Intervention study protocol

Project name: Application of Single-Port Robot-Assisted Breast-Conserving Surgery via Axillary Approach for Breast Cancer

Research unit: Army Medical Center

Study Department: Breast and Thyroid Surgery Department

Principal investigator: Yan Xu

Participating unit: Single-center

Version Number: V 2.0 Version Date: November 11,2024

declaration of secrecy

All information contained in this study protocol is owned by the investigator of this project and is provided only for review by the Clinical Research Management Committee, Ethics Committee and relevant institutions. Do not inform any third party unrelated to the study without the written consent of the Principal Investigator (PI).

Scenario summary

research topic	Application of Single-Port Robot-Assisted Breast-Conserving Surgery via Axillary Approach for Breast Cancer.
Main purpose of the study	1.To evaluate the efficacy of single-port robots in breast cancer breast consering surgery. Including differences in operative time and intraoperative number of lymph nodes detected. 2.To evaluate surgical safety: the incidence of surgical transfer and the incidence of postoperative complications.
Secondary purpose of the study	Pain and cosmetic scores of patients after breast conserving surgery under a single port robotic approach.
research design	□ Randomized controlled trial ☑ non-randomized controlled study □ Single-arm study □ Other
	☑ Single-center study □ multicenter study
	Whether blind: □ yes ☑ no
subject investigated	Patients undergoing breast-conserving surgery for breast cancer.
intervention study	Single-port Robot-assisted breast-conserving surgery for breast cancer.
endpoint criteria	Success rate of breast conservation surgery under single-port robotic approach
sample capacity	Total number of cases: 100; 20 in the test group; 80 in the control group

statistical analysis	Double data entry was carried out using Excel 2010, and data analysis was performed with SPSS 25.0. The normality of continuous variables and homogeneity of variance were examined by Kolmogorov-Smirnov test and analysis of variance test respectively. For continuous variables that conformed to normal distribution and had homogeneity of variance, the independent-samples t-test was adopted. For continuous variables that did not conform to normal distribution, the Mann Whitney U test was used. For categorical variables and count data, Fisher's exact test and Pearson chi square test were employed.
Study cycle	November 2024-December 2025

1. Research Background

Breast cancer is the second most prevalent female malignancy in China[1]. At present, the most important treatment for breast cancer is still surgical treatment[2-5]. Surgical treatment is inevitable in many cases, and with traditional surgery, it does leave a permanent scar on the chest[6]. Patients with high requirements for breast and breast aesthetic requirements are troubled by this. Studies show that young women of Asian descent (<50 years old) have more dense breasts than white women in the US[7]. So, it is more likely to the scars happen, and the scar repair after breast surgery is also more slow[8,9]. Therefore, minimally invasive breast surgery is necessary for Chinese women. Clinically, breast surgeons carry out different minimally invasive surgical methods and use different surgical approaches (such as axillary approaches) to achieve scar-free and attractive breast cancer surgery.[10,11]

The minimally invasive surgical approach enables better wound healing and less postoperative pain with the same tumor removal effect as open surgery[12]. Robotics is one of the widely used minimally invasive surgery in breast surgery,compared with open surgery, this minimally invasive technique reduces the occurrence of postoperative complications, enhances the protection of limb function, and meets the needs of patients for beauty. The study data showed that the postoperative complication rate of traditional open surgery was 7%, while the complication rate after robotic surgery was only 3.9%[13-15]. At the same time, in addition to the advantages of minimally invasive technology, robotics has its unique characteristics[16-18]. The application of robot technology makes breast surgery realize remote, digital and intelligent. Compared with the endoscopic surgery system, the robot system has a three-dimensional high-definition visual field magnified tens of times, so that the surgeon can have a clearer surgical vision, improve the surgical resolution, and increase the control of the operation. Moreover, the robots rotating wrist surgical instrument arm can rotate for 540°, enabling intuitive movement for a

more flexible and delicate operation[19]. For breast surgery with a narrow surgical area, the application of robotics is particularly important.

In 2017, robotics was first applied in breast surgery by Toesca et al[20]Since then, the application of robots in breast surgery has been further developed to form robotic prosthetic breast reconstruction and nipple-sparing mastectomy[21-23]. Compared with traditional open breast surgery, robotic breast surgery can retain normal tissue to the maximum extent, and achieve the advantages of small blood loss, less postoperative complications, postoperative symmetry, beauty and feel under the premise of complete tumor removal. However, in the clinical application process, due to the limited breast surgery area, the operation of the traditional multi-arm robot in the narrow surgery area is greatly limited, and there is the phenomenon of operating instruments and mechanical arm collision, which will lead to the failure of the advantages of the robot in breast surgery. The emergence of Single-port robot(SPr) effectively overcomes the disadvantages of multi-arm robot, not only continues the advantages of multi-arm robot surgical system, but also has advantages in minimally invasive, convenience, universality, flexibility, multi-directional operation. It is especially suitable for separation, suture, knot and other operations in a narrow space. Breast-conserving surgery has become one of the standard treatments for breast cancer due to the improved postoperative cosmetic effect, quality of life and acceptable postoperative tumor safety of breast cancer patients[24-28]. In 2024, Liao Ning, a Chinese scholar, gave an oral report on robot-assisted breast cancer breast conservation surgery at the 43rd ESSO. Considering both the completeness of lesion resection and the aesthetic integrity of breast preservation, the surgical approach of SPr approach through axillary incision is more advantageous than that of other approaches[27]。

In recent years, the domestic single-port robot surgical system has developed rapidly and its functions are increasingly perfect. The domestic Jingfeng ®SP1000 single-port robot surgical system will be used in our hospital. The public information

shows that Jingfeng ®SP1000 is the first single-port surgical robot to enter the registered clinical trial in China. Jingfeng Medical ® has cooperated with top hospitals and top experts in China to carry out in-depth clinical research and trial of all departments of single-port surgical robot. At present, Jingfeng ®SP1000 has been approved for gynecological indications, and completed registered clinical trials in urology, general surgery, thoracic surgery and other fields, successfully carried out more than 200 clinical operations, demonstrating a wide range of adaptability and excellent performance, bringing new value to scientific research and clinical fields. In addition, professor Xu Yan's team[29-31]. For the first time, the domestic Jingfeng ®EDGE SP1000 surgical system was used to successfully simulate the key steps of thyroid surgery in the oral thyroid surgery simulator, and realized the high-definition vision and high stability of single-arm robot surgical system, and its smart arm technology, hidden sleeve function and zero pressure anchor point technology are more conducive to ensure the operation safety, this successful practice provides a solid foundation and rich experience for single-port robot breast surgery and related clinical research. However, the safety and effectiveness of the procedure have not been fully verified, and whether the single-port robotic transaxillary breast cancer surgery is more advantageous than the multi-channel operating system (Xi and Si) is not reported. Therefore, this study aims to fill this gap and compare the efficacy and safety of open breast cancer surgery and single-port robot in transaxillary breast cancer surgery through a prospective, single-center phase II clinical cohort study, so as to provide scientific basis for clinical practice and promote the development of minimally invasive breast cancer surgery technology. To provide a theoretical and practical basis for the future application of EDGE SP1000 surgical system in breast cancer surgery. In addition, on this basis, we will systematically establish the technical system and standard for single-port robot breast cancer surgery in our hospital, and lead the formulation of domestic single-port robot-assisted breast cancer surgery standard, which is this the clinical promotion and application of surgery to lay a solid foundation

2. Purpose of Research

To evaluate the safety and feasibility of single-port robot in breast conserving surgery, and compare the advantages and disadvantages of single-port robot and traditional surgery in breast cancer complications, postoperative complications, perioperative recovery effect and safety of breast conserving surgery, so as to choose a more effective and safe surgical method.

3. Research Design

3.1 Overall Study Design

-Enrollment: Subjects who meet the inclusion criteria enter the study process, including SPr-breast conserving surgery or Traditional-breast conserving surgery. The choice of the two surgical methods is based on the patients economic situation and the availability of equipment.

-Preoperative hospitalization: Collect patient disease information (including mammography, breast B ultrasound, breast enhanced MRI, etc.).

-The day of operation: Record the operation time, intraoperative bleeding volume, intraoperative complications, intraoperative adverse events, etc.

-Postoperative hospitalization: Record postoperative complications (postoperative bleeding, flap or nipple areola complex necrosis, subcutaneous emphysema, infection, capsular spasm, postoperative shoulder pain and discomfort, etc.), postoperative pain score, and postoperative pathological biopsy.

-Postoperative hospital stay: Calculated based on the number of days from surgery to discharge.

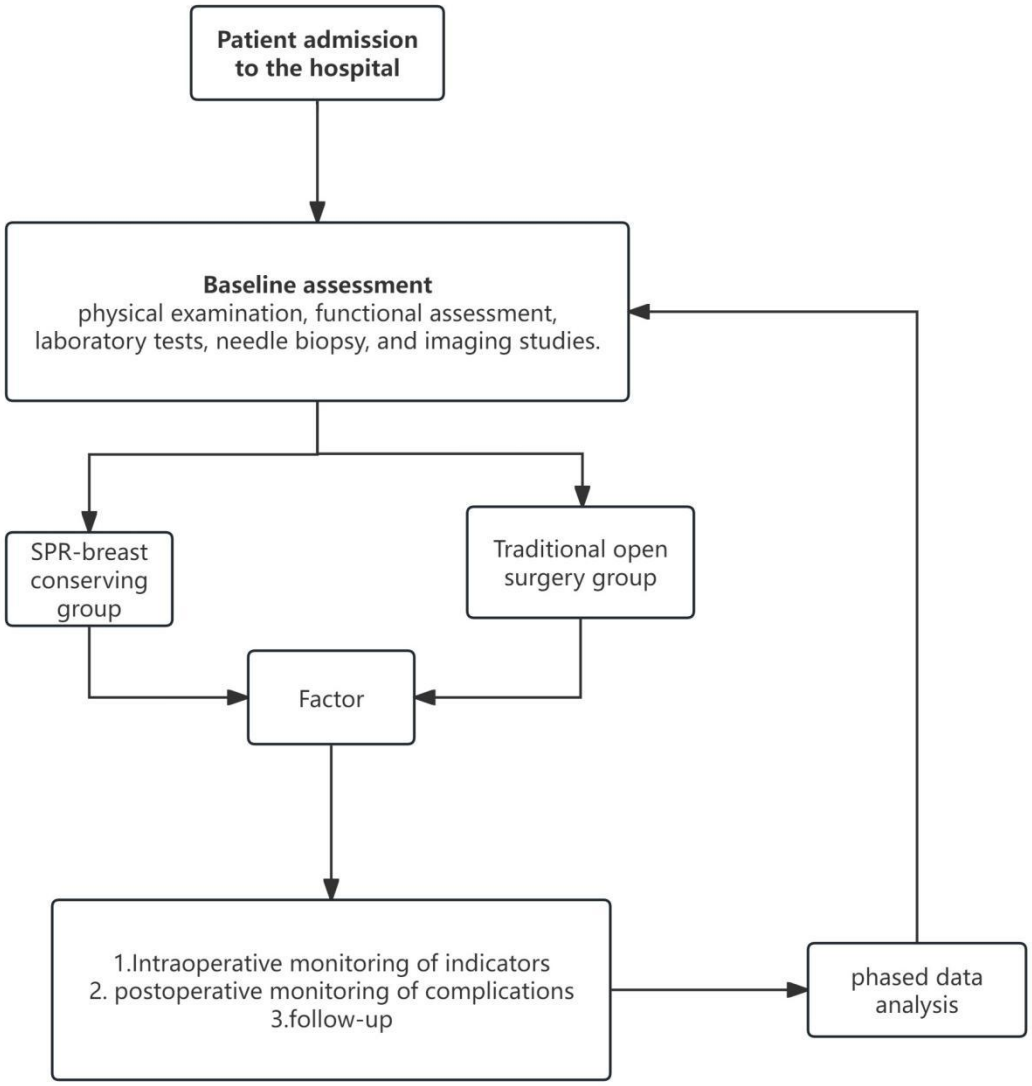
-28 days after surgery: To understand the complication rate and mortality rate within 28 days after surgery.

-90 days after surgery: To understand the complication rate and mortality rate within 90 days after surgery.

-Disease-free survival at 3 years after surgery (recurrence was defined as surgical area and distant metastasis by the time from surgery to last follow-up or date of recurrence and metastasis).

-3 year overall survival (from time from surgery to last follow-up or death).

3.2 Technical route



3.3 Study population

3.3.1 Inclusion criteria

1) The patient himself has very high requirements for beauty, and requires no scar on the chest;

2) No chest surgery and radiotherapy.

3) No contraindications to surgery and anesthesia.

4) Clinical I, stage of early breast cancer and the breast has an appropriate volume, can maintain a good breast shape after surgery.

5) Patients in the clinical period who meet the standard of breast conservation

surgery after preoperative treatment.

6) Age: 18 and 65 years old.

3.3.2 Exclusion criteria

1) Inflammatory breast cancer.

2)The tumor is extensive and it's difficult to achieve negative margins or an ideal breast - conserving appearance.

3)Diffusely distributed malignant - characteristic calcifications.

4)The margin is positive after local extensive tumor resection, and a negative margin in pathological examination still can't be ensured after re - resection.

5)The patient refuses.

3.3.3 Exit criteria

1) Those who cannot complete the single-port robot breast conserving surgery and need to be converted into traditional breast conserving surgery or endoscopic breast preservation surgery.

2) The patient voluntarily requests to withdraw from the investigator.

3) The patient is associated with other non-tumor conditions so that they cannot continue to accept the study program;

4) After inclusion in the study, the investigator cannot be completed due to other reasons.

3.4 Study grouping and methods

3.4.1 Study groups and interventions

The surgical method is based on the advice of the physician, mainly on the own choice of patients and the availability of equipment. After rigorous preoperative evaluation, patients who met the inclusion criteria were prepared for preoperative preparation (including preoperative antibiotics, etc.). The observation group was the SPr-breast conserving surgery group and the control group was the tradition-breast conserving surgery group.

3.5 Interventions

(1) SPr-breast conserving surgery group: using single port robot.

(2)Tradition-breast conserving surgery group: breast surgery was

completed with traditional surgery.

(3) Standards for suspending or modifying the planned procedure:

Conversion of SPr-breast conserving surgery to endoscopic or traditional breast conserving surgery is interruption due to technical difficulties or complications during intraoperative anatomical procedures that need to enable an open field conversion for further processing. Surgeons decide whether to switch to endoscopy or open for breast surgery amid concerns about patient safety, technical difficulties, inability to adequately complete robotic surgery or require treatment for related diseases.

3.6 Study process

Experimental procedure	Enrollment-Preoperative	On the day of the operation	Postoperative hospital stay	follow-up period				
				28d	3m	6m	1y	3y
Basic data								
Informed consent	√							
Demographic data	√							
A history of tumor-related	√							
Check-up	√							
Vital sign	√							
Disease data								
Tumor stage	√		√					
Tumor molecular typing	√		√					
Immunohistochemistry of tumors	√		√					
Preoperative puncture	√		√					

biopsy								
laboratory examination								
Routine urine test	√							
Routine blood test	√			√	√	√	√	√
Blood biochemical	√			√	√	√	√	√
Coagulation function	√							
Electrocardiogram	√							
Echocardiogram	√							
Hepatitis B etiology caused by scientific examination	√							
Liver and kidney work	√			√	√	√	√	√
Blood fat	√			√	√	√	√	√
Color ultrasound (axillary lymph nodes, supraclavicular lymph nodes, breast)	√					√	√	√
Breast molybdenum target	√					√	√	√
Mammary gland MRI	√					√	√	√
Tumor marker								
CA-153	√			√	√	√	√	√
CA-199	√			√	√	√	√	√
CEA	√			√	√	√	√	√
Surgery-related indicators								
Operation time		√						
Intraoperative bleeding		√						
Dwelling time of the			√	√	√	√	√	√

drainage tube								
Length of stay			√	√	√	√	√	√
Post-operative pain score			√					
Postoperative beauty score				√	√	√	√	√

3.8 Endpoint evaluation index

To verify the safety and efficacy of the single-port robot (SPr) in breast conserving surgery, the primary endpoint of this study was the success rate of breast conserving surgery. Successful breast-conserving surgery was determined by a negative tumor margin at least 2-3mm from normal tissue, and secondary endpoints included postoperative pain score and cosmetic score.

3.8.1 Primary endpoint indicators

Success rate of breast conserving surgery under single port robotic transaxillary approach.

3.8.2 Secondary endpoint indicators

Measurement of postoperative pain score and postoperative cosmetic score according to the scale (measured time after patient discharge).

4. Statistical analysis plan

4.1 Sample size estimation

This study belongs to the phase II clinical study, SPr-breast conserving surgery group enrolled 20 patients, and compared with the tradition-breast conserving surgery group (60 cases), aims to evaluate the single-port robot assisted axillary breast protection in the treatment of breast cancer, later further expand the sample size according to the situation, to compare the clinical efficacy of the two methods.

4.2 Statistical analysis of the population

This study, conducted only in the Army Characteristic Medical Center, is a single-center, prospective clinical cohort study designed to evaluate the safety and efficacy of single-port robots in breast cancer surgery by comparison with the traditional breast-conserving surgery group. During the trial, the clinical data will be

reviewed centrally to ensure uniform quality.

4.3 Preliminary analysis

Two-person data entry was performed using Excel 2010 and SPSS 25.0 data analysis. Baseline numerical data will be described as mean, standard deviation or median and interquartile range, and baseline categorical data will be shown as percentage. Normality and homogeneity of variance of continuous variables were tested by Kolmogorov-Smirnov test and ANA variance, respectively. Independent sample t-test for continuous variables meeting normal distribution and homogeneity of variance, Mann Whitney U test for continuous variables not meeting normal distribution, and Fishers exact test and Pearson chi square test for categorical variables and count data. Primary endpoint analysis: The success rate of breast conservation surgery under single hole robot will be compared by Chi-square test (Chi-square test) with exact test if necessary. Use multiple interpolation methods to deal with missing data. Postoperative cosmetic score and postoperative pain score were calculated and analyzed according to the standard scale.

4.4 Effectiveness analysis

The primary endpoint of this study is the success rate of breast-conserving surgery in patients with breast cancer. The success of breast-conserving surgery was determined by a negative tumor margin at least 2-3mm from normal tissue. Secondary endpoints included surgical specimen quality, functional outcome, and quality of life (postoperative pain score, postoperative cosmetic score).

4.5 Safety analysis

SPr-breast conserving surgery, as a relatively new surgical method, is still under continuous exploration. Surgical risks and complications related to intraoperative and postoperative hemorrhage, flap or nipple areola complex necrosis, subcutaneous emphysema, infection, capsule and capsular spasm, and postoperative shoulder pain and discomfort may occur during the surgical procedure and perioperative period. The difference between SPr-surgery and open-surgery lies in the different surgical approach platform, and the surgical operation procedure and principles are basically the same. In the early stage, our department has carried out more than 200 cases of Da

Vinci multi-arm robotic (Xi or Si surgical system) surgery, accumulated the experience of robotic surgery, and verified the feasibility and safety, and laid a solid foundation for the smooth development of this study. In addition, our department has rich experience in handling various perisurgical complications of breast cancer surgery, and can properly handle the perioperative complications of breast cancer surgery. Adverse events were recorded in detail and discussed during the trial.

5. Safety evaluation and disposal

Including possible adverse events and their definitions, evaluation method of correlation between adverse events and the study, severity assessment of adverse events, handling of adverse events, follow-up and reporting of serious adverse events.

5.1 Adverse events

5.1.1 Definition

(1) Intraoperative and postoperative bleeding and hematoma: the phenomenon of blood vessel rupture at the surgical site and blood outflow outside the blood vessels. After breast preservation surgery for breast cancer, bleeding may be caused by incomplete intraoperative hemostasis, or shedding of postoperative vascular ligation line, abnormal coagulation function, and increased local vascular pressure. The hematoma is a mass-like structure formed by blood accumulation in the local tissue of the operation. It is a consequence manifestation after bleeding. With the continuous accumulation of blood, the formation of hematoma area with a certain boundary, which produces pressure on the surrounding tissue.

(2) Breast flap necrosis: In breast cancer, the skin and subcutaneous tissue flap with blood supply is cut from the supply area (such as the skin tissue around the breast) to cover the surgical wound or reconstruction of partial breast structures. Breast flap necrosis refers to the situation of this part of the flap due to insufficient blood supply, infection and other factors, resulting in tissue cell death. The flap color will gradually become black and harden, lose elasticity and luster, and eventually may appear dry necrosis (such as leather-like changes) or wet necrosis (with exudation, suppuration, etc.).

(3) Necrosis of nipple areola complex: nipple areola complex includes nipple and

areola. The necrosis of nipple areola complex refers to the necrosis of nipple and (or) areola tissue due to the destruction of blood transport (such as cutting off the main blood vessels), local tension, infection and other factors. The nipple areola will appear color change (such as from pink to dark black), sensory loss, the later stage may fall off the tissue and other phenomena.

(4) Subcutaneous emphysema: a pathological phenomenon in which gas enters and accumulates in the subcutaneous tissue space after breast-conserving surgery. Under normal circumstances, there is no gas in the subcutaneous tissue. When the gas (mainly air) enters the subskin through the surgical wound or the damaged area of the surrounding tissue, and forms a certain area of emphysema, subcutaneous emphysema appears.

(5) Infection: the pathological process of bacteria, fungi, viruses and other invade the incision site, and grow and reproduce in it, causing local inflammatory reaction and (or) systemic reaction. After breast conserving surgery in breast cancer, the skin and tissue integrity. When the sterile environment of the operating room is not up to standard, the surgical instruments and dressings are not thoroughly disinfected, the concept of aseptic is not strong during the operation, the patients immunity is low (such as diabetes, malnutrition, etc.), or the postoperative incision care is improper (such as not changing the dressing in time, wound exposure to contamination, etc.).

(6) Envelar spasm: the process of contraction, thickening and hardening of the fiber capsule around the breast implant. This coating was supposed to be soft and elastic to accommodate the implant and maintain the natural shape and softness of the breast. But during the capsular contracture, it is gradually tightened, squeezing the implant.

(7) Postoperative shoulder pain: shoulder-centered pain sensation in the patient after breast conserving surgery. The pain can be unilateral (usually the shoulder on the affected side) or may involve both shoulders, but is more pronounced on the affected side.

5.1.2 Severity

Mild: The discomfort is usually transient and does not affect daily life and

normal activities.

Moderate: discomfort is enough to interfere with daily life and normal activities.

Severe: a serious obstruction to normal activities.

5.2 Adverse event management, follow-up, and reporting of serious adverse events

Detailed to the study participants before enrollment, participants were required to truthfully respond to the changes of the condition after intervention treatment, avoid inducing questions, pay close attention to the adverse events, analyze the causes and make a judgment. If adverse events occur during the study, record the time, symptoms, duration, treatment measures and outcome of adverse events in the medical record / case report form, and evaluate the relationship with the study drug; in case of laboratory abnormalities, follow up until the examination results return to normal. The serious adverse events form should be completed and reported to the Ethics Committee and the Clinical Research Management Office within 24 hours.

5.3 Evaluation of adverse events

The possible association of adverse events and surgical intervention was assessed by the following criteria:

I.Definitely unrelated: adverse events were not associated with the use of surgical intervention. E. g.: No robotic surgery was performed.

II.Probably unrelated: There is no evidence of a causal relationship between the occurrence and surgical intervention. The occurrence of adverse events is more likely to be related to other factors, such as surgical intervention or concomitant diseases. However, the correlation between the two factors cannot be excluded.

III.Possible related: The occurrence of adverse events and surgical intervention have a reasonable chronological order, and the occurrence of adverse events may be caused by surgical intervention. It cannot be excluded from other factors, such as surgical intervention or concomitant diseases. No withdrawal or unclear.

IV.Affirmation: The type of adverse event has been identified as the type of response to surgical intervention and cannot be explained by other reasons (e. g., surgical intervention and concomitant diseases). The timing of the event strongly

suggests causality.

V.Unable to assess: Lack of sufficient information to judge the causality of the event and surgical intervention. The investigator may change the causality assessment she / he does based on the follow-up information and modify the corresponding AE / SAE report.

6.Data collection and management

6.1 Data collection method

Data collection was conducted by Excel 2010 combining double data entry and CRF form. The specific requirements and implementation details are as follows:

(1) For all patients who have completed informed consent and screened qualified, the medical record and CRF form should be written carefully and detailed. All items should be filled in without empty items as far as possible.

(2) The original laboratory sheet should be complete and attached to the original case. All the original laboratory sheet, CT, MRI, colonoscopy, ultrasound, etc. should be signed and dated by physicians and researchers participating in the clinical study. and the data recorded by CRF should be checked with the medical record and the original test report.

(3) The original date (hospitalization medical record) shall be taken as the original record, any correction can only be underlined, the modified data shall be annotated, the reasons shall be explained, and signed and dated by the doctors and researchers participating in the clinical study, and the original record shall not be erased or covered.

(4) The data significantly high or beyond the clinically acceptable range shall be verified, and the physicians participating in the clinical study shall make necessary instructions.

6.2 Data management

(1) For all patients who have completed informed consent and screened qualified, the medical record and CRF form should be written carefully and detailed. All items should be filled out (see filling instructions).

(2) The original laboratory sheet shall be complete and attached to the original

cases. All the original laboratory sheet, CT, ultrasound and other cases shall be signed and dated by the doctors and researchers participating in the clinical study. The data recorded by CRF shall be checked with the medical record and the original test report.

(3) The original date (hospitalization medical record) shall be taken as the original record, any correction can only be underlined, the modified data shall be annotated, and the reasons shall be explained, and signed and dated by the doctors and researchers participating in the clinical study, and the original record shall not be erased or covered.

(4) The data significantly high or beyond the clinically acceptable range shall be verified, and the physicians participating in the clinical study shall make necessary instructions.

(5) The records of relevant intraoperative indicators must be provided by the surgeon and accurately filled in the CRF form within 6 hours after the operation.

7.Quality control

(1) Conduct comprehensive training for all participating personnel (including researchers, research nurses, data entry staff, etc.). For example, for the researcher, the inclusion criteria, exclusion criteria, and the specific operation procedures of the intervention measures should be explained in detail.

(2) The personnel participating in the clinical trial should have the corresponding professional expertise, qualification and scientific research ability, and must carefully study and discuss the clinical research plan and trial manual, and be determined after the qualification examination, and the personnel are relatively fixed. Archives management, use of drugs or devices, and correction of relevant testing instruments shall be managed by qualified personnel. Through clinical trial training to make research personnel for clinical trial scheme and its index specific connotation fully understand and understanding, for the description of conscious symptoms should be objective, do not induce or prompt: for the objective indicators shall be specified by the time, place and method of inspection, should pay attention to observe adverse reactions, and tracking.

(3) In order to eliminate the skill differences of surgeons and the potential impact

of surgeon learning curve on the results, only single-port or multi-channel robotic surgical patients with two senior physicians in our department were selected for comparative analysis. Both surgeons have completed more than 30 cases of robotic surgery and have passed the learning curve of robotic surgery.

(4) Standardized implementation of interventions

Establish the intervention implementation record system, detailed record of the time of each intervention, executor, patient response and other information. This traces the implementation of the intervention to facilitate problem detection and quality control.

(5) Normalization of follow-up

Develop a perfect follow-up plan, and clarify the follow-up time point, follow-up content and follow-up method. Follow-up personnel were trained to ensure accurate follow-up data collection.

A follow-up reminder system was established to remind patients to follow up on time through SMS and telephone calls, so as to improve the follow-up rate and ensure the integrity of the study data.

(6) Regular internal quality inspection:

The research team periodically (checks the quality of each part of the study, monthly or quarterly). The examination includes the enrollment of research subjects, the implementation of intervention measures, data collection and entry, etc. Problems are found through internal examination, such as missing follow-up data of some patients, and timely analyze the causes and take remedial measures.

Establish a quality inspection report system, form a written report on the results of each quality inspection, inform the research team members, let everyone understand the quality status of the research, and make improvement plans for the existing problems.

(7) Establish a multi-center coordination committee

The multi-center trial coordination committee has the head of each clinical trial unit and the main research coordination committee, which is responsible for the implementation of the whole trial and the study and resolution of issues related to the

trial.

(8) Data and safety monitoring Committee

The Data and Safety Monitoring Committee (DSMB) was established during the implementation phase. The DSMB member is composed of experienced gastrointestinal surgeons and statisticians who are not involved in the execution of the clinical trial. The DSMB is formed by the DSMB Chairman, working under the DSMB Charter, to report the specific outcome measures to the DSMB Chairman under strict confidentiality.

(9) All clinical and safety endpoint events were reviewed in detail by the DSMB.

(10) Image core laboratory

The imaging core imaging Laboratory has three professors as experts. Two experts independently evaluate all the imaging data of the patient, and the third expert will make the final decision in the case of inconsistent conclusions. Imaging data for all patients will be uploaded via storage media and web and evaluated by the Imaging Core Laboratory. The imaging Core laboratory evaluation includes:

In addition, imaging interpretation before patient enrollment was evaluated by at least two gastrointestinal surgeons at each subcenter, and none of the evaluators were involved in the trial execution.

(11) Pathology core laboratory

The pathology core laboratory has three professors as experts, two of the experts will independently evaluate all the pathology data of the patient, and the third expert will make the final decision in the case of inconsistent conclusions. Pathology data of all patients will be uploaded via storage media and web and evaluated by the Pathology Core Laboratory. Pathology core laboratory evaluation includes:

In addition, patient pathology interpretation before enrollment was evaluated by at least two pathologists at each subcenter, and none of the evaluators were involved in the trial execution.

VIII. Risk / benefit assessment

8.1 Benefits (personal and social benefits)

As a new surgical method, single-port robot breast-conserving surgery is still in

continuous exploration. Surgery-related risks and complications such as intraoperative and postoperative hemorrhage, flap or nipple areola complex necrosis, subcutaneous emphysema, infection, capsule and capsular spasm, and postoperative shoulder pain and discomfort may occur during the surgical procedure and perioperative period. The difference between SPr-breast conserving surgery and open breast conserving surgery is that the surgical approach is different and the surgical procedure and principles are basically the same. In the early stage, our department has carried out more than 200 cases of Da Vinci multi-arm robotic (Xi or Si surgical system) surgery, accumulated the experience of robotic surgery, and verified the feasibility and safety, and laid a solid foundation for the smooth development of this study.

This study aims to evaluate the safety and feasibility of a single-port robot-assisted transaxillary breast-conserving procedure and to evaluate the clinical efficacy of this procedure. Comparanalysis of the intraoperative complications, postoperative complications, perioperative recovery effect and safety of breast cancer with single hole robot and open surgery, so as to choose a more effective and safe surgical method.

8.2 Risks (indicating the possible risk probability, measures to minimize the possible range)

Surgery is invasive, so the risk exists in the postoperative complications of surgical procedures under equivalent conditions. Therefore, patients are tested for complications and treated for complications in time.

9. Ethics Principles and requirements for clinical research

This study will be performed strictly in accordance with clinical trial specifications, GCP principles and the Declaration of Helsinki. The informed consent will be signed by the attending physician or a qualified, strictly trained and authorized clinical staff. The trial procedure should be explained to the subject and / or authorized person and give the subject and / or authorized person sufficient time (at least 72 hours) to consider participation.

(1) Information provided to the patient or agent includes:

-Statement that the trial involves the study

-To fully and impartially explain the procedures to be followed

-Full description of the nature, expected duration, and purpose of the study

-Describe any foreseeable risks or discomfort caused to the patient

-Description of any benefits that can be reasonably expected

-Patient data will be declared as carefully handled and confidential, and the duration of data storage (15 years).

-Note that participation is voluntary, refusal to participate will not result in punishment or loss of the benefits and rights of the patient, and that the patient may stop participation at any time without punishment or loss of relevant rights, in which case the patient will receive standard treatment and an equivalent degree of care.

(2) Statement of conflict of interest

There is no personal or non-financial interest between the investigator and the subject.

(3) The Investigator states that:

1) I agree to conduct clinical trials in strict accordance with the design and specific provisions of this protocol.

2) I understand that I can interrupt or terminate the clinical trial at any time to ensure the best interests of the patient.

3) I agree that I will personally perform or supervise the clinical trial and ensure that all the researchers who assist me in performing the clinical trial are aware of their responsibilities in the clinical trial.

4) I will strictly comply with the current GCP and the Declaration of Helsinki during performing the clinical trial. And promises that the entire trial process will be consistent with ethical and ethical scientific principles.

5) During the execution of the clinical trial, I will strictly comply with all the laws and regulations related to the clinical trial and protect the rights and interests of patients.

6) I guarantee that I will meet the requirements of the ethics committee for review and approval.

7) I agree to maintain adequate and accurate medical records and ensure that

these medical records are always subject to inspection and inspection by relevant laws and regulations.

8) I agree that I will promptly report to the Ethics Committee on any changes in clinical trial activities and unexpected issues involving risks to patients or other personnel. In addition, I will not make any changes to the clinical trial protocol during the clinical trial activities until the ethics committee approves it, unless these changes are made to reduce the patients risk in an emergency situation

10.Research progress

November 2024- -June 2025: screen the enrolled patients and complete the preliminary preparation of the project

July 2025-October 2025: Patient data are collected and processed

November 2025- -December 2025: Write the result report

11.Main references

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