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Original research

Can axillary node dissection be safely omitted in the elderly? A retrospective study on axillary management of early breast cancer in older women

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ABSTRACT

Introduction: Sentinel lymph node biopsy (SLNB) is a minimally invasive technique to stage the axillary lymph node status. The burden of nodal metastasis is of great concern, as the clinical relevance and therapeutic implications of pN1mi and pN0(i+) in the sentinel lymph node (SLN) remain a matter of debate.

Materials and methods: We examined the pathological features of 901 patients above the age of 65 presenting with clinical T1–T2 N0M0 breast tumours (<3 cm), detecting tumours related to llary non-sentinel node (NSN) metastases when the SLN was minimally involved.

Results: A total of 270 patients underwent complete axillary lymph node dissection (cALND) after their SLNB specimen tested positive for macrometastasis, micrometastasis and isolated tumour cells (ITCs). Seventy-six patients were diagnosed with micrometastatic disease pN1mi (27.5%), whilst ITCs (pN0i+) were detected in seven patients (2.5%). NSNs were found to be involved in two patients (2.6%) with micrometastases at the SLN. No further metastatic disease was detected in NSNs when the SLN contained ITCs. At a median follow-up period of 5.8 years, no axillary recurrence was observed among pN1mi and pN0(i+) patients. Lobular histotype, multicentricity and lymphovascular invasion were found to be associated with NSN involvement.

Discussion: The results from our case series are supported by IBCSG 23-01 level 1 evidence, which demonstrated a local recurrence rate of 1% in 'minimally involved not-surgical treated axilla'.

Conclusions: Based on current evidence, we spare well-informed and consenting patients from further axillary surgery when the SLN is minimally involved in early breast cancer within an agreed protocol, whilst scheduling adjuvant treatment based on the patients' primary tumour characteristics.

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1. Introduction

Sentinel lymph node biopsy (SLNB) in clinical practice challenges the 'Halstedian concept' of mandatory axillary clearance for all breast cancers [1–3]. With a minimally invasive technique, SLNB accurately stages axillary lymph node status, which is considered to be one of the most significant prognostic factors in breast cancer treatment [4,5]. The introduction of screening programs worldwide has increased the number of newly diagnosed small tumours, for which breast-conserving surgery (BCS) and SLNB are suitable [6,7]. The rationale for SLNB in early breast cancer is based on the low probability of axillary node involvement. SLNB procedures are cost-effective, thus significantly reducing the overall health-care system costs. Reduced hospitalisation time and low rates of surgical complications related to complete axillary lymph node dissection (cALND), such as paraesthesia and lymphoedema, have been achieved [8]. Moreover, the sentinel lymph node (SLN) provides pathologists with a smaller amount of tissue than cALND, which

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allows enhanced pathological evaluation with serial sectioning and immunohistochemistry (IHC) stains. With this technique, pathologists can detect very low levels of disease in the axilla. A smaller number of nodes can be sectioned and evaluated with greater accuracy by pathologists [9]. Given the significant increase in the identification rate of low-volume metastases, the pathological tumour node metastasis (pTNM) classification of malignant tumours and the American Joint Committee on Cancer (AJCC) [10,11] staging definitions have been updated. According to their size, nodal metastases are classified as macrometastases (pN1a (>2.0 mm)), micrometastases (pN1mic (>0.2 mm; ≤ 2.0 mm)) and isolated tumour cells (ITCs) (pN0(i+) (<0.2 mm)). The distinction between ITCs and micrometastases is crucial, as it influences the treatment decision [12]. Micrometastases are considered true metastases, and they are generally treated with cALND when the SLN is involved. Systemic treatment decisions also consider patients with SLN micrometastasis as node positive [13]. Following the publication of the American College of Surgeons Oncology Group (ACOSOG) Z0011 trial results in 2011 [14], the omission of cALND in patients with minimal node disease in the SLNB was a fundamental issue. Moreover, Galimberti and colleagues [15] presented the results of a multicentre trial (IBCSG 23-01), specifically to determine the need for cALND in patients with micrometastases in the SLN, in *Lancet Oncology* in 2013. This was a two-group, multicentre, randomised, non-inferiority, phase 3 trial that compared no axillary dissection with axillary dissection in patients with breast cancer and micrometastases in the sentinel node. At a median follow-up period of 5 years, no significant difference was reported in the primary end point of disease-free survival (DFS), thus satisfying the criteria for non-inferiority ($p = 0.004$). Furthermore, the overall survival (OS) was the same for the observation (97.5%) and cALND (97.6%) groups, and the rates of axillary recurrence were very low (1.1% for the observation group and 0.2% for cALND), although axillary non-sentinel nodes (NSNs) were found to be metastatic in 13% of patients undergoing axillary dissection. In a similar vein, the 2011 St Gallen Conference recommended that micrometastases in a single sentinel node not be an indication for cALND irrespective of the type of breast surgery performed. Following IBCSG 23-01 and ACOSOG Z0011, we are aiming to revolutionise axillary surgery, ultimately avoiding cALND in the presence of micrometastatic SLN. Italian guidelines on breast cancer treatment (Fo.N.Ca.M.) state that cALND can be omitted for patients with ITCs in the SLNB alone, whereas cALND is still mandatory for those with micrometastatic disease. To expand the current evidence on the management of minimally involved axillary nodes, we retrospectively analysed our case series. We aimed to evaluate the presence of ITCs and micrometastases at SLNB in early breast cancer, the rate of NSNs involved when the SLN was minimally involved and the variables predicting NSN involvement.

2. Materials and methods

We retrospectively examined the histopathological features of 901 patients above the age of 65 presenting with newly diagnosed clinical T1–T2 N0M0 breast tumours (<3 cm) treated at our Breast Unit from January 2000 to April 2014. They were scheduled for BCS or mastectomy and SLNB. Patients qualified for SLNB if breast cancer was confirmed by fine-needle aspiration or core biopsy, and if negative clinical examination of the axilla was confirmed by negative ultrasound imaging and/or negative fine-needle aspiration biopsy of a suspicious node. All patients qualifying for SLNB underwent lymphoscintigraphy using ^{99m}technetium-labelled human serum albumin 3–19 h before surgery. During surgery, a handheld detecting probe was used to identify the SLN(s) and aid their removal via an axillary skin incision or the same incision as in the breast surgery. A total of 246 patients (28%) received wide local excision (WLE), 613 patients quadrantectomy (67.45%) and 42 patients (4.55%) mastectomy (Table 1). Patients treated with BCS (either WLE or quadrantectomy) were scheduled to receive adjuvant whole-breast external beam radiation therapy. All 901 patients underwent an SLNB. Each sentinel node was sectioned at 50–200-μm intervals and stained with haematoxylin and eosin (H&E). In the presence of atypical and suspicious cells, cytokeratin immunostaining was applied. Patients diagnosed with macrometastases, micrometastases or ITCs after SLNB intra- or postoperatively were further treated with cALND. All nodes with ITCs and clusters ≤0.2 mm, but >200 cells in a single section, were categorised as pN1mi (per AJCC 7th edition criteria). The data retrospectively collected for each patient included primary tumour characteristics (pathological size, tumour type (ductal, lobular or other carcinomata), nuclear grade and lymphovascular invasion (LVI) and multifocality (Table 2). All of these factors were correlated with the NSN status. Patients were followed up in the outpatient clinic by clinical examination and ultrasound scan every 6 months. The median follow-up period was 5.8 years. The authors followed the STROBE criteria.

Table 1
Surgical treatment for 901 patients presenting with cT1–T2 N0 breast cancer.

Surgical treatment	SLNB	SLNB + cALND	Total
Wide Local Excision	**195** (22%)	**51** (6%)	**246** (28%)
Quadrantectomy	**431** (47.45%)	**182** (20%)	**613** (67.45%)
Mastectomy	**5** (0.55%)	**37** (4%)	**42** (4.55%)
Total	**631** (70%)	**270** (30%)	**901** (100%)

2.1. Statistical analysis

The χ^2 test was used to determine statistical significance. To determine which pathologic features were more predictive of NSN metastases, a multivariable logistic regression model was fit to the data. The model contained pathologic variables such as primary tumour size, tumour type, nuclear grade, LVI and multifocality. Only five patients were lost to follow-up. Data were analysed using Statistical Package for Social Sciences version 20 (IBM SPSS).

Table 2
Correlation between the size of nodal metastasis within sentinel nodes (SNs+) and pathological features of breast cancer.

	SNs+	Size of metastasis when SNs+		
		Macro	Micro	ITC
T				
1mic	4 (1.5%)	2(0.7%)	0	0
1a	4 (1.5%)	5(1.8%)	3(1.2%)	0
1b	43 (16%)	33(12%)	3(1.2%)	3 (1.2%)
1c	103 (38%)	72(27%)	43(15.4%)	4 (1.5%)
2 ≤ 3 cm	116 (43%)	75(28%)	27(10%)	0
G				
1	7 (2.5%)	6(2.3%)	2(0.7%)	0
2	108 (40%)	82(31%)	22(8.25%)	0
3	155 (57.5%)	99(36%)	52(19.25%)	7 (2.5%)
LVI				
Present	153 (56.5%)	97 (36%)	54 (19.5%)	0
Absent	117 (43.5%)	94.5 (33%)	24 (9%)	7(2.5%)
Histotype				
Ductal	216 (80%)	155(57%)	52(19.7%)	7(2.5%)
Lobular	41 (15%)	27(10%)	16(6%)	0
Others	13 (5%)	5(1.8%)	8 (3%)	0
Focality				
Unifocal	250 (92.5%)	171(63.8%)	71 (25.7%)	7(2.5%)
Multifocal	8 (3%)	3(1.2%)	5 (1.8%)	0
Multicentric	12 (4.5%)	13(5%)	0	0

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