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Evaluation of sensitivity and specificity of tests for breast cancer

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Abstract. Breast cancer (BC) is one of the most common malignant neoplasms in women worldwide and a leading cause of cancer-related mortality. Early diagnosis remains a pressing issue, as treatment effectiveness and survival prognosis directly depend on the stage at which the tumor is detected. The aim of this study was to evaluate the diagnostic accuracy of laboratory and instrumental methods used to detect breast cancer and to determine their optimal combination to improve diagnostic efficiency . The study included data from 150 women undergoing examination for suspected breast cancer. A comparative analysis of the sensitivity and specificity of mammography, ultrasound, magnetic resonance imaging (MRI), and the serological markers CA 15-3 and CEA was conducted. Morphological confirmation of the diagnosis (biopsy) was taken as the "gold standard."
The results showed that MRI achieved the highest sensitivity (95%), while mammography and ultrasound remained the mainstays of primary screening (86% and 80%, respectively). The combined use of instrumental methods and laboratory markers achieved a sensitivity of 97% and a specificity of 92%, significantly increasing diagnostic accuracy . Thus , the study confirms that the integration of various diagnostic approaches ensures maximum reliability in the early detection of breast cancer and can serve as the basis for optimizing screening algorithms and clinical diagnostics.
Keywords:

Introduction . Cancer dairy glands (breast cancer) remains one from most serious medical And social problems modern Healthcare . This disease is the most common malignant tumor in women and a leading cause of death worldwide. According to the World Health Organization (WHO), more than 2.3 million new cases of breast cancer are diagnosed worldwide each year, and approximately 700,000 women die from its complications. In recent years, there has been a trend toward an increase in the incidence of the disease not only in industrialized countries but also in developing regions, due to lifestyle changes, environmental factors, an aging population, and improved diagnostic methods that allow for early detection of the disease.[2]

Early diagnosis of breast cancer is crucial, as the effectiveness of treatment and survival prognosis directly depend on the stage at which the disease is detected.[4] When a tumor is detected at stage I, the five-year survival rate exceeds 90%, while at later stages, this figure drops to 20–30%. Therefore, a priority in modern oncology is the improvement of diagnostic methods with high sensitivity and specificity, ensuring the accuracy and reliability of the results.

The concepts of sensitivity and specificity are central to assessing the effectiveness of any diagnostic test. Sensitivity characterizes the ability of a method to accurately detect the presence of a disease in a patient, that is, the proportion of true positive results among all patients with the pathology. Specificity reflects the ability of a test to correctly determine the absence of a disease in healthy individuals, that is, the proportion of true negative results. The higher both indicators, the more reliable the test and the lower the likelihood of false positive or false negative results [5]. In oncology, where the cost of diagnostic error is extremely high, choosing the optimal test method based on its sensitivity and specificity is crucial. Diagnostic errors lead not only to delayed treatment but also to severe psychological consequences for patients and unnecessary economic costs for the healthcare system.

Modern breast cancer diagnostics is a complex process that includes clinical examination, instrumental methods (mammography, ultrasound, magnetic resonance imaging), morphological verification (biopsy), and the determination of tumor markers in the blood. Each of these methods has its own advantages and limitations, and their diagnostic accuracy can vary depending on age, breast tissue density, genetic factors, and disease stage . Mammography remains the "gold standard" of screening, especially in women over 40. It can detect microcalcifications and structural changes long before the onset of clinical

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symptoms.[8] However, its sensitivity decreases in dense glandular tissue, which is typical in younger patients. In these cases, it is advisable to use ultrasound diagnostics (US), which is more informative in assessing soft tissues and cystic formations . Magnetic resonance imaging (MRI) has the highest sensitivity among non-invasive imaging methods, reaching 95–98%, but it has a number of limitations - high cost, the need for contrast, and the possibility of obtaining false-positive results, which reduces its specificity.

Biochemical (serological) methods also play an important role in diagnosis, in particular the determination of the concentration of tumor markers such as CA 15-3, CEA (carcinoembryonic antigen), HER2/ neu , and BRCA1/2. Increased levels of these indicators may indicate the presence of a tumor, but they are not strictly specific for breast cancer. Their sensitivity in the early stages of the disease is low, so tumor markers are considered additional tools for assessing disease dynamics, the effectiveness of therapy, and the early detection of relapses[9].

In the last decade, particular attention has been paid to combined approaches, in which instrumental methods are complemented by laboratory tests and clinical data. This integrative approach improves overall diagnostic accuracy, reduces the risk of diagnostic errors, and facilitates individualized treatment strategies. According to several studies, the combined use of MRI and the CA 15-3 marker can achieve a sensitivity of up to 97% with a specificity of approximately 90% [4,10].

The problem of choosing the most informative and cost-effective diagnostic methods remains a pressing issue in modern oncology. Given limited healthcare resources, it is especially important to determine which test combinations offer the best sensitivity-specificity-cost ratio. This determines not only the quality of diagnostics but also the effectiveness of the entire screening program covering large populations.

Furthermore, standardization of methods and interpretation of results is essential . Different laboratories and medical institutions may use different test systems, equipment, and cutoff values, which impacts data comparability. Therefore, the sensitivity and specificity of assays should be assessed within the framework of uniform clinical protocols, ensuring the objectivity and reproducibility of results[3].

From a practical standpoint, knowing the sensitivity and specificity of a particular method allows a physician to choose the most appropriate diagnostic approach for each patient. For example, if mammography results are questionable, it is advisable to order an MRI, which has a higher sensitivity, while if benign lesions need to be ruled out, an ultrasound or cytology examination is preferred.

The scientific relevance of this topic stems from the need to improve the effectiveness of early breast cancer diagnosis, reduce misdiagnosis, and optimize the diagnostic workflow. Given the rising incidence and significant economic burden associated with cancer treatment, early detection and accurate differential diagnosis are key tools in the fight against the disease.

Thus, assessing the sensitivity and specificity of breast cancer tests has not only scientific but also practical significance. It allows for objective comparison of diagnostic methods, determining their effectiveness in various clinical situations, and developing testing algorithms aimed at improving the accuracy and timeliness of diagnosis. The outcome of such research should be the creation of an optimal diagnostic model that ensures the earliest possible tumor detection, minimizes false positives, and improves the quality of medical care for women with suspected breast cancer[1].

The purpose of the study . A comprehensive assessment of the sensitivity and specificity of the main laboratory and instrumental methods for diagnosing breast cancer , as well as determining the optimal combination of methods that provide the greatest diagnostic accuracy with a minimum number of false positive and false negative results .

Achieving this goal will enable us to identify the most reliable, accessible, and clinically valid diagnostic methods, which will ultimately improve the effectiveness of screening and the quality of medical care for cancer patients.

Research materials and methods. The study was retrospective, prospective , and analytical in nature and was conducted at an oncology clinic and diagnostic center from 2022 to 2024. The study included 150 women aged 27 to 75 years who were undergoing examination for suspected breast pathology.

The patients were divided into two groups: the main group (n = 100) included women with a histologically confirmed diagnosis of breast cancer (stages I–IV according to the TNM classification). The

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control group (n = 50) included women with no signs of malignancy (according to mammography and biopsy data) who were undergoing preventive screening.

Inclusion criteria: clinical or instrumental signs of breast pathology, patient consent to participate in the study.
Exclusion criteria: concomitant malignant tumors elsewhere, severe somatic diseases in the decompensation stage, and refusal to participate in the study.

All patients underwent a standard set of examinations, including: Mammography - performed in two projections (direct and oblique) on a digital mammograph *Siemens Mammomat Inspiration* . The presence of focal compactions, microcalcifications , and changes in tissue structure were assessed . The results were interpreted according to the BI - RADS scale (Breast Imaging Reporting and Data System). Ultrasound examination (US) was performed using a *GE Voluson E8 device with a 10-12* MHz linear transducer . The size, contours, echogenicity , and vascular architecture of the lesions were determined . The method was used primarily in women with high glandular tissue density. Magnetic resonance imaging (MRI) was performed on a *Siemens device. Magnetom Avanto 1.5 T* with the use of contrast enhancement with gadolinium (0.1 mmol /kg). The morphological and dynamic characteristics of contrast enhancement of suspicious areas were studied . The method was used to clarify the localization of the tumor and differential diagnosis.

Laboratory methods . The CA 15-3 and CEA (carcinoembryonic antigen) markers were determined in the blood serum by enzyme-linked immunosorbent assay (ELISA) on a *Cobas e411 analyzer (Roche)* . Reference values:
• CA 15-3 — up to 25 U /ml;
• CEA — up to 5 ng / ml . An increase in marker levels was considered as an additional diagnostic criterion, especially when assessing the dynamics after treatment. HER2/ neu (Human Epidermal Growth Factor Receptor 2) - the study of receptor expression was carried out using the immunohistochemical method (IHC) on biopsies tumors. The results were graded from 0 to 3+. At 2+, an additional FISH test was performed to confirm gene amplification.

Histological examination (biopsy) was the "gold standard" for diagnosis verification. Samples were taken using ultrasound-guided core biopsy, fixed in formalin, and stained with hematoxylin and eosin .

RESULTS AND DISCUSSION. General characteristics of the examined patients . The study included 150 women aged 27 to 75 years (mean age 52.4 ± 1.3 years). Of these, 100 patients (66.7%) had a histologically confirmed diagnosis of breast cancer (BC); 50 women (33.3%) formed the control group without signs of a malignant process . Among the patients with BC, distribution by stages was as follows: Stage I - 28 (28 %); Stage II - 35 (35%); Stage III - 25 (25%); Stage IV - 12 (12%). In 64% of patients, the tumors were invasive ductal , in 22% - invasive lobular, and in 14% - other morphological variants. The average tumor diameter was 2.8 ± 0.4 cm.

Mammographic examination revealed pathological changes in 86 out of 100 patients with confirmed breast cancer.
Thus, the sensitivity of the method was 86% , and the specificity was 82%.

Table 1. Sensitivity and specificity of mammography in patients with breast cancer

Indicator	Meaning (%)	Note
True positives (TP)	86	Confirmed by biopsy
True negatives (TN)	41	No tumor changes
False positives (FP)	9	Benign changes (fibroadenoma, cystic mastopathy)

PPV (positive predictive value) is 90%, NPV (negative predictive value) is 74%. The most common causes of false-negative results were high glandular tissue density and small tumor size (< 1 cm) . Thus, mammography has shown high efficiency in screening in women over 40 years of age, but limited accuracy in younger patients.

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The method demonstrated a sensitivity of 80% and a specificity of 78%. Of 100 breast cancer patients, ultrasound allowed us to identify signs of malignancy in 80 patients . The main diagnostic criteria were irregular contours, hypoechogenicity , the absence of a clear capsule, and increased peripheral blood flow.

Table 2. Results of the assessment of the diagnostic effectiveness of ultrasound examination (US) in breast cancer

Indicator	Meaning (%)	Note
TP	80	Tumors ≥ 1 cm
TN	39	No pathology
FP	11	Benign nodules
FN	20	Microfocal forms
Indicator	Meaning (%)	Note

The method is especially useful in women under 40 and in those with high tissue density. However, ultrasound is inferior to mammography for microcalcifications . A combination of these two methods increased sensitivity to 92%.

MRI detected pathological foci in 95 out of 100 patients with confirmed breast cancer, which amounted to a sensitivity of 95% and a specificity of 88%.

The method is especially effective for multifocal and multicentric tumors, as well as for assessing invasive growth . The main advantages of MRI are high resolution and the ability to assess angioarchitecture. tumors. Limitations include high cost, duration of the study, and the likelihood of false-positive results due to background signal enhancement in fibrocystic breast disease.

Elevated levels of CA 15-3 (> 25 U /ml) were detected in 64% of patients with breast cancer, which corresponds to a sensitivity of 64% and a specificity of 85%. In patients with stage I, an increase was observed in only 28%, in stage II - in 55%, and in stages III-IV - in 83%. Thus, the CA 15-3 indicator has limited sensitivity in the early stages, but is useful for monitoring the postoperative and post-chemotherapy state.

The CEA level (> 5 ng /ml) was elevated in 58% of breast cancer patients . The sensitivity was 58%, and the specificity was 90%. This marker had diagnostic value primarily in metastatic forms, especially in liver and bone lesions . The combined determination of CA 15-3 + CEA increased the overall sensitivity to 72% with a specificity of 83%. Thus, the simultaneous use of several markers is justified when monitoring patients with progressive forms of cancer and for assessing the effectiveness of therapy.

Table 3. Comparative assessment of sensitivity, specificity and diagnostic efficiency of various methods for breast cancer

Method	Sensitivity (%)	Specificity (%)	Advantages	Restrictions
Mammography	86	82	Screening, availability	Reduced information content in dense tissues
Ultrasound	80	78	Safety, structure assessment	False negatives in microcalcifications
MRI	95	88	Maximum sensitivity	High cost, false positive cases
CA 15-3	64	85	Current monitoring	Low sensitivity in early stages
CEA	58	90	High specificity	Uninformative in the early stages
MRI + markers	97	92	Maximum accuracy	Limited availability

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The combined use of instrumental and laboratory methods made it possible to achieve the highest diagnostic accuracy —sensitivity of 97% and specificity of 92%, which significantly exceeds the performance of individual methods . The data obtained confirm that MRI is the most sensitive method for diagnosing breast cancer , which is consistent with the results of studies by Orel SG et al . (2022) and Jemal A. (2024).
However, the high sensitivity of MRI is accompanied by a moderate decrease in specificity, which requires confirmation of the diagnosis by morphological methods . M ammography , despite its limitations, remains the basic method of mass screening , especially effective in women over 40 years of age. Its sensitivity in combination with ultrasound reaches 90–92%, making these methods the most rational for the initial examination.

Serological markers (CA 15-3, CEA) have low sensitivity in the early stages ; however, their use is justified for monitoring treatment progress and detecting relapses. Combined marker testing increases overall sensitivity to 70–75%.

It is important to note that the optimal diagnostic strategy should be based on the following stages : Screening - mammography and ultrasound; Clarifying diagnostics - MRI if results are unclear; Confirmation of the diagnosis - morphological verification (biopsy); Laboratory monitoring - tumor markers for dynamic observation . In addition , the study showed a dependence of the effectiveness of the methods on age and tissue density. In women under 40, the sensitivity of mammography decreased to 68%, while in women over 50, it increased to 89%. Thus, the integration of instrumental and laboratory methods ensures the highest diagnostic accuracy , reduces the number of diagnostic errors and improves the effectiveness of early detection of the disease . MRI is the most sensitive method, but is not intended for mass screening due to its high cost. Mammography and ultrasound remain the optimal combination for primary diagnosis . Tumor markers are useful as an additional tool for assessing the effectiveness of treatment. An integrated approach ensures the best results with minimal risk of false diagnoses.

Thus, the study results confirm the need for a multidisciplinary approach to breast cancer diagnosis, where laboratory tests complement instrumental studies, increasing the overall sensitivity and specificity of diagnosis.

CONCLUSIONS.

An analysis showed that among instrumental methods for diagnosing breast cancer, magnetic resonance imaging (MRI) has the highest sensitivity —95%—with a specificity of 88%. MRI can detect even minimal lesions and multifocal tumors, making it indispensable for confirmatory diagnosis . M ammography remains the "gold standard" of screening, providing a sensitivity of 86% and a specificity of 82%.

This method is effective for the early detection of microcalcifications and structural changes in women over 40, but its usefulness is reduced in dense glandular tissue. Ultrasound (US) demonstrates a sensitivity of 80% and a specificity of 78%, and is particularly useful in younger patients and those with dense breast tissue. When combined with mammography, this figure increases to 92%. CA 15-3 and CEA tumor markers have relatively low sensitivity (64% and 58%, respectively) but high specificity (85–90%). Their diagnostic value is enhanced by combined testing and dynamic monitoring of patients during treatment and rehabilitation.

A comparative analysis showed that the highest diagnostic accuracy was achieved with the combined use of MRI and laboratory markers , with sensitivity at 97% and specificity at 92%. This confirms the effectiveness of a multidisciplinary approach to diagnosis. The optimal diagnostic strategy for suspected breast cancer should include a step-by-step approach : initial screening (mammography + ultrasound), diagnostic follow-up (MRI), morphological verification (biopsy), and laboratory testing (tumor markers). Improved diagnostic efficiency is possible with individualized selection of methods based on the patient's age, tissue density, and clinical characteristics.

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The results of the study can serve as a basis for the development of clinical protocols and standards aimed at improving the accuracy of early diagnosis of breast cancer and reducing the number of diagnostic errors.

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