

The Role of Open Biopsies in the Diagnosis of Breast Cancer in Poland and their Impact on 5-Year Survival Rates - A Retrospective Analysis

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Abstract

Introduction: Breast cancer is the most prevalent cancer in women worldwide and the leading cause of death among cancer patients. Diagnosis is based on imaging studies (ultrasound, mammography, magnetic resonance imaging) that are evaluated using the BI-RADS system. Core needle biopsy (CNB) is the crucial verification method for BI-RADS 4 and 5, while open biopsy should be used only in exceptional cases.

Aim: The aim of the study was to assess the frequency of open biopsies and their impact on the 5-year survival of women in individual Polish provinces.

Results: A retrospective analysis of data in Poland from 2014 and the first half of 2015 showed that out of 13,718 open breast biopsies, the change in

the diagnosis from benign to malignant tumors occurred within 6 months in 11% of cases, which accounts for 8.6% of new diagnoses during this period. In 10 provinces, the percentage of open biopsies exceeded the recommended level of 10%. In these regions, 5-year survival rates were lower than the national mean rates (78.8%).

Conclusions: Our findings suggest an excessive use of open biopsy in selected provinces, which may affect the quality of diagnosis and treatment outcomes. It is recommended to limit invasive procedures in favor of core needle biopsy through standardization and education of the medical staff, which may improve survival rates for breast cancer patients in Poland.

Keywords: Breast cancer; Core needle biopsy; Open biopsy; Treatment outcomes

Introduction

Breast Cancer (BC) is the most prevalent malignant tumor in women worldwide and the leading cause of cancer deaths among female patients [1]. Approximately 1.33 million women worldwide are diagnosed with BC [2]. There is an increase in BC incidence by approximately 1.44% annually in all age groups, with the highest incidence in women under 50 years of age [3]. According to the Polish

National Cancer Registry (PNCR) of 2014, 17,506 new cases of BC were reported in Poland, while the number of women diagnosed with BC exceeded 20,000 in 2019 [4]. According to the report by the Alivia Foundation (2022), Poland ranks first in terms of the number of deaths from BC among women in European Union countries (Figure 1) [5].

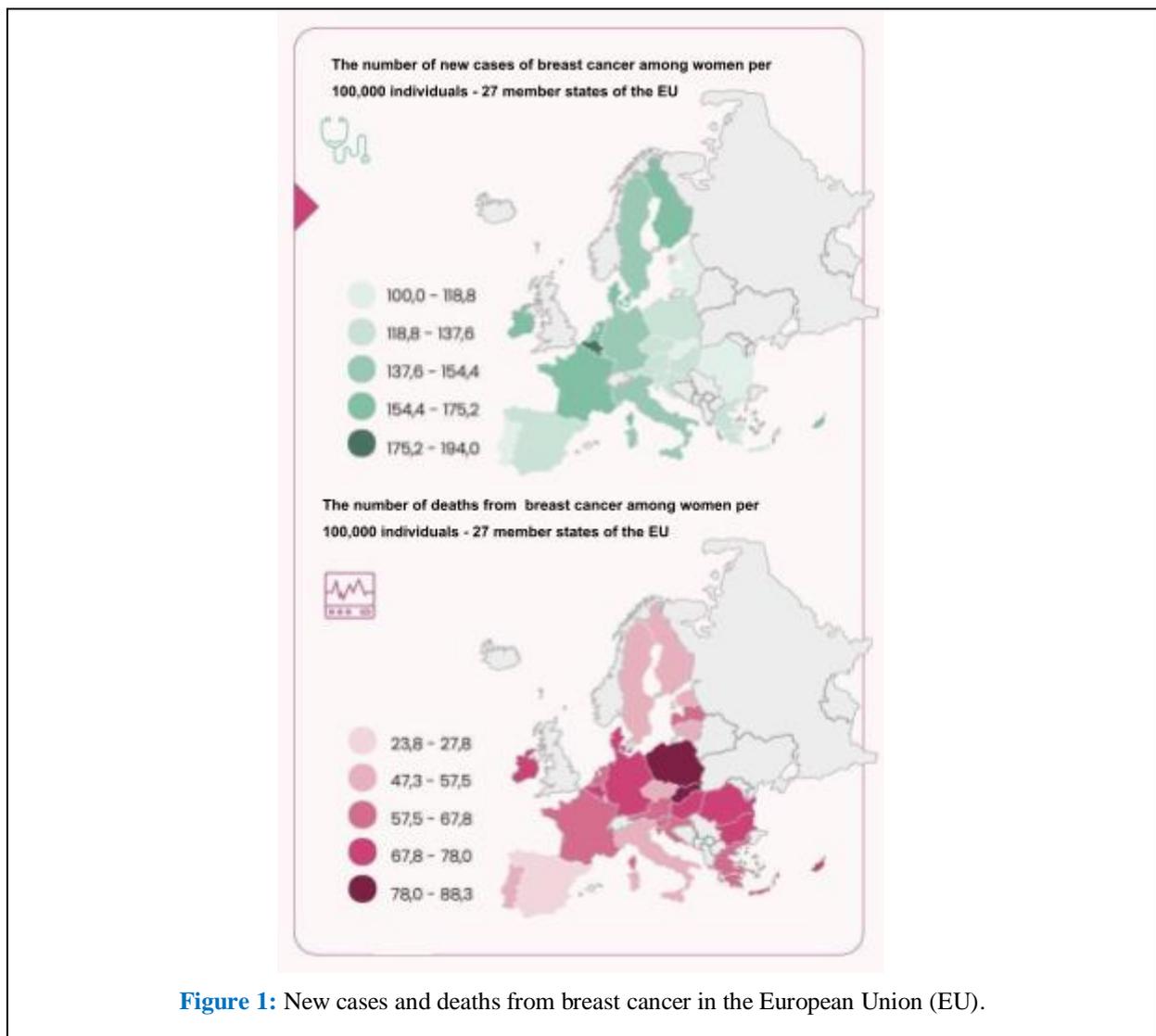


Figure 1: New cases and deaths from breast cancer in the European Union (EU).

In addition to clinical examination, the diagnosis of BC is based on imaging studies, including Ultrasound (US), mammography, spectral mammography, and, in some cases, Magnetic Resonance Imaging (MRI). All of them are

evaluated based on the standardized Breast Imaging Reporting and Data System (BI-RADS) classification. Under this classification, BI-RADS 4 and 5 results require histological verification. BI-RADS 4 indicates a risk of malignancy between

2% and 95%, while BI-RADS 5 indicates a risk >95%. In both cases, these changes require verification using invasive methods to confirm the diagnosis by microscopic examination. Currently, Core Needle Biopsy (CNB) is the standard of verification of focal lesions. As a result, it is possible to determine the type of cancer, the grade of malignancy, and predictive factors, such as steroid receptors, HER-2, or Ki-67 index, which are crucial in planning further treatment [6-9]. Core needle biopsy is mainly performed under ultrasound or mammography guidance, which allows for the precise location of lesions, including calcifications that are not detected on ultrasound. In some cases, a biopsy is also performed under MRI guidance [9,10].

This type of biopsy is currently the diagnostic method of choice in the decision-making process for BC treatment and is characterized by high diagnostic accuracy (sensitivity 94%-100%) [9,11-15]. In turn, Fine Needle Aspiration Biopsy (FNAB) is mainly used to evaluate regional lymph nodes and confirm tumor recurrence [9]. In over 90% of cases, the histological diagnosis should be performed before surgery. According to European and international recommendations, the number of open surgical biopsies performed to diagnose BC should not exceed 10% and is considered an exceptional procedure. Patients with BC should have a confirmed diagnosis before surgery [16-28]. The analysis of the use of CNB and open biopsies in the diagnosis of focal lesions in the breast can be an essential indicator of the quality of diagnosis in a given country or region, which may translate into treatment outcomes.

Materials And Methods

Our retrospective analysis is based on the findings of our study published in the paper “Analysis of diagnostic methods for focal breast lesions using

open surgical biopsies and core needle biopsies in Poland” in Medical Science Monitor in 2018 [9]. The paper developed maps of health needs in terms of open breast biopsies as a method of diagnosing BC in Poland. The analysis included data from the National Health Fund (NHF) on hospitalizations in 2014 and partly in 2015, covering patients with diagnoses according to the following ICD-10 codes:

- D24 (with subcodes) – benign neoplasm of breast
- D48.6 – neoplasm of uncertain or unknown behavior, unspecified: breast
- N60.2 – fibroadenosis of breast
- N60.3 – fibrosclerosis of breast
- N63 (with subcodes) – unspecified lump in breast
- N63.1 – unspecified lump in the right breast

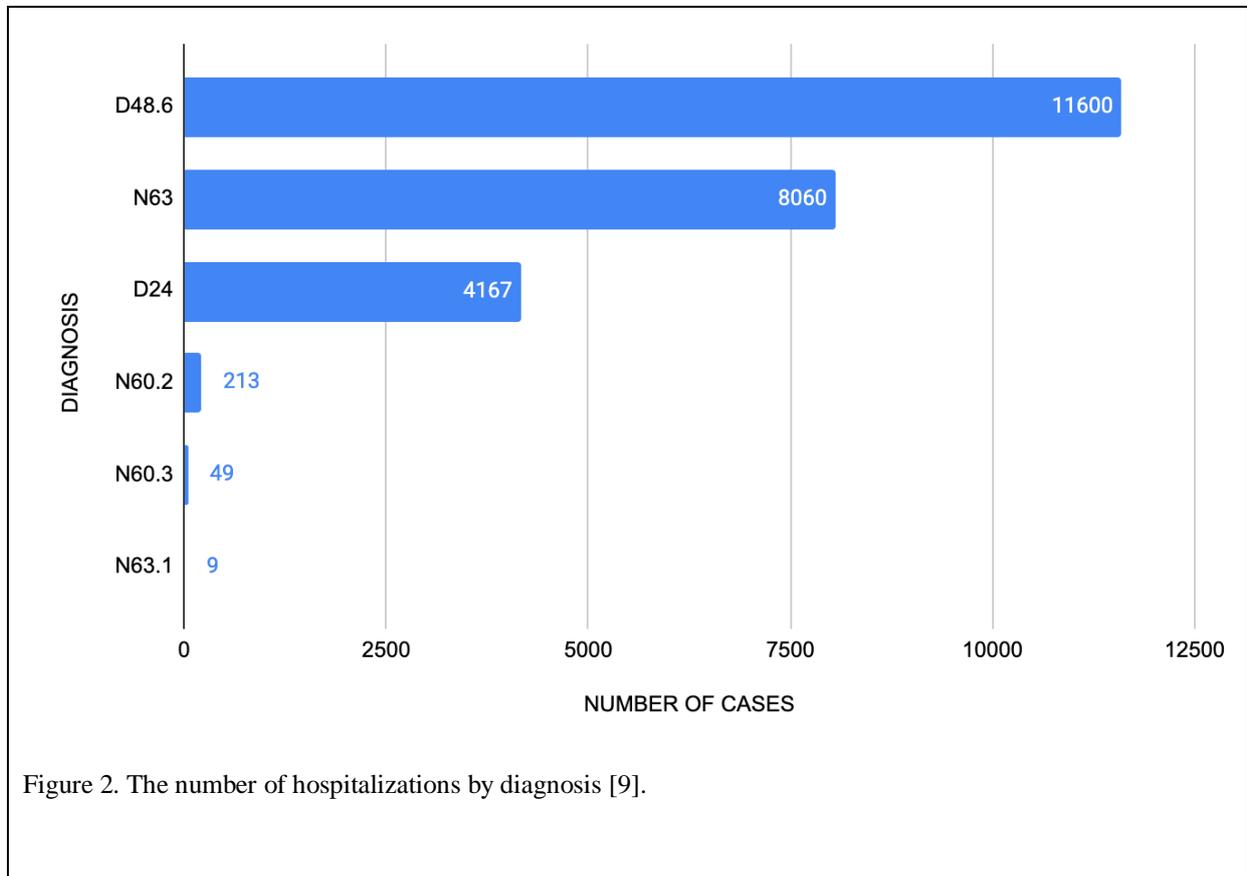
Next, we examined whether patients from the above group were hospitalized due to malignant changes (based on C50 ICD-10) from 2014 to June 2015. We adopted a 6-month period of the change in the diagnosis, which was associated with different times of microscopic diagnosis, dates of admission to the department, or access to oncology centers, depending on the Polish province. The analysis covered patients diagnosed with a benign lesion for the first time in 2014. The exclusion criteria were as follows: a history of BC (C50) and benign or unspecified changes in the breast. The analysis of these hospitalizations allowed for the identification of patients who had their diagnosis changed from a benign to a malignant tumor after open surgical biopsy due to benign breast lesions in 2014. Patients diagnosed with ductal carcinoma in situ (D05; ICD-10) were also excluded from the analysis. The results were compared with all new cases of BC in Poland with the division into provinces, according to data from the PNCR [9]. In

this analysis, we compared the 5-year survival rates of patients diagnosed with BC in 2014 in individual provinces according to the data from the PNCR with the findings from our previous paper [4,9].

Results

The previous analysis showed that the number of hospitalizations due to benign breast lesions was

24,098 in 2014. Patients were mostly hospitalized in the Departments of Surgical Oncology and General Surgery, which accounted in total for 82.08% [9]. The most common diagnoses were: D48.6, N64 and D24 (ICD-10) (Figure 2).



There were 13,718 hospitalizations during which open breast biopsies were performed. After analyzing readmissions in patients with a changed diagnosis of BC, 1,505 such cases were reported (11%). The group of patients with a changed diagnosis due to open biopsy was compared with the number of new BC diagnoses in 2014 in all provinces of Poland. The results indicated that the

group of 1,505 patients accounted for 8.60% of new BC cases out of the total number of new diagnoses in 2014 (17,506 cases) [9]. The study showed the total number and percentage of diagnoses changed from benign to malignant lesions in individual provinces of Poland in the group of patients hospitalized due to benign lesions (Table 1).

Table 1: The number and percentage of patients whose diagnoses were changed from benign to malignant tumors after removal of the lesion by an open surgical biopsy, according to the province [9].

Province	Number of patients with a changed diagnosis	Percentage of patients with a changed diagnosis	Number of patients with an unchanged diagnosis	Percentage of patients with an unchanged diagnosis
Podlaskie Province	85	23.40%	279	76.60%
Subcarpathian Province	95	15.70%	509	84.30%
Łódź Province	179	14.60%	1048	85.40%
Opole Province	20	14.50%	118	85.50%
Lower Silesian Province	128	14.20%	776	85.80%
Lubusz Province	45	13.60%	286	86.40%
Lublin Province	152	13.10%	1004	86.90%
Pomeranian Province	79	11.50%	610	88.50%
Kuyavian-Pomeranian Province	62	11.40%	483	88.60%
Warmian-Masurian Province	80	10.70%	671	89.30%
Silesian Province	217	9.80%	2001	90.20%
Masovian Province	165	9.30%	1604	90.70%
Greater Poland Province	118	7.40%	1474	92.60%
West Pomeranian Province	35	6.50%	507	93.50%
Świętokrzyskie Province	7	5.30%	125	94.70%
Lesser Poland Province	38	5.00%	718	95.00%
Poland	1505	11.00%	12213	89.00%

The number of open surgical breast biopsies during which cancer was diagnosed exceeded the recommended level of 10% in as many as 10 provinces. The lowest percentage of open breast biopsies was found in the following provinces:

Lesser Poland (5%), Świętokrzyskie (5.3%), and West Pomeranian Province (7.4%). **Figure 3** shows the comparison of the results of the number of open biopsies in individual provinces with the 5-year survival rates according to the data from PNCR.

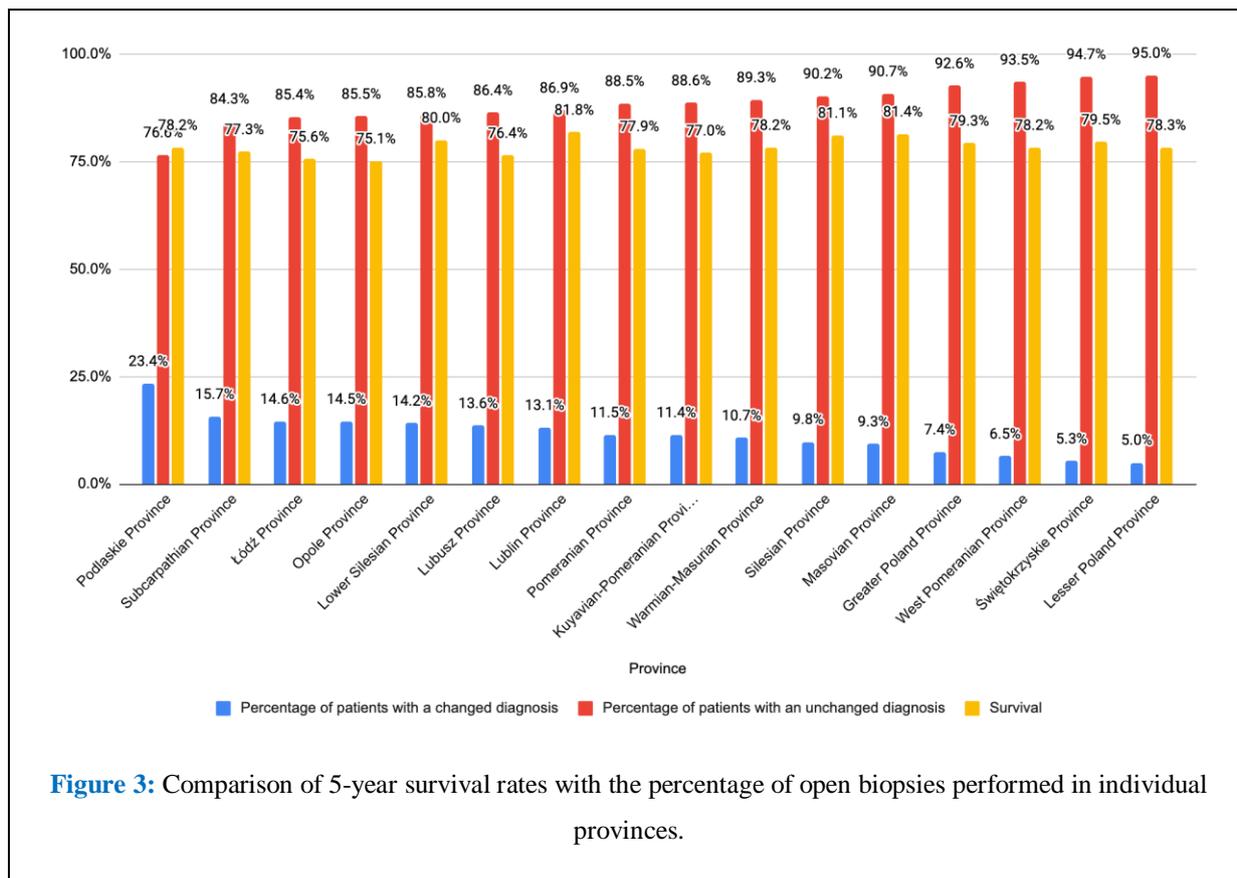


Figure 3: Comparison of 5-year survival rates with the percentage of open biopsies performed in individual provinces.

According to the data from the PNCR, the standardized mean 5-year survival rate for BC diagnosed in Poland between 2014 and 2015 was 78.8% [4]. However, the rates were below the national mean in Podlaskie, Subcarpathian, Łódź, Opole, Lubusz, Pomeranian, and Kuyavian-Pomeranian Provinces. The comparison of the data with the results of the previous analysis showed that in 7 out of 9 provinces where the rates of open biopsies confirming BC were higher than 10%, the survival rate was lower than the national mean.

Discussion

The results of the analysis indicate significant differences in the use of open breast biopsies as a diagnostic method and also differences in the 5-year survival rates of patients with BC in individual provinces of Poland. The analysis showed that the number of open surgical breast biopsies during which cancer diagnosis was confirmed exceeded

the recommended level of 10% in 10 provinces. This is clearly inconsistent with international guidelines, which recommend limiting open biopsies to exceptional diagnostic cases. This indicates an excessive use of surgical procedures in the diagnosis of BC [16,28]. Current guidelines recommend CNB as the first-line diagnostic procedure in cases of suspected malignancy based on imaging findings [8,9,17, 29,30]. Surgical biopsy should only be performed when CNB has not yielded clear results or is technically unfeasible (e.g., due to the location of a lesion, absence of a lesion in imaging studies, active anticoagulant therapy, or small breast size). In such cases, surgical removal of the tumor with intraoperative or postoperative histological analysis is possible [9,18-20]. There may be several reasons for the increased percentage of open biopsies, one of them being the lack of appropriate equipment or qualified medical staff to perform CNB, which may

affect treatment outcomes [21,22,29]. It can also be explained by a lack of knowledge about diagnostic methods, a failure to follow guidelines by referring physicians, and organizational differences in the healthcare system between various provinces. The equipment available at oncology centers is also a crucial factor.

In provinces with well-developed oncology centers that follow diagnostic standards, a low percentage of open surgical biopsies is observed, which is in line with the opinions of other experts [23,24]. In addition, diagnosis based on CNB allows for better treatment planning and reduces the incidence of local or regional recurrence. Studies showed that patients whose diagnosis was based on CNB required less extensive surgery than those diagnosed by surgical methods [25]. In terms of analyzing open biopsies in BC diagnosis, it is essential to consider the impact of these procedures on patients' quality of life. According to the study findings published in a paper comparing the impact of CNB and open biopsy on patients' quality of life, CNB was more accepted by patients because it had less impact on their quality of life. The study showed that patients who underwent open biopsy experienced greater physical discomfort and pain than those who underwent CNB [31]. These observations confirm that the excessive use of open biopsies, as indicated in our analysis, can lead to a decrease in patients' quality of life, which is particularly disturbing in the context of health outcomes. Understanding the impact of different diagnostic methods on patients' quality of life is crucial for treatment decisions. A high quality of life is not only important from patients' perspective. It also affects therapeutic outcomes [31].

In their study, Jiang et al. compared minimal access breast surgery with conventional open breast surgery. Their results indicated that patients who

underwent less invasive procedures experienced reduced postoperative immune suppression and faster recovery of preoperative immune function compared to those who underwent conventional open breast surgery. This suggests that reducing the number of open breast biopsies may lead to better clinical outcomes and higher quality of care for patients with BC [26]. Importantly, in 7 out of 9 provinces where the percentage of open breast biopsies exceeded the recommended level of 10%, the 5-year survival rates of patients with BC were lower than the national mean (78.8%). This correlation may indicate systemic problems in the diagnosis and treatment of BC, which negatively affected treatment outcomes in these regions. The reasons for these outcomes may correlate with diagnostic delays resulting from the need for more invasive procedures, which may have resulted in a delayed diagnosis and treatment initiation and may have translated into poorer treatment outcomes. A limitation of our analysis is that the retrospective nature of the study is based on administrative data, which may not reflect the complete clinical picture. In addition, the lack of detailed data on the time from diagnosis to treatment, or the type of treatment may have affected the complete interpretation of the findings. Only patients covered by the NHF were included in the analysis, which may have excluded patients from facilities not financed by the NHF. Therefore, the data may be underestimated. This is consistent with the report from the PNCR that indicates that the mean underestimation rate in BC is 14% annually [27]. Another limitation was the impossibility of assessing which center (and in which province) a patient was treated. Individuals may have been diagnosed in a center in a different province than where they received further treatment, which may have affected our findings.

The study used a multivariate analysis based on maps of health needs, which showed a large number of open breast biopsies for the diagnosis of BC. In some provinces, the results exceed the recommended level of 10% of open surgical biopsies. In 7 out of 9 provinces where the percentage of open biopsies exceeded the recommended level of 10%, the 5-year survival rate of patients with BC was lower than the national mean (78.8%). These results highlight the need for further standardization of BC-related diagnostic procedures in Poland based on international guidelines. Implementing and monitoring diagnostic practices such as CNB may improve the quality of diagnosis and contribute to improved treatment outcomes and patient survival. Measures should include training medical staff in less invasive diagnostic methods, providing medical facilities with adequate diagnostic equipment, and introducing control mechanisms and audits to monitor compliance with guidelines. Differences in survival rates between provinces also indicate

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potential problems with equal access to high-quality oncological care in Poland. Provinces with a high percentage of open biopsies may require additional support to improve BC diagnosis and treatment.

Conclusions

The findings of this study highlight the need to reduce the use of open breast biopsies and further optimize BC diagnosis in Poland. There is a need to implement systemic measures to reduce regional inequalities in access to diagnosis and treatment. These measures may improve BC treatment outcomes and reduce BC mortality rates in Poland.

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