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The First Romanian Robotic-Assisted Mastectomy: A Starting Point for a Literature Review

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Abbreviations:
IBR: Immediate Breast Reconstruction;
FDA: Federal Drug Administration;
BMI: Body Mass Index;
FFPE: Formalin-Fixed and Paraffin-Embedded;
RNSM: Robotic-Assisted Nipple-Sparing Mastectomy;
NSM: Nipple Sparing Mastectomy;
CNSM: Conventional Nipple Sparing Mastectomy;
RCT: Randomized Control Trial;
NAC: Nipple-Areola Complex;
ENSM: Endoscopic Nipple-Sparing Mastectomy.

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Rezumat

Prima mastectomie asistată robotic din România: oportunitate pentru un review al literaturii

Introducere: Progresele în domeniul chirurgiei robotice au condus la utilizarea acesteia în chirurgia sânului. Raportăm prima mastectomie cu conservarea tegumentelor şi a complexului areolo-mamelonar asistată robotic, utilizând platforma da Vinci Xi, în România, la o pacientă cu cancer mamar contralateral. Reconstrucția mamară imediată a fost efectuată folosind implant de silicon. Nu au existat complicații majore imediate. Cu această ocazie, am efectuat un review al literaturii pentru a evalua datele privind siguranța, fezabilitatea, rezultatele oncologice şi estetice ale acestei proceduri.
Metode: Am revizuit literatura de specialitate din septembrie 2015 până în august 2024 în motoarele de căutare PubMed, Scopus, and EMBASE. Au fost selectate articole originale ce au inclus paciente cu cancer mamar sau cu risc crescut de cancer mamar care au efectuat RNSM.
Rezultate: Complicațiile postoperatorii ale RNMS au fost minime şi similare celor observate în cazul NSM clasice. Mai mult, două studii au indicat că RNSM a avut rate semnificativ mai mici de necroză a tegumentelor şi a complexului areolo-mamelonar (0% vs. 12.5%, respectiv 2.4% vs. 15.2%). În plus, mastectomia asistată robotic a fost asociată cu un rezultat estetic mai bun. Cu toate acestea, costurile totale şi durata totală a intervențiilor

chirurgicale robotice au fost mai mari în comparație cu chirurgia deschisă.
Concluzie: RNSM este o tehnică fezabilă în scopuri profilactice, având atât avantaje, cât şi dezavantaje. Deşi datele emergente susțin siguranța oncologică şi potențialele beneficii, sunt necesare studii viitoare pentru a valida eficacitatea sa în tratamentul cancerului.

Cuvinte cheie: cancer mamar, mastectomie cu conservarea mamelonului, proceduri chirurgicale robotice

Abstract
Background: The advancements in the field of robotic surgery have led to its use in breast surgery. We report the first robotic-assisted nipple-sparing mastectomy (RNSM) using the da Vinci Xi surgical system, in Romania, for a patient with contralateral breast cancer. Immediate breast reconstruction was performed using a silicone implant. There were no major immediate complications. On this occasion, a systematic review was performed to examine the data on safety, feasibility, oncological and cosmetic outcomes for this procedure.
Methods: We reviewed the literature from September 2015 to August 2024 in PubMed, Scopus, and EMBASE. Original studies reporting on patients diagnosed with or at high-risk of breast cancer undergoing RNSM were included.
Results: Postoperative complications of RNMS were minimal and comparable to those observed with conventional nipple-sparing mastectomy. Furthermore, two studies found that RNSM resulted in significantly lower rates of skin and nipple-areola complex necrosis compared to open surgery (0% vs. 12.5% and 2.4% vs. 15.2%, respectively). Additionally, robotic-assisted mastectomy was linked to greater overall cosmetic satisfaction. On the other hand, the total costs and operating times for robotic procedures were higher than those for open surgery.
Conclusion: RNSM is a feasible technique for prophylactic purposes, with both advantages and disadvantages. Although emerging data support the oncological safety and potential benefits, future studies are needed to validate its efficacy in cancer treatment.

Key words: breast cancer, nipple-sparing mastectomy, robotic surgical procedures

Introduction

Breast cancer is a frequent malignancy among women, with a rising incidence worldwide, being responsible for hundreds of thousands of deaths every year (1). Breast-conserving surgery is the first option for early-stage breast cancer, yielding good oncologic and aesthetic outcomes (2). However, in some cases, mastectomy is still mandatory (3). The indications include locally advanced cases not responding to neoadjuvant therapy, multicentricity, extensive ductal carcinoma "in situ", unfavorable tumor/breast ratio even after treatment, impossibility of achieving negative margins, impossibility of postoperative radiotherapy, genetic mutations involved in breast cancer, family history of cancer and sometimes patient's will (4).

An unforeseen increase in the rate of mastectomies was observed in the last years (5,6).

The explanations include the common use of magnetic resonance imaging, the increased number of genetic testing, fear and anxiety related to the overestimation of local recurrence risk, the availability of breast reconstruction with good aesthetic results and reimbursement of this procedure (7).

Alongside therapeutic mastectomy, prophylactic contralateral mastectomy in patients with unilateral breast cancer is more and more common. The recommendations for this procedure are represented by: pathological genetic mutations (BRCA1, BRCA2, PALB2, TP53, BARD1, CHEK2, CDH1, STK11, ATM), strong family history of cancer, patient's will, young age, lobular carcinoma and symmetrization (8,9).

Bilateral prophylactic (in fact, risk-reducing) mastectomy recommendations include: pathogenic genetic mutations, family history of breast cancer with multiple first-degree relatives and/or multiple successive generations of family members with breast and/or ovarian cancer, high-risk lesions (biopsy confirmed atypical ductal or lobular hyperplasia, lobular carcinoma in situ). The indications for this surgery are not absolute and must be decided with the informed patient (8,9).

As esthetics is an important goal, secondary to oncological safety, different surgeries were used to minimize the scar and to achieve a beautiful result after mastectomy with immediate reconstruction (10).

The widespread video-assisted surgery has also reached breast surgery (11). Since Kompatscher described the technique of endoscopic capsulotomy of capsular contracture after breast augmentation in 1992, numerous reports regarding video-assisted breast augmentation have been published (12). The first report regarding video-assisted surgery for breast cancer was published in 1995 (13). Endoscopic-assisted techniques have been used in the surgical treatment of breast cancer over the past two decades, for both breast-conserving surgery and mastectomy, with or without preservation of the nipple-areolar complex, combined with delayed or immediate breast reconstruction (14-16). The primary difficulty of this technique is related to the surgeon's posture while handling the instruments (17,18).

Recent advancements in the field of robotic surgery have led to the development of robotic-assisted mastectomy. In 2015, Toesca et al. performed the first, to our knowledge, robotic-assisted contralateral risk-reducing mastectomy with immediate breast reconstruction (IBR) in three patients with BRCA mutation (19).

Currently, the da Vinci Surgical System® is used for risk-reducing mastectomies. The safety of this system for breast cancer has to be proven and currently does not have FDA clearance for the treatment or prevention of cancer. There are several clinical trials regarding robotic-assisted mastectomy for breast cancer (20).

This paper discusses Romania's first robotic-assisted mastectomy, conducted in 2019 as a contralateral risk-reducing surgery for a woman with a history of unilateral breast cancer, along with a systematic literature review.

Case Report

A 29-year-old female with no significant family or medical history discovered a lump in her left breast that was left unattended for three years. Clinical examination revealed grade 2 mammary ptosis, left nipple retraction, and a firm tumor in the central quadrant of the left breast measuring 4 x 3.5 cm, with irregular margins and adherence to the skin. Abnormal axillary lymph nodes were also noted, with a maximum diameter of 1 cm.

Ultrasound showed a 36 mm hypoechoic nodule in the left breast's central quadrant and the mammogram indicated a hyperdense spiculated opacity in the same quadrant, measuring 3.2 cm and classified as BIRADS 4. A core needle biopsy was performed, but the histopathological results were inconclusive. Computed tomography and a bone scan ruled out distant metastases.

The multidisciplinary tumor board recommended an excisional biopsy with intra-operative histopathological examination and mastectomy if the lesion was proven malignant.

The patient was admitted to the surgical ward at the Prof. Dr. Alexandru Trestioreanu Oncology Institute in Bucharest. On September 17, 2007, under general anesthesia, a tumor excision was performed. Intraoperative histopathology confirmed invasive ductal carcinoma.

A left mastectomy with the excision of the skin and the nipple-areola complex along with axillary lymph node dissection was conducted. Postoperative recovery was uneventful.

The histopathological examination of the formalin-fixed and paraffin-embedded (FFPE) tumor tissues revealed invasive ductal carcinoma, G3, with 98% estrogen receptor positivity, 90% progesterone receptor positivity, HER2 negativity, and a Ki67 index of 45%. Among 16 examined lymph nodes, 3 showed metastasis (pT2a/pN1bIII).

Following surgery, the patient received radiotherapy (45 Gy), six cycles of chemotherapy (epirubicin, cyclophosphamide, and docetaxel), and hormonal therapy with Tamoxifen. During follow-up, there was no evidence of local recurrence or distant metastasis.

In 2009, the patient was readmitted to the Prof. Dr. Alexandru Trestioreanu Oncology Institute in Bucharest for delayed breast reconstruction. A pocket was created beneath the skin and the large pectoral muscle where a Mentor Siltex Contour Profile Becker implant 160cc/300cc was placed, initially filled with 120 ml of normal saline was placed. No postoperative complications occurred, and the implant was gradually filled to its maximum capacity over the next three months.

During the 10 years following the reconstruction, there were no signs of local recurrence or distant disease. The immediate aesthetic outcome was satisfactory despite post-radiotherapy fibrosis, and the patient was pleased with the result. However, she developed over time third-degree capsular contracture and expressed interest in enhancing the aesthetic appearance of the reconstructed breast and pursuing risk-reducing contralateral mastectomy.

In January 2019, the patient was admitted to the Ponderas Academic Hospital in Bucharest for implant revision surgery and contralateral risk-reduction mastectomy with immediate breast reconstruction (*Fig. 1*).

The patient underwent a right robotic-assisted nipple-sparing mastectomy with immediate breast reconstruction using the da Vinci Xi surgical system and left breast implant revision, under general anesthesia. The robot-assisted nipple-sparing mastectomy with immediate breast reconstruction was performed by Doctor Benjamin Sarfati, assisted by Professor Alexandru Blidaru and his team: Dr. Aniela Nodiți and Dr Mihaela Alexandra Radu. The implant revision surgery was performed by Professor Alexandru Blidaru and his team.

The patient was placed in a supine position with the ipsilateral arm extended overhead, the contralateral arm adducted and covered

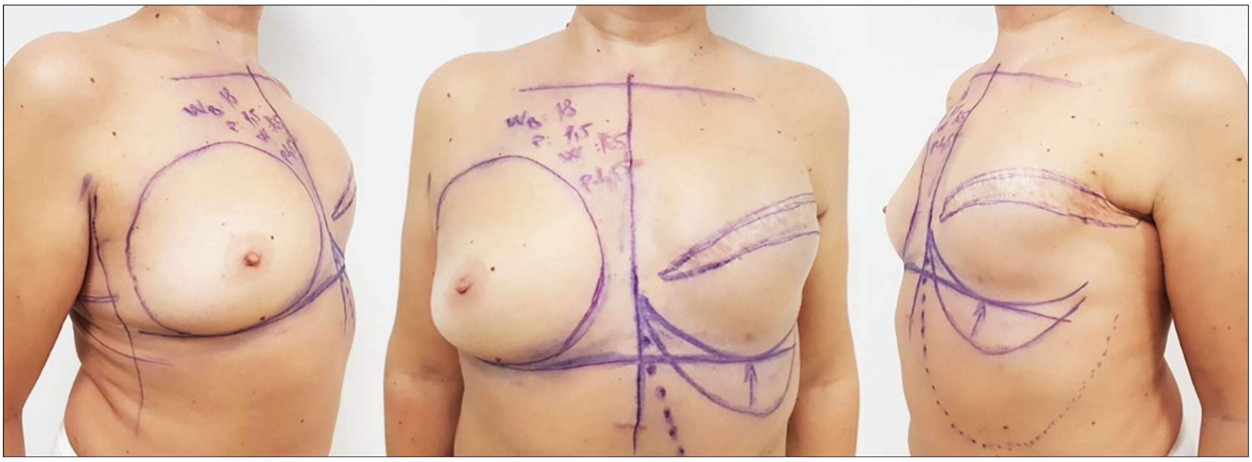


Figure 1. Preoperative markings for right robot-assisted nipple-sparing mastectomy with immediate breast reconstruction and left breast implant revision surgery

with sterile drapes. The operating table was rotated towards the opposite side. The robot was positioned on the opposite side of the operated breast. The middle of the robot's shoulder was aligned with the nipple. The robot's arms were crossed over the patient's chest. The target markings of the robot were aligned with the incision and the nipple.

Two incisions were placed on the lateral thoracic wall, 6 cm posterior from the lateral mammary fold. The first one was a high vertical 4 cm incision within the bra's footprint, while the second one was a subcentimeter vertical incision located 8 cm below.

To reduce bleeding and produce hydrodissection between the skin and breast tissue, 200 milliliters of adrenaline diluted in saline solution were injected into the subdermal layer of the breast skin using a liposuction cannula. Subcutaneous dissection was performed using manual scissors, connecting the two incisions. The 3 mm × 8 mm diameter ports were inserted and secured to the skin using stiches (two in the upper incision and one in the lower incision). A 30-degree camera was used to provide visualization, and the cavity was insufflated with CO2 gas at a pressure of 6-8 mmHg.

The gland was dissected from the subcutaneous flap from lateral to medial, followed by the dissection from the pectoralis major muscle from lateral to medial with monopolar curved scissors. The traction was performed using bipolar grasping forceps (*Fig. 2*). The assistant surgeon was standing by the patient to oversee the robot arms and trans-illumination through the breast skin (*Fig. 3*). This allows for observation of the extension of the dissection externally. Throughout the procedure, caution is taken to preserve the perforating branch from the 2nd intercostal artery, which reduces the risk of losing the nipple-areolar complex.

The robot was undocked and the ports were removed. The specimen was removed en bloc through the larger upper incision and was sent to histopathological examination (*Fig. 4*). The result of the histopathologic examination of the right breast showed no malignant lesions.

After proper hemostasis, a Mentor CPGTM 312 Gel Breast Implant Cohesive IIITM, Low Height, Moderate Plus Profile with a 465 cc volume was manually placed in the prepectoral pocket. Before inserting the implant, it was immersed in an iodine solution. The pocket was closed using sutures between the skin and thoracic wall. The drain was inserted through the inferior incision. The incisions of the right breast were sutured.

For the capsular contracture of the reconstructed left breast, an implant revision surgery was performed: removal of the Becker implant, partial capsulectomy, lowering the inframammary fold and placing a Mentor CPGTM 312 Gel Breast Implant Cohesive

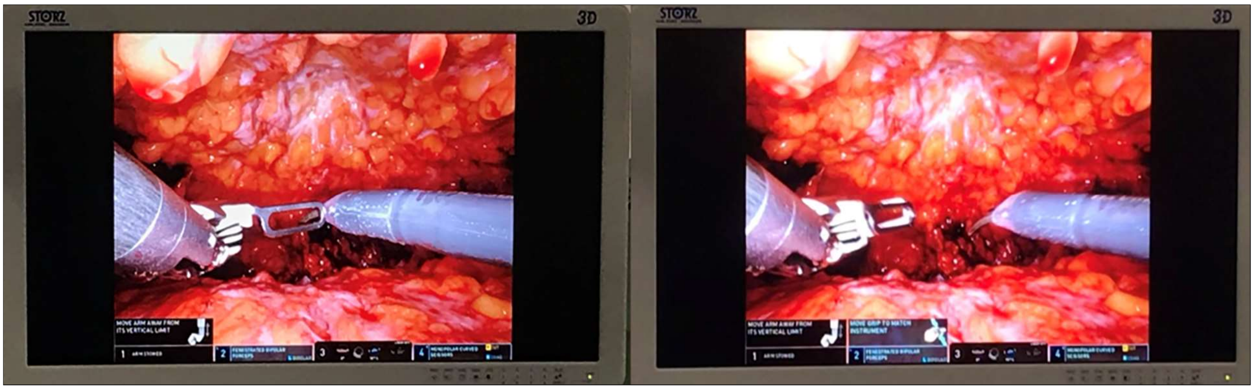


Figure 2. Intraoperative aspect during right robot-assisted nipple-sparing mastectomy with immediate breast reconstruction – dissection with monopolar curved scissors and bipolar grasping forceps

Figure 3. Intraoperative aspect during right robot-assisted nipple-sparing mastectomy with immediate breast reconstruction – da Vinci Xi surgical system

IIITM, Low Height, Moderate Plus Profile with a 465 cc volume.

The postoperative evolution was uneventful, except for a prolonged sero-hemorrhagic drainage following the robotic surgery. This was not accompanied by decreased levels of hemoglobin or periprosthetic hematoma and was treated conservatively. The bilateral postoperative aesthetic result was excellent (*Fig. 5*).

During follow-up, there were no signs of local recurrence or distant disease. However, the patient developed once again fourth-degree capsular contracture in the left reconstructed breast, leading to a decision for iterative implant revision surgery. In 2024, she was readmitted to the Prof. Dr. Alexandru Trestioreanu Oncology Institute in Bucharest for this procedure.

On March 18, 2024, under general anesthesia, the left implant was removed, and capsulotomy and partial capsulectomy were performed, followed by the placement of a Mentor CPG™ 323 Gel Breast Implant 620 cc. Postoperative recovery was uneventful aside from prolonged sero-hemorrhagic drainage, which was managed conservatively.

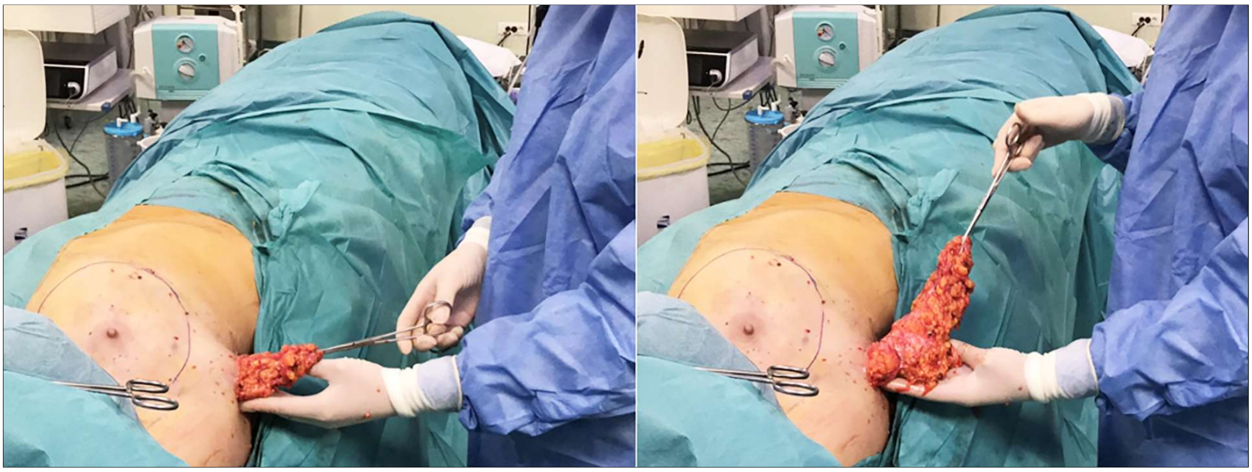


Figure 4. Intraoperative aspect during right robot-assisted nipple-sparing mastectomy with immediate breast reconstruction - removal of the specimen

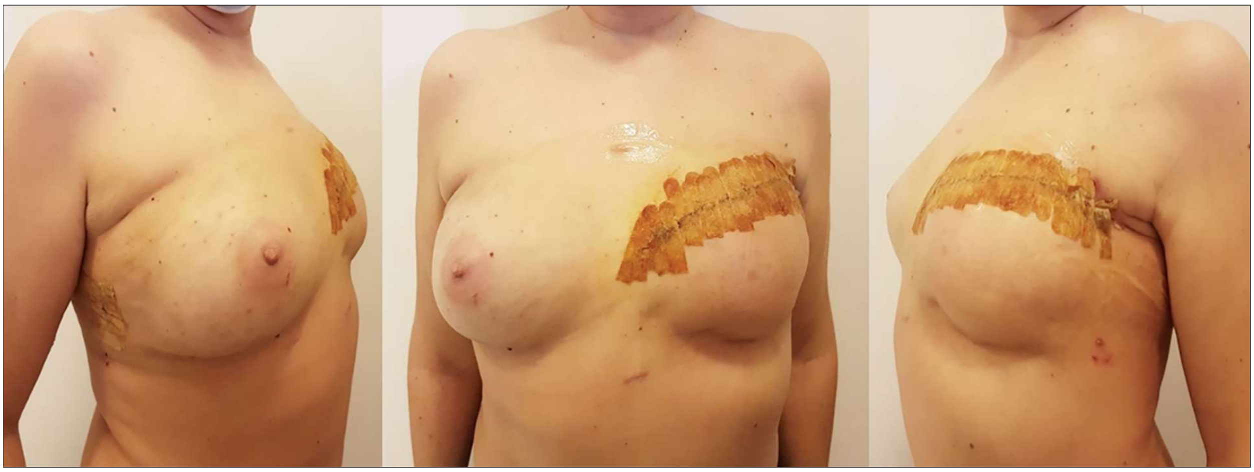


Figure 5. Postoperative results after right robot-assisted nipple-sparing mastectomy with immediate breast reconstruction and left breast implant revision surgery

Currently, there is no evidence of local recurrence or distant metastases after 17 years since the initial diagnosis, and the aesthetic result is satisfactory, with no signs of capsular contracture (*Fig. 6*).

Particularities of the Case

The patient had a locally advanced case of breast cancer at the moment of the diagnosis.

The oncological management of this case adhered to Romanian standards at the time. Today, the patient would likely receive a tumor re-biopsy, biopsy of axillary adenopathy, tumor and lymph node marking if metastatic, neo-adjuvant systemic treatment, sentinel lymph node biopsy and potentially a skin-sparing mastectomy with immediate two-stage breast reconstruction.

The patient underwent delayed breast reconstruction using alloplastic materials, yielding good aesthetic results initially.

However, capsular contracture developed gradually due to radiation therapy, necessitating two revision surgeries for implant exchange and highlighting a challenge in breast reconstruction for these individuals.

Concerned about an overestimated risk of recurrence, the patient requested a risk-

Figure 6. Results after second breast implant revision surgery

reducing mastectomy, leading to a planned bilateral procedure: risk-reducing mastectomy and revision surgery. The robotic-assisted mastectomy was performed without complications. Prepectoral immediate breast reconstruction following the nipple-sparing mastectomy, along with contralateral implant revision, resulted in a good aesthetic outcome. Although the prepectoral reconstruction remained favorable over time, another surgery was needed for contralateral capsular contracture.

Despite the advanced stage, the oncological evolution was favorable, with no sign of local recurrence or metastasis after 17 years.

Material and Methods

A systematic literature search was performed in the PubMed database, adhering to the Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The full articles were independently screened for eligibility based on predefined inclusion and exclusion criteria.

The search criteria were formulated to identify articles on "Robotic Surgery" AND "Nipple Sparing Mastectomy" AND "Breast Reconstruction." Ninety-six citations were identified by the search. Full texts were retrieved for studies that evaluated robotic-assisted nipple-sparing mastectomy (RNSM) followed by immediate breast reconstruction (IBR), reported original data and were written in English.

Inclusion and Exclusion Criteria

The inclusion criteria were:

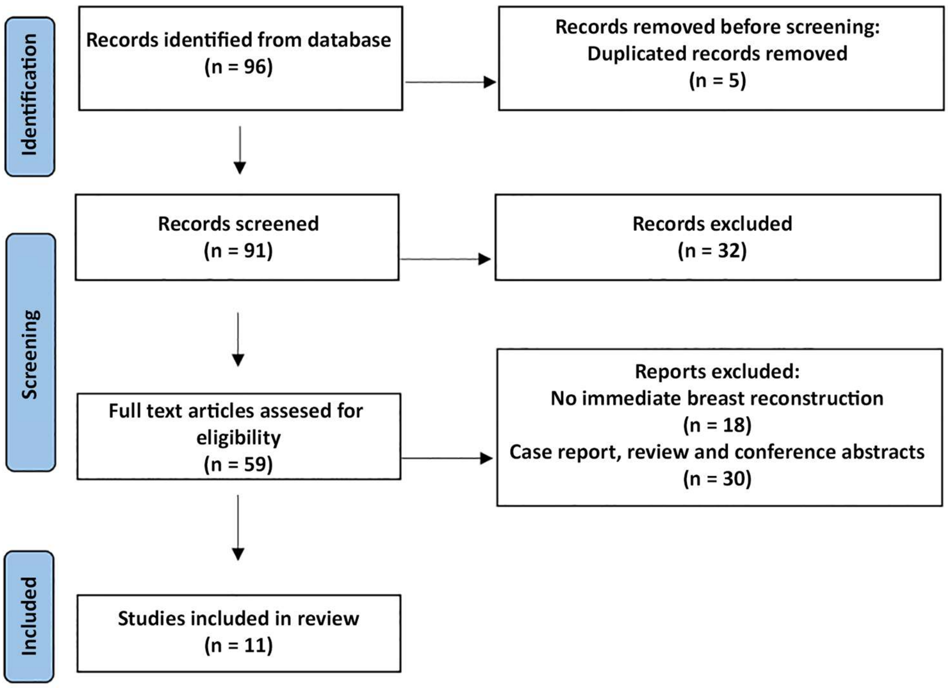
1. Participants: patients undergoing therapeutic or prophylactic RNSM with IBR.
2. Original studies.

Studies were excluded from the systematic review based on the following criteria:

1. Not possible to determine whether patients had immediate reconstruction.
2. Non-robotic endoscopic NSM and/or reconstruction.
3. Case report, review, and conference abstracts.

After applying the inclusion and exclusion criteria, eleven studies were included in the systematic review (*Fig. 7*).

Figure 7. PRISMA 2020 flow diagram



Results

We analyzed the data from the 11 studies regarding the following parameters: total operating time, conversion rate, complication rate, technique, hospitalization, cost, aesthetic outcome and oncological outcome (21-31).

Total Operating Time

A study on 10 patients and 12 procedures reported that the median total operation time was 351 minutes (267-480 minutes), while the console time was 51 minutes (18-143 minutes) (21).

A randomized controlled trial compared the open mastectomy procedure with the robotic technique and found that the latter took longer by an hour and 18 minutes (24). Another study reported similar results, with longer operation times observed in the RNSM group (25).

The learning curve for this technique depends on the surgeon's previous experience with robotic surgery. One study reported that the duration of the first robotic-assisted mastectomy they performed was 8 hours, while the 29th took only 3 hours, indicating a significant improvement (26). Similarly, another study found that the learning curve stabilized by the eighth case, as suggested by the console time (21). Another study also reported significant decreases in the time required for mastectomy, reconstruction, and total operation; these improvements appeared in the 22nd, 23rd, and 26th procedures, respectively (23). Besides the learning curve, other factors can impact the duration of surgery. Two studies found a correlation between operation time and factors such as the patient's body weight, size of the breast, lymph node involvement and implant size (22,23).

Conversion Rate

Three studies have reported on conversion rates during RNSM, with figures of 0% (0 out of 12 procedures), 1.4% (2 out of 138 procedures) and 6.9% (2 out of 29 procedures) due to technical issues (21,26,27).

Technique

A summary comparing the RNSM and IBR techniques described in the eleven studies included in this review can be found in *Table 1.*

Complications

The studies included in this review reported on grade I-III Clavien-Dindo complications such as hematoma, seroma, infection, wound dehiscence, skin necrosis and NAC necrosis, implant loss and pain.

Out of the 11 studies, complication rates were reported in seven, displaying considerable variation. The overall complication rates were as follows: 7.5% (6 out of 80 cases), 15.3% (13 out of 85 cases), 15.9% (22 out of 138 cases), 25.6% (10 out of 39 cases), and 40.7% (11 out of 27 cases) (22,23,27,28,31). Notably, two studies, with 12 and 29 procedures respectively, reported no major complications (21,26).

Four studies compared complication rates between the RNSM and CNSM. Three studies found no significant difference in the overall rates, observing 30% (12/40) versus 50% (20/40), 35% (14/40) versus 58.53% (24/41), and 41% (22/54) versus 46.8% (29/62) (24,25,30). One study reported a notable difference in high-grade post-operative complications: 17.1% (7/41) versus 34.8% (94/270) (29). A randomized control trial (RCT) concluded that patients undergoing open mastectomy had a higher likelihood of experiencing multiple complications compared to those in the robotic group (24).

Hematoma

Five studies have reported hematoma incidence rates of 1.2% (1/80), 2.6% (1/39), 2.9% (4/138), 7.4% (6/85) and 11.1% (4/27) (22,23, 27,28,31). When comparing hematoma formation rates, the RNSM and CNSM groups had the following rates: 1.9% (1/54 patients) versus 1.6% (1/62 patients), 0% (0/40 patients) versus 5% (2/41 patients), and 10% (4/40 patients) versus 17.5% (7/40 patients) (24,25,30).

Table 1. RNSM and IBR technique descriptions

Study	Sample size	Robot System	Incision	Port	Technique	Implant Pocket
Toesca et al (34,36)	24 patients 29 R-NSM and IBR (34) 40 patients 40 RNSM and IBR (36)	24 procedures with da Vinci Xi 5 procedures with da Vinci Si (34) da Vinci Xi (36)	1 cm X 3 cm incision along midaxillary line in axillary fossa	Single port with 4 mm X 5–12 mm access. Carbon dioxide insufflation: 8 mmHg. Camera: 0˚ 12-mm-diameter rigid camera.	Single port insertion. Specimen removed en bloc through the 3 cm axillary incision. Dissection of a submuscular pocket medially and inferiorly, with the complete release of the pectoralis major muscle from the thorax wall. The pectoralis major muscle attachment to the skin flap was spared. Implant inserted manually. Drains were placed in both submuscular and subcutaneous planes.	Submuscular pocket
Sanson et al (40)	79 patients 138 R-NSMs and IBR	da Vinci Xi	lateral-thoracic approach: two incisions 6-7 cm behind the lateral-mammary fold: a high vertical scar of 3-5 cm within the footprint of the bra and a sub-centimeter vertical scar, 8-9 cm below	Three 8 mm diameter ports through the lower incision. Carbon dioxide insufflation: 8 mmHg, 10 L/min. Camera: 30˚ camera	Infiltration of 1mg/mL of adrenaline diluted in saline solution to reduce bleeding. 3 ports were inserted and fixed with stitches to the skin (2 in upper incision and 1 in lower incision). Intraoperative frozen sections on a biopsy of the retroareolar ducts in the therapeutic cases. Removal of the gland en bloc through larger upper incision. Drain placed through the inferior infracentimetric scar.	Prepectoral pocket
Lai et al (37,39)	35 patients 39 RNSM and IBR (37) 51 patients 54 RNSM and IBR (39)	da Vinci Si	2.5–5 cm oblique axillary incision in the extra-mammary region	Single port. Carbon dioxide insufflation: 8 mmHg. Camera: 30˚ 12-mm diameter camera.	Subcutaneous infiltration with lidocaine 0.05% and epinephrine saline solution 1:1,000,000 to reduce bleeding. Biopsy of the retroareolar tissue to exclude NAC involvement. Gland removed en bloc through axillary incision. Implant placement in the sub-pectoral muscular pocket, which was formed by pectoralis major, serratus anterior, and fascia of external oblique muscle.	Sub-pectoral pocket
Moon et al (27)	40 patients 40 RNSM and IBR	da Vinci Si or da Vinci Xi	2.5-6 cm linear mid-axillary incision below the axillary fossa	Single-port. Carbon dioxide insufflation: 10 mmHg. Camera: 0˚ camera.	Sentinel lymph node biopsy through the incision. Insertion of a single-port device through the same incision. Dissection of the skin flap and/or retromammary space. The retroareolar tissue was resected to evaluate tumor cell involvement in a frozen section. Retrieval of the entire breast parenchyma through the same incision. Prepectoral IPBR using DTI or tissue expander.	Prepectoral pocket
Houvenaeghel et al (46)	27 patients. 27 RNSM and IBR 17 cases with robotic latissimus dorsi-flap (RLDF), 6 with RLDF and implant, 4 with implant.	14 procedures with da Vinci Si 13 procedures with da Vinci Si	4-6 cm vertical axillar incision on anterior axillary line	Three ports. Carbon dioxide insufflation: 7 mmHg. Camera: 0˚camera.	Dissection on 3–4 cm for subcutaneous plan and a limited dissection under incision along anterior axillary line. Insertion of the robotic trocars about 6 cm under axillar incision. Gland removed en bloc through axillary incision. Biopsy of the retroareolar tissue with extemporaneous analysis. Drains: dorsal area (2 through the incision) and i mastectomy area (1). Implant insertion.	Sub-pectoral pocket
Loh et at (30)	78 patients 85 RNSM and IBR	da Vinci Si	4-cm curved axilla incision along the midaxillary line n the axillary fossa.	Single-port. Carbon dioxide insufflation: 8 mmHg. Camera: 30˚ 12-mm diameter camera.	Subcutaneous infiltration of saline solution, xylocaine, epinephrine and $NaHCO_3$. Axillary lymph node surgery or sentinel lymph node biopsy if needed. Gland removed en bloc through axillary incision. Biopsy of the retroareolar tissue. Retrieval of the breast through the axillar incision. Dissection to create a muscular pocket. Implant placement. Drain placement laterally to the serratus anterior muscle and over the inframammary fold.	Sub-pectoral pocket

Table 1. Cont'd

Study	Sample size	Robot System	Incision	Port	Technique	Implant Pocket
Park et at (30)	10 patients 12 RNSM and IBR	da Vinci Si or da Vinci Xi	3.5–6 cm longitudinal incision in the anterior axillary line below the axillary fossa.	Single-port. Carbon dioxide insufflation: 10 mmHg. Camera: 0˚ camera.	Injection of indigo carmine around the NAC for sentinel lymph node biopsy. Sentinel lymph node biopsy through the incision, without robotic assistance. Resection of the retroareolar ductal tissue for frozen section examination. For 10 procedures, gasless method with a self-retractor and for two procedures insuflation of carbon dioxide gas. Removal of the breast through the axillary incision. Implant placement.	Prepectoral pocket
Go et at (19)	70 patients 81 RNSM and IBR	da Vinci Si or da Vinci Xi	2.5-6 cm incision at the nipple level along the anterior axillary line on the brassiere line.	Single-port. Carbon dioxide insufflation: 10 mmHg. Camera: 0˚ camera.	Injection of indigo carmine around the NAC for sentinel lymph node biopsy. Sentinel lymph node biopsy through the incision, without robotic assistance. Injection of a tumescent solution into the subcutaneous layer. Docking and gas inflation. Excision of nipple core or retroareolar tissue for frozen section examination. Removal of the breast through the axillary incision, with or without an 0.5-1.5 cm extension. Implant placement and fixation with acellular dermal matrix. Drain placement in the axilla and inframammary fold.	Prepectoral pocket

Seroma

The frequency of seroma formation after robotic mastectomy in two studies was 2.6% (1 out of 39 cases) and 5.1% (7 out of 138 cases) (22,27). Two studies comparing seroma rates between robotic and open surgery found lower rates in the robotic group: 7.5% (3/40) versus 15% (6/40) and 5.6% (3/54) versus 8.1% (5/62) (24,25). In another study, the rates were equal in the two groups, 5% (2 out of 40 patients versus 2 out of 41) (30).

Infection

Three studies reported infection rates following RNSM as follows: 1.2% (1 out of 80 cases treated with drain insertion and antibiotics), 1.4% (1 patient out of 85 procedures resulting in implant loss), and 6.5% (9 out of 138 cases, 4 requiring implant replacement and 5 resulting in implant loss) (23,27,28). Two studies comparing the incidence of surgical site infections between the RNSM and CNSM groups found similar rates: 5% (2/40) versus 5% (2/40) and 7.5% (3/40) versus 7.3% (3/41) (24,30). Another study reported a higher infection rate in the robotic group 7.3% (3 out of 41) versus 2.2% (6 out of 270) (29).

Wound Dehiscence

In two studies, the incidence of wound dehiscence was 1.2% (1 out of 80 cases) and 5.1% (2 out of 39 cases) respectively (22,28). Two studies comparing wound dehiscence rates after robotic and open surgery reported no significant differences: 0% (0/40) versus 2.5% (1/40) and 3% (1/40) versus 10% (4/41) (24,30).

NAC and Skin Flap Ischemia and Necrosis

Three studies reported NAC ischemia/necrosis rates as follows: 1.25% (1/80 cases of nipple necrosis requiring reintervention), 7% (5/85 cases, 4 cases of partial NAC ischemia and 1 case of total NAC necrosis) and 10.3% (4/39 cases of partial nipple ischemia treated conservatively) (22,23,28). In three studies skin flap ischemia/necrosis rates were observed at 1.4% (1/85 skin flap necrosis) and 2.5% (2/80 skin flap necrosis) and 5.1% (2/39 cases of skin flap partial ischemia managed conservatively) (22,23,28). One study reported a rate of NAC or skin flap necrosis of 1.5%, with 2 cases of major necrosis out of 138 procedures (27). When comparing the rates of skin and NAC ischemia and necrosis in the RNSM and CNSM, three studies found no significant differences in NAC ischemia/necrosis rates between the two groups, with rates of 0% (0/40) versus 5% (2/40), 13% (7/54) versus 14.5% (9/62) and 13% (5/40) versus 14% (6/41) (24,25,30). One study reported that NAC necrosis rates were significantly lower after robotic surgery, 2.4% (1 out of 41 cases) versus (15.2%, 41 out of 270 cases) (29). Another study found the rate of skin necrosis was significantly lower after robotic surgery 0% (0/40) versus 12.5% (5/40) (24).

Implant loss- Three studies reported implant loss rates of 0% (0/39 cases), 1.4% (1/85 cases due to infection), and 6.5% (9/138 cases: five from surgical site infections, two from major necrosis, and two from peri-prosthetic capsule contracture) (22,23,27). In comparing implant loss rates between robotic and open surgery, three studies found no significant difference: 0% (1 out of 54) vs. 1.6% (1 out of 620); 1.65% (2 out of 40 cases, one due to infection, one to implant exposure) vs. 2.5% (1 out of 40 cases due to infection); 2.4% (1 out of 41) vs. 0.7% (2 out of 270) (24,25,29).

Pain

There were only two studies that looked at postoperative pain. In the RCT, no significant difference was found in the levels of post-operative pain between the two groups, estimated by NSM scores (24). In a study comparing postoperative pain between RNSM and CNSM groups, there was no difference in scores for pain within 48 hours after surgery and in the number of patients needing extra pain relief (30).

Hospitalization

One study compared the hospitalization after dissection of the skin flaps and NAC performed using three techniques. Group 1 underwent NAC dissection with robotic scissors using coagulation, group 2 with robotic scissors without coagulation, and group 3 with non-robotic scissors followed by robotic dissection. The study found that post-operative hospitalization decreased from group 1 to 3 (31).

Cost

Only one study reported on cost, with higher medical expenses in the RNSM group compared to the CNMS group (10,877 ± 796 USD versus 5,702 ± 661 USD) (25).

Oncological Outcome

Among the nine studies, a total of 356 therapeutic mastectomies were performed. The oncological outcomes and safety of RNSM are evaluated based on positive margins, recurrence, and survival rates.

In one study, only one out of 35 patients requiring a therapeutic RNSM (2.9%) had a positive margin in the final histopathologic check-up (22). Three studies reported on local recurrence rates: 0% (0/35 during a mean follow-up of 8.6 ± 4.5 months), 0% (0/40 after a median follow-up of 28.6 months), 1.17% (1/85 after a mean follow-up of 11.4 +- 6.2 months) (22-24).

Aesthetic Outcome

One study found that RNSM was associated with higher overall satisfaction (92% excellent and 8% good) compared to CNSM (75.6% excellent and 24.4% good) (25).

In a randomized control trial, it was observed that patients who underwent robotic mastectomy reported significantly higher Breast-Q scores in satisfaction with breasts, as well as psychosocial, physical, and sexual well-being when compared to those who underwent an open procedure. The physical and sexual well-being domains remained stable after robotic mastectomy, whereas they significantly decreased after the open procedure when compared to baseline (24).

Discussions

The robotic-assisted nipple-sparing mastectomy provides better visibility, access and higher quality of dissection through smaller incisions compared to conventional nipple-sparing mastectomy (19). Since 2015, on average fifty robotic mastectomies have been performed annually in eight countries worldwide: USA, France, Italy, Turkey, Taiwan, Singapore, Korea, and India (1,9,14,19-39). Adopting RNSM could improve surgical practice by providing a less invasive option with improved cosmetic results. For patients, this means a physically less invasive procedure and significant psychological benefits due to a better body image post-surgery (25).

Robotic-assisted mastectomy is a surgical technique that offers certain benefits and drawbacks.

It is a minimally invasive technique that offers excellent visualization and access to surgical planes. This results in high-quality images, increased surgical precision in confined spaces and eliminates tremors (25, 29,30,35,36). However, compared to abdominal robotic-assisted surgery, robotic-assisted mastectomy relies heavily on the assistant surgeon to ensure the proper thickness of the flaps (34).

Comparing robotic-assisted nipple-sparing mastectomy with immediate breast reconstruction to open surgery, the complication rates, such as hematoma, seroma, infection, wound dehiscence, implant loss, and pain are similar (21-31). Nonetheless, one study reported that high-grade post-operative complications with RNSM were half as frequent as those with CNSM (29). The robotic-assisted technique enhances precision, potentially improving vascularization preservation. Most studies found that skin flap and NAC ischemia and necrosis rates after RNSM are low and comparable to those in CNSM (22-25, 27,28,30). Two studies found substantially lower skin and NAC necrosis rates after RNSM: 0% vs. 12.5% and 2.4% vs. 15.2%, respectively (24,29).

RNSM usually provides superior aesthetic results compared to CNSM, particularly in terms of scars, breast symmetry, and contour. These elements greatly impact patient satisfaction and quality of life, making RNSM an attractive option for selected patients (24,25).

Also, there are several advantages of RNSM compared to endoscopic nipple-sparing mastectomy (ENSM), including reduced blood loss, a shorter learning curve for surgeons, and improved patient satisfaction regarding wound characteristics such as length, location, and scar appearance (40).

However, longer operation time, longer learning curve, higher costs, low degree of standardization, limited indication and lack of research on long-term oncological outcomes are some of the disadvantages of this technique when compared to open surgery (24, 25,30,37-39).

This technique tends to have a longer operation time than open surgery, which can increase risks, especially for patients with comorbidities due to prolonged anesthesia. Improved surgical experience, training, standardization, and technology advancements can reduce operation time. Addressing factors like the learning curve, patient's body weight, breast size, lymph node involvement, and implant size is crucial for the technique's success (21-25).

RNSM is associated with a longer learning curve and is a significant factor in the implementation and success of this technique. While initial challenges are substantial, proper training and experience help surgeons achieve excellent outcomes (21,23,26).

While the conversion rate in RNSM remains a concern, it is a manageable aspect of the learning curve and procedural development. With careful patient selection, thorough preoperative planning and experience, conversion rates are likely to decrease over time, Nevertheless, acknowledging the potential for conversion and maintaining a focus on patient safety ensures that RNSM can be performed effectively and with minimal risk (21,26,27).

Robotic-assisted nipple-sparing mastectomy offers potential clinical benefits, but it is significantly more expensive than traditional methods. The higher costs result from investments in robotic systems, specialized instruments, extended surgical times, and the need for comprehensive training. Nonetheless, advancements in robotic surgery and improved accessibility may increase the cost-effectiveness of RNSM, making it more viable in the future (25).

When comparing RNSM to ENSM there are also important disadvantages: longer operation times, higher associated medical costs and equipment dependence (40).

Robotic-assisted mastectomy is currently conditionally recommended only for prophylactic purposes. However, in experimental studies, this technique is used for the treatment of selected patients with early-stage breast cancer (20).

Despite the promising findings, this article highlights several limitations, including a limited number of cases, few randomized control trials, a lack of long-term outcome data and potential biases in patient selection for RNSM. Future research should focus on randomized controlled trials and larger sample sizes to validate these preliminary results. They should explore the long-term oncological outcomes of RNSM and its applicability in a wider range of patients, including those with higher BMI or more advanced stages of breast cancer. Additionally, advancements in robotic technology and enhanced training programs could mitigate the learning curve and further improve patient outcomes. There are twelve ongoing clinical studies at various stages regarding robotic-assisted mastectomy, including eight interventional and four observational trials. Out of these, ten studies focus on robot-assisted mastectomy for breast cancer. While many studies confirm the oncological safety of this technique, additional research with a larger number of patients and longer follow-up periods is necessary to establish it as the standard of care for selected breast cancer patients who are not suitable for more conservative surgical alternatives.

Conclusions

Robotic-assisted mastectomy represents a significant advancement of video-assisted technique in breast surgery, being feasible and technically possible. This technique ensures better surgeon ergonomics and visualization compared to the video-assisted approach by minimally-invasive technique. This approach is associated with higher rates of preserving blood supply to the skin envelope of the breast and the nipple-areola complex, with a lower incidence of ischemia and necrosis. Additionally, it allows for smaller incisions for mastectomy, resulting in better aesthetic outcomes. The disadvantages of this technique remain the total cost and operating time.

Currently, robotic-assisted mastectomy is conditionally recommended for prophylactic mastectomy, which was also the indication for our presented case. The safety of this procedure in cancer treatment is not yet proven. While current evidence is promising, ongoing research and refinement of the technique are essential to fully realize its benefits.

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