Surgical Advantage of Ultrasonically Activated Devices During Axillary Lymph Node Dissection for Breast Cancer

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**Purposes:** Axillary dissection is the gold standard for axillary lymph node metastasis in breast cancer patients. We compared surgical outcomes between ultrasonically activated devices (USADs) and thermal scalpel (TS) during axillary lymph node dissection in breast cancer patients.

**Methods:** We conducted a retrospective analysis for 73 patients using TS between June 2012 to May 2016 and 63 patients using USADs between June 2016 to January 2019 in the breast cancer patients who received axillary dissection. Surgical outcomes were compared among the groups statistically.

**Results:** Median operative time in the USAD group was significantly shorter than in the TS group (136 versus 182 minutes, \( P < 0.001 \)). Intraoperative blood loss in the USAD group was also significantly lower than in the TS group (35 versus 120 mL, \( P < 0.001 \)). Furthermore, the total drainage discharge in the USAD group was also significantly lower than in the TS group (570 versus 700 mL, \( P = 0.016 \)). The lymphedema frequency in the USAD group was significantly less than in the TS groups (1 of 63 versus 7 of 73, \( P = 0.0296 \)).

**Conclusion:** The USADs could improve surgical outcomes, such as lymphedema, for axillary dissection of the breast cancer surgery compared with TS.

**Key words:** Breast cancer – Axillary lymph node dissection – Ultrasonically activated device

Breast cancer is a common disease among women worldwide. Annually, more than 90,000 women are diagnosed with breast cancer in Japan. According to a 2016 survey of the Japan Breast Cancer Society, axillary lymph node dissection (ALND) was performed in approximately 30%

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of breast cancer surgeries. Although various new drugs are constantly developed, surgery remains the main treatment in breast cancer.

Recent clinical trials imply that axillary dissection proved to be unnecessary under specific conditions. On the other hand, local control by axillary dissection has also been reported to be important for improving prognosis, and it remains an important strategy for breast cancer patients.

The problem of the ALND was that it had a long operative time with more blood loss, more postoperative drain discharge, and various complications, such as seroma, reoperation, skin necrosis, and lymphedema. Technique of the vessel sealing during surgery was a main task to improve surgical outcomes. A lymphedema is a major complication after ALND to deteriorate mental satisfaction and physical function in the breast cancer patients. The reported incidences of the lymphedema were about 15.0% to 20.0% when the electric scalpel (ES) was applied for ALND during breast cancer surgery. We need improvement in methods to reduce lymphedema.

We have used a thermal scalpel (TS) for ALND traditionally. TS believed to achieve a higher sealing effect with less tissue damage than classic ES because of mild heat, around 300°C. The TS was invented by Robert Shaw at Stanford University and was patented in 1978 as a simultaneously heat-coagulable blade to reduce blood loss, postoperative drain discharge, and nerve injury. We think that operative time, blood loss, postoperative drain discharge, and the incidence of the lymphedema can be reduced using TS during ALND, but we our daily practice has not provided us with enough outcomes. Although both ES and TS are contact devices and have shown some effect, it was not as dramatically beneficial as the changes that USAD has brought. Therefore, we have conducted a study for USAD in breast cancer surgery to solve clinical issues, such as lymphedema, which occurs in about 10% of the patient population, even in the use of TS.

The ultrasonically activated device (USAD) was covered under national Japanese insurance for laparoscopic and thoracoscopic surgery in 1998. The USAD was widely adopted in various surgical procedures. Compared with conventional techniques, the USAD demonstrated significant reductions in operative time (−27.5 minutes, \(P < 0.001\)), intraoperative blood loss (−93.2 mL, \(P < 0.001\)), and drainage volume (−138.8 mL, \(P < 0.001\)) in gastrectomy and D2 lymphadenectomy for gastric cancer. Intraoperative blood loss was significantly less in the ultrasonic dissection, 140.8 mL, versus standard electrosurgery, 182.6 mL (\(P = 0.032\)) in laparoscopic colorectal surgery. Energy-based sealing has developed rapidly during the last decade, and many new devices have become available in the daily clinical field. National Japanese insurance covered USADs for breast surgery to dissect axillary lymph nodes in 2019. Harmonic scalpels (Ethicon, Somerville, New Jersey) consist of a generator that sends electrical energy to a hand piece, where the energy is converted to mechanical energy in the form of vibrations via a piezoelectric crystal system. The blade vibrates axially at a constant frequency of 55,000 Hz. To obtain better surgical outcomes, we tried to use the USAD during ALND in the breast cancer surgery.

The clinical outcome of the USAD during ALND in breast cancer surgery has not been proven yet. The advantages of using a USAD are that it is expected to reduce operative time and serous discharge after surgery. Therefore, it could result in fast recovery without surgical complications. The aim of this study was to identify the surgical advantage of the USAD compared with the classic TS method during ALND in breast cancer surgery. We conducted a retrospective cohort analysis using USAD in the breast cancer patients who received ALND.

Methods

Patients

A retrospective analysis of 136 consecutive breast cancer patients who underwent breast surgery with axillary dissection in our single hospital was conducted. From June 2012 to May 2016, 73 consecutive patients who had TS applied were analyzed as a historical control group. From June 2016 to January 2019, 63 consecutive patients who applied USAD were analyzed as an interventional group. The total number of the patients who had breast cancer surgery performed by certified surgeons in our hospital and the patient selection are shown in Fig. 1. The protocol of this study has been approved by the internal review board (no. 282-71) in accordance with the Declaration of Helsinki. The results were evaluated in terms of operative time, blood loss, drainage output, time to axillary drain removal, and hospital stay as intraoperative and postoperative results. We examined seroma, reoperation, skin necrosis, and lymphedema as complication results.

Surgical techniques

We applied a USAD to dissect around the axillary vein, the long thoracic nerve, and the thoracic dorsal...
vein. We placed two 10Fr SB VACTM (Sumitomo Bakelite, Tokyo, Japan) drains in the axilla and chest wall after surgery. Operative time was recorded by the anesthesiologist. The blood loss was calculated by the operating room staff. The drain was removed when the discharge was less than 40 mL per 24 hours. The operative time, intraoperative blood loss, drainage output, time to axillary drain removal, and length of hospital stay were evaluated, and postoperative complications have been evaluated more than for a year. Lymphedema definitions were limb circumference increase ≥2 cm, as compared with baseline and/or the contralateral limb. The certified surgeons performed breast cancer surgery for all patients in this study.

Statistical analysis

We compared the clinical-pathologic parameters, operative time, and blood loss using the χ² or Mann-Whitney test whenever it was appropriate. A value of P < 0.05 was considered to indicate statistical significance. JMP11 software (SAS Institute, Cary, North Carolina) was used for statistical analysis.

Results

Patient characteristics are shown in Table 1. Clinical background, such as age, body mass index, tumor size, history of the neoadjuvant chemotherapy, type of the surgical procedure, and the number of dissected lymph nodes, was not significantly different among the groups.

Intraoperative variables and postoperative clinical outcomes are shown in Table 2. Median operative time in the USAD group was significantly shorter than that in the TS group (136 versus 182 minutes, P < 0.001). Intraoperative blood loss in the USAD group was also significantly lower than in the TS group (35 versus 120 mL, P < 0.001). As far as postoperative outcomes are concerned, drainage discharge in the USAD group was significantly lower than that in the TS group (570 versus 700 mL, P = 0.016). On the other hand, time to axillary drain removal (P = 0.371) and hospital stay (P = 0.219) were not significantly different between the 2 groups.

Table 1  Patient characteristics

|                      | TS (n = 73) | USAD (n = 63) | P value |
|----------------------|------------|---------------|---------|
| No. of patients      | 73         | 63            |         |
| Age, y               | 56 (31–93) | 57 (29–88)    | 0.76    |
| BMI                  |            |               | 0.87    |
| ≤20                  | 17         | 19            |         |
| 20 to ≤25            | 33         | 26            |         |
| >25                  | 23         | 18            |         |
| T                    |            |               | 0.06    |
| Tis/T1/T2            | 63         | 57            |         |
| T3/T4                | 10         | 6             |         |
| NAC                  |            |               | 0.85    |
| +                    | 40         | 29            |         |
| –                    | 33         | 34            |         |
| Surgical procedure   |            |               | 0.31    |
| BCS                  | 15         | 13            |         |
| MRM                  | 58         | 50            |         |
| No. of lymph nodes   | 15 ± 6.1   | 15 ± 8.2      | 0.98    |

BCS, breast conservation surgery; BMI, body mass index; MRM, modified radical mastectomy; NAC, neoadjuvant chemotherapy.
Postoperative complications are presented in Table 3. Complications above grade 2 and more in the Clavien-Dindo classification system occurred in 4 patients (6.35%) in the USAD group and 20 patients (27.4%) in the TS group. The frequency of seroma formation, reoperation, and skin necrosis was not significantly different between the 2 groups. On the other hand, lymphedema incidence in the USAD group was significantly less than that in the TS groups (1 of 63 versus 7 of 73, \( P = 0.0296 \)).

Discussion

We showed that median operative time in the USAD group was significantly shorter than in the TS group in this study. In addition, intraoperative blood loss and drain discharge in the USAD group were significantly lower than in the TS group. The incidence of the lymphedema in the USAD group was less than that in the TS group.

However, the surgical benefit of the energy devices for breast cancer surgery was mostly unknown. This study presented a clear clinical benefit of the USAD in breast cancer surgery. Some studies\textsuperscript{15–24} compared the clinical outcomes between conventional ES and various energy devices, especially harmonic devices. Meta-analysis has proved a clinical benefit of the energy devices, which could reduce drainage discharge, operative time, and intraoperative blood loss.\textsuperscript{25} In this report, the average drainage discharge was 587 mL in the USAD group, similar to our study (570 mL for USAD). On the other hand, the intraoperative blood loss in the USAD group was 300 mL, which was more than that in our study (35 mL). There was no previous report comparing the energy device with the TS. We have used TS for an extended period because we believe that the low temperature of the TS could be safer for protecting against nerve injury compared with the ES. Another study\textsuperscript{26} reported that the intraoperative blood loss using ES was 211 mL (120 mL for TS in this study), and the average drainage discharge was 1091 mL (700 mL for TS in this study). There was no complication of nerve injury in either group. This study was the first report to prove the clinical advantage of the USAD compared with the TS during ALND in breast cancer surgery.

The reason for reducing operative time and blood loss could be a unique structure of the USAD. The fine tip of the USAD was a shape similar to that of pediatric Kelly forceps, which are used for meticulous surgery. Therefore, USAD could achieve tight vessel sealing and a fine dissection of the tissue simultaneously. Surgeons could save time for ligating sutures and changing surgical instruments at any step during surgery. The compressed vessels during the sealing in of the USAD could obtain secure hemostasis compared with the ES or TS. All these effects of the USAD could obtain surgical benefits.

We did not prove the difference in time to axillary drain removal and hospital stays. Most patients were discharged on schedule regardless of the presence of the drain. In contrast, drain discharge in the USAD was significantly less than that in the TS. It suggests our policy for removing the drain should be reconsidered. Another reason could be that the population of this study could be too small to prove the difference.

A limitation of this study was a historical bias of recruiting patients, the retrospective cohort study, and the study in a single institute. The indication for dissecting axillary lymph node decreased due to the progression of sentinel lymph node biopsy. The neoadjuvant chemotherapy also might reduce the stage of breast cancer, although it was not significantly different between the groups. But there was no difference in patient characteristics between the USAD group and the TS group in this study.

Finally, our promising results support an expectation to prevail in using USAD in routine clinical use in the future. Therefore, we should conduct a multicenter prospective cohort study using USAD in breast cancer patients who received ALND.

Conclusion

The use of USAD in axillary dissection of breast cancer has provided useful outcomes, suggesting that it may become a standard device in the future.
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