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Research Article

Is Axillary Lymphadenectomy Necessary in Triple Negative Breast Cancer Patients Treated with Subcutaneous Mastectomy with The Immediate Reconstruction?

Piotr Kedzierawski[1,2*], Pawel Macek[1,3], Artur Bocian[4], Stanislaw Gozdz[1,5]

[1]Collegium Medicum, Jan Kochanowski University, 25-713 Kielce, Poland

[2]Radiotherapy Clinic, Holycross Cancer Centre, 25-734 Kielce, Poland

[3]Department of Epidemiology and Cancer Control, Holycross Cancer Centre, 25-734 Kielce, Poland

[4]Oncological Surgery Clinic, Holycross Cancer Centre, 25-734 Kielce, Poland

[5]Clinical Oncology Clinic, Holycross Cancer Centre, 25-734 Kielce, Poland

[*]**Corresponding author:** Piotr Kedzierawski, Collegium Medicum, Jan Kochanowski University, 25-713 Kielce, Poland

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Abstract

The aim of our study was to compare treatment outcomes of patients with Triple Negative Breast Cancer (TNBC) treated with or without a Sentinel Lymph Node Biopsy (SLNB) and with nipple sparing or skin sparing subcutaneous mastectomy with the immediate Breast Reconstruction (IBR) with a prosthesis. A total of 114 consecutive patients with TNBC were enrolled in this study treated at the Holycross Cancer Centre in Kielce, Poland between 2013 and 2020. Apart from the systemic treatment and radiotherapy, in all patients, subcutaneous mastectomy was performed. The sentinel lymph node biopsy procedure was applied in 82 patients. The restricted mean survival for non-SLNB and SLNB patients was 84.6 months and 101.9 months, respectively. A significant association of the life status was found for the clinical stage, a sentinel node biopsy procedure application, radiotherapy, complete pathological regression after neoadjuvant chemotherapy, and cancer progression. Based on the Monte Carlo simulation, it was found that without taking Clinical Stage (CS) into consideration, the distribution of possible deaths in non-SLNB patients was 99% more likely than in SLNB patients. In CS II, CS III, and CS II and III together, death rate in non-SLNB patients was 85%, 78%, and 97%, respectively and more likely than in SLNB patients.

Keywords: Bayesian statistics; Sentinel lymph node biopsy; Subcutaneous mastectomy; Triple negative breast cancer

Introduction

Breast cancer remains the most frequently diagnosed female type of cancer [1]. Triple negative breast cancer accounts for approximately 15-20% of all breast carcinomas and is immunohistochemically characterized by the lack of Estrogen Receptor (ER), Progesterone Receptor (PR) and Human Growth Factor Receptor (HER2) status [2]. The prognosis for TNBC is worse in comparison to luminal subtypes. Recurrences and deaths are observed within 3-5 years after the diagnosis [3,4]. Chemotherapy has become the main approach for the treatment of TNBC, because as studies and clinical practice showed is more responsive

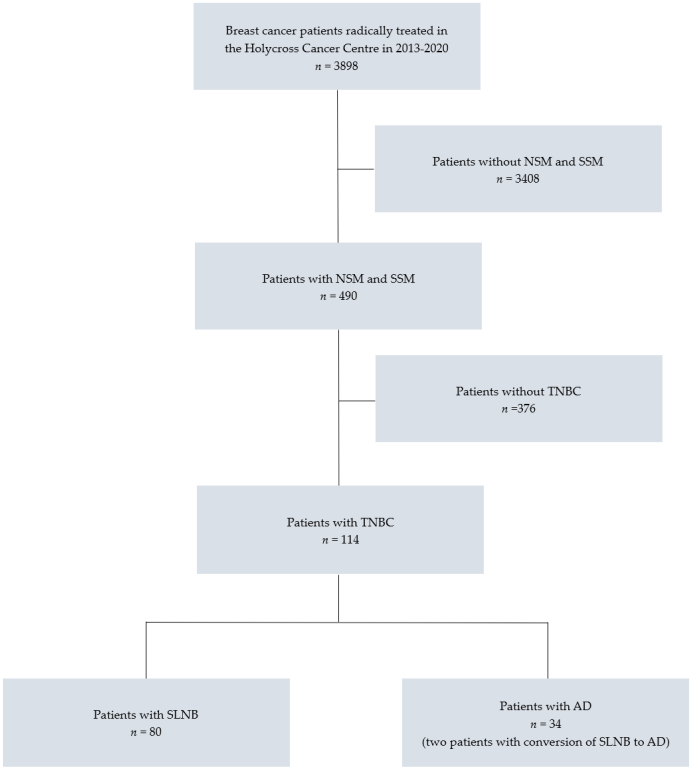
to chemotherapy than any other molecular subtypes [5,6]. Neoadjuvant Chemotherapy (NAC) allows for the reduction of the tumour volume and regional lymph nodes, what can facilitate more options for a surgical treatment. Complete pathologic regression allows to conduct a breast conserving treatment, however TNBC commonly harbours BRCA mutations, thus mastectomy is the preferred surgical treatment for patients with mutations [7]. In the last two decades, Both Nipple-Sparing Mastectomy (NSM) and Skin-Sparing Mastectomy (SSM) with the Immediate Breast Reconstruction (IBR) with a prosthesis or an expander have been used in the surgical management of nonmetastatic breast cancer patients. The literature pointed out that the outcomes of the treatment with NSM, SSM, and Modified Radical Mastectomy (MRM) are similar, but what is significant, subcutaneous mastectomies preserve the patient's body shape [8-10]. It does not adversely affect the timing of the adjuvant treatment. Moreover, it has become a preferable option in specific clinical settings, such as breast cancer with multifocality or multicentricity. The qualification for this procedure should be very cautious, because not every woman is a subject of this form of treatment. The style of life of the patient, comorbidities, age, the body mass index can influence treatment outcomes. Axillary lymph node dissection is the traditional part of the breast cancer therapy. However, this procedure has several complications such as numbness, pain, restriction of shoulder motion and upper limb oedema what can influence the quality of life of patients. The introduction of a sentinel lymph node biopsy into surgical treatment replaced routine axillary dissection and allowed to avoid complications of axillary lymphadenectomy. Concerning SLNB, we can meet three clinical scenarios: node negative breast cancer before and after NAC; node positive before the NAC and negative after NAC; and node positive that does not respond to NAC and remains positive. NSM or SSM can be connected with a sentinel lymph node biopsy in patients with clinically negative lymph nodes and is contraindicated in the third clinical scenario.

The aim of our study was to compare treatment outcomes of the patients with triple negative breast cancer treated with or without a sentinel lymph node biopsy and with nipple sparing or skin sparing subcutaneous mastectomy with the immediate reconstruction with a prosthesis.

Materials And Methods

Verification of Data

Data (n = 3898) of women treated for breast cancer in 2013–2020 was verified. In the first step of the verification, all patients without NSM and SSM treatment were removed from the database. Thereafter, the data of women with breast cancer biological subtypes other than triple-negative breast cancer was removed from the database, as well. Ultimately, 114 patients were qualified for the study. Detailed information on data verification is presented in Figure 1.



Abbreviations: NSM-nipple-sparing mastectomy; SSM-skin-sparing mastectomy; TNBC-triple negative breast cancer; SLNB- sentinel lymph node biopsy; AD-axillary dissection.

Figure 1: Flow diagram of data selection process.

Study Group

A total of 114 consecutive patients with TNBC were enrolled in this study. All diagnostic and therapeutic procedures were conducted in the Holycross Cancer Centre in Kielce, Poland in 2013-2020. The follow up

was conducted by the end of 2022. In all patients, subcutaneous mastectomy was performed. The sentinel lymph node biopsy procedure was applied in 82 patients. In 42 patients, a genetic mutation was established. In 91 cases, neoadjuvant chemotherapy was applied. Twenty three patients received Adjuvant Chemotherapy (AC) and 30 patients also adjuvant with Capecitabine after neoadjuvant chemotherapy due to the lack of complete regression of the cancer. The most common regimen of chemotherapy was 4 cycles of Adriamycin and Cyclophosphamide followed by 12 cycles of Paclitaxel. Conformal postoperative radiotherapy was applied in 43 out of 114 patients. Detailed patients characteristics and the types of treatment are depicted in Table 1 and Table 2.

Characteristic	non-SLNB (*n*=34)			SLNB (*n*=80)			*P*
	n	Row %	Column %	*n*	Row %	Column %	
Age							0.179
<55 year	29	33.0	85.3	59	67.0	73.8	
≥55 year	5	19.2	14.7	21	80.8	26.3	
Cancer type							0.352
NST	34	30.4	100.	78	69.6	97.5	
Other	0	0.0	0.0	2	100.	2.5	
Clinical stage (CS)							0.003
I	1	7.7	2.9	12	92.3	15.0	
II	24	27.6	70.6	63	72.4	78.8	
III	9	64.3	26.5	5	35.7	6.3	
Grading (G)							0.009
G1	2	66.7	5.9	1	33.3	1.3	
G2	5	12.8	14.7	34	87.2	42.5	
G3	27	37.5	79.4	45	62.5	56.3	
Gene mutation							0.823
No	22	30.6	64.7	50	69.4	62.5	
Yes	12	28.6	35.3	30	71.4	37.5	
Neoadjuvant chemotherapy							0.145
No	4	17.4	11.8	19	82.6	23.8	
Yes	30	33.0	88.2	61	67.0	76.3	
Adjuvant chemotherapy							0.085
No	14	23.0	41.2	47	77.0	58.8	
Yes	20	37.7	58.8	33	62.3	41.3	
Type of surgery							0.529
NSM	33	29.5	97.1	79	70.5	98.8	
SSM	1	50.0	2.9	1	50.0	1.3	
Radiotherapy							<0.001
No	10	14.1	29.4	61	85.9	76.3	
Yes	24	55.8	70.6	19	44.2	23.8	
Hormone therapy							0.529
No	33	29.5	97.1	79	70.5	98.8	
Yes	1	50.0	2.9	1	50.0	1.3	
Complete pathological regression							0.149
No	22	35.5	64.7	40	64.5	50.0	
Yes	12	23.1	35.3	40	76.9	50.0	
Cancer progression							0.057
No	26	26.5	76.5	72	73.5	90.0	

Yes	8	50.0	23.5	8	50.0	10.0	
Death							0.022
No	27	26.5	79.4	75	73.5	93.8	
Yes	7	58.3	20.6	5	41.7	6.3	

Abbreviations: SLNB-Sentinel Lymph Node Biopsy; NST-No Special Type; NSM-Nipple-Sparing Mastectomy; SSM-Skin-Sparing Mastectomy.

Table 1: Basic characteristic of the study group by SLNB status.

Characteristic	Total number of patients	SLNB procedure (%)	Mean number of SLNB (range)
With neoadjuvant chemotherapy	91	61 (67%)	3,75 (1-9)
With adjuvant chemotherapy	23	21 (91%)	3,13 (1-6)

Table 2: The number of SLNB procedures according to chemotherapy.

Surgical Treatment

In our group, in immediate breast reconstruction after skin or nipple-sparing mastectomy breast implants were placed in subpectoral position. Different incisions have been used to access the glandular tissue. Mostly NSM was performed through the inframammary fold incision or radial incision. It proved to be a good approach for slightly larger and ptotic breasts to preserve the blood supply of the inferior skin and allowed for better access to the superolateral part of the breast. These kinds of incisions allowed us to avoid a greater risk of nipple necrosis. In large and ptotic breasts we used a Nava skin reduction mastectomy with a de-epithelialized dermal flap from the lower pole of the breast and free graft of the nipple-areolar complex. Once the incision is made, the superior skin flap is everted and the breast tissue is retracted inferiorly. The plane between the subcutaneous fat and the glandular tissue is the border of the incision to preserve the dermal blood supply. Breast tissue is freed using this technique. Electrocautery is used to remove the breast off the pectoralis major muscle. The breast tissue is weighed by surgeons to determine the subsequent reconstruction volumes. SLNBs were performed with the similarly done incision which was used in NSM and SSM. Injections with Technetium 99 were used with the peri-areolar approach alone without using methylene blue. We used an intraoperative gamma finder to localize sentinel nodes. Breast reconstructions were made with microtextured and macrotexture prostheses placed under the pectoralis major muscle. In some cases to better cover the prosthesis we used synthetic meshes and Acellar Dermal Matrix (ADM). We used the intraoperative drainage in places where breast tissue was removed for one or two weeks following the surgical procedures. In a standard post-operative care, we used antibiotics and pain relief medicaments.

Statistical Analyses

Baseline statistics by usage of SLNB status and living status are presented as number and proportion (for row and column). The overall survival was estimated using the Kaplan-Meier method. The survival time in months was counted from the date of initiation of treatment to the date of the last observation or death of any cause. The results of the analysis were presented as 1-, 3- and 5-year survival probabilities with 95% confidence interval (95% CI). The relationships between selected clinico-pathological features and the life status were tested using the chi-square test. P values<0.05 were considered statistically significant. A priori and posteriori probability density functions of death by SLNB usage and CS status were estimated using beta distributions. Functions describing the probability of each possible hypothesis of death were obtained, provided that α death events and β non-death events occurred for each analyzed SLNB and CS status. Due to the lack of information about the distribution of the studied parameters in the population, the non-informative a priori distribution Beta (1, 1) was adopted, which assumed that all parameters in the parameter space Θ are equally probable. The posteriori beta distribution was calculated based on the following formula:

$$\text{Beta}\left(\alpha_{\text{posterior}}, \beta_{\text{posterior}}\right) = \text{Beta}\left(\alpha_{\text{likelihood}} + \alpha_{\text{prior}}, \beta_{\text{likelihood}} + \beta_{\text{prior}}\right)$$

(Formula 1) 95% credible intervals were calculated based on the quantile function for the beta distribution, determining quantiles of 0.025 and 0.975, separately for each analyzed SLNB usage and CS status. The probability of death by SLNB usage and CS status was estimated using the Monte Carlo simulation, used random sampling from two beta distributions, where each sample was selected based on its probability in the distribution. Samples from high probability areas were drawn more frequently, and sampling from two beta distributions was treated as one sample, with an assumed number of 100,000 samples. The percentage of all trials in which either of the two status SLNB and CS generated a higher probability of death than the other was calculated. It was reckoned how many times samples from the beta distribution of SLNB and CS status generating a higher probability of death were sampled more often than from the other status of these characteristics (Formula 2).

$$\text{probability superior} = \text{sum}\,\frac{(\text{A beta samples} > \text{B beta samples})}{\text{number of trials}}$$

where:

A beta samples – higher death probability beta samples

B beta samples – lower death probability beta samples

(Formula 2) Based on the Monte Carlo simulation results, the quotient of the probability distributions of death depending on SLNB and CS status was calculated (Formula 3).

$$\text{distribution of the relative differents} = \frac{\text{A beta samples}}{\text{B beta samples}}$$

where:

A beta samples – higher death probability beta samples

B beta samples – lower death probability beta samples

Results

There were 12 cases of death in the analysed group. The most common cause of death was the dissemination of the disease: to the liver, bones, and the brain. In all of the deceased, dissemination occurred within 3 years after diagnosis. In 2 patients locoregional recurrence occurred: in the skin and regional lymph nodes. Four patients are alive with cancer dissemination: to the bones and lymph nodes of the mediastinum after the salvage systemic treatment. The difference in the overall survival by SLNB usage status was significantly different p=0.026 (Figure 2). In patients without SLNB, the probability of survival at 1, 3, and 5 years was 0.968 (0.908, 1.000), 0.769 (0.619, 0.955), and 0.705 (0.535, 0.929), respectively, while in patients with SLNB it was 0.974 (0.939, 1.000), 0.947 (0.899, 0.999), and 0.914 (0.836, 0.998) respectively. Restricted mean survival for non-SLNB and SLNB patients was 84.6 months and 101.9 months, respectively.

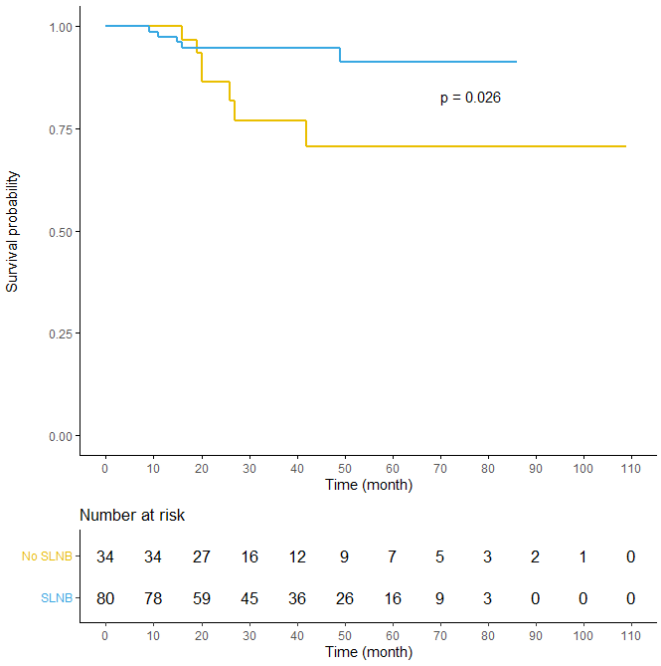


Figure 2: Overall survival in the study group by SLNB status.

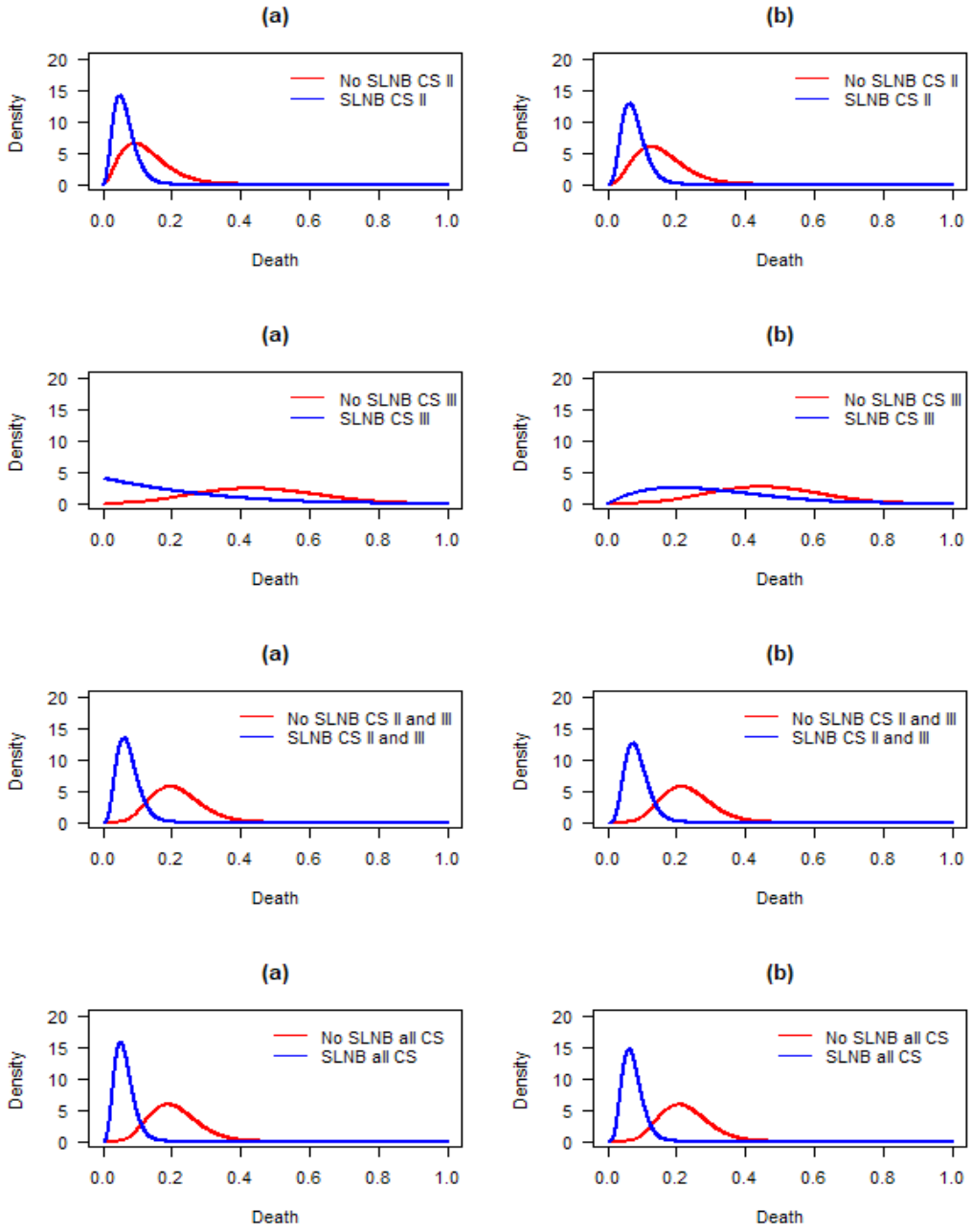
A significant association of the life status was found for the clinical stage, sentinel node biopsy procedure application, radiotherapy, complete pathological regression after neoadjuvant chemotherapy, and cancer progression (Table 3). In CS I no death was observed, in CS II and CS III death was observed in 8% and ≈36%, respectively. In patients treated with SLNB, death was recorded in ≈6% of them, and in the non-SLNB group in ≈20% of patients. About 25% of deaths were reported in patients irradiated after the surgery, and 1.4% in the group without radiotherapy. Complete pathological regression was observed in 52 patients and only 2 (4%) patients from this group died in comparison to the group without cancer complete cancer in which 10 deaths were noted. Among 16 patients with cancer progression, death was observed in 75%.

Characteristic	Alive (*n*=102)			Death (*n*=12)			*P*
	n	Row %	Column %	*n*	Row %	Column %	
Age							0.206
<55 year	77	87.5	75.5	11	12.5	91.7	
≥55year	25	96.2	24.5	1	3.8	8.3	
Cancer type							0.625
NST	100	89.3	98.0	12	10.7	100.0	
Other	2	100.0	2.0	0	0.0	0.0	
Clinical stage (CS)							0.003
I	13	100.0	12.7	0	0.0	0.0	
II	80	92.0	78.4	7	8.0	58.3	
III	9	64.3	8.8	5	35.7	41.7	
Grading (G)							0.733
G1	3	100.0	2.9	0	0.0	0.0	
G2	34	87.2	33.3	5	12.8	41.7	
G3	65	90.3	63.7	7	9.7	58.3	
Gene mutation							0.126
No	62	86.1	60.8	10	13.9	83.3	
Yes	40	95.2	39.2	2	4.8	16.7	
Neoadjuvant chemotherapy							0.660
No	20	87.0	19.6	3	13.0	25.0	
Yes	82	90.1	80.4	9	9.9	75.0	
Adjuvant chemotherapy							0.139
No	57	93.4	55.9	4	6.6	33.3	
Yes	45	84.9	44.1	8	15.1	66.7	
Type of surgery							0.066
NSM	101	90.2	99.0	11	9.8	91.7	
SSM	1	50.0	1.0	1	50.0	8.3	
Sentinel lymph node biopsy							0.022
No	27	79.4	26.5	7	20.6	58.3	
Yes	75	93.8	73.5	5	6.3	41.7	
Radiotherapy							< .001
No	70	98.6	68.6	1	1.4	8.3	
Yes	32	74.4	31.4	11	25.6	91.7	
Hormone therapy							0.625
No	100	89.3	98.0	12	10.7	100.0	
Yes	2	100.0	2.0	0	0.0	0.0	
Complete pathological regression							0.033
No	52	83.9	51.0	10	16.1	83.3	
Yes	50	96.2	49.0	2	3.8	16.7	
Cancer progression							<0.001
No	98	100.0	96.1	0	0.0	0.0	
Yes	4	25.0	3.1	12	75.0	100.0	

Abbreviations: NST-No Special Type; NSM-Nipple-Sparing Mastectomy; SSM-Skin-Sparing Mastectomy.

Table 3: Relationships between vital status and selected clinico-pathological characteristics.

Beta distributions were estimated for the probability of death by SLNB and CS status. A prior beta distributions were plotted based on the accumulated evidence, while posterior beta distributions were obtained by combining the accumulated evidence with assumed a prior distributions of the probability of death depending on SLNB and CS status (Figure 3).



Abbreviations: SLNB-sentinel lymph node biopsy; CS-clinical stage.

Figure 3: Beta distribution of death status depending SLNB status and clinical stage (CS). The (a) available data, and (b) posterior distribution.

Based on the analysis of a posteriori beta distribution plots, it was found that most of the probability density of death in SLNB patients was significantly shifted to the left indicating a lower probability of death in relation to the probability density distribution for non-SLNB patients, while the range of death probability in SLNB patients was narrower (except for CS III) than in non-SLNB patients. Unfortunately, both analyzed distributions overlapped, making it impossible to clearly confirm that death in non-SLNB group is actually more likely than in SLNB group. Also, the 95% credible intervals of death probability determined based on beta distributions of death probability according to SLNB and CS status overlapped and in some cases (e.g. CS III) were very wide, allowing too many possibilities of interpretation (Table 4).

Clinical stage	Prior		Posterior	
	non-SLNB	SLNB	non-SLNB	SLNB
CS II	2.8, 28.0	1.8, 13.5	4.5, 31.2	2.6, 15.2
CS III	15.7, 75.5	0.6, 60.2	18.7, 73.8	4.3, 64.1
CS II and III	9.3, 36.4	2.5, 14.6	10.7, 37.9	3.3, 16.1
All CS	9.0, 35.5	2.1, 12.5	10.4, 36.9	2.8, 13.8

Abbreviations: SLNB-Sentinel Lymph Node Biopsy; CS-Clinical Stage.

Table 4: 95% credible intervals of the probability of death by SLNB status and CS status.

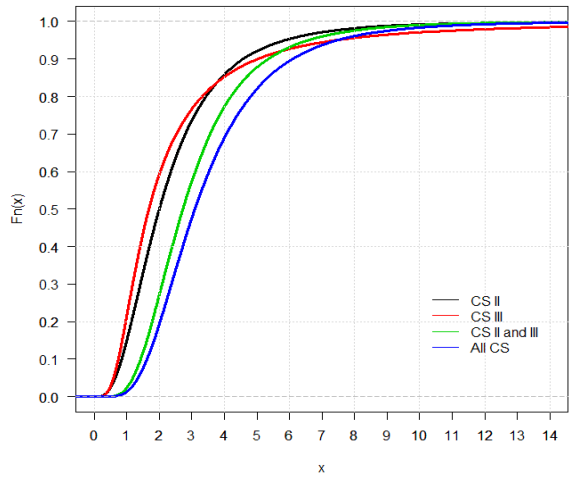
The Monte Carlo simulation was used to clarify existing doubts. One hundred thousand samples were randomly selected from both analyzed distributions. We then estimated the percentage of all trials in which the distribution of possible deaths in non-SLNB patients was more likely compared to SLNB patients. Based on the results of the analysis, it was found that without taking a clinical stage into consideration, the distribution of possible deaths in non-SLNB patients was 99% more likely than in SLNB patients. In CS II, CS III, and CS II and III together, death in non-SLNB patients was 85%, 78%, and 97%, respectively and more likely than in SLNB patients. Based on the Monte Carlo simulation results, the odds ratio of death by SLNB and CS status was calculated. For the calculated ratios of the probability of death distributions depending on the SLNB status, the values of the 25th, 50th, and 75th percentiles according to the analyzed CS indicated a higher probability of death in non-SLNB patients compared to SLNB patients (Table 5).

Clinical stage	Percentile		
	25%	50%	75%
CS II	1.3	2.0	3.1
CS III	1.1	1.7	2.9
CS II and III	1.9	2.7	3.8
All CS	2.2	3.1	4.4

Abbreviations: SLNB-Sentinel Lymph Node Biopsy; CS-Clinical Stage.

Table 5: 25th, 50th, and 75th percentiles for probability distribution quotients by SLNB status and by clinical stage.

We also found a 40% chance that, depending on CS, death in non-SLNB patients would occur ≈2 to ≈3.5 times more often than in SLNB patients (Figure 4).



Abbreviations: CS-clinical stage.

Figure 4: Empirical cumulative distributions.

Discussion

Triple-negative breast cancer is a very aggressive form of malignancy. TNBC is associated with not only a higher but also an earlier risk for relapse. Hazard rates for distant recurrence are the highest for TNBC within the first 2 years following diagnosis and relapses after 5 years are uncommon, which was confirmed in our analysis. Chemotherapy remains the standard of care for all TNBC patients. The choice of the surgery remains one of the most difficult problems in the treatment of TNBC [11]. The general trend in breast cancer, including TNBC, is the desire not only for oncological radicalism but also to ensure a good cosmetic result which is possible with organ-preserving or reconstructive plastic surgery. The general trend of recent years covers also the rejection of extensive lymph node dissections in favour of the sentinel lymph node biopsy. It should be noted that the choice of a method of surgical intervention depends on the decisions of the surgeon and the patient. Study results indicate that women with TNBC who undergo breast-conserving therapy do not have a worse prognosis than those who undergo mastectomy [12,13]. According to Rippy, 27% of patients refused to perform the organ-preserving surgery in favour of mastectomy, but the patients' choice depends on their understanding of this aspect of treatment [14]. Subcutaneous mastectomy is currently an increasingly used method of surgical treatment of patients with breast cancer. Psychological aspects are not to be forgotten in qualification to this method of treatment, and many patients choose this form of the therapy also because of fear of radiotherapy, which is an inseparable part of conserving treatment. However, in patients with triple-negative breast cancer, in whom BRCA mutations are more common than in other biological types of breast cancer, mastectomy is the recommended method, and patients are rarely treated with the breast preservation.

The condition of the axillary lymph nodes is one of the most important prognostic factors. Nowadays the sentinel lymph node biopsy in many cases replaced axillary lymphadenectomy and is also performed in patients after systemic treatment. Pathological complete regression after neoadjuvant chemotherapy is a positive prognostic factor and, additionally, axillary lymphadenectomy can be then avoided. In our study, the majority of patients underwent the sentinel lymph node biopsy, with a significant reduction of the toxicity of extended axillary surgical treatment. In the group of 61 patients, a sentinel node biopsy was performed after systemic treatment. Only in one patient, in 1 sentinel lymph node, cancer metastasis was detected. Pathological complete regression was achieved in 52 out of 91 women treated with neoadjuvant chemotherapy which allowed to use the SLNB procedure in most patients. Several clinical trials presented that complete axillary lymph node dissection had no significant effect on an overall survival, but reduced the risk of locoregional recurrence [15-18]. Contrary, Kahler-Ribeiro-Fontana et al. published their 10-year follow-up of 222 patients with cN1/N2 disease treated with NAC, 123 of whom had a negative Sentinel Lymph Nodes (SLN) and were treated with SLNB alone. At a median follow-up of 9.2 years, 2 (1.6%) of 123 ypN0 patients developed an axillary recurrence [19]. A cohort study presented by Barrio et al. found that in patients with cN1 disease rendered cN0 with NAC, with 3 or more negative SLNs with SLNB alone, nodal recurrence rates were low, without routine nodal clipping.

These findings potentially support omitting axillary dissection in such patients. Other authors recommended retrieval of more than 3 sentinel lymph nodes [20]. In our analysis more than 3 sentinel lymph nodes were found and removed. Statistically, in patients after neoadjuvant chemotherapy, the mean number of SLNs was higher in comparison to the group with adjuvant chemotherapy. Indications for radiotherapy occur in patients after mastectomy mainly due to metastases to regional lymph nodes, and the positive role of radiotherapy in TNBC patients was proved [21-24]. In our group radiotherapy was an unfavorable prognostic factor. The reason of this fact was the advanced clinical stage of the cancer and metastases to axillary lymph nodes. Forty three patients were irradiated because of these factors. Most patients in the group with SLNB were not irradiated. What is interesting in patients in whom mastectomy was the first stage of the treatment, radiotherapy of regional lymph nodes replaced axillary dissection in 7 women and only one patient out of this group died due to distant metastasis.

Conclusions

A combination of chemotherapy with subcutaneous mastectomy and sentinel node biopsy was an effective method of therapy in many patients with triple negative breast cancer. Effective systemic treatment is connected with the decrease of the surgical treatment, because in many women we can apply sentinel lymph node biopsy instead of axillary lymphadenectomy. Decreasing of the range of the treatment in an axilla region does not adversely affect treatment outcomes, in particular, the overall survival of patients.

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