STUDY PROTOCOL

PROTOCOL TITLE:

Pilot Robotic Mastectomy in Singapore (PRoMiSing I) Study: First Safety and Feasibility Prospective Cohort Study in South East Asia

PROTOCOL VERSION: 5.0

PROTOCOL DATE: 05 Jul 23

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PROTOCOL SIGNATURE PAGE

Protocol Title: Surgical and Patient Reported Outcomes in Robotic Mastectomy – A Pilot Study

Protocol Number: NA

Protocol Version/ Date: 5 dated 05 July 2023

Sponsor Name: NA

Declaration of Investigator

I confirm that I have read the above-mentioned protocol and its attachments. I agree to conduct the described trial in compliance with all stipulations of the protocol, regulations and ICH E6 Guideline for Good Clinical Practice (GCP).

Principal Investigator Name: _____

Principal Investigator Signature: _____

Date: _____

1. BACKGROUND AND RATIONALE

Conventional nipple and/or skin-sparing mastectomy (NSM/SSM) with or without immediate reconstruction is becoming one of the mainstream surgical treatment for breast cancer and risk reducing mastectomy in recent years. While this technique provides satisfactory oncologic and aesthetic outcomes, its disadvantages include skin flap and/or nipple-areolar complex (NAC) necrosis, NAC malposition/distortion as well as visible scar(s) on the breast.

In terms of technical aspects, NSM/SSM has its inherent challenges in view of limited incisions and thereby difficulties in dissection. Since 2015, a number of institutions worldwide had adopted a new technique of NSM/SSM using robotic surgical system. Institutional experiences worldwide demonstrated feasibility and safety of this technique coupled with improved patients' satisfactions.

To date, there is no center in Singapore or the region offering Robotic NSM/SSM (R-NSM/R-SSM). The authors believe that robotic mastectomy is a feasible and safe technique that can be utilized in our institution and it provides superior aesthetic outcomes with less morbidity and higher patient satisfaction if compared to conventional NSM/SSM.

The aim of this study is to conduct a single-arm prospective pilot study to investigate the safety and feasibility, as well as aesthetic outcomes, surgical complications and patients' satisfactions of R-NSM/R-SSM.

2. HYPOTHESIS AND OBJECTIVES

Hypothesis

Based on institutional cohort studies to date, we believe that robotic mastectomy is a safe surgical alternative to conventional surgery in terms of surgical outcomes while offering comparable if not superior aesthetic outcomes and improved patients' satisfactions.

Objectives

The proposed study aims to report to ascertain on the surgical outcomes, aesthetic and health related quality of life outcomes as well as satisfaction in patients undergoing robotic mastectomy.

Primary Outcomes:

1. Surgical Outcomes
    - Operative parameters - docking time, console time, reconstruction time, total operative time
    - Length of stay – defined as the length of hospitalization from admission till discharge
    - 30-days morbidity/complications

Secondary Outcomes:

1. Oncologic outcomes
   - Positivity of margins as a surrogate for short term oncologic safety
2. Health-Related Quality of Life (QOL) and Patient Satisfaction using validated Breast-Q questionnaire at 1 and 6 months after operation

Surgical Outcomes

- Operative parameters
  - Docking time – defined as time taken to dock the robot before robotic mastectomy
  - Console time – defined as time taken for robotic mastectomy robot docking time, conversion)
  - Reconstruction time – defined as time taken for breast reconstruction, if applicable
  - Total operative time – defined as time taken from axilla staging procedure, robot docking time, console time, closure and time taken for reconstruction, if applicable.
  - Length of stay – defined as the length of hospitalization from admission till discharge

- 30-days morbidity/complication
  - Wound infection requiring intervention – defined as wound infection where conservative treatment fails and requires surgical debridement
  - Flap and nipple areolar complex (NAC) necrosis – defined as ischaemia of mastectomy skin flap or nipple areolar complex necrosis
  - Postoperative hematoma/bleeding requiring intervention – defined as immediate post-operative bleeding or haematoma requiring emergent exploration and haemostasis
  - Anesthesia related complications – defined as complications related to anaesthesia conduct

Oncologic outcomes

- Positivity of margins – defined as margins involved or uninvolved. Margins involvement is defined as tumor-on-ink for invasive carcinoma and 2 mm margin or less for ductal carcinoma-in-situ

Health-Related Quality of Life (QOL) and Patient Satisfaction using validated Breast-Q questionnaire at 1 and 6 months after operation

- Health-Related QOL- defined as QOL from psychosocial, physical and sexual well-being perpectives
- Patient satisfaction – defined as satisfaction with breasts, satisfaction with outcome and satisfaction with care

3. EXPECTED RISKS AND BENEFITS

Risks associated with robotic mastectomy are similar to conventional surgical options which are as below:

- Post-surgical Pain
- Post-surgical Bleeding / Haematoma
- Wound Infection / Abscess
- Wound Breakdown and /or Necrosis
- Scar and Keloid formation.
- Shoulder Stiffness
- Numbness
- Seroma

Benefits include, but not limited to:

- Smaller incision which may translate to lesser pain and faster recovery
- Improved patients' satisfaction

4. STUDY POPULATION

4.1. List the number and nature of subjects to be enrolled.

Patients who fit the inclusion and exclusion criteria detailed below will be enrolled. Each breast operated on will be consider as 1 case eg, if a patient is scheduled for bilateral mastectomy it will be considered as 2 cases. Study may recruit up to 20 patients to achieve the target of 20 cases.

4.2. Criteria for Recruitment and Recruitment Process

Patient selection for robotic mastectomy are similar to conventional mastectomy.

4.3. Inclusion Criteria

Women aged 21-70, with invasive breast cancer, ductal carcinoma in situ (DCIS), BRCA or other breast cancer genetic mutation carriers or high risk female patients who are otherwise candidates for conventional NSM/SSM will be eligible for the study. All suitable patients will be offered the option of R-NSM/ R-SSM.

For patients with breast cancer (invasive or DCIS), selection criteria include but not limited to:

1. Early breast cancer
2. Tumor size less than 5 cm
3. No evidence of lymph node metastases
4. No evidence of skin or chest wall invasion.

4.4. Exclusion Criteria

1. Extensive axillary lymph node metastasis (Stage IIIB or later)
2. Heavy smokers (>20 cigarettes a day)
3. High risk patient with severe and poorly controlled co-morbid conditions (include but not limited to diabetes, heart disease, renal failure or liver dysfunction)
4. Poor performance status or high risk for anaesthesia (ASA 3 and above)
5. Inflammatory or Locally Advanced Breast Cancer (with or without chest wall or skin invasion)
6. Previous thoracic radiation therapy for any reason
7. Pregnancy
8. Psychiatric, addictive, or any disorders which compromises the ability to give informed consent for participation in this study

5. STUDY DESIGN AND PROCEDURES/METHODOLOGY

This study is a prospective pilot study which aims to recruit 20 patients for robotic mastectomy.

Patient selection

Patients who fulfil the inclusion and exclusion criteria will be enrolled in this study. Written informed consent pertaining to the use of clinical records or perioperative pictures will be obtained from each participant.

Pre-operative breast ultrasound, mammography and/or MRI are used to determine the eligibility of patients for robotic mastectomy. Computed tomography (CT) scan of the thorax,abdomen and pelvis as well as whole-body bone scan may be used to exclude the possibility of distant metastases in indicated cases.

Indications for robotic mastectomy include breast cancer (early stage breast cancer, tumor size of less than 5 cm, no evidence of lymph node metastases and no evidence of skin or chest wall invasion) and high risk ladies indicated for risk reducing mastectomy.

Contraindications include those with locally advanced breast cancer (with or without chest wall or skin invasion) or inflammatory breast cancer, extensive axillary lymph node metastasis (stage IIIB or later) or high risk patients with severe and poorly controlled co-morbid conditions (include but not limited to diabetes, heart disease, renal failure, liver dysfunction), pregnant ladies, patients with previous thoracic radiation as well as patients with any psychiatric, addictive, or any disorders which compromises the ability to give informed consent for participation in this study.

The inclusion and exclusion criteria are based on current evidence derived from exisiting literature on robotic mastectomy.

Data collection include clinicopathologic characteristics of patients, type of mastectomy, method of breast reconstruction (if any), operative time, intra-operative blood loss, length of hospital stay, complications and margin involvement. Patients' satisfaction and quality of life (QOL) will also be assessed using Breast-Q and QoR-15 questionnaire at screening and post operation.

Conduct of Robotic Mastectomy

- Pre-operative marking and positioning

Pre-operative marking will be done with the patient in standing and supine position. After induction of general anaesthesia, patient will then be placed in a supine position with ipsilateral arm abducted to 90° to avoid conflict with the operative procedure.

- Axillary staging procedure

In patients for whom sentinel lymph node biopsy (SLNB) is indicated, 3 to 5ml of 1% methylene blue (Merck, Darmstadt, Germany) will be injected into the breast parenchyma facing the ipsilateral axilla after induction of general anaesthesia. The breast tissue around the injection site will be gently massaged for 5 to 10 minutes. SLNB will be performed according to standard practice. Fresh frozen section will be sent for intra-operative analysis as indicated. If SLN is positive for metastases, a complete axillary lymph node dissection (ALND) up to level II will be performed.

- Robotic Docking and Mastectomy

To create working space for placement of the single port (Glove Port; Nelis Corporation, Gyeonggi-do, Korea), a 3–4 cm subcutaneous flap will be dissected with electro cautery under direct vision. The tunneling technique is then used to facilitate skin flap dissection and create space between the skin flap and the breast parenchyma. Once adequate dissection is achieved, the single port is then inserted through the axilla incision and carbon dioxide (CO2) insufflation with air pressure kept at 8 mmHg will be used to create space for mastectomy. The ipsilateral shoulder will be elevated to 30 degrees to prevent conflict between the operating table and docking of the robotic surgery system. The robotic side cart (da Vinci; Intuitive Surgical, Sunnyvale, CA, USA) is then positioned from the contralateral side or over the patient's head, with the two robotic arms endoscope extending over the patient in proximity to the ports before the ports are then docked to the robotic arms. Subsequently, the conduct of the operation is then shifted to the da Vinci Xi (Intuitive Surgical, Sunnyvale, CA, USA) robotic platform controlled by the operating surgeon at the console. A 30 degree 12 mm diameter camera (Intuitive Surgical, Denzlingen, Germany) in the upper port will be used to prevent collisions with other instruments. Dissection is carried out using a 8 mm monopolar scissors (Intuitive Surgical, Sunnyvale, CA, USA). Traction and counter-traction, along with maintaining exposure will be carried out using a 8 mm ProGrasp forceps (Intuitive Surgical, Sunnyvale, CA, USA). The location of the scissors and the ProGrasp forceps could be changed inter-variably during the operation. Dissection is first initiated from the superficial skin flaps by dissecting the septa between the skin flap and parenchyma created by the tunneling technique with monopolar scissors. A sub-areolar biopsy and fresh frozen section analysis will be performed in a nipple sparing mastectomy. If cancer cell invasion is then found in the sub-areolar area, the entire NAC will be removed and conversion to a skin sparing mastectomy will be performed. After completion of the superficial skin flap dissection, dissection of the peripheral portion of the breast parenchyma is carried out subsequently. Posterior dissection is then performed by detaching the breast tissue from the pectoralis major muscle fascia with the perforator vessels clearly identified and secured. After completion of dissection, the entire breast specimen will be removed intact through the incision.

Reconstruction

In this study, suitable participants can opt for immediate reconstruction with implant or autologous tissue (latissimus dorsi flap) reconstruction

- Immediate Implant Reconstruction

Following removal of the specimen and adequate haemostasis, copious irrigation of the mastectomy pocket will be performed. Subsequently, the lateral border of the pectoralis major muscle is elevated to allow for submuscular pocket dissection. The working space is then developed under direct vision by electrocautery with assistance of a handle light retractor. The single port will then be re-inserted with CO2 insufflation for robotic sub-muscular pocket dissection using the da Vinci surgical platform. Dissection is performed medially towards the sternal border, taking care not to injure the perforator vessels. Inferiorly, the dissection is carried out beyond the inframammary fold over the lateral aspect, below which the muscle will be released to continue the dissection to the subcutaneous plane thus allowing for a more natural placement of the implant. In the lateral border, the superficial fascia of the serratus anterior muscle will be dissected posteriorly in a limited fashion so that it will just be enough to accommodate the lateral border of the implant. After initial dissection of the sub-muscular space with the da Vinci surgical platform, the robotic instruments and single port will then be removed. The operating table will be repositioned into the sitting position. The adequacy of the sub-muscular pocket dissection is checked and completed with the assistance of a light source retractor. After creation of the submuscular pocket, an implant (Mentor Worldwide LLC, Santa Barbara, CA) will then be placed followed by drains placement in both submuscular and subcutaneous planes. An acellular dermal matrix (ADM) or mesh might be used based on surgeon's discretion.

- Immediate Pedicled Latissimus Dorsi (LD) Flap Reconstruction

Following removal of the specimen and adequate haemostasis, copious irrigation of the mastectomy pocket is performed. Subsequently, the thoracodorsal pedicle is identified and marked with a vessel loop to prevent injury during the flap harvest. Patient is then shifted to the lateral decubitus position. Two 12 mm balloon trocars (Kii Balloon blunt tip system, Applied Medical, Rancho Santa Margarita, CA, USA) will be used as working ports. The ports are then docked to the robotic arms, and CO2 insufflation is applied at 10–12 mmHg. Dissection will then start along the under surface of the latissimus dorsi muscle. Blood vessels encountered are carefully dissected, coagulated and cut with monopolar scissors. As the dissection through the under surface of the muscle to the borders is completed, further dissection over the superficial surface of the muscle ensued. The muscle is then disconnected from the infero-posterior and scapular border. Afterwards, the pedicled LD flap is exteriorized from the axilla wound and the robotic arms are then undocked. Reconstruction of the mastectomy defect will be performed with the patient turned back to a supine position. Fixation of the flap to all quadrants is performed with assistance from a handle light retractor to ensure full coverage of the defect. Care must be taken to ensure the correct axis of the vascular pedicle in order to prevent torsion of the blood supply. Drains will then placed both in the donor site as well as mastectomy cavity.

Perioperative monitoring and discharge criteria
Patients will be monitored in 23-hour ward as per current department protocol as conventional mastectomy and discharged on post-operative day 1 if discharge criteria fulfilled.

Discharge criteria include ALL of the following:

Patient MUST have ALL of the following:

- Stable vital signs
- Able to maintain pre-procedure mobility with minimal assistance as appropriate for the procedure
- Able to retain feeds
- Able to pass urine
- Has a responsible adult to accompany him/her home

Patient must NOT have ANY of the following:

- Excessive pain not relieved by oral analgesics
- Excessive nausea/ vomiting
- Severe giddiness
- Respiratory depression/ difficulty
- Bleeding from surgical wound

**Patient who doesn't fulfil ALL of the above will be admitted for further observation*

	Visit 1 (Screening)	Visit 2 (Day of Surgery)	Visit 3 (+/-2 weeks) (30th POD)	Visit 4 (+/- 2 Weeks) (6 months POD)
Consent taking	X			
Eligibility Check	X			
Adverse Event Assessment		X	X	X
Clinical Assessment	X		X	
Collection of medical information	X	X	X	X

As part of standard care, patients will be followed up as per conventional surgery. This includes twice weekly review of wound by the breast surgeon/ breast care nurses, with the earliest visit scheduled on post-operative day 4 and to continue until wound(s) have completely healed.

6. SAFETY MEASUREMENTS

6.1. Definitions

Serious adverse event (SAE) in relation to human biomedical research, means any untoward medical occurrence as a result of any human biomedical research which:

- results in or contributes to death
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in or contributes to persistent or significant disability/incapacity or
- results in or contributes to a congenital anomaly/birth defect
- results in such other events as may be prescribed

Adverse event (AE) in relation to human biomedical research means any untoward medical occurrence as a result of any human biomedical research which is NOT serious. Adverse event can be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease possibly/ probably/ definitely associated with the participant in the human biomedical research.

6.2. Collecting, Recording and Reporting of Serious Adverse Events (SAEs) to CIRB

Only related SAEs (definitely/ probably/ possibly) will be reported to CIRB. Related means there is a reasonable possibility that the event may have been caused by participation in the research. Please refer to the CIRB website for more information on Reporting Requirement and Timeline for Serious Adverse Events.

The investigator is responsible for informing CIRB after first knowledge that the case qualifies for reporting. Follow-up information will be actively sought and submitted as it becomes available.

Related AEs will not be reported to CIRB. However, the investigator is responsible to keep record of such AEs cases at the Study Site File.

6.3. Safety Monitoring Plan

The principal investigator will be responsible for ensuring participants' safety and for reporting Serious Adverse Events (SAE) and Unanticipated Problems (UP) to his Institutional Review Board (IRB) as required. The IRB will act in an advisory capacity to monitor participant safety, evaluate the progress of the study, to review procedures for maintaining the confidentiality of data, the quality of data collection, management, and analyses.

6.4. Collecting, Recording and Reporting of Reportable Adverse Events relating to Medical Device to the Health Sciences Authority (HSA)

The reporting requirements will be will be based on the reporting requirements published on HSA website at the time when the event took place.

All adverse events relating to medical device which meets the three basic reporting criteria listed below, is considered as a reportable adverse event to HSA:

- An AE (or potential AE) has occurred.
- The medical device is associated with the AE.
- The AE leads to one of the following outcomes:
  - It becomes a serious threat to public health.
  - The death of a patient, user or other person.
  - Serious deterioration in state of health of patient, user or other person.
  - There is no death or serious injury in the initial AE but it might lead to death or serious injury of a patient, user or other person if the AE recurs.

7. DATA ANALYSIS

7.1. Data Quality Assurance

The principal investigator will institute a continual quality control and quality improvement programme to ensure the collection of high-quality data. These measures include a rigorous training and vetting programme for the research co-ordinator, a practice of zero-assumption for vague and conflicting information, clear and systematic data definition guidelines and an extensive set of inter- and intra- field edits that are used to identify and correct errors in the data.

7.2. Data Entry and Storage

Data entry will be done into an encrypted REDCAP database, as well as SPSS/STATA database. The files will be secured with an ID and password. The data is manually coded and stored digitally in secured institutional cloud storage

8. SAMPLE SIZE AND STATISTICAL METHODS

8.1. Determination of Sample Size

As this is a pilot study aimed to assess feasibility and safety of robotic mastectomy, sample size calculation is not necessary. However, the principal investigator will apply the current flat rules of thumb for overall pilot trial sample size of a subsequent two-armed trial in determining the current sample size. Using this rule, a minimum pilot sample size of 20 cases is recommended.

For the sample size justification, confidence interval for one proportion approach with continuity correction method is used, which is able to identify a realistic uncertainty level about the safety endpoint based on binomial theory. A sample size of 20 cases will produce 80% confidence interval with a width equal to 28% (resulting in a 80% confidence interval of 6%-34%), when the sample proportion is 20%. Sample size calculation is performed using PASS software (PASS 14 Power Analysis and Sample Size Software (2015). NCSS, LLC. Kaysville, Utah, USA, ncss.com/software/pass.).

In addition, based on a learning curve analysis on robotic mastectomy, a minimum of 12 cases are required to reduce the operative time and a pilot sample size of 20 will allow for meaningful interpretation and analysis of learning curve data in this pilot study.

8.2. Statistical and Analytical Plans

Patient characteristics and outcome variables will be reported via descriptive statistics. Continuous variables will be presented as mean, standard deviation, median, first- and third-quartile, minimum and maximum; while binary and categorical variables will be reported as frequency and percent. 95% confidence intervals will be generated for the primary and secondary endpoints. Statistical analyses will be performed using SAS software version 9.4 for Windows (Cary, NC: SAS Institute Inc.).

9. DIRECT ACCESS TO SOURCE DATA/DOCUMENTS

The investigator(s)/institution(s) will permit study-related monitoring, audits and/or IRB review and regulatory inspection(s), providing direct access to source data/document.

10. QUALITY CONTROL AND QUALITY ASSURANCE

Data entry are assessed by the PI against source documents for accuracy. Data definition are drawn up and codes listed in a Data dictionary. Internal cross checks are performed for conflicting, unlikely and out-lying information. PI will be responsible for data quality.

11. ETHICAL CONSIDERATIONS

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with the Good Clinical Practice and the applicable regulatory requirements.

This final study protocol, including the final version of the Patient Information and Informed Consent Form, must be approved in writing by the Centralised Institutional Review Board (CIRB), prior to enrolment of any patient into the study.

The principle investigator is responsible for informing the CIRB of any amendments to the protocol or other study-related documents, as per local requirement.

11.1. Informed Consent

Written informed consent will be obtained from the patient by the principal investigator prior to any study procedures, and in a conducive environment without any coercion, duress or undue influence.

The informed consent form will also be personally signed and dated by the investigator obtaining informed consent, the trial participant or legal representative, and HBRA prescribed witness or impartial witness (if the trial participant is unable to read or personally sign or date the informed consent form).

The signature of the investigator obtaining informed consent should be consistent with the Signature Sheet.

11.2. Confidentiality of Data and Patient Records

The data in the database will be anonymised, and all patient identifiers will be coded. Patient's name and NRIC number will be stored in a separate file, which will not contain any details of their medical history. All files will be secured with an ID and password. Duplication of data is disabled.

Only the PI and research coordinator will have direct access to the research data and the rest of the study team members may request to have access via the PI. All requests to view the data will have to made through the PI and the PI will control and monitor who and how the data is accessed. Access will be controlled by password and encryption of excel files and other various software used to collate data.

12. PUBLICATIONS

We follow guidelines for authorship, acknowledgement for authorship of publication based on recommendations of the International Committee of Medical Journal Editors (http://www.icmje.org/recommendations/browse/about-the-recommendations/purpose-of-the-recommendations.html)

13. RETENTION OF STUDY DOCUMENTS

The electronic database will be retained for 7 years from the end of the study.

14. REFERENCES

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