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Robot-assisted Nipple-sparing Mastectomy With Immediate Breast Reconstruction

An initial Experience of the Korea Robot-endoscopy Minimal Access Breast Surgery Study Group (KoREa-BSG)

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Objective: The aim of this study was to present the results of early experience of robot-assisted nipple sparing mastectomy (RANSM).

Background: RANSM improves cosmetic outcomes over conventional nipple-sparing mastectomy. However, data on the feasibility and safety of the RANSM are limited.

Methods: Patients who underwent RANSM with immediate breast reconstruction as part of the Korea Robot-endoscopy Minimal Access Breast Surgery Study Group (KoREa-BSG) from November 2016 to January 2020 were enrolled. clinicopathologic characteristics, perioperative complications, and operation time were collected.

Results: Overall, 73 women underwent 82 RANSM procedures conducted by 11 breast surgeons at 8 institutions. The median patient age was 45.5 years old (20–66 years), and 52 (63.4%) patients were premenopausal. Invasive breast cancer was noted in 55 cases (40 cases were stage i, 11 cases were stage ii, and 4 cases were stage iii, respectively) and ductal carcinoma in-situ was recorded in 20 cases. Of those, 3 patients with *BRCA1/2* mutation carriers underwent contralateral risk-reducing RANSM. The median length of hospitalization was 12.0 days (5.0–24.0 days). The incision location was the mid-axillary line and the median incision length was 50.0 mm (30.0–60.0 mm). Median total operation time, median total mastectomy time, and median reconstruction time was 307.0 minutes (163.0–796.0 minutes), 189.5 minutes (97.5–325.0 minutes), and 119.5 minutes (45.0–689.0 minutes). Only 2 cases (2.5%) required reoperation. Nipple ischemia was found in 9 cases (10.9%) but only 1 case (1.2%) required nipple excision given that 8 cases (9.7%) resolved spontaneously. Skin ischemia was observed in 5 cases (6.1%) and only 2 (2.4%) cases needed skin excision whereas 3 cases (3.6%) resolved spontaneously. There was no conversion to open surgery orcases of mortality. The mean time for mastectomy among surgeons who performed more than 10 cases was 182.3 minutes (± 53.7, minutes) and 195.4 minutes (± 50.4, minutes).

Conclusion: This was the first report of RANSM conducted in the KoREa-BSG. RANSM is technically feasible and acceptable with a short learning curve. Further prospective research to evaluate surgical and oncologic outcomes is needed.

Keywords: feasibility, immediate breast reconstruction, robot-assisted nipple-sparing mastectomy, safety

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Since robotic assistance during minimally invasive surgery was first reported in 1985, robot-assisted surgery has become an important option for colorectal surgery, radical prostatectomy, radical cystectomy, gastric surgery, and hysterectomy, with the majority of surgeries being considered as safe oncologic procedures.[1] Despite the lack of a natural space for endoscopic viewing, applications of robot-assisted surgery also have been attempted for the treatment of superficial organs in thyroidectomy, oropharyngeal surgery, and plastic and reconstructive surgery.[2–5]

In recent decades, endoscopic nipple-sparing mastectomy (ENSM) has been reported to be well-tolerated, oncologically safe, and capable of increasing patient satisfaction.[6–8] However, because of 2-dimensional cameras, use of an in-line camera produces an inconsistent optical window around the curvature of the breast skin flap, especially the medial part of the breast, and the internal mobility is limited because of inflexible endoscopic instruments.[9,10] These technical limitations mean that ENSM has not been widely adopted around the globe and is instead usually performed only by some specialized surgeons in East Asia.

Toesca et al[11] reported the first case of robot-assisted nipple-sparing mastectomy (RANSM) with immediate breast reconstruction (IBR) and Park et al[12] reported the first RANSM with IBR in Korea. Since then, RANSM has shown a short learning curve and has been expected to be the next step in minimally invasive and access surgery with remarkable cosmetic outcomes using hidden incisions.[13] However, the available evidence of surgical feasibility and safety of this new and cutting-edge surgical technique is limited.[14–16] The Korea Robot-endoscopy Minimal Access Breast Surgery Study Group (KoREa-BSG) has established a degree of safety of this emerging technique. In this study, we report the early experience of RANSM with IBR in the KoREa-BSG.

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METHODS

A retrospective review was conducted to identify women who underwent RANSM with IBR as part of the KoREa-BSG multicenter trial between November 2016 and January 2020. Patients were excluded from RANSM for the following: clinically tumor measuring more than 5.0 cm in diameter, those with skin or nipple-areolar complex (NAC) tumor invasion, those with tumor-nipple distance of less than 2.0 cm, those with multiple lymph-node metastasis, those with evidence of skin or chest wall invasion, those with inflammatory breast cancer, or those scheduled for radiotherapy (RTx). There were no absolute exclusion criteria for breast size or degree of ptosis. All patients underwent physical examination, mammogram, breast ultrasonography, and magnetic resonance imaging and most patients also received chest and/or abdominopelvic computed tomography, abdominal ultrasonography or whole-body bone scan to evaluate distant metastasis. Postoperative adjuvant hormone therapy (HTx), chemotherapy (CTx), and RTx were administered to patients according to current guidelines.

Data Collection

We collected data on the following variables: age at operation, body mass index, smoking history, past medical history, prior breast surgery, family history of breast cancer, *BRCA1/2* mutation genetic test status and results, risk-reducing mastectomy status, clinicopathologic data (menopause status, pathologic stage according to the seventh edition of the American Joint Committee on Cancer classification, histopathology, nuclear grade, estrogen receptor status, progesterone receptor status, human epidermal growth factor-2 status, ki-67, pathologic invasive size, pathologic in-situ size, number of lymph node metastasis), factors for operation (incision size and location, specimen weight, total operation time, reconstruction time, predocking time, docking time, console time, reconstruction methods, robot-assisted reconstruction status, superficial and/or basal margin, nipple frozen margin, nipple permanent margin, complication status, and complication type), and adjuvant treatment (CTx status, RTx status, target therapy status, and recommendations for HTx).

Surgical Technique and Education Program

The detailed surgical technique has been previously described and slight variations were made by each surgeon[17] (Supplemental Digital Content, http://links.lww.com/SLA/C655). Most of the involved breast surgeons were educated by dry laboratory, cadaver and/or animal laboratory, and observation of RANSM before surgery. Furthermore, an experienced surgeon, HSP, who pioneered this technique and has 7 years of experience in robotic mastectomy including cadaveric skills lab training and 20 years of experience in breast surgery, helped with each operator's first RANSM when possible.

Learning Curve Analysis

The total operation time, mastectomy time, console time, and predocking was defined as the interval between the creation of the skin incision and the end of the reconstructive surgery, the interval between the time of skin incision and the time of the specimen out of the operation field, the time spent by a surgeon to operate the console for mastectomy, and the creation of the skin incision and just before robot docking including sentinel lymph node biopsy. Mastectomy time included the predocking time, docking time, and console time. To evaluate the impact of case experience accumulation on the operation time of RANSM, the mastectomy time and specimen weight were gathered and plotted in case sequence (chronological order). The cumulative sum (CUSUM) method and exponentially weighted moving average (EWMA) control chart were used to analyze the learning curve.[18–23] For the EWMA chart, we set the smoothing factor λ to 0.2 and the control limits to $\pm$ 3 standard deviations of the plotted statistic from the center line. Any data point above the upper or lower control limits represented an "out-of-control" signal.[11]

Because many of the surgeons involved experienced only a few cases, for exact evaluation of the learning curve, we analyzed the mastectomy time among the breast surgeons who had performed more than 5 cases of RANSM each. We excluded the IBR time because there were various IBR methods adopted (eg, robotic IBR, direct to implant insertion, tissue expander insertion, and using autologous tissue), which could affect the learning curve.

Statistical Analysis

Patient characteristics were compared using an independent t-test for continuous variables and Chi-squared or Fisher exact test for categorical variables. Values are reported as means $\pm$ standard deviations or medians with ranges. All tests were 2-sided and $P < 0.05$ was considered significant. All statistical analyses were done using SAS version 9.4 (SAS Institute, Cary, NC) and R version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria).

Ethics

This study adhered to the ethical tenets of the Declaration of Helsinki and was approved by the Institutional Review Board of Samsung Medical Center (Institutional Review Board no. 2020-03-022). The need to gather informed consent was waived because of the low risk posed by this investigation.

RESULTS

Clinicopathologic Characteristics

A total of 73 women underwent 82 RANSM and IBR procedures performed by 11 breast surgeons and 9 plastic surgeons at 8 institutions in South Korea. The clinicopathologic characteristics are shown in Supplemental Table 1, http://links.lww.com/SLA/C655. The median patient age was 45.5 years (20–66 years) and 52 (62.5%) women were premenopausal. The median body mass index was 21.4 kg/m^2 (16.9–30.7 kg/m^2) and 5 (6.0%) patients had a smoking history. Seven women were *BRCA1/2* mutation carriers. Preoperatively, 33 (40.2%) presented with ductal carcinoma in-situ and 40 (48.8%) had invasive carcinoma. Postoperatively, 20 (24.4%) had ductal carcinoma in-situ and 55 (63.4%) presented with invasive carcinoma. Among 55 cases of invasive carcinoma, 40 were stage I, 11 were stage II, and 4 were stage III, respectively. The median pathologic invasive carcinoma size was 11.0 mm (0.4–66.0 mm) and 66 (80.5%) had no lymph node metastasis. A total of 37 (45.1%) women demonstrated multiplicity (28 had multifocal lesions and 9 had multicentric legions). Among 7 cases of risk-reducing mastectomy, 3 cases were performed because of *BRCA 1/2* mutations and 4 cases were performed because of having a family history of breast cancer. RTx was received in 9 (11.0%) cases and CTx was administered in 17 (20.7%) cases. Among the 63 (76.8%) patients with estrogen receptor-positive disease, HTx was recommended in 100% of cases.

Surgical Characteristics

The surgical characteristics of RANSM and IBR are shown in Table 1. All robotic procedures were performed using the da Vinci Si, X, Xi or SP Surgical System (Intuitive Surgical, Sunnyvale, CA) (61 used Xi, 10 used Si, 9 used X, and 2 used SP). Sentinel lymph-node biopsy was performed in all cases of therapeutic mastectomies and was positive in 8 cases, with axillary lymph-node dissection

TABLE 1. Surgical Characteristics of Robot-assisted Nipple Sparing Mastectomy

Variables	Number (%)*
Patient positioning	
Raised arm	67 (81.7)
Laying down	15 (18.3)
Davinci system	
Si	10 (12.2)
X	9 (11.0)
Xi	61 (74.3)
SP	2 (2.4)
Axillary surgery	
No axillary surgery	9 (11.0)
SLNB only	65 (79.3)
ALND followed by SLNB	8 (9.7)
Reconstruction method	
Tissue-expander insertion	31 (37.8)
Direct implant insertion	49 (59.8)
Free flap (autologous abdomen)	1 (1.2)
Latissimus dorsi muscle flap	1 (1.2)
Robot-assisted reconstruction	
No	54 (65.8)
Yes	28 (34.2)
Gas or gasless	
Gas	65 (79.3)
Gasless	17 (20.7)

*Seventy-three patients underwent 82 RANSM procedures.

SLNB and ALND indicate sentinel lymph node biopsy and axillary lymph node dissection, respectively.

TABLE 2. Surgical Outcomes of Robot-assisted Nipple Sparing Mastectomy

Variables	
Median total operation time, min (range)	307.0 (163.0–796.0)
Tissue expander insertion (n = 31)	302.0 (205.5–452.0)
Direct to implant insertion (n = 49)	310.3 (163.0–475.0)
Autologous flap (DIEP) (n = 1)	796.0
Autologous flap (LD) (n = 1)	471.0
Median mastectomy time, min (range)	189.5 (97.5–325.0)
Median reconstruction time, min (range)	119.5 (45.0–687.0)
Tissue expander insertion (n = 31)	118.0 (45.0–233.0)
Direct to implant insertion (n = 49)	119.0 (48.0–356.0)
Autologous flap (DIEP) (n = 1)	689.0
Autologous flap (LD) (n = 1)	328.0
Median hospital stay length, d (range)	12.0 (5.0–24.0)
Median incision length, mm (range)	50.0 (30.0–60.0)
Median specimen weight, g (range)	306.0 (84.0–788.0)
Blood loss, n (%)	
< 50 mL	36 (43.9)
50–100 mL	42 (51.2)
Unknown	4 (4.9)
Clavien -Dindo complication grades, n (%)	
0	57 (69.5)
I	15 (18.3)
II	2 (2.4)
Ilia	6 (7.3)
IIIb	2 (2.4)
Complication group, n (%)	
None	57 (69.5)
Yes	25 (30.5)
Skin ischemia (spontaneous resolve)	3 (3.6)
Skin loss due to necrosis	2 (2.4)
Nipple (spontaneous resolve)	8 (9.7)
Nipple loss due to necrosis	1 (1.2)
Bleeding	1 (1.2)
Infection	5 (6.1)
Thermal injury	5 (6.1)

DIEP indicates deep inferior epigastric perforator free flap; LD, latissimus dorsi muscle flap.

performed by open procedure with 2.0 of 3.0 cm long incision extension completed at the end of the robotic procedure. None of the women having prophylaxis received an axillary staging. One had a nipple margin positive for malignancy and underwent excision of the nipple. One woman with a superficial focal abutting of the skin margin underwent RTx. Regarding breast reconstruction, 28 (34.2%) underwent robot-assisted reconstruction; most of the patients (n = 80, 98.6%) received implant-based reconstruction (37.8% underwent tissue-expander insertion and 59.8% underwent direct implant insertion). One patient received a deep inferior epigastric perforator free flap (DIEP) and 1 patient received a latissimus dorsi flap. In conjunction with the RANSM technique, thoracodorsal vessels were used as recipient pedicles for DIEP reconstruction with the same incision made for robotic mastectomy. Therefore, a separate breast incision was not necessary for exposure of the recipient pedicles in DIEP reconstruction after RANSM.

Surgical Outcomes

The surgical outcomes including complications are shown in Table 2. The median length of hospitalization was 12.0 days (5.0–24.0 days). The incision location was the mid-axillary line and the median incision length was 50.0 mm (30.0–60.0 mm). Median total operation time, median total mastectomy time, and median reconstruction time was 307.0 minutes (163.0–796.0 minutes), 189.5 minutes (97.5–325.0 minutes), and 119.5 minutes (45.0–687.0 minutes). The median total operation time and reconstruction time were longer in autologous flap procedures compared with tissue expander insertion and direct-to-implant insertion. The median specimen weight was 306.0 g (84.0–788.0 g). No patient required blood transfusion; 36 (43.9%) experienced less than 50 mL of blood loss and 42 (51.2%) lost between 50 and 100 mL.

Overall complication rates were 30.5% and only 2 cases (2.4%) required re-operation. Nipple ischemia appeared in 9 cases (10.9%), though only 1 case (1.2%) needed nipple excision; the other 8 cases (9.7%) resolved spontaneously. Skin ischemia was observed in 5 cases (6.1%) and only 2 (2.4%) cases required skin excision, whereas 3 cases (3.6%) resolved spontaneously. There was no conversion to open surgery and no case of mortality.

Preliminary Learning Curve Evaluation of R-NSM

The CUSUM and EWMA charts for mastectomy time and breast specimen weight according to the different surgeons are shown in Figure 1 and Figure 2. Surgeon A, who performed the first procedure in Korea and the most RANSM cases in Korea, performed 41 cases with a mean RANSM time of 182.3 minutes (± 53.7 minutes). The RANSM time of surgeon A decreased after 15 cases and stabilized thereafter. Surgeon B performed 14 cases and the mean RANSM time was 195.4 minutes (± 50.4 minutes). The RANSM time of surgeon B decreased after 9 cases and stabilized thereafter. Surgeons C and D performed 7 and 5 cases, respectively, and the median RANSM time was 210.9 minutes (115.0–290.0 minutes) and 214.4 minutes (185.0–235.0 minutes).

DISCUSSION

This retrospective multicenter study of 82 RANSM cases suggested that RANSM with IBR is safe and feasible for patients

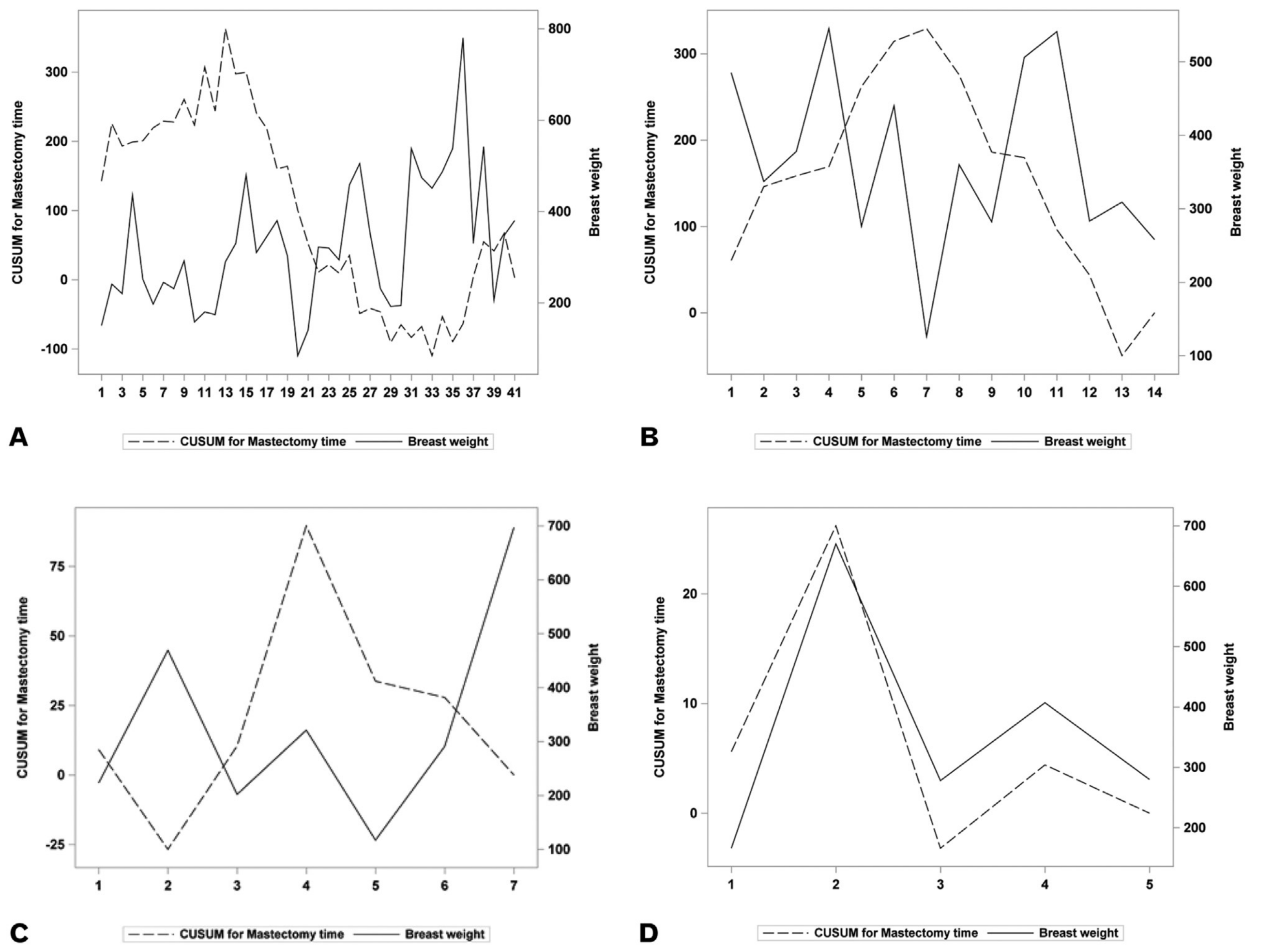

FIGURE 1. Cumulative sum (CUSUM) plots for mastectomy time of four surgeons who experienced more than 5 cases. Experience serial number of 29th and 30th in A were performed using the SP system. Lt axis indicates total mastectomy time (min);Rt axis, breast weight (gram).

with early breast cancer. Only 1 case of nipple necrosis needing reoperation occurred (1.2%) and there was no instance of open conversion. Major complications of reoperation occurred in only 2 cases (2.4%); most of the apparent complications required only observation for resolution. Operation times showed a reasonable learning curve.

NAC ischemia is the most common and concerning complication. In this study, 9 cases (10.9%) showed NAC ischemia but only 1 case (1.2%) required reoperation, whereas the other cases resolved spontaneously. This rate is acceptable and similar compared with a prior systemic review including 14 articles for conventional and endoscopic NSM that demonstrated that the partial or complete NAC necrosis rate was 15.0%.[8] Also, this rate is thought to be reasonable to compare with previous studies of RANSM performed by the pioneers of RANSM who reported the NAC ischemia/necrosis rate was between 0.0% and 13.0%.[15,24–28] Furthermore, 8 of the 10 breast surgeons in this study had only limited experience with RANSM, having performed less than 10 cases, so there is more room to reduce complications in the future. The KoREa-BSG education program, which includes dry laboratory, cadaveric and/or animal laboratory, observation surgery, and helping an experienced surgeon with the first case, may be useful for the breast surgeon preparing to conduct their first operation using this cutting-edge technique. To the best of our knowledge, no published randomized clinical studies have directly compared the complication rates between RANSM and conventional NSM. In the Global Breast Cancer Conference 2019 and American Society of Breast Surgeons conference 2019, Toesca et al presented their results of a prospective randomized clinical trial.[29] We are waiting for the final report of the prospective randomized clinical trial of robotic NSM and conventional open technique.[30]

Because this study consisted of many breast and plastic surgeons, the surgical technique was slightly modified throughout. Eight breast surgeons performed gas-inflated RANSM, whereas 2 breast surgeons conducted gasless RANSM.[12] Of the 17 cases with gasless technique, 5 cases (29.4%) had skin and/or NAC ischemia and 10 of 65 cases (15.4%) using a gas-insufflation technique had skin and/or NAC ischemia ($P = 0.2912$). Although the gasless technique could prevent postoperative complications associated with gas insufflation including subcutaneous emphysema and hypercarbia following CO_2 insufflation, this technique has the potential concern of ischemic changes in the skin and NAC due to counter-traction by a self-retractor. It is equally conceivable that the minimal counter-traction of 8 mm Hg insufflation may contribute to reducing skin and

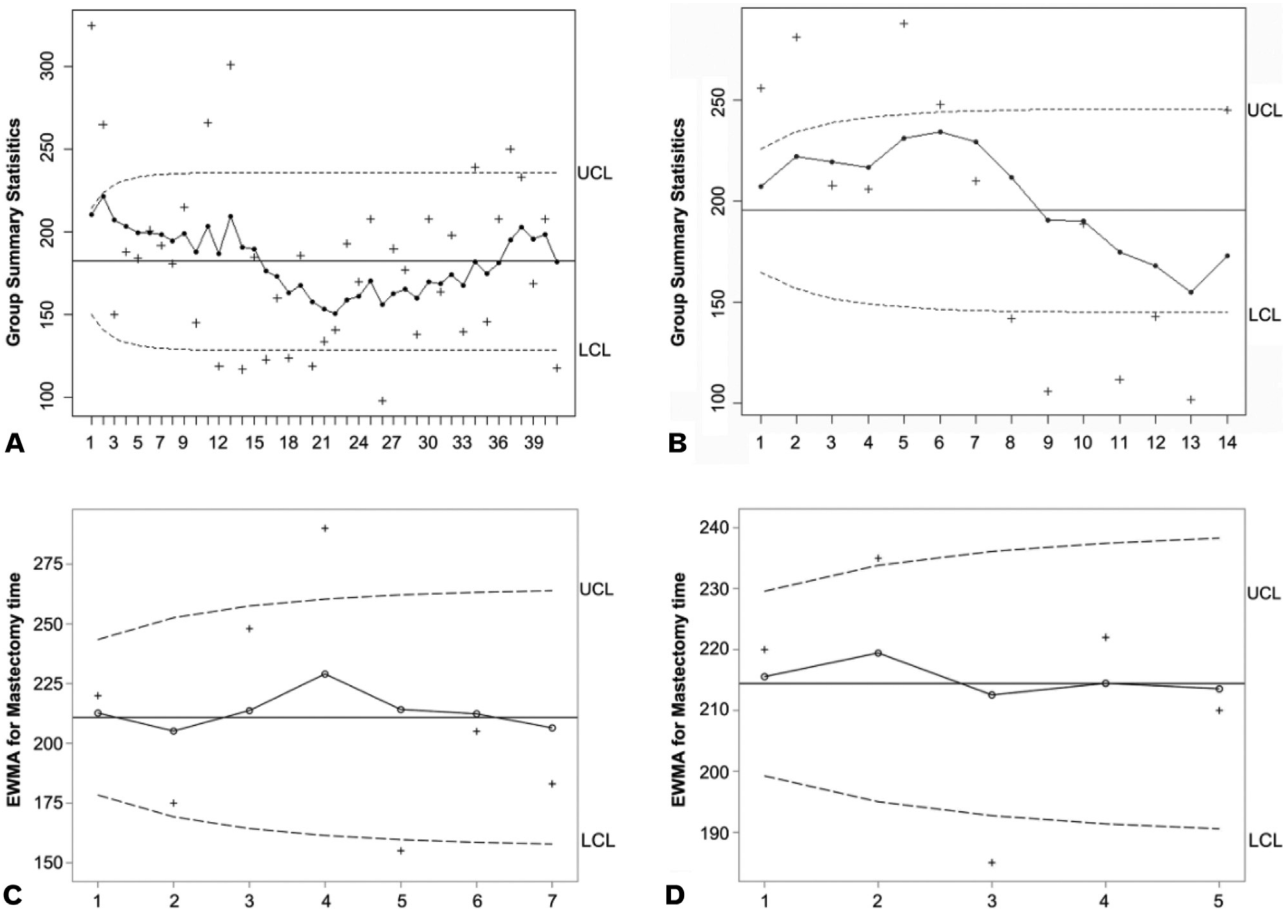

FIGURE 2. Exponentially weighted moving average (EWMA) control chart for mastectomy time of four surgeons who experienced more than 5 cases. Experience serial number of 29th and 30th in A were performed using the SP system. Smoothing parameter = 0.2, Control limits at 3*sigma, Number of points beyond limits = 0.

NAC ischemia/necrosis relative to manual retraction. On the other hand, gas-inflated RANSM could increase thermal injuries during robotic flap development because surgeons do not have tactile sensation of the patient's skin. In addition, since the gas-inflated technique is performed in a closed space, increasing temperature in the closed working space during bleeding control by internal electrocautery could also raise the risk of thermal injury. This was reported in previous studies.[11,15] Most thermal injuries resolved spontaneously, but caution is needed regarding internal temperature during internal electrocautery. Further investigation is warranted to evaluate the differences in complications between gas and gasless techniques.

In terms of the average length of hospital stay, the median length of hospitalization 12.0 days (5.0–24.0 days) in the current study was exceedingly long compared to the results from Toesca et al,[24] who reported the largest series of RANSM procedures with 94 procedures performed on 73 patients and demonstrated an average length of stay of 2.0 days. The difference in hospital stay between 2 studies is likely due to differences in the medical systems between the 2 countries. In South Korea, both patients who have undergone RANSM and patients who have undergone conventional NSM with immediate reconstruction usually stay in hospital for 7–15 days.[31,32] South Korea does not have a system of family doctors who are closely connected to physicians in general hospitals and who care for discharged patients at community-based hospitals, which could affect the longer duration of stay in South Korea. Furthermore, patients in South Korea pay a relatively low cost for hospitalization compared to western countries because of the national healthcare system in South Korea. Therefore, length of stay differences might be due to the specific circumstances in South Korea.

Almost all cases (97.6%) underwent surgery with the multiport da Vinci Si, X, or Xi system, whereas only 2 cases (2.4%) were exposed to the da Vinci SP system in a study by Park et al.[33] Use of the multiport da Vinci system presents some technical difficulties as follows: collisions between robotic arms, collisions between robotic arms and patient arms, difficulties in using the third robotic arm, and the existence of blind spots due to the rigid 3-dimensional camera scope. These authors reported several advantages of RANSM became apparent when using the SP system.[33] First, the SP system was attached to 1 instrument arm including 3 separated robot arms and 1 camera that enabled smaller incision. We observed that the incision length using the SP system (mean: 38.5 mm) was marginally smaller than the incision length obtained using the multi-port system (mean: 46.9 mm) (P = 0.0857). Second, the conduct of RANSM using the SP system can make use of the third arm, which was particularly useful for the counter-retraction of the tissue.[34] Third, the elbow movement of the robotic arms and articulation of the camera enabled better visualization of the medial part of the breast.

Also, various camera modes and clutches enabled more detailed movements and visualization of the surgical field.[35,36]

Robotic-assisted surgery is more ergonomic than conventional and endoscopic surgery because of the 3-dimensional optics, user-friendly operating system, and the intuitive robotic arms. According to these advantages, RANSM could reach an early learning curve. In this study, the EWMA chart showed that, after the 15th and ninth procedures, the RANSM time reached the learning curve. Lai et al[27] compared the learning curve analysis of ENSM and RANSM with that of CUSUM and found that the operation time improved from the 27th procedure of ENSM but the 10th procedure of RANSM. Also, Toesca et al[15] and Sarfati et al[28] demonstrated that RANSM could reach an earlier learning curve.

The United States Food and Drug Administration safety communication warned that robotically-assisted mastectomy has not been established in the prevention or treatment of breast cancer.[37] Specifically, there is only limited, preliminary evidence, so surgeons should discuss with patients the benefits, risks, and alternatives of all available treatment options to make the most informed treatment decisions.[38] Consequently, efforts are needed to accumulate evidence regarding the feasibility and oncologic outcomes of RANSM, establish training systems, and establish safety indications of the technique. As part of this effort, recently, the pioneers of RANSM reported a consensus statement on RANSM detailing the indications, contraindications, technical considerations, patient counseling, outcome measures and indicators, training and learning curve assessment.[39]

There are several limitations to this study. First, the number of operations was different between surgeons, which could affect the rate of complications and the operation time. Also, various operation techniques such as use of a gasless approach, gas inflation, or using the SP system may impact surgical outcomes. Second, we acknowledge that most of the patients in this study had early-stage disease and favorable biologic characteristics. Also, we could not analyze oncological outcomes because of the study design. However, this study is the first report of the KoREa-BSG with patients from multiple centers and a second largest number of RANSM procedures.

In conclusion, we suggest that RANSM with IBR is acceptable and feasible to deploy patients with early breast cancer and the need for risk-reducing surgery. Further prospective registries or randomized controlled trials for RANSM are warranted for evaluating surgical outcomes, patient satisfaction, and oncological outcomes.

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