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Ultrasonic scissors decrease postoperative bleeding complications in mastectomy: A retrospective multicenter cohort study on 728 patients

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ABSTRACT

Introduction: The aim of this study was to evaluate the rate of postoperative bleeding complications (primary outcome) and any other surgical complications (secondary outcome) in mastectomy between two surgical instruments, ultrasonic SonoSurg® scissors (US) and traditional electrocautery (EC).
Materials and methods: In total 728 patients undergoing mastectomy in two adjacent university hospitals were retrospectively evaluated in terms of postoperative bleeding episodes, surgical site infections, skin flap necrosis, and any reoperations for 30 postoperative days. A propensity score matching was performed to acquire balanced groups. Patients consuming medications affecting hemostasis were excluded from the study. A multivariable logistic regression analysis was conducted to define the odds ratio (OR) for each complication separately. A cost analysis was performed.
Results: The rate of postoperative bleeding complications was significantly lower in patients operated with US (0.3% vs 11.5%, OR 0.020, 95% CI 0.034–0.14) when compared to EC.
The rate of surgical site infections (OR 0.65, 95% CI 0.35–1.23) was similar with both instruments, but there were less skin flap necroses (OR 0.35, 95% CI 0.13–0.98) in US group. For any reoperation, the OR for US was 0.13 (95% CI 0.046–0.39), mainly due to the lower number of acute bleeding complications. Even though the US instrument is more expensive than EC, the total cost of the treatment is lower in patients operated with US (3419 vs. 3475 euro).
Conclusions: US seems to be associated with a lower risk of bleeding complications in mastectomy.

1. Introduction

Mastectomy bears a higher risk of postoperative complications, when compared to breast conserving surgery (BCS) [1,2]. Complications i) delay the initiation of adjuvant treatment, which worsens the prognosis, ii) add morbidity and anxiety for the patient and iii) increase the cost of the treatment [3–5]. Therefore, all measures to reduce the number of complications are necessary.

The most common complications after mastectomy are postoperative bleeding, surgical site infection (SSI), and skin flap necrosis (SFN) [6–9]. Postoperative seroma formation is frequently encountered after mastectomy, and some consider it as a complication, whereas many others as an inevitable nuisance with few effective methods for prevention [6,10]. The only successful treatment for seroma formation seems to be repeated aspiration, and surgical interventions are only rarely beneficial [11].

Several studies have investigated the effect of the surgical instrument used in mastectomy on the rate of postoperative complications. A traditional scalpel is nowadays seldom used, since electrocautery (EC) offers an economical alternative with less intraoperative bleeding [12]. Some more advanced technologies, such as bipolar scissors and ultrasound energy instruments (US) have also been used in mastectomy [13]. The most investigated ultrasound instrument appears to be Harmonic Scalpel® (Ethicon, USA) [14,15]. Ultrasonic SonoSurg® scissors (US) is an alternative ultrasonic instrument of another manufacturer (Olympus Medical Instruments, Tokyo, Japan). To date, it has not been investigated in trials considering breast surgery.

1.1. Background and aim of this study

Turku University Hospital and Helsinki University Hospital are

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two adjacent university hospitals with many similarities, including demographic similarity between the patients treated, and common national treatment guidelines for breast cancer.

In Turku University Hospital, US was introduced in mastectomy in the early 2000's. US was observed to decrease the number of bleeding complications, which encouraged us to introduce the same day mastectomy pathway.

In Helsinki University Hospital, EC is used in most patients undergoing mastectomy. Patients stay one night in the hospital after the surgery.

The aim of this study was to compare the rates of postoperative mastectomy complications between EC and US in these two adjacent high-volume breast cancer centers and to evaluate the total cost of the treatment.

2. Materials and Methods

One of the participating hospitals introduced US (US Group) in mastectomy and the other used EC (EC Group). Until the introduction of US, the surgical protocol was compatible in both hospitals. The comparison was made in terms of postoperative bleeding episodes, SSI, SFN, and overall re-operations for 30 postoperative days. A cost analysis was performed.

2.1. Technical considerations of EC and US

2.1.1. Electrocautery

In EC, the instrument either cuts or coagulates the tissue by heating it. The effect depends on the characteristics of the electric current used. The coagulation effect is achieved using interrupted current mode which “burns” the tissue (obliterative coagulation) at high temperatures. The tissue is dehydrated and oxidized, forming eschar sealing the bleeding area. The cutting effect is achieved by using continuous current vaporizing the tissue at a temperature of 250–350 °C, as the tissue requires a temperature of 200 °C to be vaporized [16–19]. Due to the high temperature, EC also causes thermal injury to the surrounding tissue not intended to be dissected [20].

In breast surgery and especially mastectomy, the wound complications are supposedly encountered more often in EC dissection, since the high temperature easily damages the subdermal vascular plexus. The use of EC is also shown to be associated with a higher rate of seroma formation, assumably since the technique does not enable complete occlusion of lymphatic channels [21].

2.1.2. Ultrasonic technology

The operating principle of ultrasonic instrument is not based on electric current and heating, but to the high frequency vibration of the instruments cutting blade. The vibration is transmitted to the tissue, resulting to denaturing of collagen molecules and forming of a coagulum. The mechanism causes notably less heating compared to EC [19,22,23]. The SonoSurg® instrument investigated in the present study has been previously investigated in a trial comparing different instruments in thyroid surgery. In that trial, the mean temperature of cutting blade was 81.5 °C with the medium power setting and 99.2 °C with the maximum power, and the highest temperature measured was 114.41 °C [24]. The relatively low temperature with limited lateral spreading of heat causes less thermal injury to adjacent tissues compared to EC, which should reduce the number of skin flap complications [25,26]. Furthermore, the scissor mechanism of the instrument allows grasping tissues, such as blood vessels for more controlled hemostasis. The direct application of the device produces dissection and hemostatic effect, with obliteration of blood vessels up to 7 mm. After obliteration, the burst pressure for 4–5 mm arteries is shown to be 900 ± 579 mmHg and 734 mmHg for 5–7 mm arteries ensuring superior hemostasis [27,28].

2.2. Patient selection

During the study period (from January 1st, 2012 to June 30th, 2018) all female patients undergoing unilateral mastectomy without immediate reconstruction were reviewed. In EC Group, only information of the patients who received adjuvant chemotherapy was available. Patients who i) had received neoadjuvant chemotherapy, ii) had underwent previous breast surgeries or iii) had medication affecting hemostasis or had postoperative thrombosis prophylaxis were excluded from the study.

2.3. Sample size

We expected the rate of bleeding complications to be 3% in US Group and 9% in EC Group. To be able to prove this with a probability of 0.05 for a type-I error and power of 90%, the sample size required is 654 patients [29].

2.4. Collected information

For all patients, information of age, American Society of Anesthesiologists (ASA) Physical Status Classification, body mass index (BMI), current smoking, diabetes and the tumour size were recorded.

Considering surgical procedure, antibiotic prophylaxis, performed axillary procedure, operation time (min) and the amount of bleeding in surgery (ml) were recorded. The operation time was defined as the time from the first skin incision to the final closure of the wound.

All patient records for 30 postoperative days were reviewed, and any surgery-related complications (bleeding/haematoma, SSI, SFN, reoperations) were recorded. Seroma formation demanding mere aspiration was not considered as a complication. Diagnoses of SSI were re-evaluated according to the CDC (Centers for Disease Control and Prevention) criteria [30,31]. A clinical diagnose of SFN and bleeding/haematoma were made by attending surgeon or another physician.

The research protocol of the study was approved by Helsinki University Hospital and the Hospital District of Southern Finland (T218/2019).

2.5. Perioperative protocol

In US Group, the outpatient mastectomy pathway of care was introduced in 2013, and since then approximately 30% of the patients have been treated as outpatients. The rate of complications has been similar before and after the introduction of the outpatient mastectomy [32]. Antibiotic prophylaxis for all patients was used in US Group since April 2016. In EC Group and in US Group before April 2016, antibiotic prophylaxis was used based on surgeon's preference.

The perioperative protocol during the study period is illustrated in Fig. 1.

2.6. Surgical technique

An elliptical incision was planned. The skin incision was made with a scalpel. The skin flaps were prepared either with US (US Group) or EC (EC Group). In EC Group a bipolar forceps were used for hemostasis, and when axillary lymph node dissection (ALND) was performed, usually a bipolar instrument, most often LigaSure®, (Medtronic, Dublin, Ireland) was used.

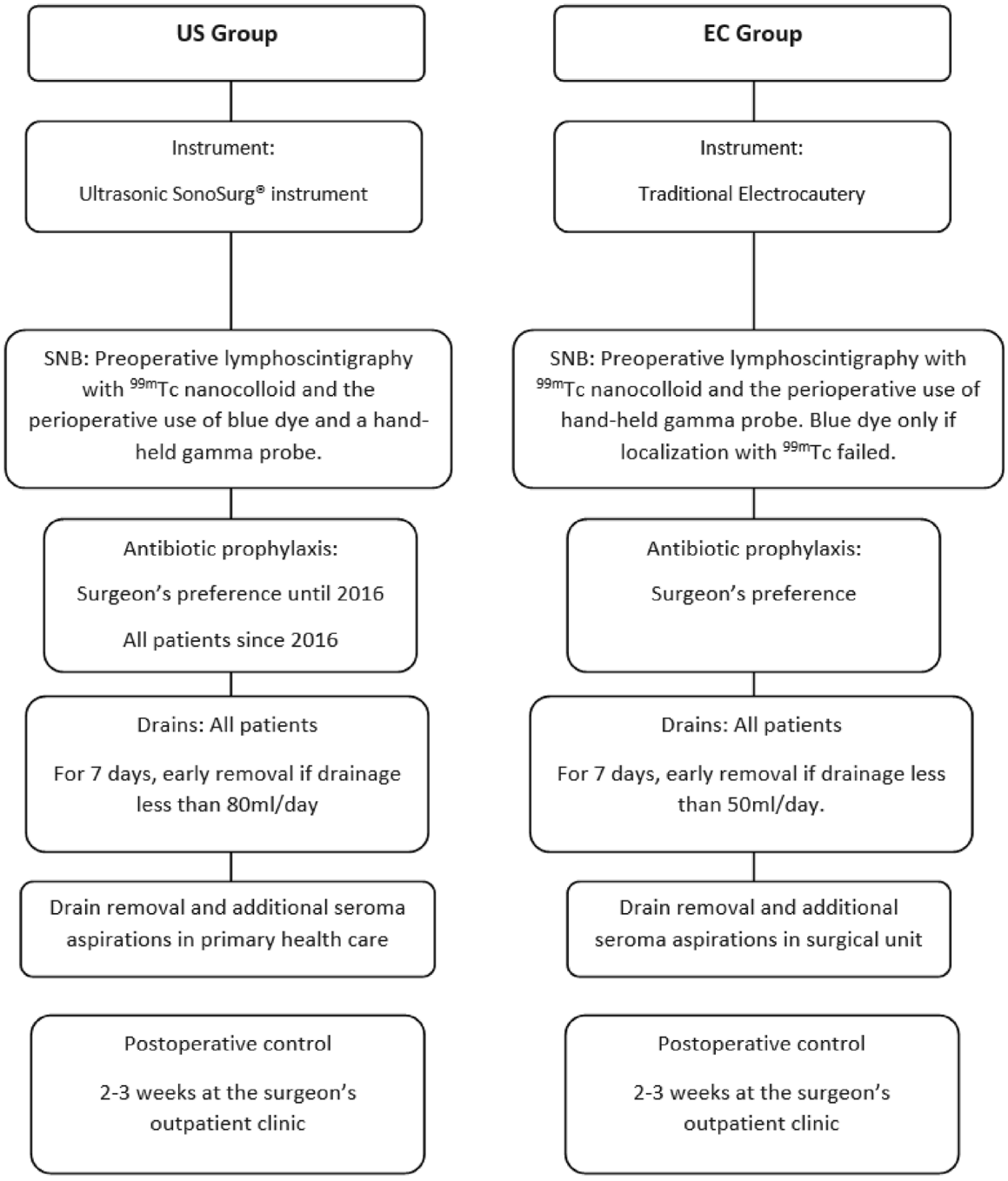

Fig. 1. The perioperative protocol followed in mastectomy.
LWMH = Low molecular weight heparin, SNB = sentinel node biopsy.

The dissection was made following the plane of superficial fascia, leaving skin flaps approximately 5–10 mm in thickness. The breast tissue was removed with the pectoralis fascia. Sentinel node biopsy (SNB) was performed according to the local practice (Fig. 1). The frozen section study of excised sentinel nodes and immediate ALND for sentinel-positive patients were used routinely in all patients until 2018, but only in selected cases after 2018 according to the updated guidelines. When ALND was performed, the thoracodorsal pedicle and the long thoracic nerve were preserved. Level II lymph nodes were dissected in all patients undergoing ALND, and level III if multiple lymph node metastases were known, or macroscopically suspicious lymph nodes were detected.

One drain was inserted from a separate stab and secured with a suture to the skin. In wound closure, subdermal tissue was approximated with absorbable sutures and the skin was closed with intracutaneous continuous sutures.

The patients were discharged according to the local practice. Drains were usually removed a week after the operation, or earlier if the amount of seroma was low. A postoperative check-up control was instructed two to three weeks after the operation. Patients were given contact information to the hospital in case of any concerns.

2.7. Complication data collection

The patient records for 30 postoperative days were evaluated. Information of any deviation from the normal course of recovery was collected from the electronic patient information registers. Information of antibiotic prescriptions was acquired from national Prescription Centre. Postoperative complication diagnoses (T81 in ICD-10) or any infections registered in the Hospital Districts Antibiotic and Infection Register (SAI) were acquired. Laboratory test information was collected, and any blood transfusions given, or bacterial culture samples taken (purulent drainage, blood) were recorded.

2.8. Statistical analysis

Patient characteristics between EC and US groups were compared using chi-square test (categorical variables), two-sample *t*-test (continuous variables with normal distribution) or Wilcoxon test (continuous variables with non-normal distribution). As the primary data proved to be extremely heterogenous, a propensity score matching based on all baseline characteristics was performed. One-to-one matching without replacement was used to balance patients by the nearest-neighbour principle with a caliper size of 0.2. Matched groups were compared to ensure all baseline characteristics were balanced, indicating no need for double adjustment. A bivariate analysis was performed to identify predictors of postoperative complications.

All complications were individually compared with all patient and operation related variables. The variables having a relationship $p < 0.15$ were qualified to multivariable logistic regression analysis. In logistic regression analysis, the variable having the highest p-value was disqualified one by one until only statistically significant variables ($p < 0.05$) were remaining. As a result, the odds ratio (OR) for any complication in the US group vs. EC group was defined.

All data were analysed using JMP 15 Pro (SAS Institute Cary, North Carolina, USA) analysis software except the propensity score matching, which was performed using R statistical software (version 4.2.0, R core Team, Vienna, Austria).

3. Results

In total, 1479 patients underwent mastectomy during the study period, 854 patients with US and 625 patients with EC. Baseline demographics were compared, and it was detected that due to having information of only patients undergoing adjuvant chemotherapy in EC Group, the demographics were highly different. For example, the mean age of the patients was 69(±15) years in US Group and 56(±12) years in EC Group, respectively (data in detail not provided). To acquire balanced cohorts, a propensity score matching was performed (Fig. 2). After propensity score matching, there was 364 patients in both groups, fulfilling the requirement of the sample size calculation.

The characteristics of the patients and information of the surgical procedure are presented in Table 1.

The number of complications is presented in Table 2 and the OR for all complications separately is shown in Table 3. The variables used in logistic regression analysis are the ones listed in Table 1.

The increased number of reoperations in EC Group is explained mostly by the acute bleeding complications, as 20 of the 28 patients undergoing re-operation had a bleeding complication. In total 20 of the 42 bleeding complications (48%) occurred within 24 h of the primary operation. ALND did not increase the risk of bleeding complications when compared to SNB (25/214 = 11.7% vs. 17/150 = 11.3%, respectively). In total 21 patients suffered an SFN, and four of them (19%) had a preceding bleeding episode requiring reoperation. All reoperations performed were due to complications and no reoperations were performed for oncological indications.

Prophylactic antibiotics did not decrease the number of SSI's (OR 1.04, 95% CI 0.50–2.17, p = 0.91).

3.1. Cost analysis

EC is an economical instrument (approximately 25 euros/piece) compared to much more expensive US (approximately 350 euros/piece). To evaluate the cost effectiveness of the instrument, we calculated the total costs of treatment for both patient groups (Table 4). The fares used are approximate values as they are in Finnish public hospitals (year 2022).

4. Discussion

To date, this is the first study to investigate the risk of postoperative complications in mastectomy patients operated with ultrasonic SonoSurg® instrument. This study demonstrates that US offers a superior haemostasis compared to EC. Postoperative bleeding and related reoperations are risk factors for SFN, and by preventing the bleeding complications, the number of SFN can be reduced likewise. Same day mastectomy seems to be safe when the operation is performed with US instrument.

4.1. Postoperative bleeding

The risk of postoperative bleeding after mastectomy is reported to be 2–11% [2]. In the present study, patients operated with US had a very low risk of bleeding (0.3%), whereas the risk of bleeding in EC Group was close to the upper limit of the scale (11.5%). In the EC Group, 5.8% of the patients suffered a bleeding complication within 24 h of the primary operation, supporting the assumption that the procedure is not well suitable for same day treatment.

The risk factors for postoperative bleeding in breast cancer surgery are medication affecting blood clotting, such as anticoagulants and non-steroidal anti-inflammatory drugs, and advanced age [33]. Advanced age was detected to be a risk factor also in the present study, but patients with antithrombotic medications were excluded from the study. This information was collected, however, and it was detected that before propensity score matching, there were only four patients with anticoagulant therapy and ten patients with antiplatelet therapy in the EC Group. Most of these patients also had a bridging therapy perioperatively, but none of the patients in the US Group were treated in such manner. These patients could not be reliably matched for the statistical analysis and thus it was decided to exclude such patients and to reach more balanced cohorts and more reliable results.

In US group, the primary pain medication prescribed was paracetamol, and in EC group either paracetamol or NSAID was commenced. As the majority of bleeding episodes happened shortly after the primary operation, we do not expect the NSAID medications to have effect on the results.

Interestingly, the amount of intraoperative bleeding was similar in both treatment groups (50 ml, IQR 20–100 ml in US Group and 50 ml, IQR 30–100 ml in EC Group, p = 0.34). This observation supports the assumption, that the instruments offer an equal haemostasis during the surgery and that there are no significant differences in the surgical technique. The rate of postoperative bleeding episodes, however, is much higher in the EC Group, suggesting that the US may provide more stationary blood vessel occlusion when compared to EC.

The amount of intraoperative bleeding in both groups of the study are low compared to previous literature, as Huang et al. conducted a meta-analysis of 11 RTC's and 702 patients undergoing mastectomy and concluded the mean blood loss to be 300 ml for US (Harmonic Scalpel®) patients and 399 ml for EC patients, respectively [14].

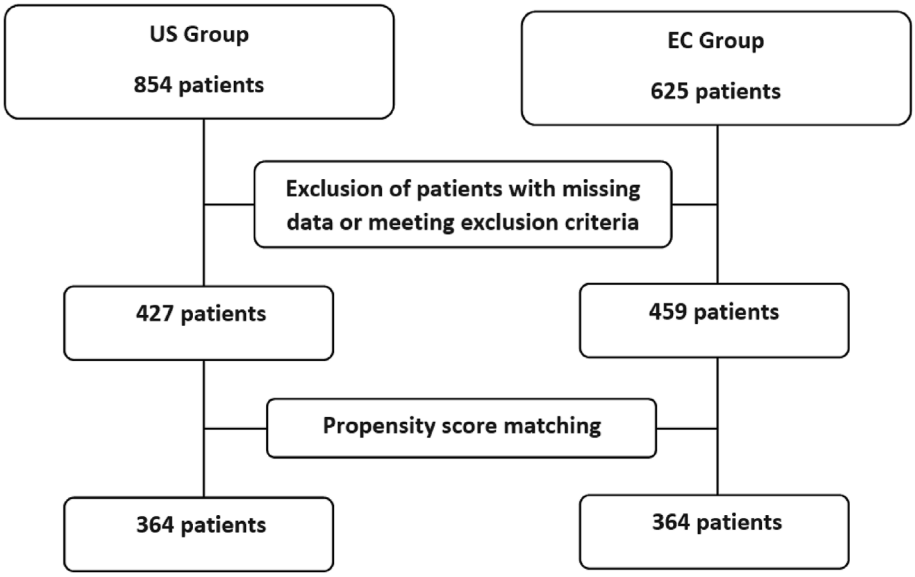

Fig. 2. Total number of patients in each phase of the patient selection.

Table 1
Patient characteristics. Data presented as (n, %) unless otherwise specified. BMI = body mass index, IQR = inter quartile range. ASA = American Society of Anesthesiologist, US = Ultrasonic instrument group, EC = electrocautery group, SNB = sentinel node biopsy, ALND = axillary lymph node dissection.

	US Group	EC Group	p-value
Number of patients	364	364	
Age, years (median, IQR)	56 (49–64)	55 (48–63)	p = 0.29
BMI, kg/m^2 (median, IQR)	25.2 (22.3–28.6)	24.8 (22.2–27.9)	p = 0.30
Diabetes	16 (4.4%)	13 (3.6%)	p = 0.57
Smoking	85 (23%)	74 (20%)	p = 0.32
ASA Classification			p = 0.22
I	90 (25%)	74 (20%)	
II	228 (63%)	247 (68%)	
III	44 (12%)	41 (11%	
IV	2 (0.6%)	0 (0%)	
Breast cancer tumour size, mm (median, IQR)	27.5 (17–50)	27 (18–43)	p = 0.35
Axillary procedure			
SNB	135 (37%)	150 (41%)	p = 0.25
ALND	229 (63%)	214 (59%)	
Antibiotic prophylaxis	88 (24%)	200 (60%)	p < 0.001*
Operation time, min (median, IQR)	107 (91–124)	90 (77–114.5)	p < 0.001*
Intraoperative bleeding, ml (median, IQR)	50 (20–100)	50 (30–100)	p = 0.34
Manner of discharge			p < 0.001*
Same day	95 (26%)	0 (0%)	
Overnight	269 (74%)	364 (100%)	

Table 2
The number of complications according to the unit patients were operated. Data are presented as *n* (%).

	US Group	EC Group	p-value
Number of patients	364	364	
Bleeding complications	1 (0.27%)	42 (11.5%)	p < 0.001*
Surgical site infections	19 (5.2%)	29 (8.0%)	p = 0.14
Skin flap necrosis	7 (1.9%)	14 (3.9%)	p = 0.12
Any complication	25 (6.9%)	75 (20.8%)	p < 0.001*
Any reoperation	4 (1.1%)	27 (6.9%)	p < 0.001*

US = Ultrasonic instrument group, EC = electrocautery group.

4.2. Skin flap necrosis

There is a wide variation in the reported incidence of SFN after mastectomy. In National Surgical Quality Improvement Program (NSQIP) data, SFN and other wound issues required a reoperation only in 0.3% of patients, but also much higher numbers, up to 30%, have been reported in literature [2,34]. In the present study, the OR for SFN was lower in US Group (OR 0.35, 95% CI 0.13–0.98, p = 0.04) presumably being related to the wider lateral thermal damage caused by the EC. Possible technical reasons for this are discussed more detail in chapter "3.6. Technical considerations". Furthermore, it was detected that 19% of patients (4/21) suffering a SFN had a preceding acute bleeding requiring a reoperation, which also proves to be a risk factor for SFN. Current smoking was also heavily associated to the higher risk of SFN (8.2% in smokers vs. 1.4% in non-smokers, p < 0.001).

4.3. Surgical site infections

The reported rate of SSI after mastectomy in previous literature is highly varying (3–41%), but it is most often estimated to be 4–10% [8,35–39]. The SSI rate in the present study is concordant with these estimations (5.2% in US Group and 8.0% in EC Group). Since haematoma is supposed to be an optimal growth medium for

Table 3
Odds ratio for complications in relation to the surgical instrument used in mastectomy.

	Odds ratio for ultrasound scissors	95% confidence interval	p-value	Other variables of statistical significance
Bleeding complications	0.020	0.0028-0.15	$p < 0.001$*	Older age ($p = 0.024$)
Surgical site infections	0.65	0.35-1.23	$p = 0.21$	high amount of intraoperative bleeding ($p = 0.021$), High ASA Classification ($p = 0.024$)
Skin flap necrosis	0.35	0.13-0.98	$p = 0.04$*	Old age ($p = 0.019$), high amount of intraoperative bleeding ($p = 0.003$), smoking ($p < 0.001$)
Any Complication	0.26	0.16-0.42	$p < 0.001$	Older Age ($p < 0.001$), High BMI ($p = 0.003$)
Any reoperation	0.13	0.046-0.39	$p < 0.001$	Older Age ($p = 0.039$)

BMI = body mass index, ASA = American Society of Anaesthesiologists.

Table 4
Total costs of the treatment protocol (euro).

	US Group	EC Group
Instrument/piece	350	25
• for 364 patients	**127 400**	**9100**
Primary operation	2500	2500
• for 364 patients	**910 000**	**910 000**
Cost of primary hospitalization/day	600	600
Number of patients	269	364
Total cost	**161 400**	**218 400**
Readmission to ED	400	400
• Number of cases	24	55
Total cost	**9600**	**22 000**
Cost of hospitalization/day	600	600
• Number of days	39	68
Total cost	**23 400**	**40 800**
Cost of reoperation	1700	1700
• number of cases	4	27
Total cost	**6800**	**45 900**
Cost of additional control visits (outpatient clinic)	250	250
• number of cases	25	75
Total cost	**6250**	**18 750**
Total cost of treatment	**1 244 450**	**1 264 950**
Total cost/patient	**3418.82**	**3475.14**

bacteria [40], and the EC group was shown to have a higher rate of bleeding complications, it may be that some of the SSI's are predisposed by small subclinical hematomas. In previous literature, postoperative bleeding, smoking and diabetes have been suggested to be risk factors for SSI [2,41], but none of these associations was detected in the present study. Antibiotic prophylaxis is controversial in mastectomy, but in the present study it did not seem to have influence on the number of SSI's.

4.4. Overall reoperations

The overall rate of any reoperation in EC Group (6.9%) exceeds the number published in NSQIP data (3.1%), whereas US Group (1.1%) falls below this [2]. The difference is mostly explained by the rate of bleeding complications and related reoperations. In NSQIP data, 1.9% of the patients underwent a reoperation due to bleeding.

4.5. Cost analysis

US is more expensive instrument than traditional EC, but as we have shown here, choosing more expensive instrument may prove to be more cost efficient, when all the costs are considered. EC seems to offer a shorter operation time than US (90 vs. 107 min, respectively), but we did not recompensate this in the cost analysis, as the difference does not seem to allow more efficient use of the operating room capacity.

In the present study, we did not consider non-economical expenses, such as delays in adjuvant therapy or patient discomfort and anxiety, nor costs of sick leaves which would require multiple assumptions. We can assume, however, that including these aspects would prove the US instrument even more efficient than the current cost analysis suggests.

4.6. Limitations of this study and further study

The present study was conducted on a retrospective basis, and therefore the results should be secured in a prospective trial.

Seroma formation is frequently encountered after mastectomy, and this subject was not investigated in the present study. We suggest a trial comparing SonoSurg® to other ultrasonic instruments and EC in terms of seroma formation.

Patients consuming medications affecting blood clotting were not included in this study, and this would be an important patient group to be studied in the future.

Since the comparison was made on two different hospitals, and there are inevitable some differences in local protocols, we are not able to identify in what extent such variation explains the differences detected in the study. However, the surgeons in these adjacent hospitals follow the same national treatment guidelines for breast cancer and are frequently in contact to each other, so the treatment policies should be rather concordant. Technical variations between individual surgeons may affect the results. There may be surgeon specific variation in documenting complications.

The complication rates reported are in the limits of what is presented in the current literature, and there may be unidentified factors that bias the results. The primary patient data was heterogeneous, and despite propensity score matching, it may be that there are differences that the matching cannot eliminate.

5. Conclusion

The postoperative bleeding complications may be decreased using ultrasonic SonoSurg® scissors compared with electrocautery.

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Role of the funding source

The funding source had no role in the design, conduct, analysis, or reporting of the study.

Data sharing

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

This research study was conducted retrospectively from data obtained for clinical purposes. The research protocol of the study was approved by the Hospital District of Southern Finland (T218/2019) and Helsinki University Hospital. No ethical approval was required for this retrospective study.

CRediT authorship contribution statement

Anselm Tamminen: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Writing – original draft, Visualization. **Tuomas Huttunen:** Conceptualization, Methodology, Investigation, Writing – review & editing. **Tuomo Meretoja:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision. **Laura Niinikoski:** Conceptualization, Methodology, Writing – review & editing. **Ilkka Koskivuo:** Conceptualization, Methodology, Resources, Writing – review & editing, Supervision.

Declaration of competing interest

None of the authors have any conflict of interest with respect to this manuscript.

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