = 25)	Low thermal dissection (n = 25)	*p*-value
Age* (year)	59.32±2.09	60.44±2.09	0.786
Body mass index*	26.20±1.09	25.00±0.89	0.398
Underlying disease			
Diabetes mellitus	6 (24%)	2(8%)	0.127
Hypertension	12 (48%)	8 (32%)	0.153
Breast weight (g)#	720 (195 to 1,000)	550 (145 to 960)	0.265
Previous radiotherapy (%)	0 (0)	2 (8)	0.153
Previous systemic chemotherapy (%)	2 (8)	2 (8)	1.000

* mean ± SD, # median (range), NS = Not significant

dissection group (Table 2).

Discussion

Seroma is one of the bothersome complications after mastectomy. It may decrease the patient's quality of life[2]. There was moderate evidence to support the risk of seroma formation in individuals with greater body weight or in patients who underwent modified radical mastectomy might have more amount of seroma formation post-mastectomy. Also, there was study by Porter et al described about the use of electrocautery which was significantly associated with incidence of seroma production up to 30%[8]. Since the seroma production is a multi-factorial causes, we in this study controlled the factor which we can manipulate. We decided to control the surgical equipment factor. There were several surgical devices that were compared with traditional electrosurgery system such as laser scalpel or ultrasonic scalpel. Those previous studies showed no significant effect on seroma formation. However, there were few reports compared to the traditional electrosurgery with the new low thermal dissection system.

The low thermal tissue dissection system was introduced in a few years. Fine et al has published a case report which suggested that the low thermal dissection system for subcutaneous tissue dissection may help to reduce the risk of skin flap necrosis along with less seroma production[5].

Our study is the first prospective randomized controlled trial comparing total drainage volume following mastectomy between traditional electrosurgery and low thermal tissue dissection system conducted in Asian population. Findings from our study could not demonstrated advantages of the novel low thermal tissue dissection system. The results demonstrated that there is no significant difference in post-operative seroma production and intra-operative parameters such as estimated blood loss, operative time, post-operative clinical short-term outcomes and post-operative complications. Also, the drainage duration is similar in both groups.

Our findings contrasted with those reported from previous study by Dogan et al which claimed that Plasmakinetic cautery has brought a better outcome by reducing seroma in post-mastectomy patients[4]. On the other hand, there were also other studies from Brgoch et al, and Alptekin et al. reported that the low thermal dissection system might not be an alternative for reducing seroma production[9,10].

The difference of our results from previous studies are possibly due to the lymph node dissection method and the dissimilarity of the average breast weight of the sample population. In our study, we included both patients who underwent sentinel lymph node biopsy and axillary lymph node dissection. More patients underwent axillary lymph node dissection in the low thermal tissue dissection group than the traditional group (Low thermal group; ALND = 44%, Traditional group: ALND = 28%). This might be responsible for higher drainage volume in low thermal tissue dissection group. The average breast weight in previous study from Turkey was 1,152 grams in traditional electrosurgery group and was 1,090 grams in the low thermal group. Meanwhile in our study, the average breast weight was 720 grams in traditional electrosurgery group and was 550 in the low thermal group. The difference of the breast volume might also be one of the factors in the difference in the results.

Conclusion

This study demonstrated no statistically significant advantages of the low thermal tissue dissection system over the traditional electrosurgery system in mastectomy patients.

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Table 2. Comparison of results between two groups

	Traditional electrosurgery (n = 25)	Low thermal dissection (n = 25)	*p*-value
Procedure			0.243
TM with SLNB	18 (72%)	14 (56%)	
TM with ALND	7 (28%)	11 (44%)	
Drainage volume (ml)	590 (135 to 2,144)	790 (92 to 2,150)	0.621
Drainage Duration (days)	4 (2 to 16)	4 (2 to 11)	0.510
Estimated blood loss (ml)	30 (5 to 100)	30 (10 to 100)	0.562
Operation time (mins)	75 (45 to 170)	70 (40 to 140)	0.271
Hospital stay (days)	3 (2 to 12)	4 (2 to 11)	0.928
Pain score	0 (0 to 3)	0 (0 to 3)	0.912
Aspiration after drainage removal (times)	2 (0 to 9)	4 (0 to 9)	0.399
Other post-operative complications			
Bleeding	0	1 (4%)	0.609
Skin flap necrosis	0	0	1.000

TM = total mastectomy, ALND = axillary lymph node dissection

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What is already known on this topic?

Controversy remains unclear in the use of low thermal dissection system during mastectomy for the treatment of breast cancer.

What this study adds?

Results from this study cannot support the use of recent low thermal dissection system in terms of reducing seroma production.

Potential conflicts of interest

PEAK Plasmablade® used in this study was supported by Medtronic co., Ltd.

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การเปรียบเทียบการใช้เครื่องจี้ไฟฟ้าแบบดั้งเดิมและเครื่องจี้ไฟฟ้าแบบความร้อนต่ำในการผ่าตัดเต้านม: การศึกษาแบบสุ่มและมีกลุ่มควบคุม

มงคล บุญศรีพิทยานนท์, พิริฐิมา วชิรปราการสกุล, พงษ์เทพ พิศาลธุรกิจ, ธนากร ธราพงษ์พันธ์, สืบวงศ์ จุฑากิสิทธิ์

วัตถุประสงค์: เพื่อทำการเปรียบเทียบปริมาณคัดหลั่งในผู้ป่วยที่ได้รับการผ่าตัดเต้านมออกทั้งหมด ระหว่างกลุ่มที่ได้รับการใช้เครื่องจี้ไฟฟ้าแบบดั้งเดิมและเครื่องจี้ไฟฟ้าแบบความร้อนต่ำ

วัสดุและวิธีการ: เป็นการศึกษาแบบสุ่มและมีกลุ่มควบคุม โดยรวมผู้ป่วยที่ได้รับการผ่าตัดเต้านมออกทั้งหมดจำนวน 50 ราย ที่สาขาศัลยศาสตร์ ศีรษะ คอ และเต้านม โรงพยาบาลศิริราช ผู้ป่วย 25 รายได้รับการผ่าตัดเต้านมออกทั้งหมดโดยใช้เครื่องจี้ไฟฟ้าแบบดั้งเดิม ในขณะที่ผู้ป่วยอีก 25 ราย ได้รับการผ่าตัดโดยใช้เครื่องจี้ไฟฟ้าแบบความร้อนต่ำ (พีคพลาสมาเบลด) จำนวนสารคัดหลั่งรวม จำนวนวันในการใส่สายระบาย ประมาณการเสียเลือด ระยะเวลาในการผ่าตัด จำนวนวันนอนโรงพยาบาล คะแนนความปวด จำนวนครั้งในการดูดระบายน้ำเหลืองหลังถอดสายระบายออก และภาวะแทรกซ้อนอื่น ๆ ภายหลังการผ่าตัดได้ถูกบันทึกไว้ และนำมาคำนวณเปรียบเทียบกันระหว่างทั้งสองกลุ่ม โดยใช้โปรแกรมสถิติ เอสพีเอสเอส

ผลการศึกษา: อายุเฉลี่ยของผู้ป่วยในกลุ่มควบคุมที่ได้รับการผ่าตัดโดยใช้จี้ไฟฟ้าแบบดั้งเดิม คือ 59.32±2.09 ปี และกลุ่มทดลองที่ได้รับการใช้เครื่องจี้ไฟฟ้าแบบความร้อนต่ำ คือ 60.44±2.09 ปี โดยรวมแล้วทั้งสองกลุ่มได้รับชนิดของการผ่าตัดไม่แตกต่างกัน ค่ามัธยฐานของจำนวนน้ำเหลืองที่ได้รับการระบายเท่ากับ 590 มิลลิลิตร ในกลุ่มที่ได้รับการผ่าตัดด้วยเครื่องจี้ไฟฟ้าแบบดั้งเดิม และเท่ากับ 790 มิลลิลิตรในกลุ่มที่ได้รับการผ่าตัดด้วยเครื่องจี้ไฟฟ้าแบบความร้อนต่ำ ค่ามัธยฐานสำหรับวันที่นอนโรงพยาบาลเท่ากับ 3 วัน ในกลุ่มที่ได้รับการผ่าตัดด้วยเครื่องจี้ไฟฟ้าแบบดั้งเดิม และเท่ากับ 4 วันในกลุ่มที่ได้รับการผ่าตัดด้วยเครื่องจี้ไฟฟ้าแบบความร้อนต่ำ

สรุป: เครื่องจี้ไฟฟ้าแบบความร้อนต่ำไม่สามารถแสดงผลการรักษาที่ดีกว่า เมื่อเทียบกับการใช้เครื่องจี้ไฟฟ้าแบบดั้งเดิม ในการผ่าตัดเต้านมออกทั้งหมด