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THE ROLE OF VACUUM ASPIRATION BIOPSY IN THE DIFFERENTIAL DIAGNOSIS OF FOCAL LESIONS OF THE MAMMARY GLANDS

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Annotation: to determine the role of vacuum aspiration biopsy in the differential diagnosis of focal pathology of the mammary gland.

a retrospective study was conducted in 57 women aged 19 to 77 years (mean age 39.7±13.2 years) who sought medical care in the period from 2018 to 2021 with complaints of a palpable formation for dynamic observation or screening examination. All patients had hypo- and/or anechoic focal lesions in the mammary glands visualized by ultrasound examination (US) and the BI-RADS category 2–4 was established. To clarify the diagnosis, a vacuum aspiration biopsy (VAB) procedure under ultrasound control was performed followed by morphological examination. A total of 90 focal lesions were examined.

of 90 examined focal lesions of the mammary glands, diagnosed in 57 women, 86 (95.5%) lesions were histopathologically benign pathology. In 58.8% of focal lesions, fibroadenoma (FA) was verified. In 41.5% of foci, it was combined with other benign changes, including high-risk ones. The malignant nature of the formation was diagnosed in 4 (4.5%) cases, while based on ultrasound, a malignant neoplasm was assumed and the BI-RADS category 4c was established in only 2 of them. Simple FA (34.4%), sclerosing adenosis (8.9%) and atypical hyperplasia (1.1%), as well as their combination (24.4%), often do not have specific signs during ultrasound diagnostics and in most cases are visualized as typical benign FA, which complicates the differential diagnosis of these pathologies and requires morphological verification of the diagnosis.

Ultrasound based on a combination of ultrasound signs does not allow for a detailed determination of the nature of a focal lesion. Ultrasound-guided VA, being a minimally invasive technique, makes it possible, without surgical intervention, to obtain the best material for histological examination and thus demonstrates a higher level of accuracy in the differential diagnosis of focal lesions of the mammary glands and allows for the deficiencies of ultrasound diagnostics to be compensated for.

Key words: vacuum aspiration biopsy of the mammary gland, atypical hyperplasia, fibroadenoma, sclerosing adenosis, breast cancer, differential diagnostics.

Introduction

Due to the widespread prevalence of breast diseases, including malignant neoplasms (MN), in the female population, they are a pressing problem of modern healthcare throughout the world.

According to data for 2022–2024, breast cancer ranks first among all oncological diseases in Uzbekistan (18.3% in 2021) [1–3]. In 2024, 72.5% of newly diagnosed breast cancers were diagnosed at stages I–II, and 27.1% at stages III–IV. The increase in the number of cases registered at an early stage (an increase in this indicator over 10 years from 65.0 to 72.5%) determines the importance of screening examination and diagnosis of precancerous conditions [1].

Digital mammography and ultrasound examination (US) remain the "gold standard" for diagnosing breast pathologies [4]. Ultrasound is an important component of diagnostic examination of women under 40 years of age, as well as an additional method for suspicious and unclear clinical or mammographic results. In addition to diagnostic areas of application, this method is used as a control during invasive procedures.

In addition to differential diagnostics of cystic and solid lesions, clear ultrasound criteria developed by the American College of Radiology (ACR) allow one to determine the nature of focal breast lesions and thereby increase the clinical effectiveness of this method. According to studies, the sensitivity and specificity of ultrasound in differentiating benign from malignant lesions are 95.95 and 91.42%, respectively [5].

Despite the importance of differential diagnostics of breast cancer, a group of benign changes is also of great interest. Attention to them is associated, firstly, with their wide prevalence, and secondly, with the possibility of malignancy and the development of malignant neoplasms against their background [6–8].

At the same time, differential diagnostics of different histological groups of benign changes is difficult, since in most cases they do not have a specific ultrasound picture and, according to the results of ultrasound, the preliminary diagnosis of all focal lesions with typical benign ultrasound signs sounds like “fibroadenoma”, and according to the BI-RADS (Breast Imaging Reporting and Data System) ACR scale, BI-RADS categories 2 and 3 are established (benign and probably benign pathologies, respectively), as a result of which, according to some authors, only observation of the lesions is recommended [9, 10].

The high probability of developing malignant neoplasms against the background of certain types of benign changes is a serious problem and requires constant monitoring, and in the case of malignancy, timely treatment.

The aim of the study: to determine the role of vacuum aspiration biopsy in the differential diagnosis of focal pathology of the mammary gland.

Material and methods

The study was performed retrospectively. At the first stage, 13,079 results of ultrasound examinations of the mammary glands performed between 2018 and 2021 at the Mammological Center LLC (Vladivostok) were analyzed. The result of each study was assessed in accordance with the BI-RADS system for recording the results of radiation examinations of the mammary gland.

The study was conducted in compliance with ethical requirements, all study participants confirmed the possibility of using the data by signing informed consent.

In approximately half (7124 (54.5%)) of the cases, the study results corresponded to categories 2 and 3. The group of studies with the BI-RADS 1 category constituted less than half (41.8% (n=5473)) of all the studies conducted. Categories BI-RADS 4–6 were encountered much less frequently: BI-RADS 4 — 2.24% (n=293), BI-RADS 5 — 1.13% (n=148), BI-RADS 6 — 0.15% (n=19). Thus, the frequency of occurrence of breast changes diagnosed by ultrasound (categories BI-RADS 2–6) was 58% (n=7586) among all studies for this period, in the structure of which benign and probably benign changes predominated.

At the second stage, among all ultrasound examinations performed (n=13,079), a group of patients with focal pathology of the mammary glands was identified that met the criteria:

1. established BI-RADS category 2–5;
2. presence of single or multiple focal lesions or areas of the mammary gland with hypoechoic and/or anechoic echostructure (including those described as cysts);
3. age of patients starting from 15 full years.

The following patients were excluded from this group:

- younger than 15 years;
- pregnant or lactating;
- with diagnosed hyperechoic lesions only;
- with diagnosed lymphadenopathy of the axillary, supraclavicular and infraclavicular lymph nodes, but without focal lesions of the mammary gland.

The selected group at the second stage included 6147 ultrasound results. The frequency of occurrence of hypoechoic and/or anechoic focal lesions was 81.3% (n=4997) of all pathological changes in the mammary gland. The main part of these lesions were anechoic focal lesions — 4069 (66.2%), and in 940 (15.3%) cases, anechoic lesions were combined with hypoechoic lesions..

In order to establish the diagnostic value of the VAB in the differential diagnosis of focal lesions of the mammary gland among patients diagnosed with hypo- and/or anechoic focal lesions (6147 ultrasounds), a study group of 57 patients aged 19–77 years (mean age 39.7±13.2 years) was retrospectively identified. They applied to the Mammology Center LLC for the following reasons: the presence of a palpable formation, for dynamic observation or screening examination, and who underwent a total of 73 ultrasounds, according to the results of which 90 focal lesions were diagnosed.

The criterion for selecting the study group was the presence of an established histological diagnosis, the material for which was obtained using ultrasound-guided VA, which was indicated in the ultrasound reports.

All 57 patients underwent ultrasound-guided IABP to establish a histological diagnosis of visualized focal lesions. A total of 90 procedures were performed. In cases of high probability of a benign lesion (BI-RADS categories 2–3, as well as 4a), IABP was used not only for diagnostic but also for therapeutic purposes as an alternative to surgical intervention, and in cases of high probability of malignant neoplasm (BI-RADS category 4c), IABP was only a diagnostic method [11–14].

Ultrasound-guided vacuum aspiration biopsy was performed at the medical institution OOO Innomed Plus in a unit equipped with an EnCor™ Classic VAB device (manufacturer BARD, Inc) with disposable probes of 7G and 10G sizes (depending on the purpose of the study), a SonoSite 180 ultrasound device (manufacturer FUJIFILM SonoSite, Japan), and an operating table. The linear sensor was positioned above the lesion throughout the intervention, displaying the image on the screen.

The VAB method involves capturing not only the focal lesion area, but also a small amount of surrounding tissue. This method, in addition to verifying the diagnosis, allows you to obtain information about background changes in the mammary gland that could have caused the development of this focal lesion.

The ultrasound findings with the established BI-RADS category of the ultrasound scans were compared with the results of the histological examination..

To evaluate the results of the study, statistical indicators were calculated using the standard Microsoft Office Excel 2016 package. Using this program, the mean value (M), standard deviation (σ), arithmetic mean error for the age of patients, as well as the occurrence of various characteristics of focal lesions in B-mode were calculated.

To analyze the diagnostic value of standard ultrasound (B-mode and color Doppler mapping mode), the information content indicators were calculated - sensitivity, specificity and accuracy, positive predictive value (PPV) and negative predictive value (NPV). The reliability of quantitative differences between ultrasound signs of different groups of benign tumors was determined using the parametric Student's t-test for relative values with the level of $p<0.05$ generally accepted for medical research.

Results and discussion

Based on the ultrasound results, focal lesions were diagnosed in all 57 patients: in 20 (35.1%) patients, the pathological process was multiple, in 15 (26.3%) of these patients, focal lesions were detected in both mammary glands. In the remaining 37 (64.9%) patients, a single focal lesion was observed.

Based on the totality of ultrasound characteristics of focal lesions, the BI-RADS category was established. The BI-RADS category 2 was established in 20 (35.1%) patients, BI-RADS 3 — in 28 (49.1%), BI-RADS 4 — in 9 (15.8%). Thus, the most common category was BI-RADS category 3, which was established in almost half of the patients; it is worth noting that, according to the literature, this is the proportion of all detected neoplasms that is assessed as BI-RADS 3 [15, 16]. In the BI-RADS category 4, subcategory 4a was established in 4 (7%) patients, 4c — in 2 (3.5%). The subcategory was not established in 3 (5.3%) cases, therefore, due to the small sample, the BI-RADS 4 category was considered as a single category, which included patients with an expected risk of breast cancer based on ultrasound results.

Based on the results of ultrasound diagnostics, the benign nature of the focal formation was assumed in 48 (84.2%) patients, and probably malignant (from 2 to 95%) - in 9 (15.8%).

A total of 90 neoplasms were identified, which were visualized in all quadrants of the mammary gland, as well as in the periareolar region. About half of all pathological changes were localized in the upper lower quadrant (n=44, 48.9%), the second most common was the periareolar zone (n=24, 26.7%), and even less frequently, changes were localized in the upper upper quadrant (n=12, 13.3%). The least number of pathologies were diagnosed in the lower quadrants: 3 in the lower upper quadrant (3.3%) and 7 in the lower lower quadrant (7.8%).

According to the ultrasound results, fibroadenoma (FA) was suspected in 60 (66.7%) lesions, cysts in 19 (21.1%), malignant neoplasms in 3 (3.3%), and 8 (8.9%) lesions were not identified. The group of undefined lesions included lesions with undefined nosology and without a combination of typical signs.

All 57 patients underwent the ultrasound-guided IABP procedure to establish a histological diagnosis of visualized focal lesions (n=90); this method of confirming the diagnosis was chosen as the most representative and accurate [17, 18].

Histopathologically, 86 (95.5%) breast lesions were benign and 4 (4.5%) were malignant. Benign breast neoplasms were represented by the following nosologies: FA (31 (34.4%)), sclerosing adenosis (SA) (8 (8.9%)), a combination of these nosologies (20 (22.2%)), nodular form of fibrocystic mastopathy (FCM) (13 (14.4%)), atypical hyperplasia (AH) (1 (1.1%)), AH with FA (1 (1.1%)), AH with FA and SA (1 (1.1%)), cysts (5 (5.6%)) - such a distribution of morphological forms is typical for nodular lesions of the mammary gland [19].

Malignant neoplasms of the mammary gland were represented by infiltrating non-specific carcinoma (2 (2.3%)); invasive ductal carcinoma (1 (1.1%)); infiltrating tubular carcinoma (1 (1.1%)).

Fibroadenoma, the most frequently (66.7%) suspected pathology on ultrasound, was diagnosed in 53 (58.8%) histological reports; in 22 (41.5% of all diagnosed FA) cases, this focal formation was combined with other benign pathologies - SA, AG, or SA and AG simultaneously, which was not established in any ultrasound report.

Malignant neoplasms were diagnosed in 4 (4.4%) cases, while only 3 malignant neoplasms were suspected based on ultrasound. One lesion, determined as malignant neoplasm by ultrasound, turned out to be CA morphologically.

The relationship between ultrasound findings and histological examination results is presented in the table.

Table. Relationships of nosologies based on the results of ultrasound and morphological examination

Table. Nosology ratios according to the ultrasound and morphological examination results

Ultrasound		Morphological examination								
		FA FA	FA with SA/AH FA with SA/AH	AG AH	SA SA	Cyst Cyst	ZNO MT	FCM FCM	No changes	Inflammation
FA /FA	n=60	27	19	1	1	1	2	6	2	1
Cyst	n=19	-	2	-	5	4	-	5	-	3
ЗНО / FCM	n=3	-	-	-	1	-	2	-	-	-
Not defined	n=8	4	1	-	1	-	-	2	-	-
Всего / Total	n=90	31	22	1	8	5	4	13	2	4

Note. *FA — fibroadenoma, SA — sclerosing adenosis, AH — atypical hyperplasia, FCM — fibrocystic mastopathy, MT — malignant tumor.*

In 5 (62.5%) cases, sclerosing adenosis was visualized as an anechoic formation with clear, smooth contours of a regular shape, which made it impossible to differentiate it from cysts, which in this study had similar characteristics in 60% of cases. Therefore, in 4 (50%) cases of verified SA, a cyst was suggested in the conclusion of ultrasound diagnostics (in another case, the conclusion was unspecified).

Nodular FCM (n=13) was the most heterogeneous group according to histological findings. After histological examination, the following changes were attributed to it: focal stromal, lobular, ductal and sclerosing hyperplasia; tortuous and cystically dilated ducts; fibrosis; focal stromal proliferation; focal apocrine metaplasia of the epithelium. In ultrasound, these changes also had typical characteristics of simple FA: hypoechoic echostructure (n=9, 69.2%) with clear, smooth contours of regular shape (n=12, 92%) of homogeneous structure (n=11, 84.6%). The differences in the frequency of occurrence of typical signs of FA (hypoechoic formation with clear, smooth contours of regular shape) in single FA and nodular form of FCM were not statistically significant (t-criterion 1.2, $p>0.05$).

Таким образом, доброкачественные патологии не имеют специфических признаков для каждой группы и в большинстве случаев визуализируются как типичные ФА, а в 50% случаев СА имеет типичные признаки кисты.

The results of two conducted VABs showed no pathological changes. These cases demonstrate the possibility of false-positive diagnosis of focal lesions using ultrasound.

In this study, 4 (4.4%) malignant neoplasms were verified using VA. However, using ultrasound, a high probability of cancer was assumed only in two of them. These neoplasms had the following characteristics: hypoechoic echostructure, uneven, clear contours, irregular shape. Perinodular blood flow was determined in 1 neoplasm. The remaining 2 cases of verified cancer were visualized as typical benign pathologies - hypoechoic neoplasms with clear, even contours of a regular shape without blood flow, in connection with which these neoplasms were classified as BI-RADS 2, presumptive nosological diagnosis: FA.

Thus, the ultrasound picture of benign formations, regardless of the group, in most cases were characterized by the following: regular shape, clear, smooth contours, homogeneous echostructure, avascularity. Only in a small percentage of benign formations had any peculiarities. Thus, the combination of FA with SA and/or AG more often had an anechoic echostructure and uneven contours than single FA (0% and 9.7% versus 13.6% and 22.7%, respectively), which indicates a combined pathology. A single SA area had typical signs of a cyst, which complicated differential diagnosis, but more often than cysts, it had unclear, uneven contours and an irregular shape (12.5% versus 0% for a cyst). The presence of AG can be determined in 33.3% of cases by the presence of one of three signs: unclear, uneven contour or the presence of blood flow [20].

Breast diseases in the female population undoubtedly have high social significance and are an important problem of modern society. The high prevalence of breast changes in women is confirmed by the high frequency of diagnosis in the analysis of 13,076 ultrasounds. From 2018 to 2021, more than half (58%) of all conclusions indicated some changes in the mammary glands.

In addition to the great importance of instrumental differential diagnostics of malignant and benign tumors, the complexity also lies in the differential diagnostics of various groups of benign tumors, interest in which is associated with the risk of malignancy, which determines the correct choice of treatment method, taking into account possible negative consequences.

According to ultrasound assessments, benign pathology was assumed in 84% of the patients studied over the entire period (BI-RADS 2–3). According to the results of morphological examination, benign pathology was diagnosed in 95% of patients, which confirms its high prevalence rate.

In addition to the high number of benign changes in both age groups, attention to them is primarily associated with the possible risk of their malignancy, as well as, in most cases, with the lack of the possibility of differential diagnostics based on the results of ultrasound examination of various groups with both high and low risk, due to the lack of a specific ultrasound picture.

Today, based on the results of ultrasound, all typical benign formations are given a preliminary diagnosis of "fibroadenoma", which, according to many authors, does not require morphological confirmation.

Fibroadenoma was diagnosed in 53 (58.8%) of 90 focal lesions. In 22 (41.5% of all diagnosed FA) cases it was combined with other benign pathologies, which was not established in any ultrasound report. CA in 62.5% of cases had characteristics similar to cysts (60%).

In diagnostics and differential diagnostics of FA, the sensitivity of ultrasound was 96%, specificity - 59%, accuracy - 80%, PPV - 77%, APV - 91%..

The study found that FA as the most common benign focal lesions are often combined with high-risk pathologies. Differential ultrasound diagnostics of combined pathology and solitary FA shows that the differences in FA and its combination with SA and/or AG are statistically insignificant ($p>0.05$). In addition, the differences in the ultrasound signs of FA and nodular FCM were also statistically insignificant ($p>0.05$), which confirms the complexity of differential diagnostics of these nosologies.

Therefore, it is not possible to differentiate the combination of FA with pathology of medium and high risk of developing malignant neoplasms based on ultrasound characteristics, which is especially important in the presence of hypertension.

Conclusion

Thus, it can be concluded that, despite the high sensitivity, i.e. the ability to determine FA by typical signs, the number of false-positive results, low specificity, and the lack of statistical significance in distinguishing ultrasound signs of a single FA and its combination with another benign pathology, as well as nodular FCM,

show reduced efficiency of ultrasound in the differential diagnosis of benign formations. From this, it can be concluded that establishing a diagnosis only on the basis of ultrasound without morphological confirmation of the nature of the formation is impossible. VAB demonstrates the required level of accuracy in the differential diagnosis of focal lesions of the mammary glands and allows to compensate for the shortcomings of ultrasound diagnostics.

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