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# Peculiarities of diagnostics of breast diseases and management of patients' observation in Ukraine who plan to implement reproductive plans

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In Ukraine, breast cancer ranks first in the structure of oncological diseases among the female population. Changes in hormonal status and the formation of post-traumatic syndrome affect the development of infertility and breast diseases among women of reproductive age.

**Aim:** to analyze the complex of diagnostics and monitoring of breast diseases in patients planning pregnancy using assisted reproductive technologies, in order to improve early diagnosis of breast diseases.

**Materials and methods.** 162 patients were examined at the Kyiv Mammological Center. The average age of the examined women was 33.7±3.4 years. All patients underwent a general clinical examination, ultrasound examination of the mammary glands, mammography, and morphological verification of formations.

**Results.** During the general clinical evaluation, 64% of the patients reported no complaints, and 36% of patients had complaints (breast pain, discomfort). Structural sonographic pathology (BI-RADS 1) was found in 23% of patients. The most common fibrocystic changes in the mammary glands are BI-RADS 2, which was found in 31% of observed persons. Simple cysts with typical ultrasound signs were found in 24% of patients. The next examination was offered to women after 6 months, and macrocysts were found in 7% of patients. BI-RADS 3 was found in 26% of the examined patients. The most common ultrasound findings were fibroadenoma (24%) and cysts with inflammatory changes (2%). Among BI-RADS 4, the most common morphologically verified lesions are atypical ductal hyperplasia (8%), complex sclerosing lesions (16%), intraductal lesions (10%). BI-RADS 5 was detected in 4% of patients.

**Conclusions.** In the comprehensive examination of women planning to undergo assisted reproductive technology procedures, it is necessary to apply general clinical assessment, ultrasound diagnostics, and, when indicated, mammographic imaging and morphological verification of detected lesions.

The study was conducted in accordance with the principles of the Declaration of Helsinki. The research protocol was approved by the Local Ethics Committee of the institution cited in the manuscript, and written informed consent was obtained from all participants.

The authors declare no conflicts of interest.

**Keywords:** breast, cancer, women, stress, mammography, ultrasound examination.

## Особливості діагностики захворювань молочної залози та менеджмент спостереження пацієнток в Україні, що планують реалізацію репродуктивних планів

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В Україні рак молочних залоз займає перше місце у структурі онкологічних захворювань серед жіночого населення. Зміни гормонального стану, формування посттравматичного синдрому впливає на розвиток безпліддя, захворювань молочної залози в жінок репродуктивного віку.

**Мета:** проаналізувати комплексу діагностику стану молочної залози та менеджмент спостереження в пацієнток, що планують вагітність шляхом допоміжних репродуктивних технологій для покращення ранньої діагностики захворювань молочної залози.

**Матеріали та методи.** Обстежено 162 пацієнтки на базі мамологічного центру м. Київ. Середній вік – 33,7±3,4 років. Усім пацієнткам проводили загальноклінічне обстеження, ультразвукове дослідження молочних залоз, мамографію, морфологічну верифікацію утворень.

**Результати.** При загальноклінічному обстеженні 64% пацієнток не мали скарг, 36% жінок мали скарги (біль, дискомфорт у молочній залозі). У 23% пацієнтів констатували структурну сонографічну патологію (BI-RADS 1). BI-RADS 2 виявлені у 31%, найбільш розповсюджені фіброзно-кістозні зміни молочних залоз. Прості кісти з типовими ультразвуковими ознаками виявлені у 24% пацієнток. Наступний огляд жінкам був запропонований через 6 місяців, де в 7% було виявлено макрокісти. BI-RADS 3 виявлені у 26% обстежених пацієнтів. Найбільш розповсюджені ультразвукові знахідки – це фіброаденома (24%), кісти із запальними змінами (2%). Серед BI-RADS 4 найбільш розповсюджені виявлені морфологічно верифіковані утворення – атипова протокова гіперплазія (8%), комплексні склерозуючі утворення (16%), внутрішньо протокові утворення (10%), BI-RADS 5 виявлено у 4%.

**Висновки.** У комплексному обстеженні жінок, що планують проведення допоміжних репродуктивних технологій, необхідно застосовувати загальноклінічне обстеження, ультразвукове обстеження, за необхідністю та за показаннями – це і мамографічне обстеження та морфологічну верифікацію утворень.

Дослідження виконано відповідно до принципів Гельсінської декларації. Протокол дослідження ухвалено Локальним етичним комітетом зазначеної в роботі установи. На проведення досліджень отримано інформовану згоду пацієнток.

Автори заявляють про відсутність конфлікту інтересів.

**Ключові слова:** молочна залоза, рак, жінки, стрес, мамографія, ультразвукове дослідження.

In Ukraine, according to the National Cancer Registry, breast cancer takes the first place in the structure of cancer among the female population. Official statistics show that in 2023, about 12,582 cases of breast cancer were registered in Ukraine, with a mortality rate of 3,513 cases. There is literature evidence of the contributing effect of stress on the development of breast diseases, including cancer [7].

For the past 11 years, Ukrainian women have been living daily in the stress of everyday life. The war that Russia has launched on the territory of Ukraine is forcing women to defend their families, their country, and their own lives. Stress triggers a cascade of stress mechanisms that affect the organism at the mitochondrial level and change hormonal status.

Chronic stress is considered a physiological reaction of the body, either as a prolongation of acute stress or as a response to a long-term stimulus. This is the period of formation of disorders at the cellular level, with the development of pre-disease symptoms.

Chronic stress (CS) contributes to the initiation of lipid peroxidation processes with increased levels of free radicals and mitochondrial destruction. It depletes adrenal cortisol, and as a result, cortisol is primarily synthesized from pregnenolone. Also, cholesterol increases prolactin levels, but hyperprolactinemia inhibits STAR (steroidogenic acute regulatory protein), which ensures cholesterol transport to mitochondria.

Thus, changes in hormonal status and the formation of post-traumatic syndrome affect the development of infertility in women of reproductive age. Therefore, pregnancy planning is not only a family but also a national goal in Ukraine.

***The aim*** of the study: to analyze comprehensive diagnostics of the breast and management of observation in patients planning pregnancy through assisted reproductive technologies in order to improve early diagnosis of breast diseases.

## Materials and methods of the study

We included 162 patients who were examined at the Mammology Center in Kyiv. The average age of the examined was 33.7±3.4 years. All patients were examined by general clinical examination, breast ultrasound (US), mammography (MG), and morphological verification of lesions according to modern guidelines. US examination of the mammary gland was performed according to the standard method using a «Siemens Acuson 3000» US scanner with a 14 mHz linear sensor. MMG was performed on the Amulet Innovality machine.

The prospective study aimed at a comprehensive examination of women planning assisted reproductive technologies with ultrasound

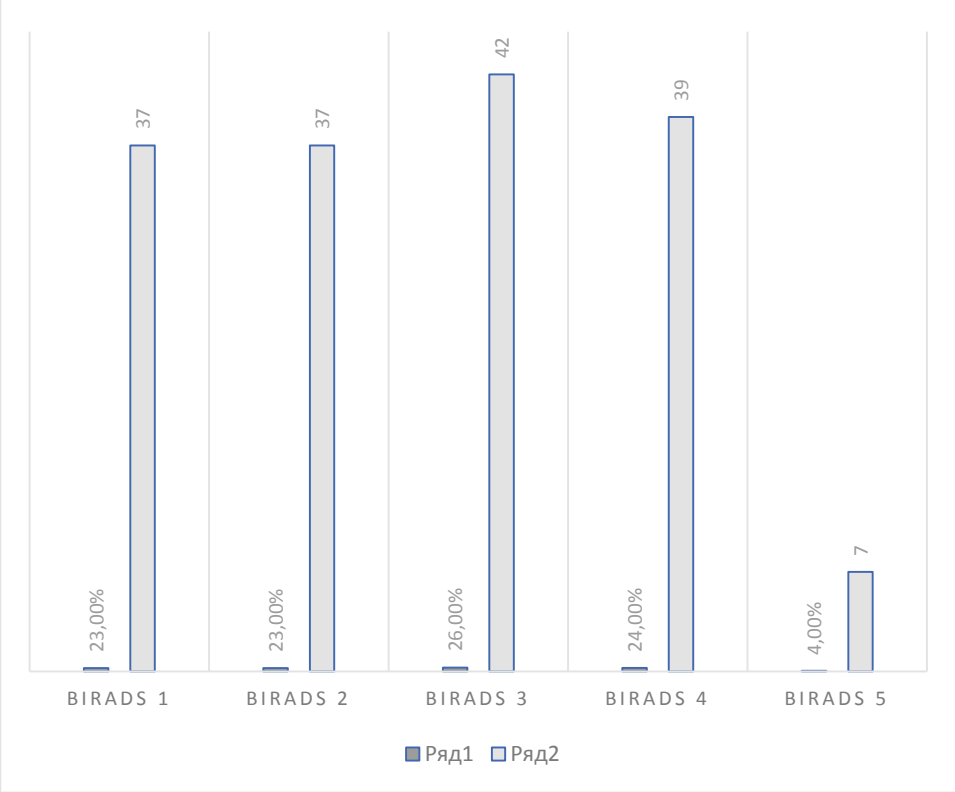



***Fig. 1.*** Ultrasound examination of the mammary glands and stratification of detected lesions based on BI-RADS recommendations

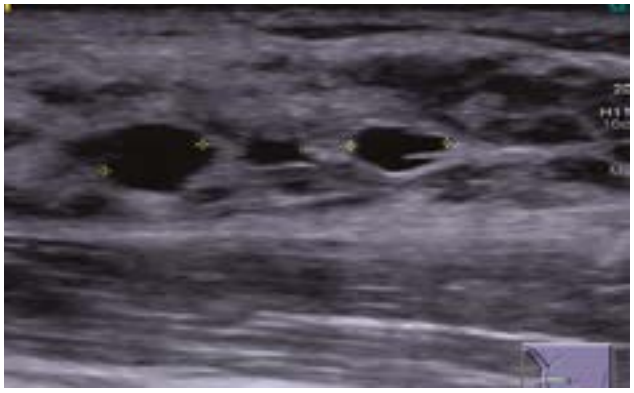


***Fig. 2.*** Simple cysts of the breast

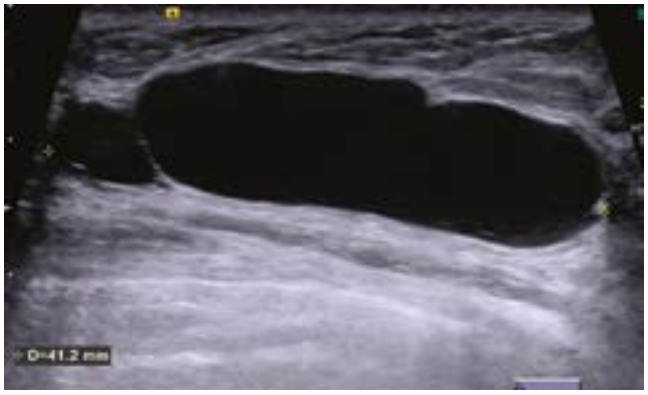



***Fig. 3.*** Macrocyst

and mammography examination, with the determination of the most common pathology for each category of the BI-RADS (Breast Imaging-Reporting and Data System), and defining the management of surveillance for patients in this category [9].

The study was conducted in accordance with the principles of the Declaration of Helsinki. The research protocol was approved by the Local Ethics Committee of the institution cited in the manuscript, and written informed consent was obtained from all participants.

## Results of the study and discussion

During the general clinical examination, 104 (64%) of patients had no complaints, 58 (36%) of patients had some complaints, particularly breast pain, discomfort, and palpable tumor.

The second stage of the diagnostic investigation was based on breast ultrasonography for all patients and stratification of the detected lesions based on the BI-RADS recommendations (2013) [9].

Based on the data that has been obtained (Fig.1), 37 (23%) of patients were diagnosed with structural sonographic pathology (BI-RADS 1).

BI-RADS 2 (benign findings) were detected in 37 (31%), the most common being fibrocystic changes in the mammary glands.

Simple cysts with typical US features (echo-negative structure, homogeneous content, clear, sharp contours, avascular on color Doppler mapping (CDM) were found in 28 of patients (Fig. 2). The next appointment was offered in 6 months.

Typical ultrasound appearance of simple cysts, macrocysts, and observational management are presented in clinical cases 1 and 2.

**Clinical case 1**

A 34-year-old patient underwent a preventive ultrasound examination. Multiple hydrophilic formations with homogeneous contents were detected (Fig. 2). Diagnosis: fibrocystic changes in the mammary glands. BI-RADS 2/2. The next examination is recommended in 6 months.

In our study, fibrocystic changes in the mammary glands with macrocysts were detected in 9 patients. (Fig. 3).

Ultrasound features included a size of more than 20 mm, a clear, sharp contour, and homogeneous content. This is demonstrated by the following clinical case 2.

**Clinical case 2**

A 32-year-old female patient underwent a preventive US examination. Multiple hydrophilic formations with homogeneous contents were detected (Fig. 3), some with a maximum size of up to 41 mm.

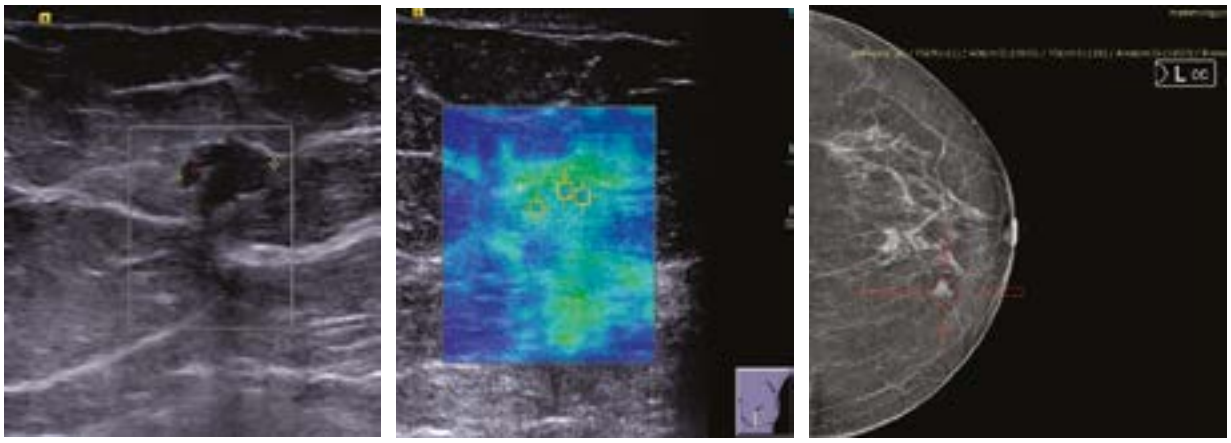
Diagnosis: fibrocystic changes of the mammary glands. Macrocysts of the right breast. BI-RADS 2/2. Recommended: aspiration trepan biopsy of the macrocyst, next examination in 3 months.

Fine needle aspiration/core biopsy of macrocysts was performed with subsequent dynamic observation in 3 months.

Category 3 includes masses with typical ultrasound features of fibroadenomas and cysts with inflammatory changes.

Our study found BI-RADS 3 (probably benign lesions) were found in 42 (26%) of the examined patients. The most common US findings were fibroadenoma 39 (24%) and cysts with inflammatory changes 3 (2%). This group includes fibroepithelial formations consisting of both epithelium as well as stromal components, which includes the usual fibroadenoma.

Ultrasound signs of fibroadenoma include: hypoechoic mass with a limited edge, oval shape, and parallel orientation; in case of CDM: avascular, with peri- or intranodular circulation (Fig. 4).



A B C

***Fig 4.*** Ultrasound and mammographic signs of fibroadenoma: A – a hypoechoic mass with a clear, even contour, horizontal orientation; B – elastography: medium density formation; C – mammographic signs of fibroadenoma

Observation management: US examination in 6 months. In case of an increase in size of 30% more than during this period, trepan biopsy is required, which can be demonstrated by the following clinical case.

Cysts with inflammatory changes have the following US signs: echo-negative heterogeneous content and perinodular blood flow at CDM. Fine needle aspiration was done, and appropriate treatment was performed (Fig. 5).

Observation management: repeated US examination according to the doctor's prescription or after 3 months.

The given nosologies are demonstrated in the following clinical cases 3 and 4.

**Clinical case 3**

A 35-year-old patient underwent a preventive US examination. A hypoechoic mass with a clear, even contour, horizontal orientation was detected (Fig. 4). Diagnosis: mass in the right breast, with signs of a limited type of growth (fibroadenoma). BI-RADS 3/1. Recommended: next examination in 3 months.

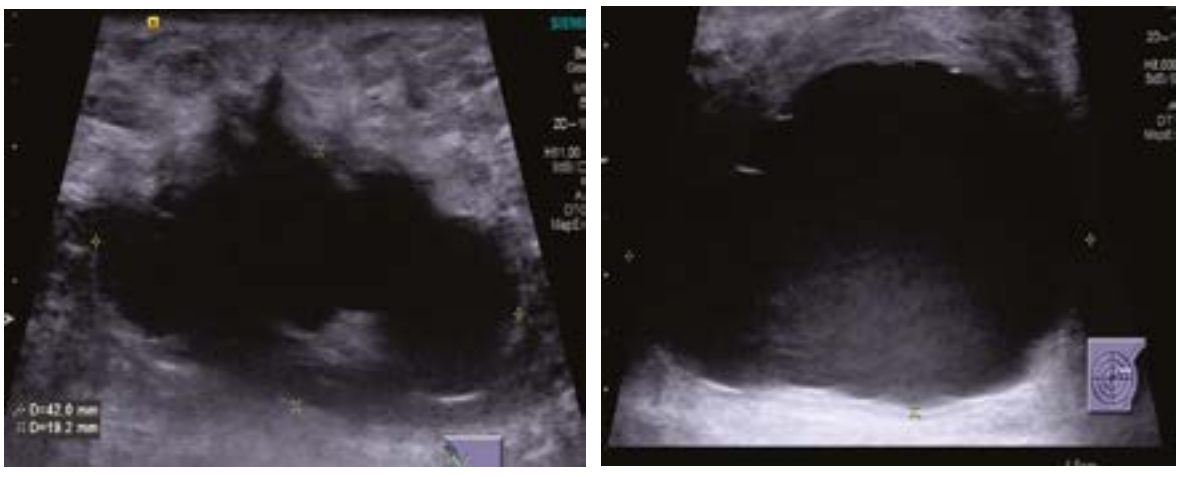
**Clinical case 4**

A 36-year-old female patient underwent a preventive ultrasound examination. An echonegative heterogeneous mass with a clear, even contour, horizontal orientation, and perinodular blood flow were detected on ultrasound (Fig. 5).

Diagnosis: cyst of the right breast, with inflammatory changes. BI-RADS4 A/1. Recommended: fine needle aspiration next examination in 3 months.

The following categories are BI-RADS categories 4 and 5. BI-RADS 4 and 5 lesions are subject to morphologic verification.

All the lesions are classified depending on their morphology to the following categories. B0 – inappropriate or undiagnosed specimen. B1 –



A B

***Fig 5.*** Macrocyst with signs of inflammation: A – echonegative formation without clear contours; B – an echonegative heterogeneous mass with a clear, even contour

a variant of the norm or a benign finding. B2 – a benign finding. B3 – lesions with an uncertain potential for malignancy, lesions with a high risk of malignancy. B4 – suspicious for malignancy. B5 – malignant [8].

Morphologic category B3 is a heterogeneous group that includes various morphologic lesions, such as atypical ductal hyperplasia, lobular carcinoma in situ, intraductal lesions, radial scar, fibroadenoma lesions, atypical apocrine adenosis, etc. In our study, the most common morphologically verified lesions detected among BI-RADS 4 category – 39 (24%), were atypical ductal hyperplasia in 18 patients, complex sclerosing lesions in 10 patients, intraductal lesions in 11 patients, and BI-RADS category 7 (4%).

Recent literature suggests that category 4 is morphologically classified as category B3. The risk of malignancy ranges from 0–5% to 20–25% [8].

Therefore, it is crucial to understand the diagnosis and management for each nosological group and the approach in case of additional hormonal stress on the body during additional reproductive technologies (ART).

**Atypical ductal hyperplasia (ADH)** is the most common B3 lesion: a small focus, intraductal epithelial proliferation ≤2 mm, with often associated calcifications, also known as «atypical intraductal epithelial proliferation». The risk of malignancy is 5–50%.

The difference from ductal carcinoma *in situ* (DCIS) is based on size only; over 2 mm is DCIS.

US, MMG, and magnetic resonance examination with intravenous contrast (MRI) were used during the diagnostics. The most common US signs of ADH include the presence of a hypoechoic formation of various shapes, a macrolobular/wavy contour. It's avascular or with peri-/intranodular circulation for CDM. On elastography – medium or mosaic density. MMG: calcification is possible (not always), the presence of a neoplasm, and local asymmetry. MMG with contrast and MRI are used. Surgical treatment is the only solution.

**Complex sclerosing formations (radial scar, sclerosing adenosis)** are a benign proliferative lesion of the breast characterized by lobulocentric proliferation of acini around the terminal duct with the development of stromal sclerosis and compression of its lumen. In case of sclerosing adenosis, the risk of developing breast cancer, particularly invasive carcinoma, is increased by 1.5–2 times during life.

Ultrasound examination, MG, and MRI are used in diagnostics.

Ultrasound diagnostics: hypoechoic, malformed, avascular/hypovascular in case of CDM, medium/high density in case of elastography. MMG: includes a pattern of spiculated deformation of the left breast architecture, concomitant microcalcifications. MRI, MG with contrast: uninformative [1,3]. Tactics – surgical treatment.

Intraductal papilloma (IDP) is a benign lesion of papillary architecture, including fibrovascular stroma covering the epithelium with associated myoepithelium. The lesion may be associated with hyperplasia, apocrine metaplasia, squamous cell metaplasia, infarction, or fibrosis.

DCIS in papilloma is diagnosed if there is low-grade atypical hyperplasia 3 mm in size or more. Therefore, if atypical hyperplasia is present, it's crucial to assess the degree to differentiate it between papilloma with atypical hyperplasia and DCIS in papilloma.

Multiple peripheral papillomas are more commonly associated with atypical hyperplasia and/or DCIS compared with single intraductal papillomas. A combination of basal cytokeratins (CK5, CK14), myoepithelial (SMM), and ER immunohistochemistry may help distinguish benign papillomas from patients with atypical hyperplasia and/or papillary DCIS.

Ultrasound, MG, and MRI are used in diagnostics [5].

Ultrasound diagnostics: Ductal ectasia with intraductal lesion and intralesional blood flow.

Mammography: normal appearance, either duct ectasia or retroareolar mass (it may be of different localization or cluster calcification in 25%).

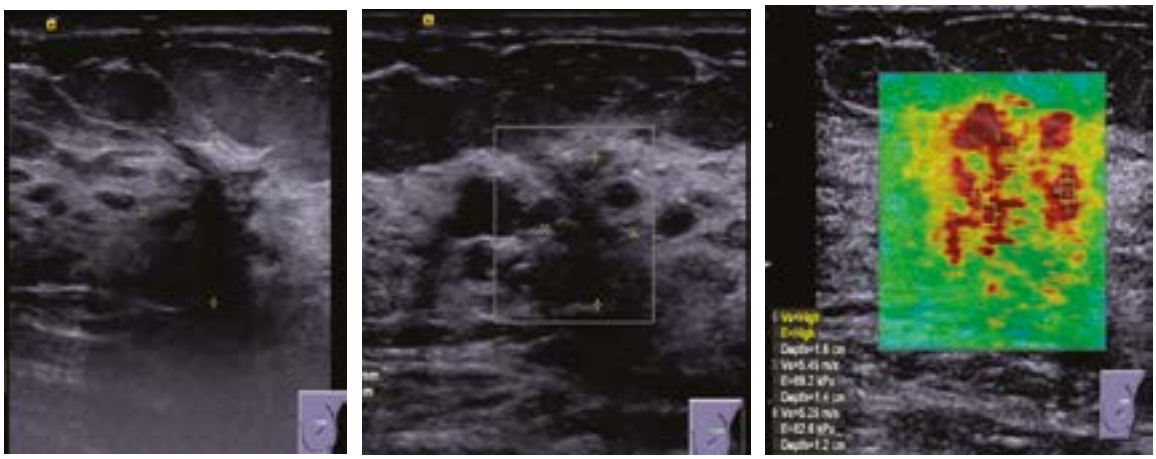
MRI: visualized as delineated or non-delineated formations related to the duct, single or multiple.

In the diagnosis of IDP without atypical hyperplasia, the risk of developing carcinoma in situ is up to 10%; in the presence of atypical hyperplasia it is up to 27–36%.

All papillomas, with or without ADH, are classified as B3 lesions.

The management of IDP without concomitant atypical hyperplasia is treated with vacuum-assisted biopsy and, in case of complete removal, visualization observation is enough. In case of IDP with concomitant atypical hyperplasia, surgical excision is recommended.

BI-RADS 5 lesions have US and mammographic signs of malignancy.



A B C

***Fig. 6.*** Left breast at 12/B, showing a hypoechoic formation with a vague, uneven contour, spiculation and angulation of the contour. BI-RADS right 1, left 4C: A – a hypoechoic formation with a vague, uneven contour, spiculation and angulation of the contour; B – a hypoechoic formation with a vague, uneven contour, spiculation and angulation of the contour, avascular on mapping; C – formation on high-density elastography

Ultrasonographic signs: vertical orientation of the formation with poor, uneven contours (spiculation, angulation of the edges of the structure, microlobulation of the contour); severe hypoechogenicity (sometimes anechogenic) with a heterogeneous structure. Dorsal shadow (dorsal strengthening in the presence of a fluid component in the mass). Intrafocal calcifications. Extension to the ducts beyond the formation (duct extension). In case of CDM, chaotically located intranodular colored loci directed to the center. Sometimes the formation is avascular.

MMG signs: a formation of vertical orientation with unclear, uneven contours (spiculation, angulation of the edges of the formation, microlobulation of the contour).

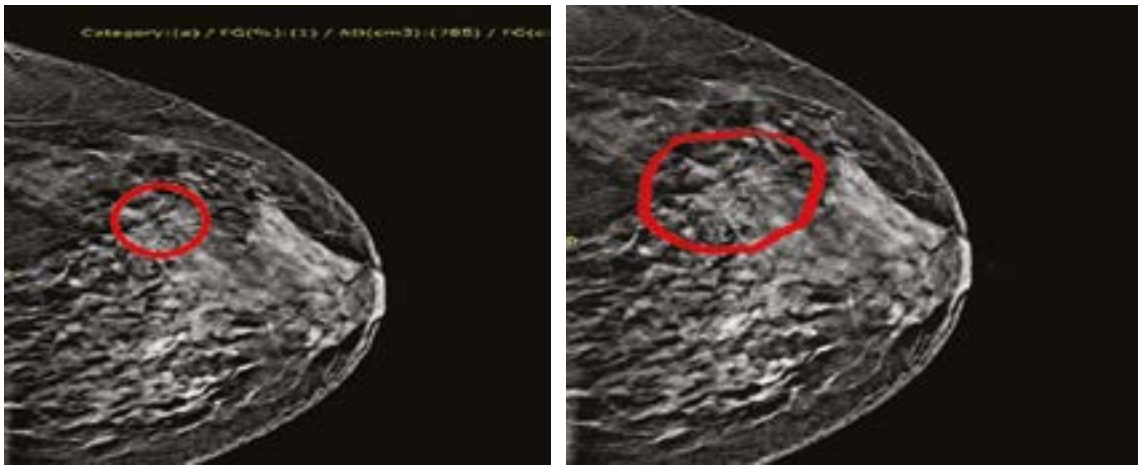
The following clinical cases demonstrate the described nosological examples of categories BI-RADS 4 (clinical cases 5 and 6) and BI-RADS 5 (clinical case, and indicate the management of the observation.

**Clinical case 5**

A 38-year-old patient, with no complaints at the time of examination, underwent a preventive examination: ultrasound examination, mammographic examination, morphological verification of the formation, and examination by a mammologist.

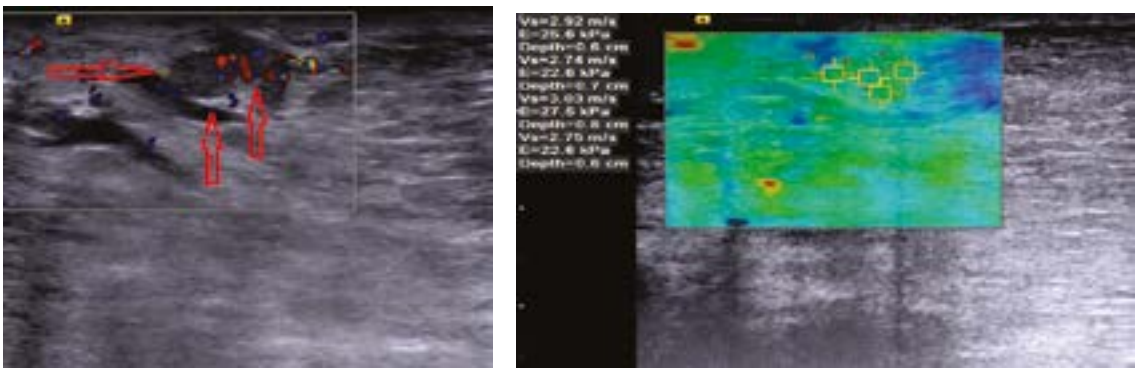
An echonegative mass with an indistinct, uneven contour, vertical orientation, avascular blood flow on CDK, high density on elastography (Fig. 6). Diagnosis: suspicious mass of the left breast BI-RADS 1/4C. Recommended: MG, morphological verification of the mass on the left.

The figure shows a mammographic picture of a spiculated deformation of the left breast architecture (Fig. 7).



A B

***Fig. 7.*** Left breast contains a spiculated deformity of tissue architecture: A – a spiculated deformity of tissue architecture; B – a spiculated deformity of tissue architecture



A B

***Fig.8.*** Hypoechoic intraductal formation with a clear, even contour, intrafocal circulation, medium density on elastography: A – hypoechoic intraductal formation with a clear, even contour, intrafocal circulation; B – medium density on elastography

The patient was admitted for a core biopsy. The histological investigation revealed the presence of a complex sclerosing formation of the breast (radial scar). Surgical treatment is recommended.

**Clinical case 6**

A 41-year-old patient, at the time of examination, had bloody discharge from the nipples, underwent a preventive examination: ultrasound examination, mammographic examination, morphological verification of the formation, and examination by a mammologist. A hypoechoic intraductal formation with a clear, even contour and intrafocal blood flow was detected via ultrasound examination (Fig. 8).

Mammography demonstrates a retroareolar mass BI-RADS 1/4. Recommended: morphological verification of the mass on the left (Fig. 9).

Morphological verification was completed. Intraductal papilloma with atypical ductal hyperplasia. Surgical treatment is the management tactic.

**Clinical case 7**

The patient is 41 years old. At the time of the examination, she had no complaints. A preventive examination by a mammologist, an ultrasound examination, and a mammographic examination are offered.

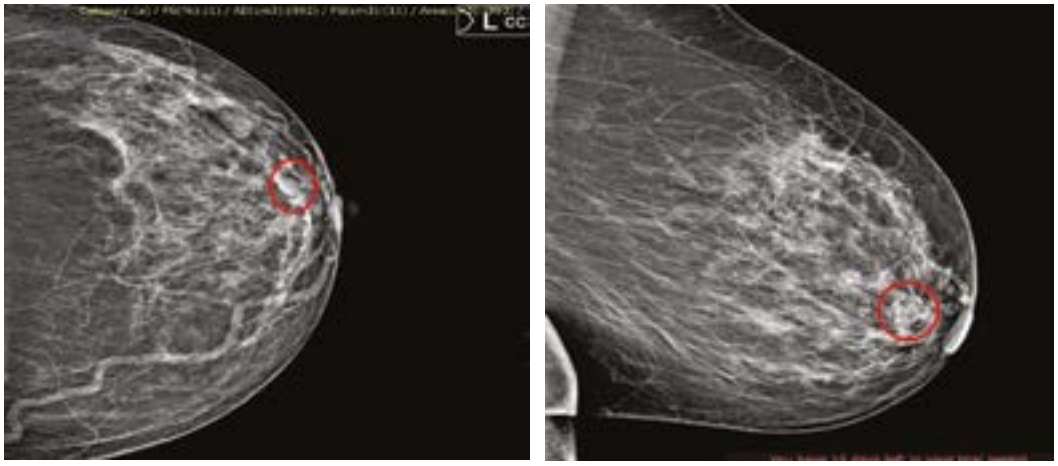
Ultrasound examination of the mammary glands, visualized as a hypoechoic abnormal shape mass without clear boundaries, with perinodular circulation, high density on elastography (Fig. 10).

Mammography demonstrates of an area with pleomorphic calcifications is visualized (Fig. 11).

Morphological verification was performed – carcinoma.

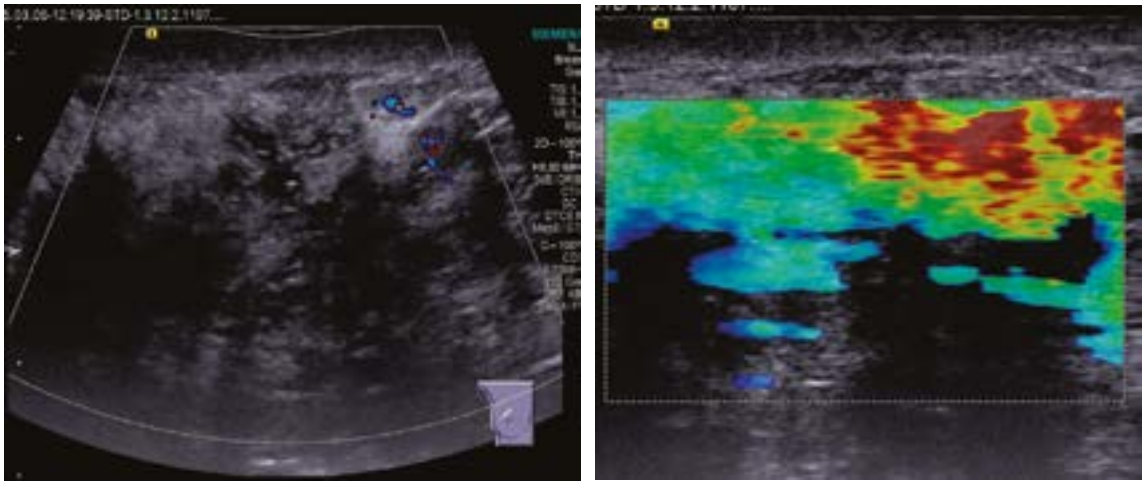
A prospective examination of women of reproductive age who plan to use assisted reproductive technologies confirmed the need for a comprehensive preventive examination of women, including breast ultrasound and mammography.

Diagnosis and management of findings were based on BI-RADS recommendations, which



A B

***Fig.9.*** MG picture of a retroareolar mass



A B

***Fig. 10.*** Hypoechoic abnormal shape mass without clear boundaries, with perinodular circulation, high density on elastography: A – hypoechoic abnormal shape mass without clear boundaries, with perinodular circulation; B – high density on elastography

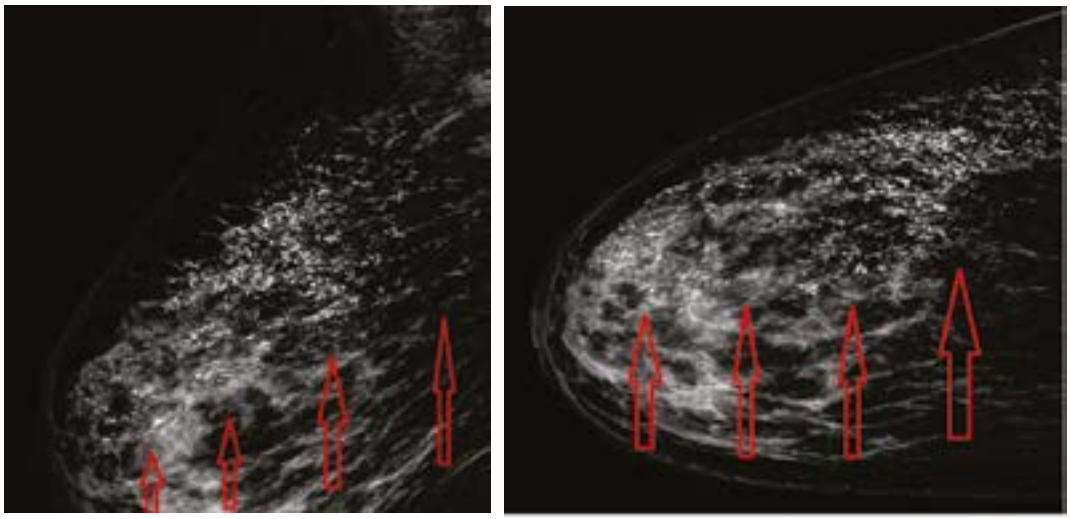


***Fig. 11.*** MG: an area with pleomorphic calcifications is visualized: A – an area with pleomorphic calcifications is visualized; B – an area with pleomorphic calcifications is visualized

made it possible to form indications for surgical treatment for this category of women [2,3,8].

In order to comply with the internal protocol, indications for surgical treatment were formed.

1. The presence of an intraductal mass with cytologic or histologic verification (intraductal papilloma) and the existence of a corresponding clinical picture (nipple discharge).

The need for cytologic examination of nipple discharge:

– in case of unilateral transparent discharge (dewdrop type);

– serous discharge;

– bloody and dirty nipple discharge.

2. Formations of any size with an undefined contour, hypervascularization, and high density on elastography.

3. Benign lesion (fibroadenoma, localized adenosis) larger than 20 mm.

4. Fibroadenoma that has increased during the observation period from 3 to 6 months by more than 30%.

5. Malignant tumors (BI-RADS category 5).

6. Breast lesions of morphological verification B 3 category.

7. According to the woman's desire.

## Conclusion

A comprehensive examination of women planning to undergo assisted reproductive technologies should include a general clinical examination, US examination, and, if necessary and as indicated, MMG and morphological verification if assigned. The complex of the proposed examinations improves the early diagnosis of breast cancer and diseases that have a risk of developing breast cancer.

*The authors declare no conflicts of interest.*

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