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Analysis of Diagnostic Methods for Focal Lesions in Breast Glands with Use of Open Surgical Biopsies and Core-Needle Biopsies in Poland

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Background:

Numerous studies confirm the benefits of using core-needle biopsy (CNB) for diagnosing patients with suspected breast cancer, thus reducing the costs and the stress, and allowing optimum treatment planning. The present study examined the number of patients in Poland who had been diagnosed with breast cancer through inpatient open surgical biopsy (OSB) and CNB by province.

Material/Methods:

This retrospective study used a health needs map to identify patients in 2014 and partially in 2015 who had had OSB or CNB of the breast performed on an inpatient basis due to benign breast lesions and whose diagnosis had been changed from benign to malignant.

Results:

Among the total number of hospitalizations (13 718 cases with OSB) due to benign lesions of the breast, 1506 patients had their diagnosis changed to malignant, constituting 8.59% of new breast cancer diagnoses across the country. The resulting diagnosis change from benign to malignant varied significantly across provinces, from 5.3% to 23.4%. Among the total of 7205 hospitalizations in 2014 with CNB performed using different methods, there were 1574 malignancies, amounting to 8.9% of new diagnoses in Poland. The use of inpatient CNB to diagnose breast cancer differed significantly across provinces, from 0.6% to 34.4%.

Conclusions:

OSBs are too often used to diagnose focal lesions in breast glands in Poland. In some regions, CNBs are too frequently performed on an inpatient rather than outpatient basis, thereby requiring an analysis of the quality of and access to modern diagnostic methods.

MeSH Keywords:

Biopsy • Biopsy, Large-Core Needle • Neoplasms

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Background

Breast cancer is the most common malignant tumor in women. Approximately 1.33 million women in the world live with a breast cancer diagnosis made within the past 5 years. In Poland, it is the second most common cause of death amongst women under 65 years of age due to malignancies. According to the Polish National Cancer Registry (KRN) of 2014, there were 17 506 new cases of breast cancer recorded in Poland [1].

In the diagnostic methods for detecting focal lesions in breast glands, the basis for diagnosis, besides physical and clinical examinations, are imaging tests such as ultrasonography (US), mammography, spectral mammography, and, in selected cases, magnetic resonance imaging (MRI). All imaging tests of breast glands are subject to descriptive standardization according to Breast ImagingReporting and Data System (BI-RADS) categorization. The following BI-RADS categories of imaging results – 4 (malignancy risk from 2% to 95%, a given lesion needs verification) and 5 (malignancy risk >95%, a given lesion needs verification and further treatment) – are subject to verification through invasive procedures, because the absolute condition for starting breast cancer treatment is the microscopic diagnosis [2].

In these cases, for many years, the approach to confirming or excluding the presence of malignancy has been the fine-needle aspiration biopsy (FNAB) procedure. It is an easy-to-perform cytological examination which requires no complicated set of instruments and makes it possible to obtain diagnosis in a very short time. As a consequence of the progress in understanding the biology of breast cancer and in the development of modern treatment methods, it was necessary to redefine the approach to obtaining the diagnostic material. Currently, the standard method for verifying lesions described as BIRADS 4 or 5 is core-needle biopsy. This procedure allows for collecting cancerous tissue samples for histopathological examination and establishing the basic essential information, such as the histopathological type of cancer, its histological grading, and the distinction between preinvasive (in-situ) and invasive carcinoma. The procedure is performed under the guidance of ultrasound or mammographic stereotaxy to assess calcifications and lesions invisible on ultrasonography. In clinically palpable tumors, it can be performed free-hand.

Unlike FNAB, core-needle biopsy makes it possible to assess the predictive factors that are extremely important for treatment planning (e.g., steroid receptors, HER-2, and Ki-67 receptors). When performed on an outpatient basis, it limits the cost, reduces the psychological trauma and pain, and ensures quicker recovery of the patients, both physically and socially. The core-needle biopsy procedure is the diagnostic method of choice in making decisions about breast cancer treatment [3–6].

The procedure is characterized by high diagnostic adequacy (sensitivity of 94–100%) [7–11]. Fine-needle aspiration biopsy (FNAB) is currently reserved only for assessing the presence of cancer cells in the lymph nodes of the regional lymphatic basin and for assessing local recurrence. It is also used for verifying non-cancerous lesions rated as BIRADS 3 in imaging tests. The only exception in Poland regarding the application of FNAB in the diagnosis of invasive lesions is the assessment (according to the recommendations by the National Consultant for Oncological Surgery) of very suspicious, clinically palpable lesions where no inductive treatment is planned, and with consistent clinical, mammography, and ultrasonography images (BI-RADS 5) [12].

The analysis of CNB and OSB application for assessing focal lesions in breasts allows for evaluating the diagnostic quality in a given country and region.

Material and Methods

The present study was retrospective in nature, on the basis of the health needs map for benign tumors published in December 2016. Health needs maps have been prepared separately for each province and cover all of 2014. As set out in the regulation by the Minister of Health, the maps consist of 3 parts: demographic and epidemiological aspects, analysis of resources status and use, and prognoses. All the works to date concerning health needs maps are available at the following website: http://www.mapypotrzebzdrowotnych.mz.gov.pl/.

Health needs maps served as a basis for preparing this paper, which elaborates on the maps in selected aspects. The analysis used individual data on the services demonstrated by health-care providers to the National Health Fund (NFZ). We present information about hospitalizations, using products from the 1a and 1b catalogue. The data cover hospitalizations which were completed in 2014 for patients whose main reason for hospitalization included the following diagnoses, according to ICD-10:

- D24 (with subcodes) Benign neoplasm of breast
- D48.6 Neoplasm of uncertain behavior of other and unspecified sites: 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

Further analysis encompassed those patients who had been hospitalized due to benign or unspecific focal lesions in breast glands and subsequently, in a defined period of time, admitted to hospital and discharged with a breast cancer diagnosis (C-50). Taking into account the variable waiting time for histopathological results, the variable time of additional examinations required

for treatment initiation, the variable waiting time for hospital admission as well as the differences in access to oncological centers across the provinces of Poland, a 6-month interval of lesion observation in the diagnosis was used for the study. In order to select the right group of patients for the analysis of a diagnosis change from benign to malignant, a survey was done on the histories of patients who had been hospitalized in 2014 (from January to December) due to benign lesions. In the first step, the patients were verified in terms of any previous diagnoses which would exclude them from the analysis. The exclusion criteria encompassed the following diagnoses:

- Breast cancer (C50), is a given patient had appeared with this diagnosis before (patients' histories were verified back to the year 2011); in these patients, it is not possible to determine whether the hospitalization with the C50 diagnosis was a continued treatment of a previously diagnosed disease or the search for "a change of diagnosis".
- Benign or unspecified lesions in breasts; if a given patient appeared with this diagnosis in 2013, the analysis concerns patients who appeared with the given lesion in 2014 for the first time, and, in the above-mentioned case, the hospitalizations in 2014 were probably a continuation of a diagnostic and therapeutic process commenced in 2013.

It was subsequently examined whether, in the years 2014–2015 (until June), the patients from the above-mentioned group (from the list of 2014, with account being taken of the exclusions based on their history) had been hospitalized due to malignant lesions.

A significant indication regarding this analysis was also the removal of a benign lesion during the first hospitalization. As a result, the qualification for further analysis was given only to those cases where at least 1 of the following procedures had been performed:

- 85.12 Open biopsy of breast
- 85.21 Local excision of lesion of breast
- 85.22 Resection of quadrant of breast
- 85.24 Excision of ectopic breast tissue
- 85.25 Excision of nipple
- 85.26 Excision of breast tumor BCT
- 85.29 Other excision or destruction of breast nipple tissue(s)
- 85.9 Other operations on the breast
- 85.99 Other breast operations

The above measures made it possible to establish a group of patients hospitalized in 2014 (from January to December) for benign lesions, who subsequently had their diagnosis changed to malignant upon surgical removal of the lesion. The analysis excluded patients diagnosed with preinvasive cancer (D-05). The system included no data to classify focal lesions in breasts according to BI-RADS; therefore, only the ICD-10 classification was taken into account.

A comparative analysis was also carried out, verifying the cases of patients who had core-needle biopsy performed as one of the inpatient procedures, and this group was excluded from the comparative analysis and included into a separate analysis:

- 85.113 Transdermal core-needle biopsy of the breast
- 85.114 Transdermal targeted core-needle biopsy of the breast
- 85.13 Vacuum-assisted core-needle biopsy of the breast
- 85.131 Ultrasound-guided vacuum-assisted core-needle biopsy of the breast
- 85.132 Stereotactic vacuum-assisted core-needle biopsy of the breast

In the material under analysis, there were 32 hospitalizations where both core-needle biopsy and open surgical biopsy were performed. Since the size of this group was too small, it was not covered by a separate study. A separate analysis was also conducted for hospitalizations with core-needle biopsy which resulted in a change of diagnosis from benign to malignant, comparing them with all new cases of breast cancer in the particular provinces, according to the Polish National Cancer Registry (KRN). In this case, account was taken only of those patients who had had their diagnosis changed in 2014 (from January to December).

Results

In total, 24 000 hospitalizations were recorded in the period from January 1 to December 31, 2014 in Poland due to benign lesions in the breast gland. The highest number of hospitalizations in the period under analysis was demonstrated in oncological surgery wards (11 700) and general surgery wards (8000), (total 82.08%).

The diagnoses analyzed were most commonly reported according to ICD-10:

- D48.6–11600, next; N63–8060, D24–4167,
- N60.2-213, N60.3-49,
- N63.1-9 hospitalizations (Figure 1)

There were 13 718 hospitalizations with breast lesions surgically removed (through the so-called open surgical biopsy) due to benign or suspicious focal lesions in the breast gland. The analysis of these cases in terms of a diagnosis change from benign to malignant by the end of 2014 and partially in 2015 indicated that 1505 patients (11%) had had their diagnosis changed from benign to malignant. The study showed a the total number and percentage of diagnoses changed to malignant in the particular provinces of Poland in the group of patients hospitalized due to benign lesions (Table 1).

It was concluded that in Lublin Province, Lubuskie Province, Podlasie Province, Lower Silesia Province, Łódź Province, Opole

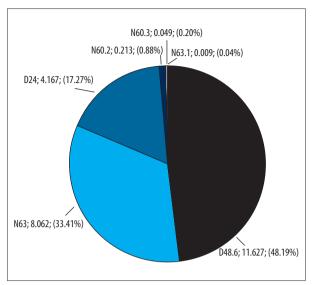


Figure 1. Hospitalizations by ICD-10 diagnosis (number of hospitalizations in thousands).

Province, and Podkarpacie Province, the number of open surgical biopsies which yielded breast cancer diagnoses was considerably higher than 10%. Borderline results were obtained in Warmia-Masuria Province (10.7%), Kujawy-Pomerania Province (11.4%), and Pomerania Province (11.5%). The study also encompassed this group in the context of all new breast cancer diagnoses in 2014 in all the provinces in Poland. The results indicate that, within the total number of new diagnoses in 2014, amounting to 17 506 cases, the group of 1505 patients under analysis represented 8.59% of the newly-diagnosed breast cancer cases.

Further analysis showed that the number of patients who had appeared in the system with a changed diagnosis from benign to malignant decreased proportionally with the passage of time from the procedure, reaching the highest level in the first 2 months (Figure 2).

A separate comparative analysis encompassed a group of patients who, during their hospitalization with a diagnosis of

Table 1. Numbers and percentages of patients who had their diagnosis changed from benign to malignant after lesion removal upon open surgical biopsy, by province.

Polish province (Voivodeship)	Number of patients with altered diagnosis	Percentage of patients with altered diagnosis	Number of patients with unchanged diagnosis	Percentage of patients with unchanged diagnosis
Podlasie Province	85	23.4%	279	76.6%
Podkarpacie Province	95	15.7%	509	84.3%
Łódź Province	179	14.6%	1048	85.4%
Opole Province	20	14.5%	118	85.5%
Lower Silesia Province	128	14.2%	776	85.8%
Lubuskie Province	45	13.6%	286	86.4%
Lublin Province	152	13.1%	1004	86.9%
Pomerania Province	79	11.5%	610	88.5%
Kujawy-Pomerania Province	62	11.4%	483	88.6%
Warmia-Masuria Province	80	10.7%	671	89.3%
Silesia Province	217	9.8%	2001	90.2%
Mazovia Province	165	9.3%	1604	90.7%
Wielkopolska Province	118	7.4%	1474	92.6%
West Pomerania Province	35	6.5%	507	93.5%
Świętokrzyskie Province	7	5.3%	125	94.7%
Małopolska Province	38	5.0%	718	95.0%
Poland	1505	11.0%	12 213	89.0%

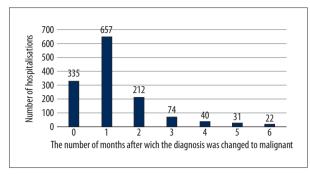


Figure 2. A change of diagnosis from benign to malignant at monthly intervals for patients who had their lesions surgically removed.

benign lesions, had core-needle biopsy performed as one of the procedures and whose diagnosis had been changed from benign to malignant following the core-needle biopsy procedure.

The total number of hospitalizations reported in 2014 amounted to 7205, with coreneedle biopsy performed using different methods and yielding 1574 malignant and 5631 benign

diagnoses. In the total number of diagnostic procedures for focal lesions in breast glands through core-needle biopsy (during hospitalization), the breast cancer diagnosis amounted to 21.8% (Table 2). The analysis of hospitalizations with core-needle biopsy resulting in a change of diagnosis from benign to malignant was compared with all new cases of breast cancer in the particular provinces, according to the Polish National Cancer Registry (KRN) (Table 3). Account was taken only of those patients who had had their diagnosis changed within the whole year of 2014. Comparing this result against all new cases of breast cancer diagnosed in Poland, it constituted 8.99% of new diagnoses for the whole country. Here again. the number of patients who had appeared in the system with a changed diagnosis from benign to malignant following coreneedle biopsy decreased proportionally with the passage of time from the procedure, reaching the highest level in the first 2 months (Figure 3).

We found that in the provinces of Lower Silesia, Warmia-Masuri, and Pomerania, the numbers of core-needle biopsy procedures during hospitalization resulting in breast cancer

Table 2. Numbers and percentages of patients who had their diagnosis changed from benign to malignant after core-needle biopsy, by province.

Polish province (Voivodeship)	Number of patients with altered diagnosis	Percentage of patients with altered diagnosis	Number of patients with unchanged diagnosis	Percentage of patients with unchanged diagnosis
Lublin Province	28	44.4%	35	55.6%
Silesia Province	137	35.2%	252	64.8%
Lower Silesia Province	604	33.6%	1193	66.4%
Podlasie Province	5	31.3%	11	68.8%
Warmia-Masuria Province	140	27.2%	375	72.8%
Mazovia Province	72	25.4%	211	74.6%
Kujawy-Pomerania Province	36	23.7%	116	76.3%
Pomerania Province	193	21.9%	690	78.1%
Łódź Province	34	20.4%	133	79.6%
Wielkopolska Province	181	17.6%	850	82.4%
Świętokrzyskie Province	66	8.8%	683	91.2%
Małopolska Province	44	7.4%	549	92.6%
West Pomerania Province	10	7.4%	125	92.6%
Podkarpacie Province	16	6.0%	249	94.0%
Lubuskie Province	8	4.8%	157	95.2%
Opole Province	0	0.0%	2	100.0%
Total for Poland	1574	21.8%	5631	78.2%

Table 3. Numbers and percentages of patients with a benign lesion, whose diagnosis was changed upon core-needle biopsy on an inpatient basis compared with the total quantity of new breast cancer cases according to the Polish National Cancer Registry (KRN) in 2014 in the particular provinces.

Polish Province (Voivodeship)	The incidence of breast cancer in 2014 according to the date from the Polish National Cancer Registry (KRN)	The number of patients with a benign lesion, whose diagnosis was changed upon core-needle biopsy on an inpatient basis in 2014	Percentage of patients, whose diagnosis was changed upon core-needle biopsy on an inpatient basis in 2014 in the context of new cancer diagnoses in this province
Lower Silesia Province	1426	490	34.4%
Warmia-Masuria Province	576	114	19.8%
Pomerania Province	1085	160	14.7%
Świętokrzyskie Province	513	46	9.0%
Wielkopolska Province	1795	141	7.9%
Silesia Province	2051	110	5.4%
Kujawy-Pomerania Province	984	32	3.3%
Lublin Province	849	24	2.8%
Małopolska Province	1389	35	2.5%
Mazovia Province	2370	57	2.4%
Łódź Province	1394	27	1.9%
Lubuskie Province	449	7	1.6%
Podkarpacie Province	870	11	1.3%
West Pomerania Province	854	8	0.9%
Podlasie Province	475	3	0.6%
Opole Province	426	0	0.0%
Poland	17506	1265	7.2%

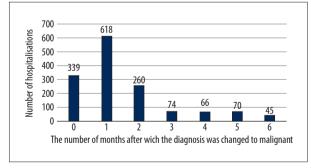


Figure 3. A change of diagnosis from benign to malignant at monthly intervals for patients who had core-needle biopsy performed on an inpatient basis.

diagnosis, compared to all new diagnoses in 2014 reported in those provinces according to the Polish National Cancer Registry, were significantly higher than in other provinces, amounting to 34.4%, 19.8%, and 14.7%, respectively.

Discussion

In many provinces of Poland, the number of open surgical biopsies yielding breast cancer diagnoses exceeds the recommendations from consensus conferences and national guidelines (below 10%), showing that surgical procedures are overused in the diagnosis of breast cancer. Current guidelines recommend core-needle biopsy as the first diagnostic procedure where malignancy is suspected on the basis of imaging tests [5,6]. It is currently believed that surgical biopsies (tumor excision) should be performed only in cases of the socalled "non-diagnostic" biopsy result, in which there is no correlation among the clinical and imaging tests and the biopsy/biopsies performed; lack of material in the core-needle biopsy or unsuitability of the material for assessment is an indication for another procedure. Without prior microscopic diagnosis, a tumor may only be removed when it is not possible to carry out coreneedle biopsy. This happens when a given lesion is located in

a site where a biopsy procedure is technically difficult to perform, has not been shown on ultrasonography or mammography, or when the patient is on active anticoagulation therapy or the breast size is too small. In such cases, it is recommended that the tumor be removed and intraoperative histopathological examination performed [13–15].

The number of diagnostic interventions involving surgical removal of a breast tumor for microscopic verification of malignancy-suspicious lesions in the currently applicable diagnostic procedure, compliant with European and international guidelines, should not exceed 10%. A higher number of diagnoses made by means of this method may indicate inadequate access to modern diagnostic tools or insufficient quality of diagnostic tests in the preoperative diagnosis of breast cancer, which may directly translate into treatment results [16–18].

The high indicators of these interventions in some of the regions may potentially be explained by the low level of knowledge about modern diagnostic options based on image – guided core-needle biopsy (e.g., ultrasonography, mammography or MRI), the inadequate knowledge about the benefits of such an approach, and the financial factors in the decision – making process. The large number of surgical biopsies may also be associated with the provinces which have an insufficient number of oncological centers with modern diagnostic tools or where such centers are difficult to access [16,19].

It can be observed that the low rate of open surgical biopsies in the context of breast cancer diagnosis correlates with the provinces with dynamic oncological centers using diagnostic methods based on state-of-the-art standards. These observations are consistent with the opinions of other authors analyzing this topic [20,21].

Interesting data are provided by the observational results of those hospitalizations, the reason of which was the core-needle biopsy of focal lesions in the breast gland. The correlation of the share of core-needle biopsies during hospitalization resulting in breast cancer diagnoses compared to all the new cases in certain provinces indicates that it seems reasonable to ask why in these regions so many procedures were performed on an inpatient rather than an outpatient basis.

The inpatient CNB procedure, besides resulting in measurable savings from the payer's point of view, provides clear benefits for patients, with less psychological trauma, less pain, quicker recovery of social and physical fitness, shorter convalescence time, and the possibility of quick diagnosis. Apart from the beneficial short-term effects with regard to the quality of life after core-needle biopsy on an outpatient basis, the preoperative outpatient diagnostics based on core-needle biopsy help to plan the optimum treatment method and do not affect

such results as the incidence of local or regional recurrence. According to the data based on the results of numerous analyses, patients with preoperative diagnostics involving core-needle biopsy have a smaller scope of surgeries than patients diagnosed using a surgical procedure [14,23,24].

We found no differences in this study between the group with surgical biopsy and the group with core-needle biopsy during the procedure in which cancer was diagnosed up until the patient's appearance for treatment. In both groups, the vast majority of patients appeared in the system within the first 2 months.

A separate analysis is intended to encompass those patients in the context of treatment in the particular provinces, which will help to reveal the areas where the accessibility and quality must be improved in both the diagnostic and the treatment process.

This study has several limitations. The group at hand included patients who were the beneficiaries of the payer (NFZ) in Poland, and it was impossible to present results from other centers without NFZ contracts due to the absence of reporting requirements. A comparison was made between the percentage share of a diagnosis change from benign to malignant and the entire number of new breast cancer cases diagnosed in 2014, among which there could have been cases diagnosed through open surgical biopsy and core-needle biopsy in centers without NFZ contracts, and subsequently revealed in statistics as malignant lesions in patients who continued their breast cancer treatment based on the NFZ services. Therefore, the number of open surgical biopsies and core-needle biopsies with breast cancer diagnosis may be underestimated. This is consistent with the data of the Polish National Cancer Registry (KRN), where the underestimation average for breast malignancy diagnosis is 14% a year [24].

In summary, the present study used a multifactorial method of analysis based on health needs maps in order to demonstrate the high number of surgical procedures (open biopsies) and core-needle biopsies of focal breast lesions performed on an inpatient basis to establish a diagnosis in breast diseases in 2014. The results for several provinces exceed the recommended level of 10% of open surgical biopsies. There were many hospitalizations based on the core-needle biopsy procedure. The results of the present study may be useful in achieving rates of core-needle biopsy use on an outpatient basis close to 90% and in reducing the open surgical biopsy procedures to the recommended 10% in the case of focal lesions in breasts with suspected malignancy in Poland. It seems necessary to carry out continuous training for physicians dealing with these issues in order to make them aware of the benefits of using image-guided core-needle biopsy in the diagnostic process.

Conclusions

- Open surgical biopsies are still too often used to diagnose focal lesions in breast glands in some regions of Poland.
- The core-needle biopsy procedure is too frequently performed on an inpatient rather than outpatient basis.

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