ORIGINAL ARTICLE

Özgün Araştırma

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Geliş tarihi / *Received* : August 14, 2023
Kabul Tarihi / *Accepted* : November 06, 2023
E-Yayın Tarihi / *E-Published* : September 01, 2024

Cite this article as
Bu makalede yapılacak atıf
Basturk T., Yuceer RO., Basturk S., Duran M. Diagnostic Effectiveness of BI-RADS Classification in Suspected Breast Lesions: A Single Center Experience in the West Anatolia
Akd Med J 2024;10(3): 520-527

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DOI: 10.53394/akd.1343088

Diagnostic Effectiveness of BI-RADS Classification in Suspected Breast Lesions: A Single Center Experience in the West Anatolia

Şüpheli Meme Lezyonlarında BI-RADS Sınıflamasının Tanısal Etkinliği: Batı Anadolu'da Tek Merkezli Deneyim

ABSTRACT

Objective:
In this study, we aimed to investigate the histopathological and radiological compatibility of the lesions grouped as BI-RADS (Breast Imaging Reporting and Data System) categories 3, 4, and 5 with breast ultrasonography (US) and mammography and performed tru-cut biopsy (TCB) under US guidance.

Material and Methods:
Between January 2019 and December 2022, 196 consecutive female patients who were diagnosed with BI-RADS 3, 4, and 5 lesions by US and mammography and underwent US-guided TCB were retrospectively scanned and included in the study. Lesion localizations, largest diameters, biopsy results, and the relationship of benign-malignant lesions with age were examined. Negative predictive value (NPV) for malignancy in BI-RADS 3 lesions and positive predictive value (PPV) for malignancy in BI-RADS 4 and 5 lesions were calculated.

Results:
In patients with a mean age of 50.38±13.53 (18-80), the probability of malignancy increased over the age of 52. There was no statistical difference between the sizes and locations of benign and malignant lesions ($p>0.05$). There was a statistically strong and significant correlation between BI-RADS and histopathological diagnosis ($p<0.0001$, $r=0.725$). The NPV for malignancy in BI-RADS 3 lesions was 93.5%, and the PPV for malignancy in BI-RADS 4 and 5 lesions was 61.4% and 96.7%, respectively.

Conclusions:
The NPV rate for malignancy in BI-RADS 3 lesions is relatively low. In BI-RADS 4 lesions, the PPV for malignancy is low because the lesion spectrum is quite wide, and the division into subcategories is subjective. The PPV for malignancy in BI-RADS 5 lesions is quite high.

Key Words:
Breast mass, BI-RADS, Breast tru-cut biopsy

ÖZ

Amaç:

Bu çalışmada, meme ultrasonografisi (US) ve mamografi ile BI-RADS (Breast Imaging Reporting and Data System) 3, 4 ve 5 olarak gruplandırılan ve US eşliğinde tru-cut biyopsi (TCB) yapılan lezyonlardaki histopatolojik ve radyolojik uyumluluğun araştırılması amaçlanmıştır.

Gereç ve Yöntemler:

Ocak 2019-Aralık 2022 tarihleri arasında US ve mamografi ile BI-RADS 3, 4 ve 5 meme lezyonu saptanan ve US eşliğinde TCB yapılan ardışık 196 kadın hasta retrospektif olarak taranarak çalışmaya dahil edildi. Lezyon lokalizasyonları, en büyük çapları, biyopsi sonuçları ve benign-malign lezyonların yaşla ilişkisi incelendi. BI-RADS 3 lezyonlarında malignite için negatif prediktif değer (NPD), BI-RADS 4 ve 5 lezyonlarında malignite için pozitif prediktif değer (PPD) hesaplandı.

Bulgular:

Yaş ortalaması 50,38±13,53 (18-80) olan hastalarda 52 yaş üzerinde malignite olasılığı artmaktadır. Benign ve malign lezyonların büyüklükleri ve lokalizasyonları arasında istatistiksel olarak fark izlenmedi ($p>0.05$). BI-RADS ile histopatolojik tanı arasında istatistiksel olarak güçlü ve anlamlı bir korelasyon vardı ($p<0.0001$, $r=0.725$). BI-RADS 3 lezyonlarda malignite için NPD %93,5 ve BI-RADS 4 ve 5 lezyonlarında malignite için PPD sırasıyla %61,4 ve %96,7 bulundu.

Sonuç:

TCB, BI-RADS 3, 4 ve 5 olarak gruplandırılan lezyonların tanısı için etkili ve güvenilir bir yöntemdir. BI-RADS 3 lezyonlarda malignite için NPD nispeten düşüktür. BI-RADS 4 lezyonlarda, lezyon spektrumunun genişliği ve alt kategorilere ayırmadaki subjektif kriterler nedeni ile malignite için PPD düşüktür. BI-RADS 5 lezyonlarda ise malignite için PPD oldukça yüksektir.

Anahtar Kelimeler:

Meme kitlesi, BI-RADS, Meme tru-cut biyopsi

INTRODUCTION

Breast cancer is the most common type of cancer in women and is responsible for many cancer-related deaths in women living in developed and developing societies (1). Breast cancers are usually epithelial tumors of ductal and lobular origin (2). Many breast cancers present with a palpable mass, an inflammatory lesion, nipple discharge, and mammographic abnormalities (3).

In recent years, breast lesions can be detected in smaller sizes with successful screening programs and high-resolution radiological imaging (4). The Breast Imaging Reporting and Data System (BI-RADS) guides radiological reporting of breast lesions and guides treatment. Classification comprises seven categories and provides communication between radiologists and clinicians (5, 6). Currently, excisional biopsy is not the first choice in the histopathological evaluation of breast lesions due to both the psychological and physiological stress on the patient and the cost (7, 8). Standard interventional methods in evaluating breast lesions suspicious for cancer are thin and thick needle biopsies. Most breast malignant lesions are solid, and tru-cut biopsy (TCB) is one of the basic methods to evaluate solid breast masses. TCB has high accuracy and has replaced fine needle aspiration biopsy over time due to the low number of controversial reports. TCB has high sensitivity and specificity. When malignancy is detected, it is easier to categorize cancer and receptor studies can be done easily. Thus, a better preoperative treatment plan can be made (9, 10).

This study aimed to investigate the histopathological and radiological compatibility of lesions evaluated as BI-RADS categories 3, 4, and 5 by breast ultrasonography (US) and mammography and in whom US-guided TCB was performed in the light of current literature.

MATERIAL and METHODS

This study retrospectively analyzed patients who underwent US-guided breast TCB in the Radiology Department of Isparta City Hospital between January 2019 and December 2022. Patients with BI-RADS 3, BI-RADS 4, and BI-RADS 5 breast lesions in the US and mammography were included in the study. Prior to the study, research permission was obtained from the Ministry of Health of the Republic of Turkey. After obtaining written permission from the hospital management, electronic hospital data were examined. This research complies with all the relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration, and was approved by the Süleyman Demirel University Faculty of Medicine Ethics Committee (approval number: 44-06.03.2023). Breast lesions were radiologically grouped as BI-RADS 3, BI-RADS 4, and BI-RADS 5 (Figure 1).

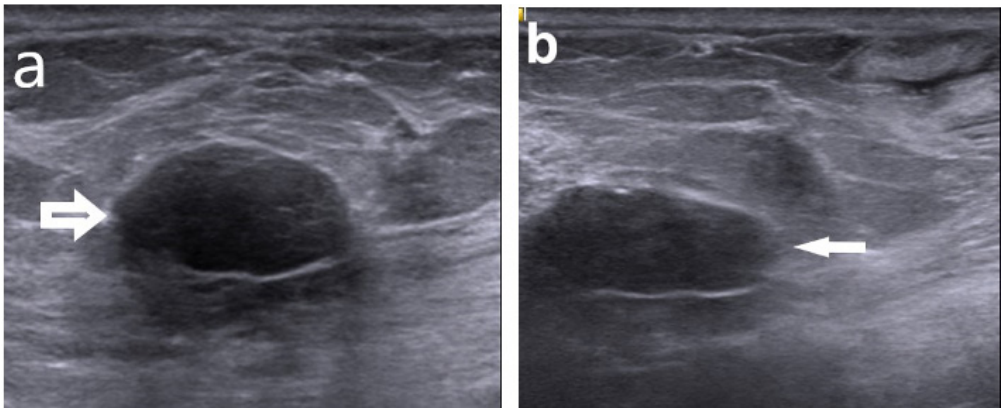

Figure 1. a: A BI-RADS 3 oval mass (white arrow), with circumscribed margins and parallel orientation. b: A BI-RADS 4 oval shaped hypoechoic mass (white arrow) with an indistinct margin.

The location of the lesion in the breast is right and left: upper outer quadrant, upper inner quadrant, lower outer quadrant, lower inner quadrant, and retroareolar region. Patients were grouped into decades according to age. The relationship between benign and malignant lesions and age was evaluated. The largest diameter of the lesions was recorded. All patients were informed in detail before the procedure, and their written consent was obtained. The patients were questioned regarding allergy history, bleeding diathesis, and drug use. A biopsy was performed in all patients using a US (Toshiba Aplio 500; Toshiba Medical Systems, Tokyo, Japan) device and an 11–5 MHz high-frequency linear surface probe. A sterile sheath was placed on the US probe, and the patients were placed in the supine or decubitus position, depending on the localization of the lesion.

The biopsy site was sterilized with polyvinyl iodide, and 2-5 ml of local anesthesia was applied to the skin and subcutaneous region with a 21 G needle (0.80 x 38 mm, 5 ml) under US guidance.The biopsy procedure was performed with 14, 16, and 18 G, 10-15 cm fully automatic biopsy guns (Geotek Estacore, (Ankara, Turkey) (Figure 2).

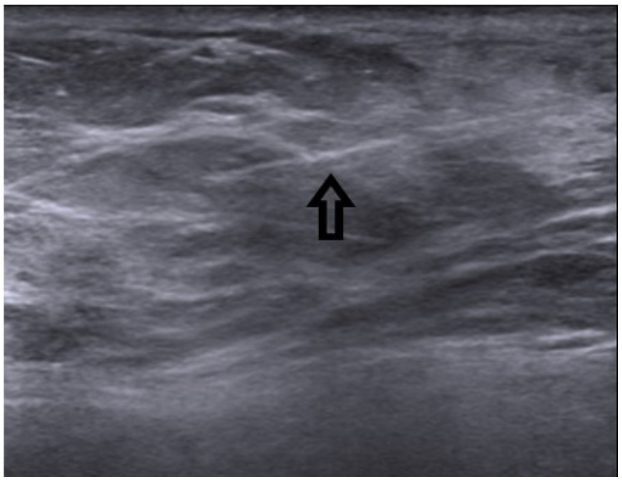

Figure 2. Ultrasound image shows echogenic biopsy needle (black arrow).

With a pointed scalpel, an incision was made as far as the needle could enter, and the needle was advanced to the edge of the mass by real-time tracking along the long axis of the probe. At least two samples were taken from each lesion, with the system penetrating 22 mm into the lesion and taking 17 mm long samples. The samples were sent to the pathology laboratory in formol solution in a closed container without damaging their integrity. At the end of the procedure, the needle entry site was covered with a sterile sponge and compressed for about 10 minutes.

The patients were informed about possible complications and asked to come for control in cases of skin discoloration, severe pain, persistence of pain, and stiffness. After the histopathological examination, the lesions were grouped as malignant and benign, and benign and malignant diagnoses were recorded. A negative predictive value (NPV) for malignancy in BI-RADS 3 lesions and a positive predictive value (PPV) in BI-RADS 4 and 5 lesions were calculated.

Statistical Analysis

Statistical analyses were performed using SPSS (Statistical Package for the Social Sciences) 26.0 software. The conformity of the variables to the normal distribution was examined by visual and analytical methods (Kolmogorov-Smirnow and Shapiro-Wilk tests). Descriptive statistics of subjects were given as numbers and percentages for categorical variables, median (min-max), and mean standard deviation for continuous variables. The relationship between BI-RADS and histopathological values, with data on descriptive features, was investigated by logistic regression analysis. Positive and negative predictive values were calculated to evaluate the diagnostic performance of a tru-cut biopsy according to the BI-RADS classification. The relationship between categorical variables was assessed with the Pearson correlation test. A p-value less than 0.05 was considered statistically significant.

RESULTS

The study included 196 patients with BI-RADS 3, BI-RADS 4, and BI-RADS 5 breast lesions in the US and mammography. Thirty-seven patients in whom US and mammography were done at other hospitals, with a history of a breast biopsy, pathologically inadequate or suspicious results, or a history of breast surgery were excluded. The mean age of the 196 patients included in the study was 50.38±13.53 (18-80). The age range with the highest number of patients was the fifth decade (Table I).

Table I. Distribution of patient ages by decade

Age Range	Number of Patients	Percentage (%)
11-20	1	0.5
21-30	14	7.1
31-40	30	15.3
41-50	57	29.1
51-60	50	25.5
61-70	27	13.8
71-80	17	8.7

The logistic regression analysis observed a significant relationship between the patient's age and the pathological diagnosis. In the ROC analysis, 52 years was determined as the cut-off value in the distinction between benign and malignant. The "p" value was below 0.001, and the area under the curve (AUC) was calculated as 0.774 (Figure 3).

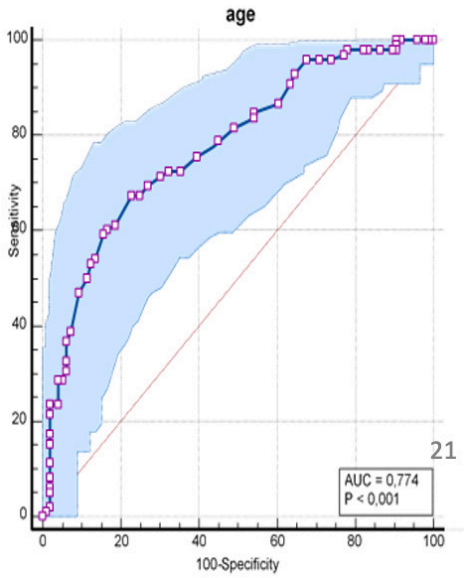

Figure 3. ROC analysis of patient age.

The lesion size ranged from 5 mm to 70 mm, with an average size of 20.24±12.64 mm. There was no statistically significant difference between the sizes of malignant and benign lesions (p> 0.05). 103 (52.6%) of the lesions were on the right, and 93 (47.4%) were on the left. The masses were in the upper outer quadrant in 117 (59.7%) patients. There were 27 lesions (13.8%) in the lower inner quadrant, 21 (10.7%) in the upper inner quadrant, 20 (10.2%) lesions in the lower outer quadrant, and 11 (5.6%) lesions in the retroareolar region.

There was no statistical difference between the localization of benign and malignant lesions in the breast (p>0.05).

In the radiological examination, 78 (39.8%) of the lesions were classified as BI-RADS 3, 57 (29.1%) as BI-RADS 4, and 61 (31.1%) as BI-RADS 5. In the histopathological examination, 96 (49%) of the lesions were benign, 98 (50%) were malignant, and 2 (1%) were ductal carcinoma in situ (DCIS). Of the malignant cases, 94 (95.9%) non-specific invasive ductal carcinomas, 3 (3%) lobular carcinomas, and 1 (1.1%) mucinous carcinoma were detected. 52 (54.2%) of the 96 benign lesions were fibrocystic changes (Table II).

Table II. Frequencies of benign and malignant diagnoses in the patient population

	Number of diagnoses	Percentage (%)
Invasive ductal carcinoma, NST	94	47.96
Lobular carcinoma	3	1.53
Mucinous carcinoma	1	0.51
Ductal carcinoma in situ	2	1.02
Fibrocystic changes	52	26.53
Epithelial hyperplasia	7	3.57
Fibroadenoma	23	11.73
Inflammation	14	7.14
Total	**196**	**100**

Abbreviations: NST; No special type

The frequencies of malignant and benign lesions in BI-RADS 3, 4, and 5 groups, excluding lesions diagnosed as DCIS, are shown in Figure 4.

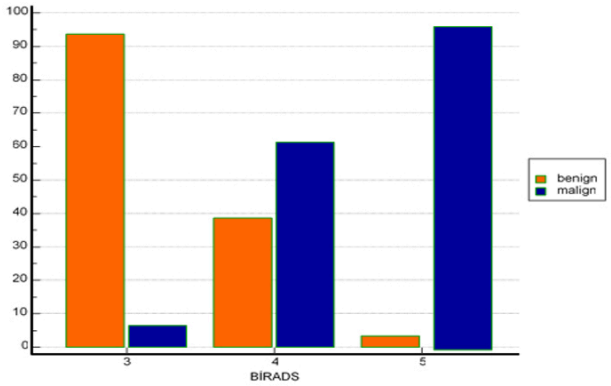

Figure 4. Benign/malignant diagnosis frequencies in BI-RADS 3, 4, and 5 lesions.

A statistically strong and significant correlation was found between BI-RADS and histopathological diagnosis (p<0.0001, r = 0.725) (Table III).

Table III. Relationship between BI-RADS classification and histopathological diagnosis

	BI-RADS			p value
Histopathological diagnosis	**3**	**4**	**5**	
Benign	72 (92.3%)	22(38.6%)	2 (3.3%)	0.0001
Malign	5 (6.4%)	35 (61.4%)	58 (95.1%)	
DCIS	1 (1.3%)	0 (0%)	1 (1.6%)	

Abbreviations: DCIS; Ductal carcinoma in situ

The NPV for malignancy in the BI-RADS 3 group was 93.5%, and the PPV for malignancy in the BI-RADS 4 and 5 groups was 61.4% and 96.7%, respectively. Fourteen G biopsy needles were used in two (1%) patients, 16 G needles in 13 (6.6%) patients, and 18 G biopsy needles in 181 (92.3%) patients. In three (1.5%) patients, hematomas were detected, which resorbed in approximately 20 days and bothered the patients significantly. Minor hematomas with slight skin discoloration and mild hardness on palpation were observed in 18 (9.2%) patients. Pseudoaneurysm was observed in 1 (0.5%) patient in whom 14 G needle were used.

DISCUSSION

The results of the present study showed that patient age was significantly related to the pathological diagnosis, with a cut-off value of 52 years distinguishing between benign and malignant cases. Lesion size did not differ significantly between malignant and benign cases. The localization of lesions in the breast did not show a statistical difference between benign and malignant cases. The BI-RADS classification showed a strong and significant correlation with the histopathological diagnosis, with a high negative predictive value (93.5% in BI-RADS 3) and a positive predictive value (96.7% in BI-RADS 5) for malignancy. The majority of benign lesions were fibrocystic changes.

US-guided TCB is the preferred method primarily because it can be performed quickly and is an inexpensive method for the diagnosis of breast lesions (11). During the procedure, while the needle enters the tissue, the piece triggered by the spring system cuts the tissue and collects it in the area inside the needle. The TCB method can be applied together with US, stereotaxic, or magnetic resonance imaging (MRI). The US-guided method is faster and more comfortable, and it is used more frequently than other methods. 14–18 G needles can be used in breast biopsies (12–14). Pathological evaluation can be made with high accuracy with appropriate samples. In addition, when malignancy is detected, it is easier to type the cancer, and receptor studies can be done easily. Thus, the most appropriate preoperative treatment planning is possible (2).

When the patient ages were grouped according to decades, as in the studies of Radhakrishna et al. and Chaitanya et al., the group with the highest frequency of patients in our study was the 5th decade (2, 15). In our study and that of Radhakrishna et al. and Eda Elverci et al., the most frequently detected benign lesion was fibrocystic changes (2, 16).
Fifty-two (26.53%) of 196 lesions were reported as fibrocystic changes. The most common malignant diagnosis in our study was invasive ductal carcinoma, which constituted 47.96% of all lesions. This was similar to most studies in the literature (2, 15–19) (Table IV).

Table IV. Number of cases in our study and some studies in the literature, the most common benign and malignant lesions

Study	Number of cases	Most common benign lesion	Most common malignant lesion
Selvi Radhakrishna et al.[2]	437	Fibrocystic disease	Invasive ductal carcinoma
Sarangan et al.[17]	106	Fibroadenoma	Invasive ductal carcinoma
Eda Elverci et al.[16]	186	Fibrocystic disease	Invasive ductal carcinoma
Kim MJ et al.[18]	71	Fibroadenoma	Invasive ductal carcinoma
Arsalan et al.[19]	50	Ductal hyperplasia	Invasive ductal carcinoma
Chaitanya et al.[15]	100	Fibroadenoma	Invasive ductal carcinoma
Present study	196	Fibrocystic disease	Invasive ductal carcinoma

Breast cancer is one of the cancers whose incidence increases with age. For this reason, it is recommended that patients under the age of 40, without any risk factors and evaluated as BI-RADS 3, be followed up without any intervention (20). In our study, the threshold value was found to be 52 in the ROC analysis for the evaluation of benign and malignant lesions according to age. Accordingly, the probability of malignant lesions increases significantly in patients over 52 years of age. Our data are compatible with the literature and show similarities with the increase in the incidence of breast cancer in the population according to age. However, in addition to mammography, breast US and MRI would be appropriate for the lesions to be classified as BI-RADS 3. The BI-RADS 3 classification continues to be an important problem for radiologists and clinicians, especially in young patients who are out of follow-up due to the malignant biopsy result (5). The probability of malignancy in BI-RADS 3 lesions is less than 2%. In our study, the pathology was reported as benign in 72 (92.3%) of 78 (39.8%) lesions evaluated as BI-RADS 3. The NPV for malignancy in BI-RADS 3 lesions was 93.5%. The comparison of the NPV we found for malignancy in BI-RADS 3 lesions with some studies in the literature is presented in Table V. We think that the negative predictive value for malignancy may be higher with advanced imaging methods such as breast MRI and elastography. This may be the reason why the NPV was relatively low in our study. In our study, 35 (61.4%) of the lesions evaluated as BI-RADS 4 were diagnosed as malignant, and 22 (38.6%) were diagnosed as benign. The malignancy rate in BI-RADS 4 lesions is reported to be 2–95%. Malignancy rates in this study were consistent with the literature. Since most of the lesions in this group are benign lesions, it would be beneficial to evaluate mammographic and ultrasonographic findings together with advanced radiological examinations. Breast MRI, which provides high soft tissue resolution, is important in the evaluation of these lesions because it offers dynamic examination and includes some special sequences such as diffusion. Breast elastography is also an important test that has been reported to be useful in the differentiation of malignant and benign lesions (21, 22). BI-RADS 4 lesions are subdivided

into BI-RADS 4a, 4b, and 4c and include many lesions, including inflammatory lesions, breast abscesses, and hyperplasia. There are no definitive diagnostic criteria for subgroups, and discrimination is made according to the suspicion of malignancy by the radiologist and clinician (16, 23). Eda Elverci et al. reported that the PPV for malignancy in BI-RADS 4 lesions was 38.7%, while Sarangan et al. reported it as 56.25% (16, 17). In our study, the PPV for malignancy in BI-RADS 4 lesions was found to be 61.4%, and its comparison with some studies in the literature is given in Table V. When BI-RADS 4 lesions are sub-categorized as BI-RADS 4a, 4b, and 4c and histopathologically correlated with BI-RADS 4b and 4c lesions, the PPV for malignancy will be higher (23). In our study, no subgrouping was performed for BI-RADS 4 lesions.The probability of malignancy in BI-RADS 5 lesions is over 95%, and 58 (95.1%) of the lesions evaluated as BI-RADS 5 in our study were diagnosed as malignant, and 2 (3.3%) were diagnosed as benign. Selvi Radhakrishna et al. reported the PPV for malignancy in BI-RADS 5 lesions as 93.25%, Kim MJ et al. over 95%, and Chaitanya et al. as 100% (2, 15, 18). In our study, PPV for malignancy was found to be high in BI-RADS 5 lesions, consistent with the literature, and it was 96.7% (Table V).

Table V. Negative predictive value and positive predictive value of tru-cut biopsy for malignancy in BI-RADS 3, 4, and 5 lesions

Authors	BI-RADS 3 NPV	BI-RADS 4 PPV	BI-RADS 5 PPV
Selvi RadhaKrishna et al[2]	98.5%	70%	93%
Sarangan et al[17]	82.9%	56.2%	95%
Eda Elverci et al [16]	97%	38.7%	100%
KimMJ et al [18]	87.5%	58%	100%
Arsalan et al [19]	82.5%	33.3%	100%
Chaitanya et al [15]	87.5%	49%	100%
Present Study	93.5%	61.4%	96.7%

Abbreviations: NPV; Negative predictive value, PPV; Positive predictive value

Local anesthesia complications and allergic reactions (toxicity, local allergic reactions, idiosyncrasy, anaphylactic shock) may occur during or immediately after the TCB procedure. Infection, abscess, hematoma, aneurysm development, and anxiety are other complications of the procedure (24, 25). Intravenous injection and hematoma development resulting from extravasation are the most common complications related to local anesthesia injection (26). In the literature, bleeding is reported as the most common complication after the TCB procedure, followed by infection as the second. It has been emphasized that complications such as aneurysms, fistulas, and necrotizing infections are rare (25, 27). The most important complications in our study were hematoma in 3 patients and pseudoaneurysm in 1 patient, which bothered the patient significantly and resorbed in approximately 20 days. A 14-gauge needle was used in the patient who developed a pseudoaneurysm. In this patient, the vascularity of the lesion, which was found to be malignant as a result of a biopsy, was significantly higher. We think that pseudoaneurysms developed due to the use of thick needles in the lesion with increased vascularity. Minor skin discoloration and minor hematomas felt as mild hardness on palpation occurred in 18 patients. The incidence of hematoma in our study is lower than in the literature, and we think that this is mostly due to the use of an 18-gauge needle in the biopsy procedure and the significant compression applied to the biopsy site for about 10 minutes.

Limitations of study

This study has a retrospective design, which may introduce selection bias and limit the generalizability of the findings. The study also had a relatively small sample size, which may affect the statistical power and precision of the results. Additionally, the study did not utilize advanced imaging techniques such as breast MRI and elastography, which could provide additional information for the evaluation of breast lesions. Furthermore, the study did not subcategorize BI-RADS 4 lesions, which may have influenced the accuracy of predictions for this category. Future research with larger sample sizes and prospective designs, including the use of advanced imaging methods and subclassification of BI-RADS 4 lesions, would be beneficial to further validate the findings of this study.

CONCLUSION

Breast tru-cut biopsy is an effective and reliable invasive method used in the diagnosis of lesions grouped as BI-RADS 3, 4, and 5 using US and mammography. The NPV rate for malignancy in BI-RADS-3 lesions is relatively low. Higher NPV can be achieved with the use of additional radiological methods such as breast MRI and elastography. In BI-RADS 4 lesions, PPV is low due to the wide lesion spectrum and subjective criteria for subcategorization. With more objective and clear rules for subclassification, more accurate predictions can be obtained for BI-RADS 4 lesions. In BI-RADS 5 lesions, the PPV for malignancy is quite high.

Ethics Approval:
The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Süleyman Demirel University Faculty of Medicine (44-06.03.2023).

Conflict of Interest:
The Authors declare that they have no conflict of interests.

Informed Consent:
Informed consent was obtained from all individual participants included in the study.

Availability of Data and Materials:
The datasets generated and analyzed during the current study are available from the corresponding author, (T.B.), upon reasonable request.

Funding:
This research received no external funding. The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. No writing assistance was utilized in the production of this manuscript.

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