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Evaluating the breast cancer quality of care indicators in Iran; multicenter study

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Abstract

Background Data on quality-of-care indicators for breast cancer patients is limited in low—and middle-income countries. We evaluated the indicators in Iran.

Method A total of 21 quality-of-care indicators of breast cancer management defined by EUSOMA 2017 were selected. The indicators were retrospectively evaluated based on the data from the Clinical Breast Cancer Registry established in 11 provinces of Iran.

Result In the study of 6,293 patients evaluated on 21 indicators, 15 indicators were more than 5% below EUSOMA's standard levels.

Conclusion The defined indicators had a value lower than the suggested standards by EUSOMA. This study's results highlight important clues for intervention in improving breast cancer outcomes in Iran and other low—and middle-income countries.

Keywords Breast Neoplasm, Quality of Care, Indicators, EUSOMA, Healthcare, System, Developing, Countries

Introduction

Breast cancer is the most common malignancy among women in Iran and around the world [1]. Based on the Human Development Index (HDI), the mortality-to-incidence ratio of this cancer is lower in high-income countries (HIC) than in low- and middle-income countries (LMICs), indicating a poorer prognosis in the latter group [2]. The disparity in breast cancer outcomes is influenced by organized mammography screening

programs in high-income countries (HICs) and the timely, high-quality care provided to patients for diagnosis, treatment, and follow-up [3, 4].

In 2010, the European Society of Breast Cancer Specialists (EUSOMA) established indicators to monitor specialized breast cancer clinics in Europe, which were revised in 2017 and 2024 [5, 6]. This comprehensive set of indicators offers detailed insights into diagnosis, surgery, radiotherapy, chemotherapy, hormone and targeted therapy, patient follow-up, and genetic testing. It's crucial to highlight that despite initial shortcomings, the systematic implementation of the program and targeted interventions led to significant improvements and reduced disparities in EUSOMA-certified breast centres

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[7]. Quality-of-care indicators for breast cancer are well-monitored in high-income countries but not in low- and middle-income countries like China, South Africa, and Mexico. Limited evaluation reports are available for these countries [8–11]. We aimed to utilize EUSOMA's quality-of-care indicators in a large cohort of breast cancer patients in Iran to evaluate the situation of breast cancer care in Iran.

Methods

We analyzed data from 6,970 breast cancer patients registered in the Clinical Breast Cancer Registry of IR Iran (CBCR-IR) [12]. The registry collected data on patients diagnosed between June 2014 and December 2020 in 12 centres from 11 provinces. To compare the results with EUSOMA standards, we excluded 349 (5%) metastatic patients, 283 (4%) patients older than 70, and 46 (0.7%) patients with extensive missing information; we included 6,293 (90.3%) patients with primary breast cancer in our analyses.

Patient follow-up

The data registered in the Clinical Cancer Registry (CBCR) of the Islamic Republic of Iran were updated and modified to become evaluable. The update was based on collecting more information from the medical records of the patients at the hospitals and also through phone calls.

Quality-of-care indicators of breast cancer patients

Quality-of-care indicators were selected according to the EUSOMA (2017 version) [5] and reviewed by four oncologists and one epidemiologist in a focus group discussion (FGD). Indicators which couldn't be assessed by the data registered in the Clinical Breast Cancer Registry (CBCR) were excluded, and we also classified indicator 6 (Pathologic Evaluations) into two separate indicators (6.1 (pathological examination), and 6.2 (immunohistochemistry [IHC] processing)). Table 2 presents the indicators' definitions and lists and compares the current study's results with EUSOMA standard levels (ESL). The TNM staging method (7th edition) was used for staging [13]. Then, Ia, Ib, and Ic were categorized as Stage I. IIa, IIb as Stage II, IIIa, IIIb, and IIIc as Stage III. The molecular subtype classification was also conducted using data associated with estrogen and progesterone receptors, HER2, and KI67 receptor status on immunohistochemistry (IHC) [14].

Statistical analysis

We used a radar diagram to show the difference between the minimum standard and the current situation for every indicator. P values lower than 0.05 ($p < 0.05$) were considered statistically significant. The STATA 14 was

used to conduct the statistical analysis. We used Microsoft Excel to draw the radar chart (Fig. 1).

Results

This study analyzed 6293 patients. The mean patient age was 48.1 + 10.1 years. More than 60% of the patients were diagnosed at Stage I and II, and 25% were at Stage III (Table 1). The following five sections discuss patient compliance with the quality-of-care indicators.

Pretreatment diagnostic radiological evaluations

The patients who were diagnosed with breast cancer at early stages (Stage II and lower) did not require metastasis workup. (indicator No. 4) Only 40% of the early-stage patients did not undergo baseline-staging tests (e.g. US of the liver, chest X-ray and bone scan), which was lower than EUSOMA standard level (ESL = 95%) (Table 1). In addition, metastasis workup for patients at Stage III and higher was 34.5% lower than the minimum defined standard level indicator No. 5 (ESL = 85%).

Pretreatment molecular and pathological evaluations

The percentage of the histopathology reports incorporating all prognostic factors, such as histopathology type and grade, tumour size, nodal involvement, margin involvement, and lymph vascular involvement (LVI), was 34.4% lower than the minimum expected standard level (Indicator 6.1, ESL = 95%). Indicators linked with detecting hormone receptors (ER, PR) and HER2 on IHC were 19.2% lower than the standard values (Indicator 6.2, ESL = 95%).

Surgery

We observed that 82.5% of the patients had undergone at least one surgery for breast tumour, which was 2.8% higher than the minimum defined standard value (Indicator No. 7, ESL = 80%). Breast reconstruction after the surgery was 12.5%, 27.5% lower than the standard value (Indicator No. 8, ESL = 40%). Performing sentinel lymph node biopsy (SLNB) (without ALND) for node-negative patients was 38.4% lower than the defined standard level (Indicator No. 9, ESL = 90%). Breast-conserving therapy (BCT) for tumours under three centimetres was only 6.1% lower than the EUSOMA standard level (Indicator No. 11, ESL = 70%). However, 63.2% of the patients with tumour sizes equal to or smaller than two centimetres had received BCT, which was 16.8% lower than the minimum standard value (Indicator No. 12, ESL = 80%).

Systemic treatment

The proportion of trastuzumab treatment in HER2-expressing patients was 26.9% lower (indicator No. 15,

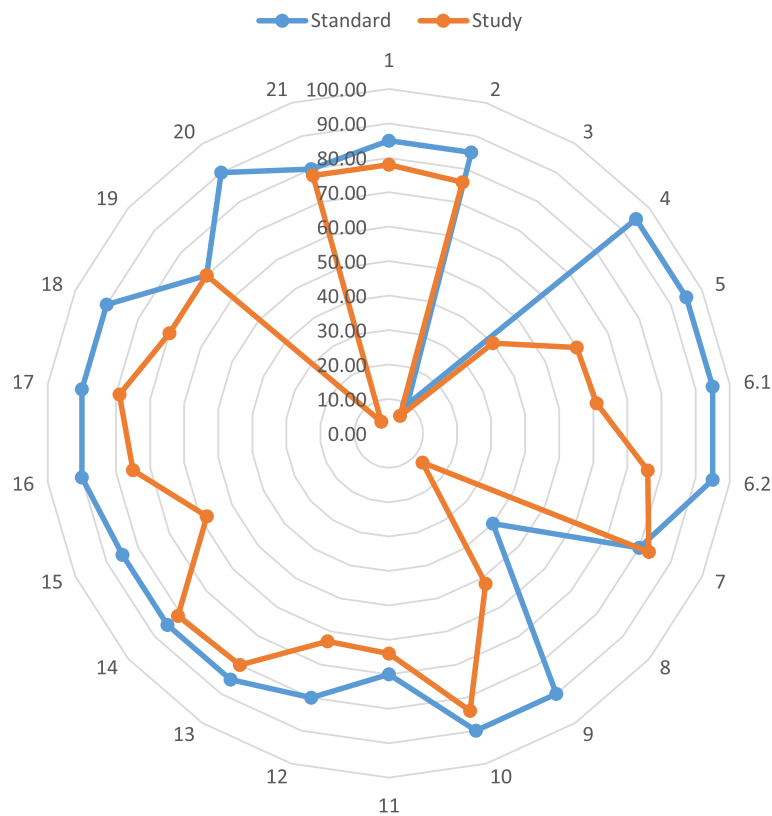


Fig. 1 Comparing EUSOMA recommended standards with adherence to indicators among Iranian breast cancer patients (2014–2020)

Table 1 Patients characteristics, registered in clinical breast cancer registry in Iran 2014–2020

Variable	Number	Percent	Variable	Number	Percent
Age at Diagnosis			Year at Diagnosis		
< 40	1,341	21.31	2014	670	10.65
40–50	2,469	39.23	2015	744	11.82
50–60	1,651	26.24	2016	681	10.82
60–70	832	13.22	2017	991	15.75
Stage at Diagnosis			2018	1,272	20.21
I	1,173	18.64	2019	1,156	18.37
II	2,773	44.06	2020	779	12.4
III	1,595	25.35	City		
Unknown	752	11.95	Tehran	2,997	47.62
Tumor Grade			Isfahan	1,487	23.63
I	678	10.79	Sabzevar	135	2.15
II	3,046	48.46	Khorramabad	155	2.46
III	1,683	26.77	Babol	187	2.97
Unknown	879	13.98	Bushehr	231	3.67
Molecular Subtype			Kermanshah	378	6.01
Luminal A	1,916	30.45	Arak	241	3.83
Luminal B	705	11.2	Zahedan	142	2.26
Her2 +	1,458	23.17	Urmia	340	5.4
Triple Negative	716	11.38			
Unknown	1,498	23.8			

Table 2 Indicators definition and the status of the indicators among Iranian breast cancer patients (2014–2020) compared to the minimum standards defined by EUSOMA

Indicators	Definition	Level of Evidence	Minimum standard*	Current Study	Difference	N _{eligible}	N _{Compliant}
Diagnostic Evaluations							
1	Proportion of women with breast cancer who preoperatively underwent mammography and ultrasound of both breasts and axillae	3	90%	77.8%	12.2%	6293	4894
2	Proportion of women with breast cancer (invasive or in situ) who had a preoperative histologically or cytological confirmed malignant diagnosis (B5 or C5)	3	85%	76.3%	8.7%	6293	4805
3	Proportion of cancer cases examined by MRI before treatment	4	10%	6.4%	3.6%	6293	401
4	Proportion of women with stage I or primary operable stage II, breast cancer who do not undergo baseline-staging tests (e.g. US of liver, chest X-ray and bone scan)	3	95%	40.2%	54.8%	3946	1588
5	Proportion of women with stage III breast cancer who undergo baseline staging tests (US of liver, chest X-ray and bone scan)	3	95%	60.7%	34.3%	1595	968
Pathologic & Molecular Evaluation							
6.1	Proportion of invasive cancer cases for which the following prognostic/predictive parameters have been recorded: histological type (according to WHO Classification of Tumors of the Breast), grading (according to WHO and EU Guidelines: Elston and Ellis modified Bloom and Richardson-Grading system Elston, CWet al. 1991),. In addition to the above parameters, the following parameters must be recorded after surgery: Pathological stage (pT and pN, or ypT and ypN in case of PST), size in mm for the invasive component, Peritumoral vascular invasion (L,V), Distance to nearest radial margin	2	95%	60.6%	34.4%	6293	3812
6.2	ER, PgR*, HER-2/neu Evaluation	2	95%	75.8%	19.2%	6293	4768
Surgery							
7	Proportion of patients (invasive cancer only) who received a single (breast) operation for the primary tumour (excluding reconstruction)	2	80%	82.8%	2.8%	6293	5214
8	Proportion of patients receiving immediate reconstruction at the same time of mastectomy	3	40%	12.5%	27.5%	6293	5507
9	Proportion of patients with invasive cancer and clinically negative axilla who underwent sentinel lymph-node biopsy (SLNB) only (excluding patients who received PST)	1	90%	51.6%	38.4%	1296	668
10	Proportion of patients with invasive cancer who underwent sentinel lymph-node biopsy with no more than 5 nodes excised	1	90%	84.3%	5.7%	668	105
11	Proportion of patients (BRCA1 and BRCA2 patients excluded) with invasive breast cancer not greater than 3 cm (total size, including DCIS component) who underwent BCT as primary treatment	1	70%	63.9%	6.1%	3594	2295
12	Proportion of patients with non-invasive breast cancer not greater than 2 cm who underwent BCT	2	80%	63.2%	16.8%	2005	1267
Systemic Treatments							
13	Proportion of patients with endocrine sensitive invasive cancer who received endocrine therapy	1	85%	80%	5%	2884	3605
14	Proportion of patients with ER- (T > 1 cm or Node +) invasive carcinoma who received chemotherapy	1	85%	81%	4%	3401	2758
15	Proportion of patients with HER2 positive (IHC 3+ or in situ hybridization positive FISH-positive) invasive carcinoma (T > 1 cm or N+) treated with chemotherapy who received adjuvant trastuzumab	1	85%	58.1%	26.9%	1519	882
16	Proportion of patients with inflammatory breast cancer (IBC) or locally advanced non-respectable carcinoma who received neo-adjuvant chemotherapy	2	90%	74.5%	15.5%	766	195

Table 2 (continued)

Indicators	Definition	Level of Evidence	Minimum standard*	Current Study	Difference	N _{eligible}	N _{Compliant}
Radiation Therapy							
17	Proportion of patients with invasive breast cancer (M0) who received postoperative radiation therapy (RT) after surgical resection of the primary tumor and appropriate axillary staging/surgery in the framework of BCT	1	90%	78.8%	11.2%	3220	78.8
18	Proportion of patients with involvement of axillary lymph nodes (pN2a) who received post-mastectomy radiation therapy to the chest wall and all (non-resected) regional lymph-nodes	1	90%	70.4%	19.6%	838	590
19	Proportion of patients with involvement of up to three axillary lymph nodes (pN1) who received post-mastectomy radiation therapy to the chest wall and non-resected axillary lymph-nodes, including level IV (supraclavicular), and in medially located tumors, the internal mammary lymph-nodes	1	70%	69.5%	0.5%	1598	1111
Multidisciplinary Treatments							
20	Proportion of cancer patients to be discussed pre or postoperatively by a multidisciplinary team	3	90%	4%	86%	6293	252
Waiting Time							
21	Time interval of six weeks, from the date of first diagnostic examination within the breast center to the date of surgery or start of other treatment	4	80%	77.9%	2.1%	4478	3488

ESL = 85/12%), and neoadjuvant chemotherapy was 15.5% lower in our patients (indicator No. 16, ESL = 90%).

Radiotherapy

We found that radiotherapy after BCT was 11.2% lower than the minimum expected standard (indicator No. 17, ESL = 90%). In patients who underwent a mastectomy, radiotherapy in stage N2a or higher was 19.6% lower than the standard (indicator No. 18, ESL = 90%). Still, the current study's radiotherapy rate in N1 stage patients was similar (69.5%) to the expected level (indicator No. 17, ESL = 70%).

Multidisciplinary treatment

Only 4% of the patients had received multidisciplinary treatment, while it is recommended that more than 90% of the patients undergo it.

Discussion

To the best of our knowledge, the present study was the first multicenter registry-based study in a developing country such as Iran reporting the quality of care of patients with breast cancer using a set of quality indicators. The data from the (CBCR-IR) effectively assesses EUSOMA indicators. Regrettably, 15 out of 21 indicators did not meet the minimum standards. (Table 2).

All the defined indicators were selected from EUSOMA 2017; based on the findings of this study, the indicators were measurable in Iran. All the indicators

were measured and registered at every healthcare centre; hence, the indicators can be evaluated and monitored in our country [5].

Of the 21 indicators, 15 were lower than the defined minimum Standard (Table 2). At the time of the study, there was no program to register the information regarding the patient's quality-of-care indicators. The patient's data was retrospectively registered in the system in the present study. Besides, there was the possibility of error or fault in registering the information at various stages (i.e., creation and safekeeping of the clinical records and when registering the patients' information from their history). European countries have also experienced difficulties developing similar quality-of-care monitoring systems, and the quality of the information was gradually modified through feedback to the centres. [7, 15].

Quality Indicators for diagnosis

Considering the low probability of metastasis [16] and based on indicator No. 4, patients diagnosed at an early stage of breast cancer do not require metastasis workup. More than 54% of the patients had at least one metastasis workup, indicating the patient's possible unnecessary interventions. Similar findings were reported in France [16] and Portugal [17]. Patient preference, pressures on the specialists, clinical specialists' fear of failure in metastasis diagnosis, diverse treatment approaches between the clinicians [18, 19] and lack of agreement on guidelines at the national level are among the most significant

causes of overdoing such tests. Considering the economic and healthcare burden and the possibility of conducting unnecessary interventions after metastasis evaluation, developing an educational program for physicians and patients and monitoring the national guidelines are warranted. Patients in stage III and above require metastasis evaluation in at least 95% of the cases. However, only 61% of the patients had a metastasis workup. With the accessibility to CT-scan equipment and specialists, MRI, radiologists, and adequate public insurance coverage in Iran for conducting the related tests [18], it seems that errors in registering correct information cause a lower frequency of the performed tests than the minimum expected standard.

Since many pathology centres may lack the required immunohistochemistry equipment and trained technicians and pathologists, the indicators histopathology and molecular basement are separated, although EUSOMA [5, 7] has merged these indicators. Pathological assessments were 34.1% lower than the standards, whereas immunohistochemistry assessments were 19.2% lower than the expected minimum standard. The primary cause of discrepancies in pathology indicators with the standards resides in the difference in pathologists' preferences in reporting and their different levels of access to sufficient information about the patient history, especially as there was no agreed-upon guideline [19]. Documented pathology reports are among the prerequisites for patients' registration with the Clinical Breast Cancer Registry System, which reduces the possibility of missing information. On the contrary, since centres other than the primary pathology centres may conduct IHC tests, and since the conducted IHC test reports may not be stored in the patient's record, the possibility of missing data on the receptors is high. Therefore, administrative actions to register such information in patients' history are essential so that we can conclude the exact percentage of such tests performed on patients in the future.

Quality indicators for surgery

The percentage of patients who had undergone only one surgery for breast cancer was 2.8% higher than the minimum standard (80%). European studies estimated the rate of the second surgery to be approximately 16% of patients, US studies estimated 25 to 40%, and Norwegian studies estimated about 6%, which indicates that the 17% second surgery in Iran was acceptable [16, 17, 20, 21]. The percentage of primary breast reconstruction right after the first surgery was 27.5% lower than the minimum standard. Breast reconstruction surgery is considered an aesthetic surgery in Iran as insurance does not cover the related expenses. The surgeons' opinions may also favour delayed surgery, and patients' requests and different views

compared with the participants of the other studies may also be other causes for this discrepancy.

Sentinel lymph node biopsy (SLNB) without axillary lymph node dissection (ALND) in patients clinically regarded as N0 was 38.4% lower than the defined minimum standard (90%). SLNB is considered a staging step, and conducting ALND after a negative SLNB is an overtreatment. In another similar finding in France [16], SLNB frequency was lower than the standard level, and surgeons' inclination toward conducting surgeries in bigger tumours but with negative lymph nodes was the primary cause of lower values for this indicator. Focusing the investigation on smaller tumours in the present study demonstrated an acceptable increase in the standard, indicating the surgeons' probable inclination toward aggressive treatment caused by ALND instead of SLNB [16]. On the other hand, cancer or lack of access to SLNB equipment may be the reason for the lower frequency of SLNB in Iranian patients [22]. Correct reporting of SLNB cases may also be an imperative factor. In Germany [2], for instance, in SLNB cases where palpable lymph nodes were extracted during the SLNB cases, they were registered in the data bank as ALND. In the present study, it is also possible for some pathology reports not to have included SLNB, or in some cases, the registering employee may have considered palpable node removal as ALND [2].

According to EUSOMA recommendations, 70 and 80% of patients with tumours smaller than three and two centimetres require BCS in the cases, respectively. The present study's findings indicated that 63% of these patients received BCS treatment. Besides the tumour size, patient preference and the possibility of conducting post-surgery radiotherapy were among the factors contributing to a lower BCS percentage than the minimum standard, especially in patients with tumours smaller than two centimetres [23]. Consistent with the findings of the present study, researchers in Australia and China mentioned lower accessibility to radiation oncologists as the primary factor leading to the selection of MRM (Modified Radical Mastectomy) instead of BCS [8, 24]

Quality indicators for systemic treatment

Trastuzumab targeted therapy was conducted in 58.1% of the patients with HER2-positive receptors, while the minimum intended standard was 85%. Different studies reported that the high costs of trastuzumab medication therapy have limited access to treatment, especially in low- and middle-income countries [25]. Nevertheless, biosimilar drugs in Iran were widely used and covered by public insurance; accordingly, further studies are crucial to investigate the cause of the lower reported percentage of this significant indicator [25]. Neoadjuvant

chemotherapy was used in 15% less than the minimum EUSOMA standard per cent among patients with inoperable tumours. Similar studies in Slovenia and Portugal also reported lower values than the standard. The physicians' decision-making about treating patients with complex cases may vary due to the complications and consideration of each patient [17, 21].

Quality indicators for radiotherapy

Radiotherapy was delivered to 78.8% of patients undergoing BCS and 70% of Node-positive patients undergoing MRM. Studies in the US [26, 27], Portugal [17], and China [28] reported lower radiotherapy after surgery. European countries, including Norway [20], France [16], and Germany [2], reported higher radiotherapy standards. Geographic disparity was the most significant factor affecting the frequency of post-surgery radiotherapy in the USA [26, 27]. In Australian cities far from radiotherapy centres, most surgeons were inclined toward MRM surgery so that the patients would not require radiotherapy [23]. Based on a recent study in Iran [22], the ratio of radiotherapy machines to the number of patients was acceptable; however, most devices are located in large cities, which designates the issue of geographic access regarding tumour treatment. The present study has collected most of the information from Tehran and Isfahan. Many of the patients who visit these large cities come from far distances; for instance, a study at the Cancer Institute of Tehran [29], a primary centre accountable for the largest portion of the data used in the present study, demonstrated that more than 35% of the patients who visited the centre to receive treatment had travelled distances over 450 kms. The patients may stay in Tehran for one or several days for the surgery; however, radiotherapy requires a minimum stay of 20 days in these cities, which may cause serious financial burdens for patients, leading to a lower proportion of radiotherapy. Financial support from the government and NGOs may improve the coverage of radiotherapy.

Multidisciplinary treatment

Multidisciplinary treatment (MDT) refers to patient treatment being designed by a team of breast surgeons, clinical and medical oncologists, radiologists, pathologists, and psychologists. Research has demonstrated the impact of MDT on improving patient treatment and outcome [22, 30]. While sending all breast cancer patients for MDT consultation should be a standard practice, less than five per cent of the patients in Iran are reviewed by MDT. Instead, the patient may be transferred between the various treatment groups after each team's decision. Multidisciplinary tumour boards in Iran only attend

to a limited percentage of patients to solve complex, advanced, recurrent, and particular issues.

Strengths and Limitations

This multicenter study includes a large and diverse sample size from various regions of the country, providing a comprehensive assessment of breast cancer care indicators in Iran. However, retrospective data may introduce limitations and biases commonly associated with such studies. Socioeconomic factors, such as education and cultural barriers, may influence patient visits and adherence to these indicators. Unfortunately, these socioeconomic factors were not collected in our database, highlighting the need for future efforts to gather and analyze their impact on the quality of care for these patients.

Conclusion

This study demonstrated that all selected indicators were measurable, and most were lower than the defined minimum standards. Patients visited by a multidisciplinary team, conducting metastasis workup in stage I or II patients, conducting metastasis workup in stage III patients or higher, reporting all the prognostic and predictive factors in pathology and immunohistochemistry, conducting SLNB in node-negative patients and not doing ALND, and conducting targeted therapy in HER2 + patients, were respectively those with the highest differences to the defined standards minimum standards. Intervention is warranted to mitigate the gaps in quality of care and regular assessment of the quality of care indicators. As the present study only included public centres affiliated with universities, future studies should consist of a larger hospital network to promote the quality of care for all breast cancer patients in Iran.

Abbreviations

ALND	Axillary Lymph Node Dissection
BCS	Breast Conserving Surgery
BCT	Breast Conserving therapy
CBCCR-IR	Clinical Breast Cancer Registry of IR Iran
EUSOMA	European Society of Breast Cancer Specialists
ESL	Estimated Standard Level
FGD	Focused Group Discussion
HDI	Human Development Index
HIC	High-income countries
LMICs	Low- and middle-income countries
LVI	Lymphovascular Invasion
SLNB	Sentinel lymph node biopsy

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Not Applicable.

Authors' contributions

All authors contributed significantly to the conception and design of the work, approved the submitted version, and affirmed the integrity of all project and article procedures.

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Data availability

The datasets analyzed in this study are not publicly available. However, anonymous data may be shared upon mutual agreement with the principal investigator (Kazem Zendeheidi), subject to additional approval from the Research Ethics Committee.

Declarations**Ethics approval and consent to participate**

Study approved by Ethics Committee of Tehran University of Medical Sciences (ethics code: IR.TUMS.VCR.REC.1398.1015). The study utilized administrative and clinical data from patient files archived in the medical records departments of participating hospitals. All patients admitted to these hospitals provided written consent for the use of their data in educational and medical research. Consequently, additional informed consent for the use of patient data in the hospitals and the development of the Clinical Breast Cancer Registry of IR Iran was deemed unnecessary. The Research Ethics Committee reviewed the study protocol and waived the requirement for additional informed consent for this research. However, verbal informed consent was obtained from patients via telephone for the collection of follow-up data.

Consent for publication

This document does not contain any personal or individual information.

Competing interests

The authors declare no competing interests.

Disclaimer

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