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# Based on the results of 18F-FDG PET-CT examination, omitting SLNB does not increase the risk of local recurrence and distant metastasis in ALN-negative breast cancer

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► ***Original article***

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## ABSTRACT

***Background:*** In breast cancer (BC) patients with axillary lymph node (ALN)-negative findings on 18F-fluorodeoxyglucose (18F-FDG) positron emission tomography-computed tomography (PET-CT), the prognostic impact of omitting sentinel lymph node biopsy (SLNB) was investigated. ***Materials and Methods:*** Fifty-eight BC patients were enrolled from four hospitals in Jilin Province from January 2020 to December 2020. Random assignment placed these patients into two groups. In the control group (CG), routine SLNB or ALND was performed. In the observation group (OG), 18F-FDG PET-CT was used for detection of ALN; SLNB was omitted when findings were negative, while ALND was performed if ALN-positive findings were observed. Robot-assisted breast-conserving surgery was performed in both groups. Comparisons were made regarding surgical outcomes, complications, and survival rates. ***Results:*** In the CG, twenty-nine patients underwent SLNB, with six cases of sentinel lymph node metastasis, who then received ALND; five patients directly underwent ALND, while one patient did not undergo axillary surgery. In the OG, four patients were found to be ALN-positive on 18F-FDG PET-CT, and these patients underwent ALND. When compared with the CG, the OG had significantly shorter surgery duration and less intraoperative blood loss ($P<0.05$). The OG demonstrated significantly shorter surgery duration and reduced intraoperative blood loss compared with the CG ($P<0.05$). No statistically significant differences were found between the two groups in recurrence-free survival, distant metastasis-free survival, progression-free survival, or overall survival ($P>0.05$). ***Conclusion:*** Based on 18F-FDG PET-CT findings, omitting SLNB reduces surgical trauma and complications, and does not compromise prognosis.

## INTRODUCTION

Breast cancer (BC), a common malignant tumor in women, arises from the epithelial cells within the breast [1]. Statistics from 2021 indicate that the global age-standardized rates for BC incidence and mortality were 26.88 and 8.54 per 100,000, respectively [2]. As a country with a high incidence of BC, China's age-standardized incidence rate was 33.4% higher (35.85 vs. 26.88 per 100,000) and mortality rate was 22.4% higher (10.45 vs. 8.54 per 100,000) than the global average. Over the last 30 years, figures for the incidence and mortality rates have revealed a marked upward trend [3], which reveals a serious health problem of Chinese women. For BC patients without distant metastasis, active cooperation with treatment often leads to a favorable prognosis - a five-year survival rate of 87% is achievable (even 99% for early-stage patients) [4]. Therefore, taking effective measures to accurately assess a patient's condition and formulate targeted treatment plans is of great significance for improving patient prognosis.

Regarding BC, axillary lymph nodes (ALN) status is an essential factor for staging the tumor, planning surgery, and assessing prognosis [5, 6]. Currently, sentinel lymph node biopsy (SLNB) is the most important clinical method to evaluate whether BC has spread to the ALN. The recommendation of the American Society of Clinical Oncology is that early-stage BC patients with sentinel lymph node (SLN) metastasis undergo axillary lymph node dissection (ALND), whereas ALND is not necessary for those without SLN metastasis [7, 8]. This approach can reduce the physical trauma associated with ALND. Overall survival and disease-free survival were found to be similar between patients who underwent SLNB and those who underwent ALND in the National Surgical Adjuvant Breast and Bowel Project (NSABP) B32 trial. This trial included 5,611 BC patients with negative lymph node metastasis [9]. However, as an invasive procedure, SLNB can still cause a range of complications, potentially affecting subsequent treatment progression. For example, Zhang reported that approximately 5.5% of patients who received SLNB experienced upper limb dysfunction after

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surgery, and after optimizing SLNB, the risk of upper limb dysfunction in patients after surgery was significantly reduced [10]. Reports have also indicated that the SLNB false-negative rate can range 12.6%-14.2% [11, 12].

In developed countries, 18F-fluorodeoxyglucose (18F-FDG) PET-CT is considered the gold standard noninvasive imaging method for health screenings and cancer detection, such as in the USA and Japan, while in developed countries such as Germany, South Korea, the United Kingdom, and France, it serves as an important diagnostic tool for clinical oncology. According to research findings, 18F-FDG PET-CT demonstrates moderate diagnostic precision when assessing lymph node metastasis in BC [13, 14], and current guidelines further advocate its application in the staging evaluation of BC [15]. This study aims to prospectively explore the risk of local recurrence and distant metastasis in negative ALN BC patients determined by 18F-FDG PET-CT, after exemption from SLNB, so as to furnish evidence-based backing for the refinement of personalized surgical strategies in clinical practice.

For the first time in the Chinese population, this study prospectively evaluates whether SLNB exemption, based on 18F-FDG PET-CT findings, influences the long-term prognosis of negative ALN BC patients. This study confirms that this approach reduces surgical trauma and complications without increasing the risk of recurrence, thus providing new evidence for the application of precision medicine in BC surgery.

## MATERIALS AND METHODS

### *Case data*

A simple random sampling method was employed in the study to select 68 BC patients treated between Jan. 2020 and Dec. 2020 at 4 hospitals in Jilin Province. The following were the inclusion criteria: (a) diagnosed with BC based on the diagnostic standards in the "NCCN Clinical Practice Guidelines: Breast Cancer (2020.V3)" [16], confirmed by pathological examination; (b) aged ≥18 years; and (c) willingness to undergo breast-conserving surgery. The following were the exclusion criteria: (a) presence of other malignant tumors or distant metastases, (b) multifocal BC, (c) severe liver or kidney dysfunction, (d) coagulation disorders, (e) poorly controlled diabetes, (f) severe mental or psychological disorders, and (g) pregnancy or lactation. The following were the dropout criteria: (a) failure to follow-up, and (b) missing clinical data. Following inclusion and exclusion criteria application, a total of 58 patients were enrolled and assigned to either a control group (CG) or an observation group (OG) based on whether they underwent 18F-FDG PET-CT. All participants gave written informed consent and agreed voluntarily to take part in the study. The medical ethics committee granted approval for the study protocol (Approval No. 202401-01-01). The study was carried out in accordance with the ethical standards for human research established by the Declaration of Helsinki. [17]. Both groups underwent conventional breast-conserving surgery. In the CG, SLNB was also performed; in the OG, preoperative 18F-FDG PET-CT imaging was carried out. Those with negative ALN were exempted from SLNB, while those with positive ALN underwent conventional SLNB or ALND. Both groups included patients who postoperatively received whole-breast radiotherapy.

### *Main equipment and reagents*

This subsection details the primary imaging, surgical, and analytical tools employed in this study, along with the key reagents used for tracer identification and lymph node mapping.

$^{18}$F-FDG PET-CT scanner: Discovery PET/CT 710 (General Electric Healthcare, USA)

Robotic surgical system: da Vinci Xi Surgical System (Intuitie Surgical Inc., USA)

Tracer: $^{18}$F-FDG (Atom High-Tech Co., Ltd., China)

Methylene blue injection (Jiangsu Jichuan Pharmaceutical Co., Ltd., China)

Statistical analysis software: SPSS 26.0 (IBM Corporation, USA)

Survival analysis software: GraphPad Prism 9.5 (GraphPad Software, USA)

### *$^{18}$F-FDG PET-CT examination*

Prior to the scan, BC patients were required to fast for 6–8 hours, and their blood glucose level was confirmed to be ≤11.1 mmol/L. After a 15-minute period of lying supine, 18F-FDG was administered intravenously through the antecubital vein on the side opposite the affected breast, at a dosage ranging from 0.08 to 0.2 mCi/kg. A supine rest period of 1 h was then observed by the patients. Prior to the scan, patients were instructed to void their bladders. During the procedure, they were positioned supine, after which a spiral CT acquisition was carried out. (TV 160 kV, TC 100 mA, ST 5 mm). The whole-body scan included six to eight bed positions (e.g., skull base to mid-thorax, mid-thorax to upper abdomen, upper abdomen to pelvis, and lower extremities), with each bed position scanned for two to three minutes to acquire 3D images. PET images were acquired using a 3D scanning mode (figure 1).

### *SLNB*

Fifteen minutes before the surgery, 2 ml of methylene blue was intradermally injected into the patient's areolar region. Local massage was performed to enable the methylene blue to enter the subcutaneous lymphatic network. A circular area with a radius of 5 cm, centered at the axillary hairline,

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was marked. To create an endoscopic working space, an incision was made below the clavipectoral fascia. The boundaries of this space were defined by the lateral margin of the pectoralis major muscle, the lateral branch of the third intercostal nerve, and the lateral thoracic vein. The sentinel lymph node was then located by following the visible lymphatic channels. All blue-stained lymphatic vessels were excised. The first blue-stained lymph node was accessed, and palpation of the axillary region was performed. Any enlarged or firm lymph nodes were completely excised and immediately sent for pathological examination. If the sentinel lymph node was not visualized or pathological examination indicated SLN metastasis, ALND was performed. Postoperative procedures included routine hemostasis, drainage, and suturing.

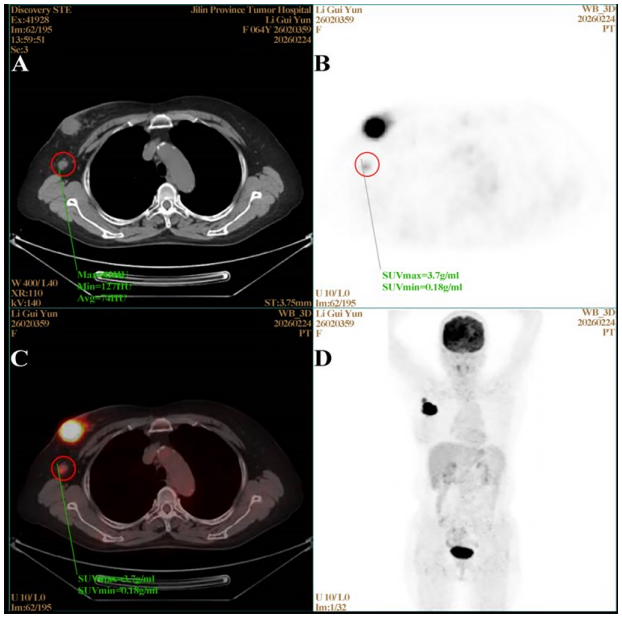



**Figure 1.** Representative 18F-FDG PET-CT images displaying a hypermetabolic lesion in the right chest wall/pleura: **A)** Plain CT scan in axial position, showing the anatomical structure of the chest in cross-section, with bilateral lung fields, mediastinum, chest wall, and ribs visible. The red arrow points to the right chest wall/pleural area, where an increase in local density or nodular changes are visible. **B)** PET axial image, corresponding to the PET metabolic image at the same level, with a low metabolic grayscale background. The red arrow points to the same area, thereby revealing a clear focal high metabolic concentration lesion, which indicates the presence of metabolically active lesions in this region. **C)** The PET-CT fusion axial image precisely integrates PET metabolic information with CT anatomical structures. The red arrow clearly indicates the metabolic hyperactivity lesion in the right chest wall/pleura, which perfectly corresponds to the abnormal density area on CT, thus clarifying the location and metabolic activity of the lesion. **D)** Whole-body PET MIP images reveal the distribution of radioactive uptake throughout the body. Normal physiological hypermetabolic organs-such as the brain, liver, spleen, and bladder-are clearly visible. Additionally, an abnormal hypermetabolic lesion is observed in the right chest region, which aligns with the localization on the axial images, thereby indicating that the lesion is located in the right chest.

***ALND***

After excision of the fatty and lymphoid tissues located in the interval, the clavipectoral fascia was incised. The axillary space was then meticulously explored. The long thoracic nerve and the thoracodorsal nerve were carefully spared during this exploration. The extent of nodal resection (level I alone or levels I and II) was determined based on preoperative imaging findings, intraoperative assessment of nodal status, and tumor characteristics, in accordance with the staging guidelines of AJCC. Resection of the corresponding level I or levels I–II lymph nodes was carried out, and the axillary adipose and lymphoid tissues were removed en masse. Standard postoperative measures comprised hemostasis, drainage, and wound closure.

***Robot-assisted breast-conserving surgery (RABCS)***

Preoperative imaging was performed to determine the size and location of the tumor; based on this, the incision site and size were planned-for example, either a single axillary port or an inframammary fold incision. Subsequently, robotic arms, a 3D high-definition camera, and an energy platform were inserted through the incision. Excision of the tumor and a 1 cm margin of surrounding normal breast tissue was carried out under robotic assistance. The excised tissue was labeled and sent for pathological examination. If any margin was positive, additional tissue was excised until negative margins were achieved. Postoperative procedures included routine hemostasis, drainage, and suturing. Figure 2 presents the bedside robotic arm, incision establishment, and intraoperative field of view for the RABCS.

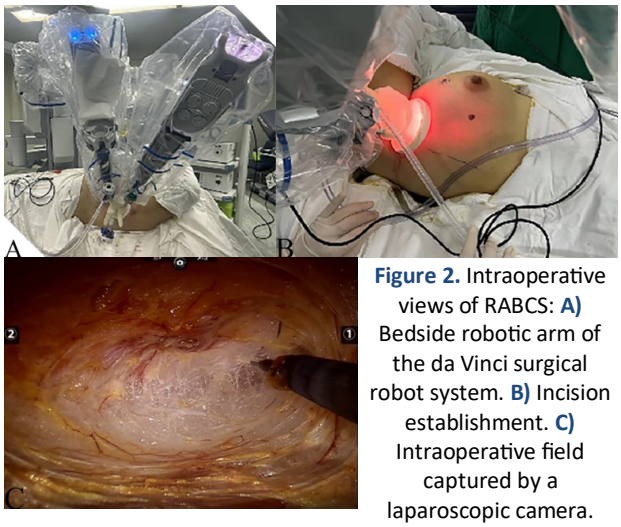



**Figure 2.** Intraoperative views of RABCS: **A)** Bedside robotic arm of the da Vinci surgical robot system. **B)** Incision establishment. **C)** Intraoperative field captured by a laparoscopic camera.

***Indicators of observation***

(a) Surgical-related indicators were recorded for both groups, including surgical approach (breast surgery or axillary surgery), surgical duration, robotic-assisted time, incision size, intraoperative blood loss, number of drainage tubes, and duration of tube placement. Furthermore, (b) the frequency of

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postoperative complications was documented for each group. (c) A 60-month follow-up was carried out, during which the rates of recurrence-free survival, progression-free survival, distant metastasis -free survival, and overall survival were determined for both groups.

### *Statistical analysis*

Statistical computations and data processing were conducted utilizing SPSS 26.0 software. Assessment of continuous variable normality was carried out by means of the Kolmogorov–Smirnov test. Variables conforming to a Gaussian distribution were summarized as mean ± standard deviation (M±SD) and underwent comparison through the independent t-test. For variables deviating from normality, descriptive summaries employed median accompanied by interquartile range [M (P25, P75)], with group comparisons relying on the Mann–Whitney U test. Categorical parameters were expressed as frequencies with corresponding percentages [n (%)] and evaluated via the $\chi^2$ test. Generation of survival curves was accomplished using GraphPad Prism version 9.5, while survival outcome comparisons were executed using the log-rank method. Statistical significance was defined as a two-tailed P-value falling below 0.05.

## RESULTS

### *Comparison of patient baseline characteristics*

No statistically significant differences were observed between the two groups regarding baseline characteristics, including age, body mass index (BMI), tumor size, tumor location, pathological type, T-stage, N-stage, estrogen receptor, progesterone receptor, human epidermal growth factor receptor-2, Ki67 proliferation index, fluorescence in situ hybridization, molecular subtype, and preoperative adjuvant therapy (all P > 0.05) (table 1).

### *Comparison of surgical-related indicators in patients*

Thirty-five in the CG patients (100%) underwent breast-conserving surgery. Among them, 29 patients (82.86%) underwent SLNB, with SLN metastasis detected and proceeding to ALND in 6 cases. Additionally, five patients (14.29%) directly underwent ALND, and one patient (2.86%) did not undergo axillary surgery. In the OG, 19 from among 23 patients (82.61%) underwent breast-conserving surgery, while 4 patients (17.39%) underwent breast segmental resection. In the latter subgroup, all four patients exhibited positive ALN involvement on 18F-FDG PET-CT and consequently received simultaneous ALND. With respect to the surgical interventions performed on the breast and axilla, statistically meaningful disparities emerged between the two cohorts (P < 0.05). When contrasted with the reference arm, subjects in the observational arm exhibited a mean decrement of 26.06 minutes in total procedural duration, accompanied by a reduction of 10 mL in intraoperative hemorrhagic volume (P < 0.05). No appreciable intergroup divergences were detected concerning the duration of robotic facilitation, the length of the surgical incision, or the quantity of drainage catheters placed (P > 0.05) (table 2).

**Table 1.** Comparison between the control and observation groups of baselines clinicopathological characteristics [, n (%)].

| Item | Control group (*n* = 35) | Observation group (*n* = 23) | $t/\chi^2$ | *P* |
|---|---|---|---|---|
| Age , years | 51.89±9.43 | 48.61±9.11 | 1.312 | 0.195 |
| Body mass index | 23.27±4.02 | 22.79±4.33 | 0.431 | 0.668 |
| Tumor size, cm | 1.60 ± 0.83 | 1.67 ± 0.60 | -0.347 | 0.730 |
| Tumor location | | | 0.500 | 0.479 |
| Left breast | 18 (51.43) | 14 (60.87) | | |
| Right breast | 17 (48.57) | 9 (39.13) | | |
| Pathological type | | | 5.319 | 0.150 |
| Invasive ductal carcinoma | 29 (82.86) | 18 (78.26) | | |
| Intraductal papilloma with focal canceration | 3 (8.57) | 0 (0.00) | | |
| Paget's disease of the nipple | 0 (0.00) | 2 (8.70) | | |
| Other | 3 (8.57) | 3 (13.04) | | |
| T-stage | | | 1.154 | 0.562 |
| is | 3 (8.57) | 4 (17.39) | | |
| 1 | 22 (62.86) | 14 (60.87) | | |
| 2 | 10 (28.57) | 5 (21.74) | | |
| N-stage | | | 3.615 | 0.306 |
| 0 | 23 (65.71) | 18 (78.26) | | |
| 1 | 7 (20.00) | 5 (21.74) | | |
| 2 | 1 (2.86) | 0 (0.00) | | |
| 3 | 4 (11.43) | 0 (0.00) | | |
| estrogen receptor | | | 0.001 | 0.975 |
| Negative | 9 (25.71) | 6 (26.09) | | |
| Positive | 26 (74.29) | 17 (73.91) | | |
| progesterone receptor | | | 0.416 | 0.519 |
| Negative | 8 (22.86) | 7 (30.43) | | |
| Positive | 27 (77.14) | 16 (69.57) | | |
| human epidermal growth factor receptor-2 | | | 0.145 | 0.704 |
| Negative | 18 (51.43) | 13 (56.52) | | |
| Positive | 17 (48.57) | 10 (43.48) | | |
| Ki67 | | | 2.411 | 0.492 |
| Not detected | 2 (5.71) | 0 (0.00) | | |
| Low expression | 17 (48.57) | 14 (60.87) | | |
| Medium expression | 15 (42.86) | 9 (39.13) | | |
| High expression | 1 (2.86) | 0 (0.00) | | |
| Fluorescence in situ hybridization | | | 1.479 | 0.477 |
| Not detected | 26 (74.29) | 19 (82.61) | | |
| Negative | 5 (14.29) | 1 (4.35) | | |
| Positive | 4 (11.43) | 3 (13.04) | | |
| Molecular Subtype | | | 6.100 | 0.107 |
| Luminal A | 2 (5.71) | 3 (13.04) | | |
| Luminal B | 27 (77.14) | 14 (60.87) | | |
| human epidermal growth factor receptor-2 positive | 3 (8.57) | 6 (26.09) | | |
| Triple negative | 3 (8.57) | 0 (0.00) | | |
| Preoperative Adjuvant Therapy | | | 0.000 | 1.000 |
| No | 33 (94.29) | 21 (91.30) | | |
| Yes | 2 (5.71) | 2 (8.70) | | |

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**Table 2.** Comparison of surgical parameters between the two groups: impact of 18F-FDG PET-CT-based SLNB omission [$\bar{x}\pm s$, M (P25, P75)].

| Item | Control group ($n$ = 35) | Observation group ($n$ = 23) | $t/\chi^2/Z$ | $P$ |
|---|---|---|---|---|
| Breast surgery | | | 4.110 | 0.043 |
| Breast conserving surgery + Robot | 35 (100.00) | 19 (82.61) | | |
| Segmental mastectomy + Robot | 0(0.00) | 4(17.39) | | |
| Axillary surgery | | | | |
| Sentinel lymph node biopsy | 29 (82.86) | 4 (17.39) | 24.255 | <0.001 |
| Axillary lymph node dissection | 11 (31.43) | 0(0.00) | 6.993 | <0.001 |
| Surgical Duration (min) | 110.54±32.41 | 84.48 ± 16.13 | 3.570 | 0.001 |
| Robot assistance time (min) | 13.51±3.71 | 12.52 ± 3.22 | 1.049 | 0.299 |
| Surgical Incision size (cm) | 3.59±0.84 | 3.65 ± 0.71 | -0.311 | 0.757 |
| Intraoperative blood loss (ml) | 20 (10,40) | 10 (10, 27.5) | -1.979 | 0.048 |
| Number of drainage tubes | | | 1.105 | 0.293 |
| 1 | 29 (82.86) | 22 (95.65) | | |
| 2 | 6 (17.14) | 1(4.35) | | |

### *Comparison of postoperative complications in patients*

In CG, postoperative complications occurred in 22 patients: one patient experienced delayed wound healing combined with subcutaneous effusion, one patient developed wound infection alone, and twenty patients exhibited subcutaneous emphysema alone. An absence of postoperative complications was noted in the OG. The overall rate of postoperative complications was significantly reduced in the OG compared with that observed in the CG ($P < 0.05$) (table 3).

**Table 3.** Comparison of postoperative complication rates between groups: assessing surgical safety with SLNB omission [n (%)].

| Complications | Control group ($n$ = 35) | Observation group ($n$ = 23) | $\chi^2$ | $P$ |
|---|---|---|---|---|
| The total number of complications | 22 (62.86) | 0 (0.00) | 23.292 | <0.001 |
| Delayed healing | 1 (2.86) | 0 (0.00) | 0.000 | 1.000 |
| Incision infection | 1 (2.86) | 0 (0.00) | 0.000 | 1.000 |
| Subcutaneous fluid collection | 1 (2.86) | 0 (0.00) | 0.000 | 1.000 |
| Subcutaneous emphysema | 20 (57.14) | 0 (0.00) | 20.060 | <0.001 |

### *Comparison of survival rates in patients*

In the CG, local recurrence occurred in one patient and distant metastasis in another. Similarly, in the observation group, one patient experienced local recurrence and one developed distant metastasis. According to the Pearson $\chi^2$ test, analysis of recurrence-free survival, disease-free survival rate, and overall survival revealed no appreciable differences between the groups ($P > 0.05$). A lack of statistical significance across these survival endpoints was further confirmed by log-rank testing ($P > 0.05$) (table 4; figure 3).

**Table 4.** Five-year survival outcomes comparison: recurrence-free, metastasis-free, progression-free, and overall survival rates [n (%)].

| Item | Control group ($n$ = 35) | Observation group ($n$ = 23) | *Pearson* | | *Log-rank* | |
|---|---|---|---|---|---|---|
| | | | $\chi^2$ | $P$ | $\chi^2$ | $P$ |
| Recurrence-free survival | 34 (97.14) | 22 (95.65) | 0.000 | 1.000 | 0.087 | 0.769 |
| Distant metastasis-free survival | 34 (97.14) | 22 (95.65) | 0.000 | 1.000 | 0.087 | 0.769 |
| Disease-free survival rate | 33 (94.29) | 21 (91.30) | 0.000 | 1.000 | 0.173 | 0.678 |
| Overall survival | 35 (100) | 23 (100) | — | — | — | — |

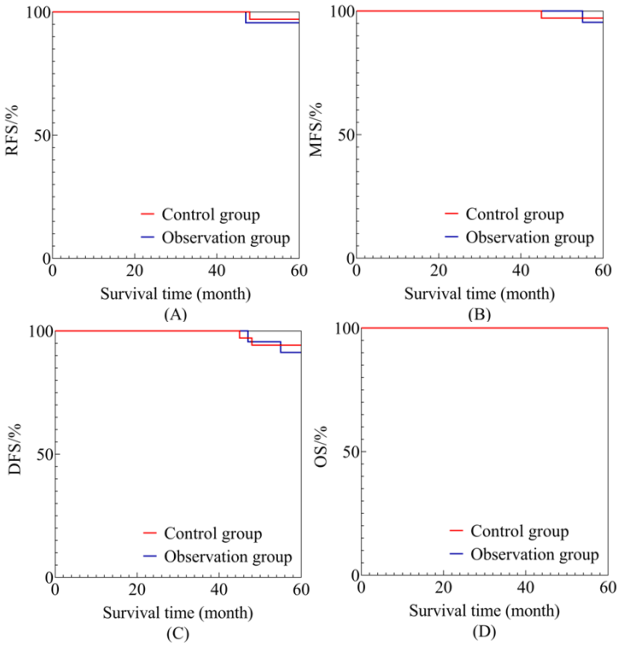



**Figure 3.** Kaplan–Meier survival curves comparing between two groups.

## DISCUSSION

The ipsilateral SLN is the first site of distant metastasis in BC. Therefore, SLNB can accurately determine the occurrence of tumor metastasis. However, only 15%–20% of patients who undergo SLNB exhibit lymph node metastasis [18]. If all patients are assessed for ALN involvement through SLNB, it may reveal that almost 80% of BC patients with negative ALN results assume risks of complications associated with SLNB. This study revealed that among 35 patients in the CG, 22 (62.86%) experienced complications of varying severity (including one patient with two complications), such as delayed wound healing, wound infection, subcutaneous effusion, and subcutaneous emphysema. Notably, subcutaneous emphysema occurred in 20 cases, which significantly diverges from previously reported common SLNB complications such as lymphedema, nerve injury, and

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shoulder dysfunction [19, 20]. This discrepancy may be attributed to the endoscopic SLNB technique employed in this study: (a) SLNB requires the dissection of axillary soft tissues to locate and excise lymph nodes, potentially disrupting local tissue planes and increasing the risk of $CO_2$ gas infiltration into subcutaneous spaces during endoscopic cavity creation; (b) compared to simple breast-conserving surgery, breast-conserving surgery combined with SLNB requires an expanded operative field and may require a longer operative time [21]. Moreover, continuous tissue retraction or repeated dissection during surgery may exacerbate subcutaneous tissue damage, thereby increasing the risk of residual $CO_2$ gas.

Recent large-scale randomized controlled trials have provided compelling evidence for the feasibility of omitting SLNB in carefully selected patients. According to the SOUND trial, for patients presenting with small BC (≤2 cm) and a negative axillary ultrasound, omission of SLNB resulted in five-year distant disease-free survival of 98.3% (vs. 98.7%) and overall survival of 98.2% (vs. 98.2%) compared to standard SLNB, with axillary recurrence rates remaining rather low (0.4%) [22]. Similarly, the INSEMA trial-which involved over 5,500 patients-confirmed noninferior five-year invasive disease-free survival (91.9% vs. 91.7%) when SLNB was omitted in clinically node-negative patients, accompanied by significantly reduced lymphedema (1.8% vs. 5.7%) and improved arm mobility [23]. These findings align with our results that reveal reduced surgical morbidity without compromising oncological safety.

The $^{18}$F-FDG PET-CT diagnoses diseases by evaluating glucose uptake in lesions, leveraging the high metabolic activity of malignant tumors to differentiate benign from malignant lesions and characterize tumor features. It is widely employed in BC-related diagnosis, including male BC [24], inflammatory BC [25], and disease staging and management [26]. For predicting ALN metastasis in BC, $^{18}$F-FDG PET-CT demonstrates high specificity (88.6%), although its overall performance is comparable to MRI and ultrasound [27]. Artificial intelligence-assisted systems based on $^{18}$F-FDG PET-CT have achieved an AUC of 0.868 for ALN metastasis prediction, with sensitivity 73.5% and specificity 89.0%, respectively. When combined with clinician input, specificity improves to 94.3%–100% [28], thereby suggesting that $^{18}$F-FDG PET-CT, with clinician collaboration, may achieve high specificity while avoiding SLNB-related complications and reducing false-negative ALN results. Among 23 patients in the OG, $^{18}$F-FDG PET-CT detected ALN metastasis in four cases, thus prompting ALND. During the five-year follow-up, only one distant metastasis and one local recurrence occurred. recurrence-free survival, disease-free survival rate, and overall survival showed no significant differences compared to the CG ($P > 0.05$). Furthermore, no complications were recorded in the OG, indicating that omission of SLNB in BCpatients whose ALN status is negative on 18F-FDG PET-CT does not appreciably impact local recurrence or distant metastatic spread; the OG also experienced markedly shorter operative durations and less intraoperative hemorrhage relative to the CG ($P < 0.05$). While advancements in SLNB techniques have reduced procedural times, omitting SLNB in ALN-negative patients further streamlines surgery and minimizes trauma, thereby decreasing bleeding.

Certain limitations warrant acknowledgment in the present investigation. Bias may stem from the constrained sample size. Moreover, the five-year follow-up interval might prove inadequate for ascertaining long-term oncological outcomes, given that among early-stage BC patients younger than 70 years, ten-year survival figures have been documented within a range spanning 74.2% to 83.3% [29]; (c) the study did not fully evaluate confounding factors and, thus, whether the reduction in surgery time and blood loss is directly related to the exemption from SLNB remains to be further investigated.

## CONCLUSION

This prospective study revealed that the detection of ALN-negative BC on $^{18}$F-FDG PET-CT among patients who are exempt from SLNB did not increase the incidence of local recurrence and distant metastasis. The five-year survival rate showed no difference, but it effectively avoids the complications associated with SLNB, shortens the surgical time, and reduces intraoperative bleeding. Future research should increase the sample size and extend the follow-up period to further validate the impact of the detection of ALN-negative BC on 18F-FDG PET-CT among patients exempt from SLNB on their prognosis, thereby encouraging the application of precision medicine in BC surgical treatment.

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***Conflict of Interest***: No conflict of interest.

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***Ethical considerations***: The study protocol received approval from the medical ethics committee (approval number: 202401-01-01); written informed consent was obtained from each patient before participation.

***Authors' contributions***: S.C. and Y.S., contributed to the study conception and design. Material preparation, data collection, and analysis were performed by M.Y.，Y.H., M.D., Q.X., L.H. and D.W. The

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first draft of the manuscript was written by S.C. and Y.S., and L.H. and D.W., commented on previous versions of the manuscript. All authors reviewed and approved the final manuscript.

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