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Evaluation of safety and operative time in tumescent-free robotic nipple-sparing mastectomy: a retrospective single-center cohort study

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Purpose: Tumescent in nipple-sparing mastectomy (NSM) has been reported to increase the risk of necrosis by impairing blood flow to the skin flap and nipple-areolar complex. At our institution, we introduced a tumescent-free robotic NSM using the da Vinci single-port system (Intuitive Surgical, Inc.).

Methods: We conducted a retrospective analysis of patients who underwent tumescent-free robotic NSM between October 2020 and March 2023 at Asan Medical Center (Seoul, Korea). Clinicopathological characteristics, adverse events, and operative time were evaluated.

Results: During the study period, 118 patients underwent tumescent-free robotic NSM. Thirty-one patients (26.3%) experienced an adverse event. Five patients (4.2%) were classified as grade III based on the Clavien-Dindo classification and required surgery. The mean total operative time was 467 minutes for autologous tissue reconstruction (n = 49) and 252 minutes for implants (n = 69). No correlation was found between the cumulative number of surgical cases and the breast operative time (P = 0.30, 0.52, 0.59 for surgeons A, B, C) for the 3 surgeons. However, a significant linear relationship (P < 0.001) was observed, with the operative time increasing by 13 minutes for every 100-g increase in specimen weight. **Conclusion:** Tumescent-free robotic NSM is a safe procedure with a feasible operative time and few adverse events. **[Ann Surg Treat Res 2024;107(1):8-15]**

Key Words: Local anesthetics, Minimally invasive surgical procedures, Operative time, Postoperative complications, Robotic surgical procedures

INTRODUCTION

As the oncological outcomes of breast cancer treatment improve [1], the cosmetic aspect of treatment has gained importance. Although the number of breast-conserving surgeries has increased, a significant proportion of patients still undergo mastectomies [1,2], Evidence on the safety of immediate reconstruction after nipple-sparing mastectomy (NSM) in both upfront and neoadjuvant settings is accumulating [3-5], and patients who require mastectomy are increasingly choosing NSM [6]. However, open NSM is difficult to operate far from the incision, and endoscopic NSM often results in collisions between instruments [7]. In contrast, robotic NSM enables convenient and precise dissection of all surgical areas with

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a small incision. Introduction of the da Vinci single-port (SP) system (Intuitive Surgical, Inc.) has highlighted the cosmetic advantages of a single small incision. In 2018, when this new surgical system was adopted, reports of robotic NSM performed by breast surgeons increased rapidly [8], suggesting that the popularity of this surgery is growing.

However, robotic NSM has not yet been approved by the U.S. Food and Drug Administration (FDA), which has issued safety communication [9]. Robotic NSM still faces challenges in terms of verifying oncologic safety, learning curve, and cost-effectiveness. In particular, there are concerns about whether oncologic safety can be ensured through accurate removal of breast tissue [10]. Accordingly, publications in robotic NSM have not increased significantly in the United States and Europe, and reports on the development of the main surgical technique have mainly come from countries that continuously perform robotic NSM, such as South Korea [8,11].

In robotic NSM, finding the correct dissection plane for the skin flap can be challenging due to the absence of tactile sensation. Additionally, bleeding during robotic surgery can obstruct the field of vision, which focuses on a narrow area. To address these issues, tunneling techniques using scissors and injection of a tumescent solution have been widely used to separate subcutaneous fat from the breast tissue and prevent bleeding during surgery. While the use of tumescent has been considered an essential procedure for robotic NSM [12,13], it has been reported to increase the risk of necrosis by impairing blood flow in the skin flap and nipple-areolar complex (NAC) [14-16]. Furthermore, when performing the tumescent injection, it is difficult to accurately hydrodissect the conventional mastectomy plane because there is no visual confirmation of the avascular plane between the subcutaneous fat and breast tissue [17,18].

Concerned about these shortcomings of tumescent, our institution is implementing a tumescent-free robotic NSM procedure using the da Vinci SP system. We aimed to report early results on the safety and operative time of this tumescent-free robotic NSM by collecting the results of more than 100 cases.

METHODS

Ethics statement

This study was approved by the Institutional Review Board of Asan Medical Center (No. 2022-0282), and the requirement for informed consent was waived due to the retrospective nature of the study. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Data and study population

From the Breast Cancer Registry of the Asan Medical Center (Seoul, Korea), we identified and analyzed patients who underwent tumescent-free robotic NSM between October 2020 and March 2023. The Breast Cancer Registry of Asan Medical Center received an Elimination of Cancer Project Fund grant from the Asan Cancer Institute of Asan Medical Center and has been collecting and maintaining data prospectively since 1989, including patient demographic information, body measurements, reproductive history, past medical history, familial history, preoperative test results, preoperative systemic treatment, surgical details, postoperative pathologic report, adjuvant and neoadjuvant therapy, surgical-related side effects, and oncologic outcomes. For robotic surgery, details of surgeryrelated adverse events were also collected. The indications for tumescent-free robotic NSM align with those for conventional NSM, encompassing patients requiring mastectomy without clear involvement of the NAC. All surgeons had more than 8 years and 2,000 cases of experience in breast surgery prior to performing the tumescent-free robotic NSM.

Operative technique

The process of our tumescent-free robotic NSM is as follows. The arm on the side of the breast to be operated on was extended laterally or rotated towards the head, and a 3.5-4.5 cm incision was made along the mid-axillary line. The skin flap was then dissected manually using electrocautery, without using tumescents or tunneling around the incision site. After completing sentinel lymph node biopsy or axillary lymph node dissection, the breast tissue was lifted using a retractor. The entire retromammary space was then dissected to the end of the breast tissue, and all perforator vessels in the medial portion were ligated. After inserting the robotic port into the incision and injecting gas, the robot was connected to the port and the skin flap was dissected. Upon reaching the NAC, frozen biopsy was performed to assess the resection margin in this area. If a tumor was found during frozen biopsy, the NAC was removed. After the breast tissue was removed, the operation was transferred to a plastic surgeon. Blood flow to the skin flap and NAC was assessed using indocyanine green (ICG) fluorescence, and the breast was subsequently reconstructed.

Outcomes

We investigated the number of patients who experienced adverse events. Adverse events included hematoma, NAC or skin necrosis, and infection of the breast; the rest were classified as other. In autologous tissue reconstruction, abnormalities in the autologous tissue harvest area were not included as adverse events. We also monitored the progress of all patients who experienced adverse events up to 1 month after surgery. The severity of postoperative adverse events



was classified according to the Clavien-Dindo classification. In addition, we analyzed the operative time for breast surgeries based on the cumulative number of surgical cases experienced by surgeons and breast size.

Statistical analysis

A comparison of autologous tissue and implant reconstruction surgery times was performed using Student's t-test. The relationship between breast operative time and the surgeon's number of case experiences or specimen weights was examined using a linear regression equation. Statistical significance was defined as a two-tailed P-value less than 0.05. All statistical analyses were performed using Excel and R Statistics ver. 4.3.0 (The R Foundation).

RESULTS

Demographic and surgical data

A total of 118 patients underwent tumescent-free robotic NSM during the study period. Preoperative patient characteristics included a mean age at diagnosis of 45.9 years, mean body mass index (BMI) of 26.3 kg/m², germline mutation in 3.4% (n = 4), smoking history in 5.1% (n = 6), comorbidity in 14.4% (n = 17, history of cancer in 8.5% (n = 10), diabetes mellitus in 1 0.8% (n= 1), multifocal lesions in 36.4% (n = 43), multicentric lesions in 12.7% (n = 15), and bilateral breast cancer in 0.8% (n = 1). The patient with bilateral breast cancer underwent robotic NSM with a multifocal ductal carcinoma in situ on the right side and partial mastectomy with a single invasive ductal carcinoma on the left side. The right side was included in the analysis but the left side was not. Histology revealed ductal carcinoma in situ in 10.2% (n = 12) and invasive ductal carcinoma in 78.0% (n = 92). The average number of harvested lymph nodes was 3.7, and the number of positive lymph nodes was 2.1. Estrogen receptorpositive cases accounted for 83.1% (n = 98), progesterone receptor-positive cases accounted for 75.4% (n = 89), and human epidermal growth factor receptor-2 positive cases accounted for 22.0% (n = 26). In all patients, a frozen biopsy of the NAC resection margin was performed, resulting in 3.4% (n = 4) positive results. All the patients with positive frozen results had their NAC removed and had cancer in the NAC, as confirmed by permanent biopsy. There were no false negative results of frozen biopsy of NAC. The pathologic T-stage was Tis in 8.5% (n = 10), T1 in 61.0% (n = 72), and T2 or higher in 24.6% (n = 29) of patients. Pathologic N-stage was N0 in 81.4% (n = 96), N1 in 17.8% (n = 21), and N2 or higher in 0.8% (n = 1) (Table 1).

Adverse events

Thirty-one patients (26.3%) experienced an adverse event, with 8 patients (6.8%) experiencing grade II or higher adverse events, which required more than the usual symptomatic care
 Table 1. Baseline patient demographics, preoperative characteristics, and pathologic data

Variable	Data		
No. of patients	118		
Age at diagnosis (yr)	45.9 ± 8.2		
Body mass index (kg/m^2)	26.3 ± 34.7		
Germline mutation status			
Affected	4 (3.4)		
Wild-type	41 (34.7)		
Unknown	73 (61.9)		
ASA PS classification			
1	6 (5.1)		
II	112 (94.9)		
Tobacco smoking			
Never smoked	112 (95.0)		
Current smoker	3 (2.5)		
Past smoker	3 (2.5)		
Comorbidity	17 (14.4)		
Family history of breast cancer			
None	98 (83.0)		
Yes (1st degree relative)	18 (15.3)		
Yes (2nd or 3rd degree relative)	2 (1.7)		
Multiplicity			
Single lesion	60 (50.8)		
Multifocal lesions	43 (36.4)		
Multicentric lesions	15 (12.8)		
Cancer location	(
Bilateral	1 (0.8)		
Unilateral. left	60 (50.8)		
Unilateral, right	57 (48.4)		
Tumor size (mm)	15.4 ± 20.8		
Histology			
Ductal carcinoma in situ	12 (10.2)		
Invasive ductal carcinoma	92 (78.0)		
Lobular carcinoma <i>in situ</i>	1 (0.8)		
Invasive lobular carcinoma	7 (5.9)		
Mucinous carcinoma	2 (1.7)		
Tubular carcinoma	$\frac{2}{4}(3.4)$		
No. of lymph nodes harvested	37 + 44		
No. of positive nodes	2.1 ± 4.0		
Estrogen receptor	2		
Negative	20 (16.9)		
Positive	98 (83.1)		
Progesterone recentor	,		
Negative	29 (24.6)		
Positive	89 (75.4)		
HFR2	05 (75.1)		
0	32 (27 1)		
1_	35 (29.7)		
2+	28 (23.7)		
3+	23 (19 5)		
Silver in situ hybridization	25 (15.5)		
Amplified	3 (2 5)		
Non-amplified	23 (19 5)		
Not-performed	23 (19.3) 92 (78 O)		
Ki-67 (%)	32(70.0) 23.1 ± 20.1		
Frozen biopsy performed	118 (100)		

Table 1. Continued

Variable	Data	
Positive surgical margin	7 (5.9)	
NAC involvement		
Frozen	4 (3.4)	
Permanent	4 (3.4)	
Pathologic T-stage		
ТО	7 (5.9)	
Tis	10 (8.5)	
T1	72 (61.0)	
Τ2	22 (18.6)	
Т3	7 (5.9)	
Pathologic N-stage		
NO	96 (81.4)	
N1	16 (13.6)	
N1mi	5 (4.2)	
N2	1 (0.8)	
Pathologic TNM stage		
0	11 (9.3)	
1	63 (53.4)	
II	33 (28.0)	
111	5 (4.2)	
pCR	6 (5.1)	

Values are presented as number only, mean ± standard deviation, or number (%).

ASA PS, American Society of Anesthesiologists physical status; HER2, human epidermal growth factor receptor 2; NAC, nipple-areolar complex.

according to the Clavien-Dindo classification. The number of grades I, II, IIIa, and IIIb was 23 (19.5%), 3 (2.5%), 4 (3.4%), and 1 (0.8%), respectively (Table 2). Two patients (1.7%) had a hematoma at the breast surgery site; one of these patients received bleeding control in the operating room under general anesthesia, and the other patient improved after a blood transfusion. Two patients (1.7%) had NAC necrosis, and both had to undergo NAC removal. One patient (0.8%) had skin necrosis and underwent debridement under local anesthesia in the operating room. Two patients (1.7%) experienced infection; 1 was located in the NAC and the other in the axilla, both of which improved after antibiotic treatment. Twenty patients (16.9%) had seroma and improved after observation or aspiration. One patient showed improvement after chest tube insertion for pneumothorax under local anesthesia, and 3 patients had minor skin adverse events, which improved after conservative treatment (Table 3).

Operative time

The total operative time for tumescent-free robotic NSM was 467 minutes for autologous tissue reconstruction (n = 49) and 252 minutes for implants (n = 69). When implants were used for reconstruction, the operative time for the breast was 159

 Table 2. Adverse events during 1-month follow-up (n = 118)

Variable	Data		
Adverse events	31 (26.3)		
≥Grade II	8 (6.8)		
Clavien-Dindo classification			
Grade I	23 (19.5)		
Grade II	3 (2.5)		
Grade IIIa	4 (3.4)		
Grade IIIb	1 (0.8)		
Type of adverse event			
Hematoma	$2(1.7)^{a}$		
NAC necrosis	$2(1.7)^{b}$		
Skin necrosis	1 (0.8) ^{c)}		
Infection	2 (1.7) ^{d)}		
Seroma	20 (16.9) ^{e)}		
Others	4 (3.4) ^{f)}		

Values are presented as number (%).

NAC, nipple-areolar complex.

 $^{a)}$ Grade IIIb, 1; grade II, 1. $^{b)}$ Grade IIIa. $^{c)}$ Grade IIIa. $^{d)}$ Grade II. $^{e)}$ Grade I. h Grade IIIa, n = 1; Grade I, n = 3.

minutes, and the reconstruction time was 94 minutes. When autologous tissue was used, the breast operative time was 172 minutes and the reconstruction time was 291 minutes. There was no significant difference in the breast operative time between the 2 reconstruction methods (P = 0.15), but autologous tissue reconstruction took longer (P < 0.001). There was no correlation between the cumulative number of surgical cases and breast operative time (P = 0.30, 0.52, 0.59 for surgeons A, B, C) for the 3 surgeons. As the specimen weight increased by 100 g, the linear relationship in which the operative time increased by 13 minutes (P < 0.001), with an R-squared value of 0.18 (Fig. 1).

A case of tumescent-free robotic nipple-sparing mastectomy

A 44-year-old female with a BMI of 17.7 kg/m² visited the hospital due to a palpable breast mass. Vacuum-assisted breast biopsy revealed ductal carcinoma *in situ* in the right breast. Preoperative mammography revealed extremely dense breast tissue and very thin subcutaneous fat. Dissection between the breast tissue and subcutaneous fat was performed without using tumescent, and frozen biopsy of the subareolar resection margin and sentinel lymph node biopsy were all negative. The breast operative time was 168 minutes. In the ICG test for the skin flap, the manual dissection site and NAC showed low blood flow. Implant restoration was performed, and 1 year later, the surgical scar was located in a position covered by underwear, and the skin and NAC were well preserved (Fig. 2).



Table 3. Details of adverse event	S
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Patient No.	Type of adverse event	Clavien-Dindo classification	Case summary
1	Others	Grade I	A skin glue allergy was alleviated after applying a steroid ointment.
2	Others	Grade IIIa	Pneumothorax developed and improved after chest tube insertion.
3	Infection	Grade II	Redness around the NAC occurred and was treated with antibiotics for a week.
4	Others	Grade I	Breast ecchymosis improved after conservative treatment.
5	Others	Grade I	Breast surgical wound erythema was improved after conservative treatment.
6	Skin necrosis	Grade IIIa	Debridement for breast skin necrosis was performed under local anesthesia.
7	Infection	Grade II	Axillary lymphorrhea was improved after using antibiotics for 2 weeks.
8	Hematoma	Grade IIIb	Hematoma in the operated breast was resolved after bleeding control under general anesthesia in the operating room. A blood transfusion was performed.
9	NAC necrosis	Grade IIIa	Debridement (NAC removal) for NAC full-thickness necrosis was performed under local anesthesia.
10	NAC necrosis	Grade IIIa	Debridement (NAC removal) for NAC necrosis was performed under local anesthesia.
11	Hematoma	Grade II	A hematoma in the operated breast developed and a blood transfusion was performed.

NAC, nipple-areolar complex.

The seroma in 20 patients improved spontaneously or through aspiration and was omitted.



В 300 Surgeon A (n = 45) Surgeon B (n = 25) Surgeon C (n = 21) Breast operative time (min) 200 100 P = 0.298, R² = 0.03 P = 0.523, R² = 0.02 P = 0.857, R² = 0 0 10 20 30 40 Patients (n)

Fig. 1. Operative time. (A) Breast operative time and reconstruction time for robotic nipple-sparing mastectomy according to reconstruction type. (B) Number of cumulative operation cases and breast operative time (minutes). (C) Breast specimen weight (g) and breast operative time (minutes).

DISCUSSION

In this study, tumescent-free robotic NSM was performed on

118 patients, with 26.3% experiencing adverse events. Due to an adverse event, 6.8% of patients required more than conservative treatment and 4.2% required surgery, but all recovered well.



Fig. 2. A 44-year-old female with thin skin and scant subcutaneous fat who underwent tumescent-free robotic nippleareolar complex (NSM). (A) Mammography. (B) Ultrasonography. (C) MRI. (D) Console view of the operative field. (E) Indocyanine green dye test after robotic NSM.

The mean breast operative time was 164.7 minutes, and there was no difference in the breast operative time according to the cumulative cases among experienced surgeons.

In other studies on robotic NSM where the tumescent technique appears in text or figures, hematoma occurred in 1.2% [19], NAC necrosis in 0%–1.2% [17,19], skin necrosis in 2.5%–4.3% [17,19], and infection in 1.2% [19] all of which were similar to the results of our study. In our study, 4.2% of patients with Clavien-Dindo classification grade III or higher required surgical intervention, which is a smaller proportion than the 10.9% reported in another multicenter study without information on whether the tumescent technique was used [20]; which may be because the patients in our study had the retromammary space dissected before skin flap dissection. The pneumothorax case in our study may have occurred during injection of indigocarmin dye to mark the border of the breast or may have been due to excessive pressure during mechanical ventilation, but the exact cause is unknown.

The authors also had experience with robotic NSM using tumescent, but the tumescent-free technique showed less bleeding the surgeon had to control which resulted in easier surgery in the authors' experience. The retromammary space was dissected first and the perforator vessels were ligated to block the main blood flow to the breast, resulting in less bleeding when the skin flap was dissected. It is possible that it is difficult to dissect the bloodless plane because tumescent is injected without visualization of the surgical plane, and other studies comparing whether tumescent is used in conventional surgery showed a tendency to use tumescent for postoperative bleeding events or hematoma [21-23].

The reason for poor blood flow at the manual dissection site compared to the robotic dissection site during the ICG test could be the blockage of blood flow to the breast skin by the incision [24]. Another possible cause is the effect of the retractor and the manual traction. It has been reported that a large fill volume during breast reconstruction increases the risk of mastectomy flap necrosis with the use of tumescent anesthesia [15,25], and excessive traction puts pressure on the skin flap. In smoking patients or when using tumescent anesthesia during surgery, even if there is no skin necrosis, there are many false positives that show low perfusion on the ICG test [26], making it difficult to judge solely using the ICG test. However, since ICG positivity tends to cause more active debridement during reconstruction [27], efforts to reduce tension are required during manual surgery.

The robotic breast operative time was reported as 143 minutes in 1 study, representing the tumescent technique in the methods section [19], and 205 minutes in another study (representing the tumescent technique in the figure), excluding reconstruction time from the total operation time [17], and 164.7 minutes in our study, which falls between the other 2 studies. A study by Lai et al. [17] reported that the docking time decreased from 20 minutes to 6-8 minutes as case experience increased, and the robotic NSM time decreased to approximately 100 minutes as experience accumulated [17]. In our study, there was a slight tendency for the breast operative time per surgeon to decrease by 2 to 4 minutes per 10 case experiences, for which the distribution was wide with an R-squared value of less than 0.1. Since the surgeons who participated in the robotic surgery at our institution had already undergone more than 2,000 breast surgeries before starting tumescent-free robotic NSM and experienced robotic NSM using tumescent anesthesia, it seems that the effect of case experience was insignificant for them. A new method, robotic NSM, is increasing in popularity, and the use of tumescent anesthesia is common; however, water splashing during electrocautery and bleeding during tunneling makes the operation difficult. These data show that surgery without tumescent anesthesia is possible with a practicable operative time if there is sufficient prior experience with open NSM.

Since our data only included tumescent-free robotic NSM, direct comparison with tumescent-using robotic NSM was not possible. Instead, we had to compare it with results from other studies. As our study aimed to report early postoperative outcomes of tumescent-free robotic NSM, our data included follow-up of the patients until the first postoperative visit and could not identify any long-term adverse events that occurred thereafter. Most complications after breast surgery are concentrated in the early postoperative period [28], and our study provides significant insights into the safety of this new surgical method. Although our study did not investigate oncological outcomes, the resection range of robotic NSM was the same as that of conventional NSM, and minimal access breast surgery (though most were endoscopic) was found to have no significant difference in long-term oncologic outcomes compared with conventional breast surgery [29]. After adequate long-term follow-up data have been accumulated, we will report the oncologic outcomes. Given that all surgeons included in our study were highly experienced in open NSM, the distribution of operative times may differ when performed by a surgeon with limited experience in open surgery. The relatively small number of adverse events in our study may be because, in addition to not using tumescent anesthesia, the blood supply to the breast was cut off in advance by first dissecting the retromammary space,

In conclusion, tumescent-free robotic NSM is a safe procedure with few adverse events and feasible operative time. We will further compare the safety of tumescent-using robotic mastectomy and tumescent-free robotic mastectomy.

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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