# RESEARCH

# Patients' Choice on Axillary Lymph Node Dissection Following Sentinel Lymph Node Micrometastasis — First Report on Prospective Use of a Nomogram in Very Low Risk Patients

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Abstract The optimal locoregional treatment of patients diagnosed with sentinel node (SN) micrometastasis is controversial. A previously reported and validated nomogram was used to calculate the risk of non-SN metastasis in patients with SN micrometastasis over a period of 2 years. Patients were given detailed information about the risk, consequences and treatment options of non-SN involvement, the risk and potential complications of unnecessary completion axillary lymph node dissection (ALND), the imperfectness of the nomogram, and other factors that may influence their selection of further treatment. They also received a questionnaire to monitor factors influencing their decisions. Of the 25 patients participating in the study, 10 have opted for ALND. The only factor that seemed to influence their choice was fear from disease recurrence. Giving detailed information to SN micrometastatic patients is a patient-centered alternative to current recommendations

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Department of Surgery, Bács-Kiskun County Teaching Hospital, Nyíri út 38., 6000 Kecskemét, Hungary on performing ALND in all such patients or omitting ALND in all of them.

**Keywords** Sentinel lymph node · Non sentinel lymph node · Micrometastasis · Nomogram · Patient's choice · Axillary lymph node dissection

### Abbreviations

ALND	Axillary lymph node dissection
ASCO	American Society of Clinical Oncology
ITC	Isolated tumor cells/clusters
NSN	Non-sentinel lymph node
SN	Sentinel lymph node

# Introduction

The size of sentinel lymph node (SN) metastasis is associated with the risk of non-sentinel lymph node (NSN) metastasis [1–4], therefore low volume SN involvement belonging in the staging categories of micrometastasis or isolated tumor cells is rarely associated with NSN involvement [4–6].

The more thorough attention given to the SNs has resulted in an increased detection rate of micrometastases [7, 8], and this has led to the introduction of the ITC category to describe a type of nodal involvement that should not be considered a metastasis from the point of view of staging and treatment [9–11]. On this basis, minimal nodal involvement has been arbitrarily split into a node-negative subcategory (i.e. pN0(i+) for ITC) and a node-positive one (pN1mi for micrometastasis). Accordingly, guidelines suggested that patients with ITC in the SN needed no completion axillary lymph node dissection (ALND) but this operation was routinely recommended for patients with

SLN micrometastasis [12]. On the other hand, the possibility of omitting ALND was also raised at the St Gallen Consensus Conference in 2009 [13] and this possibility was further supported and recommended in 2011 [14]. Up to one fifth of surgeons in the United States also deviated from the completion ALND recommendation of the American Society of Clinical Oncology (ASCO) guidelines, especially in patients with micrometastasis [15]. The Hungarian Consensus Guidelines published in 2010 after a wide professional debate in 2009 recognized the low risk of further nodal involvement in patients with SN micrometastasis but also acknowledged the lack of uniformity in surgical recommendations; it was suggested that patients falling into this category should be given detailed information and they should be involved in the decision making on whether ALND would be performed or not [16].

The definitions published in the sixth editions of the TNM staging books [10, 11] did not allow a perfect distinction between SN micrometastases and ITC [17–19], although an improvement could be reached after visual, case centered training [20]. The slightly updated definitions of these staging categories in the 7th edition of the TNM books [21, 22] have also improved reproducibility.

NSN involvement risk can be estimated by several tools, including nomograms, scores and clinical prediction rules. Eight such tools were previously compared in our institution. Based on the 138 SN metastatic patients with small (up to 15 mm) tumors (out of 506 patients undergoing SN biopsy), the performance of the French micrometastasis nomogram [23] was found to be good: it selected 38/58 (66 %) micrometastatic patients as having low risk (not exceeding 10 %) for NSN involvement, and 2/36 (0.06, 95 % CI: 0.02-0.18) were eventually found to have NSN metastasis after ALND, in contrast with 6/20 (0.3, 95 % CI: 0.15-0.52) of the remaining micrometastatic patients [24]. This nomogram predicts the risk of NSN metastasis on the basis of 4 variables (tumor size categorized as <10 mm, 11-20 mm or >20 mm; the presence or absence of lymphovascular invasion; the detection of SN metastasis by hematoxylin and eosin stain versus cytokeratin immunohistochemistry; and finally the primary tumor histological type being mixed ductal and lobular versus not mixed (i.e. pure) type. These variables can result in 24 potential combinations which are all presented in a table with their associated risk of NSN involvement. The published table values make the French micrometastasis nomogram easy to use [23].

Patients with micrometastatic SNs were given the option of having completion ALND or omitting this procedure and the present article reports on their decisions and possible contributors to these decisions.

## **Materials and Methods**

Each of the 25 patients detailed in the Results had an appointment where a physician and a qualified nurse discussed with her the details of her disease and the risks and options related to micrometastatic SN involvement and ALND. Patients wishing to have one or two relatives or close friends involved were given the opportunity to do so. Patients (and/or accompanying persons) were then given time to decide till the multidisciplinary meeting scheduled the same week or the week after, and they were also given the opportunity to ask questions not only during and at the end of the specific appointment, but also at a later time, before the multidisciplinary meeting. They were also given an abridged written information sheet as a reminder of the things discussed during the appointment and a questionnaire they had to return at the time of the multidisciplinary meeting.

The information given to the patients (and accompanying persons when applicable) had to be patient tailored, but basically followed the details summarized (for the medically qualified readers) in the 4 paragraphs below:

The traditional treatment of the axilla was ALND, before the introduction of SN biopsy. ALND is associated with a potential morbidity including arm swelling of various degree, paraesthesia, minor loss of sensory and motor nerve functions. To diminish these unwanted complications, complete ALND has been widely replaced by the dissection of the lower and mid (level I and II) axillary lymph nodes. SN biopsy affords a selective approach to the axilla and patients with a negative SN need no further surgery. The morbidity of SN biopsy is not nil, but has a much better profile than ALND. SN biopsy has a reported rate of false negativity of about 5-10 %, meaning that patients with axillary lymph node involvement are not discovered with SN biopsy in 5-10 % of the cases; these patients may be considered as undertreated, but this rate is accepted by all, because ALND in patients with negative lymph nodes - on the other hand — is overtreatment.

Overall, micrometastases in the SN are also associated with NSN involvement in about 10 % and the treatment recommendations for this type of SN involvement are not uniform. There are several models based on histopathologic and clinical features to predict the risk of NSN involvement in patients with SN involvement. Several of these have been tested in our institution, and the French micrometastasis nomogram was found to be reliable, it is also used to help decision making. These mathematical models and tools are not perfect, they are better than tossing a coin but are worse than an always reliable risk allocator, they are somewhere in the middle between these two extremes. As all patients underwent axillary ultrasound screening, it was also mentioned that patients without suspicious nodes in the axilla are reported to be less likely to have NSN involvement if the SN is metastatic than patients without such an axillary screening, but the nomogram we use does not consider this potential variable.

There is also evidence to suggest that patients with an axillary lymph node involvement do not necessarily relapse in the axilla, as the relapse rate at this site is lower than we could expect from the risks of having positive lymph nodes left behind; this may be due to the role of other forms of adjuvant treatment. Therefore, having a metastatic lymph node left behind does not necessarily equate with undertreatment. Axillary recurrences may rarely occur after ALND too, and can often be removed surgically. Axillary radiotherapy (although definitive evidence is still awaited for) is probably also an effective way of regional disease control, and radiation oncologists have decided to include the axilla in the radiation fields if no ALND was performed, despite the fact that this may also be considered an overtreatment for patients without metastasis in the NSNs, and this adjuvant treatment option may also have side effect overlapping with those of ALND.

Finally, the nomogram based risk of having NSN involvement (potential risk for undertreatment if left in situ) was given in parallel with the risk of not having NSN involvement (risk of overtreatment by unnecessarily removing negative nodes). It was also made clear that the question of overtreatment could be only established after the removal and pathologic analysis of the NSNs. The need (or its lack) for secondary surgery on the basis of the resection margins of the primary tumor was also mentioned to patients treated with breast conserving surgery.

The questionnaire collected data on the highest education, age, the acceptable risk of being undertreated (by leaving metastatic lymph nodes in the axilla) on a percentage scale at steps of 5 %, the acceptable risk of being overtreated (by retrospectively unnecessarily removing negative lymph nodes from the axilla) on a percentage scale at steps of 10 %, the decision to have or omit completion ALND, potential factors contributing to the decision making and people involved in decision making. For the factors contributory to the decision, the following were listed, and additional ones could be optionally added if applicable: written information, fear from overtreatment, fear from second anesthesia/operation, fear from additional time spent in hospital, economic/income related issues, need for second operation irrespective of SN status, fear from recurrence of the disease, physician's advice, anything else. The physician delivering the information never helped the patient by making the decision instead of her. It was mentioned that the decision was rather personal and that two people could make two different decisions in the same setting, depending on individual differences, perceptions of risk and fears. However, when a patient was shifting towards one option or the other and sought reinforcement, she was reinforced in her decision, as both options were considered acceptable alternatives. Third party physicians' opinion was also mentioned as a potential external help — physician's advice in the questionnaire could reflect either the mentioned reinforcement or third party medical opinion, without distinction between the two.

The data collected were analyzed after 2 years of data collection. The transition between the 6th and 7th edition of the TNM with a minor impact on the distinction between ITC and micrometastasis occurred during the data collection period. Cases differently classified according to the latest edition (i.e. ITC rather than micrometastasis) were also given the option to chose on the basis of the above extended information flow, but were also informed about the fact of this transition in staging and the fact that on one basis, their disease belonged to the ITC category, which was not given further treatment per institutional policy, staging allocation and guideline recommendations.

Statistical comparisons between the group choosing ALND versus the group choosing its omission were done by means of the Fisher's exact test for categorical values and the Student's *t* test for continuous variables. The level of significance was set at p < 0.05.

The Institutional Review Board considered the study design only as an informed consent collection with extended information flow, and qualified the study as a noninterventional one. The Institutional Data Safety Manager approved the anonymous data collection and analysis by means of the questionnaire.

#### Results

Between January 2009 and December 2011, 263 successful SN biopsy procedures were done on primary invasive breast cancer patients not receiving neoadjuvant therapy. Altogether, 30 patients with micrometastasis in their SN were diagnosed during the study period, and 25 were willing to take part in the extended information flow analysis, but 3 denied the questionnaire. Therefore, 22 questionnaires of 25 patients with micrometastatic SNs were considered in the analysis of decision making. Three of them had ITC on the basis of the more recent TNM definitions [21, 22], but would have been diagnosed as micrometastatic on the basis of the previous version interpretations [10, 11, 17, 20].

All but 2 patients had breast conserving surgery, and either received adjuvant radiotherapy or are/were scheduled for it in the course of their ongoing treatment. Two patients underwent mastectomy either because of a centrally located tumor in a relatively small breast or because of a large area of associated microcalcification representing extensive intraductal component. Of the 5 micrometastatic patients not taking part in the study, one had positive findings during intraoperative imprint cytology and had an immediate ALND, and 2 other patients also underwent ALND.

Although the length of the appointment delivering the information was not permanently monitored, the shortest session lasted 45 min and the longest duration was 75 min. Ten patients chose to have an ALND and 15 chose the omission of ALND. None of the patients had mixed ductal and lobular carcinoma (one of the variables considered by the nomogram). Other details considered by the nomogram and the data collected by the questionnaire are given in Table 1. Additional factors (not listed in Table 1) influencing patients' decision for not having ALND included old age, slow expected disease progression on the basis of primary tumor characteristics and previous thromboembolism. The series is small, and no statistically significant differences were noted in the distribution of the evaluated parameters between those electing for ALND rather than no ALND, except for the proportion of patients being afraid of disease recurrence. Therefore, fear from axillary recurrences, whatever its risks and consequences, seemed to be the most important thing resulting in the choice of ALND.

Of the 10 patients choosing ALND, one had no ALND performed because of a post SN biopsy axillary suppuration. Of the remaining ALND patients, a median number of 12 NSN were removed, and two patients were found to have additional lymph node involvement in the axilla. One patient had a calculated risk of 19 % and was found to have 7/ 17 NSNs involved, whereas the other had a calculated risk

of 12 % and had 1/9 NSNs involved. No patients had locoregional recurrence of breast cancer after a median follow-up of 9 months (range: 0–23 months).

Of the three patients denying the questionnaire, one admitted that she did not understand many of the issues discussed, one said to understand the information given but did not want to use the questionnaire, and the cause of denial remained unknown for the third patient.

## Discussion

Locoregional treatment and the need for completion ALND in patients with micrometastasis in the SN is controversial [25]. Some would suggest ALND for all such patients [12], whereas others suggest no need for ALND in this patient group [14]. A selective policy may also be applied, and this may be helped by the use of NSN involvement predictive tools. This later approach was our policy, in keeping with Hungarian national guidelines [16].

Although the overall risk of NSN metastasis is around 10–15 % with micrometastases and slightly lower for ITC [5, 6], SN metastasis size is not the only influential parameter, and there are other potential factors affecting the risk of NSN involvement. Some micrometastases may be associated with substantial risk on the basis of the other factors [24]. Several predictive tools dedicated for patients with SN micrometastasis have been published [23, 26, 27], but only the one used in the current report was validated in our institution [24]. It is felt that such internal validations are

	All ( <i>n</i> =25)	ALND ( <i>n</i> =10)	no ALND ( $n=15$ )	р	Test
Age (years) mean ± SD; median (range)	60±12; 57 (41–79)	56±12; 53 (41-76)	63±11; 60 (42–79)	0.17	t
Education (low/medium/high)	7/9/6	3/5/2	4/4/4	0.76	FET
Tumor size (mm) mean ± SD; median (range)	16±7; 14 (5–35)	17±6; 16 (6–27)	16±8; 14 (5–35)	0.77	t
pT1a&b/pT1c/pT2	3/15/7	1/6/3	2/9/4	0.99	FET
LVI (present/absent)	10/15	6/4	4/11	0.21	FET
Micrometastasis detected by IHC (yes/no)	15/10	11/4	4/6	0.21	FET
Nomogram based risk of NSN involvement (%) mean $\pm$ SD; median (range)	13±6; 12 (6–28)	15±7; 16 (6–28)	12±6; 12 (6–28)	0.19	t
Acceptable risk of potential overtreatment (%) mean ± SD; median (range)	36±37; 20 (0-100)	30±34; 20 (0-90)	42±40; 20 (0-100)	0.49	t
Acceptable risk of potential undertreatment (%) mean $\pm$ SD; median (range)	8±7; 5 (0-25)	5±7; 5 (0-20)	10±8; 7.5 (0-25)	0.41	t
Factors influencing decision:					
Written information (yes/no)	11/11	3/7	8/4	0.20	FET
Fear from disease recurrence (undertreatment) (yes/no)	10/12	8/2	2/10	0.008	FET
Fear from potential overtreatment (yes/no)	3/19	0/10	3/9	0.22	FET
Fear from second operation (yes/no)	4/18	1/9	3/9	0.59	FET
Economic/income issues (yes/no)	2/20	0/10	2/10	0.48	FET
Physicians advise (yes/no)	11/11	6/4	5/7	0.67	FET

Table 1 Parameters assessed in the study population with subset results for those choosing ALND and those choosing to omit this operation

*ALND* axillary lymph node dissection; *IHC* immunohistochemistry; *FET* Fisher exact test; *LVI* (lympho)vascular invasion; *NSN* non-sentinel lymph node; *pT1a*, *pT1b*, *pT1c*, *pT2* tumor categories according to the TNM classification of breast cancers [10, 11]; SD standard deviation; *t* Student's *t*-test

important, because of the many interinstitutional differences in the parameters assessed by nomograms [28] and the variable applicability of different nomograms in different institutions [28, 29].

Two fifths of the patients with micrometastatic SNs in this series opted for ALND. Although small numbers limit the value of statistical tests, only the proportion of patients being afraid of disease recurrence was statistically different between those electing ALND and those choosing to omit this second operation. No other parameter monitored proved significantly different between the two groups (Table 1). It therefore seems that it is not the calculated risk itself, but its perception that influenced patient decision. Fear from potential undertreatment extrapolated to disease recurrence whatever small its risks were (the oral information flow was centered on this area) was greater than fear from overtreatment and potentially unnecessary ALND in patients opting for completion axillary clearance. This conclusion has to be considered with some reservations, because it is based on only 25 patients' choice, although it reflects 2 years of experience in the field. Despite the small number, this experience is instructive, and reflects that patients' choice can be quite unpredictable, and that a nomogram based risk estimation can be of help to only a proportion of the patients.

If there is not much therapeutical benefit expected from ALND following the finding of micrometastatic SNs, it is arguable to what extent patients should be informed about the risks of leaving positive nodes behind. The ASCO guidelines from 2005 practically recommending ALND for all SN micrometastatic patients might be outdated, and accordingly, 36 % of such patients had no ALND on the basis of a National Cancer Database derived analysis [15]. A Survival, Epidemiology and End Results database analysis also suggested that 38 % of SN micrometastatic patients had SN biopsy alone, with no significant differences in overall survival between the SN biopsy alone versus the completion ALND cohorts after a median follow-up of 50 months [30]. The most recent St Gallen consensus recommends the omission of ALND in all patients with SN micrometastasis [14], and would allow an easier schematic decision making. In this small series, detailed information (and perhaps confusion arising from it) resulted in two fifths of the patients choosing completion ALND rather than its omission. Although this may be considered a form of overtreatment for patients with low volume, micrometastatic SNs, especially in the light of the American College of Surgeons Oncology Group Z0011 trial suggesting no survival disadvantage even in a subset of SN macrometastatic patients without ALND [31], it was no overtreatment for two patients having NSN metastasis disclosed following axillary clearance. It is felt that giving very detailed information to SN micrometastatic patients and give more ground to their perception of risks (associated with ALND or its omission) can be a patientcentered alternative to follow current recommendations on either performing ALND in all such patients [12] or omitting ALND in all of them [14]. However, the delivery of information should be tailored according to patients' need in order to decrease distress [32].

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