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Retrospective Evaluation of Coaxial Core Needle Biopsy Results Performed on Mammographic Suspicious Microcalcifications of the Breast

Memenin Kuşkulu Mikrokalsifikasyonlarına Mamografide Yapılan Koaksiyel Kalın İğne Biyopsi Sonuçlarının Retrospektif Değerlendirilmesi

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Abstract

Objective: Breast microcalcifications (MCs) are detected in approximately one-third of screening mammograms and are associated with about 40% of breast cancers. The gold-standard procedure for histopathological evaluation of MCs is stereotactic vacuum-assisted biopsy; however, it is costly and not easily accessible. The aim of this study was to evaluate the feasibility of stereotactic coaxial core needle biopsy (CNB), a less expensive and simpler technique, for MCs detected on mammography and to investigate its specificity, positive predictive value (PPV), negative predictive value (NPV), and sensitivity.

Methods: Between 2020 and 2024, 76 who underwent stereotactic coaxial CNB for breast imaging reporting and data system (BI-RADS) category 4-5 MCs detected on mammography were retrospectively reviewed.

Results: The specificity and PPV of the biopsy procedure were 100%, while the sensitivity and NPV were 71.4% and 85.7%, respectively. A calcification size of ≤10 mm (p=0.077) and obtaining ≥10 samples (p=0.034) were found to be significant factors for biopsy accuracy. Segmental distribution, fine pleomorphic and fine linear morphologies, and BI-RADS categories 4C and 5 were significantly associated with malignancy (p<0.001).

Conclusion: For MCs detected on mammography that are suspected to be malignant but not localized by ultrasonography, coaxial CNB performed under mammographic guidance provides high diagnostic accuracy and reliability.

Keywords: Mammography, microcalcification, core needle biopsy, breast cancer

Öz

Amaç: Meme mikrokalsifikasyonları (MK), tarama mamogramlarının yaklaşık üçte birinde tespit edilir ve meme kanserlerinin %40'ı ile ilişkilidir. MK histopatolojik yaklaşımda altın standart işlem sterotaktik vakum aspirasyon biyopsisidir fakat erişimi zor ve yüksek maliyetlidir. Bu çalışmanın amacı, mamografide saptanan MK'lara ucuz ve kolay bir teknik olan sterotaktik koaksiyel kalın iğne biyopsinin (KİB) kullanılabilirliğini değerlendirme özgüllüğü, pozitif öngörü değer (PPD), negatif öngörü değer (NPD), duyarlılığını araştırmaktır.

Yöntem: 2020-2024 yılları arasında, mamografide saptanan meme görüntüleme raporlama ve veri sistemi (BI-RADS) 4-5 MK'lara sterotaktik koaksiyel KİB yapılan 76 olgu retrospektif olarak taranmıştır.

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Öz

Bulgular: Biyopsi işleminin özgüllüğü ve PPD'i %100 bulunmuştur. Duyarlılığı %71,4, NPV'i %85,7 bulunmuştur. Kalsifikasyon boyutunun 10 mm ve altında olması biyopsi parça sayısının 10 ve üzerinde olması biyopsi doğruluğu için anlamlıydı (p=0,077, p=0,034). Dağılımının segmental, morfolojik bulgularının ince pleomorfik ve ince lineer olması, BI-RADS 4C ve 5 katagori malignite için anlamlıydı (p<0,001).

Sonuç: Mamografide saptanıp ultrasonografi ile lokalize edilemeyen malignite şüpheli MK'larda mamografide yapılan koaksiyel KİB'si, yüksek doğruluk ve güvenilirlik sunmaktadır.

Anahtar Kelimeler: Mamografi, mikrokalsifikasyon, kalın iğne biyopsi, meme kanseri

Introduction

Mammography is the primary imaging modality for the screening and early diagnosis of breast cancer[1,2]. On mammographic examination, microcalcifications (MCs), architectural distortions, and asymmetries-which may not be detected on ultrasonography-can be identified and are considered important indicators of early breast cancer[3].

According to the breast imaging reporting and data system (BI-RADS) classification system proposed by the American College of Radiology to standardize breast imaging reporting, high-risk breast lesions categorized as BI-RADS 4A, 4B, 4C, or 5 may represent ductal carcinoma *in situ* (DCIS) and/or invasive breast carcinoma; therefore, histopathological confirmation is required[4]. In the diagnosis of these lesions, core needle biopsy (CNB) methods are increasingly used. CNB is a rapid, easy-to-perform, cost-effective biopsy technique that is well tolerated by patients. However, for lesions detected only on mammography, the biopsy procedure must be performed under stereotactic guidance[5].

Obtaining an adequate tissue sample during biopsies of MCs is often challenging. Liberman et al.[6] showed that using 14-gauge needle biopsies, five biopsy samples were sufficient to achieve a definitive diagnosis in 99% of the 92 mass lesions, whereas only 53% of the 87 calcification clusters could be diagnosed with a similar tissue volume.

Unlike in ultrasound-guided procedures, needle localization is not possible in stereotactic biopsies. Therefore, to ensure procedural success, as much tissue as possible must be obtained. In stereotactic CNB, unlike vacuum-assisted biopsy (VAB), the biopsy gun is removed from the breast after each sampling; it is then reinserted and fired again for the next sample[7]. Therefore, the VAB technique is currently the preferred choice[5]. However, due to the high cost of the VAB unit and vacuum biopsy needles, access to this method is limited[8]. The cost of VAB is reported to be 2.2 to 12.5 times higher than that of CNB[9]. In one study, VAB demonstrated 100% specificity, 91.3% sensitivity, and 100% positive predictive value (PPV) in detecting malignant lesions, with an negative predictive value (NPV) of 80%[10]. Another study comparing stereotactic CNB and VAB found that for the VAB group, the overall PPV was 100%, the NPV was 95.8%, and the diagnostic accuracy was 97%, whereas for the CNB group, the PPV was 100%, the NPV was 80%, and the diagnostic accuracy was 84.8%[11]. CNB is a cost-effective procedure with a substantially lower complication rate. In our study, we performed the procedure under coaxial needle guidance, allowing multiple samples to be obtained from the same location without changing the entry site. Since only 22.4% of histopathological evaluations of MCs yield a malignant diagnosis, cost-effective procedures associated with fewer complications should be preferred[12].

The aim of this study was to investigate the specificity, PPV, sensitivity, and NPV of the minimally invasive coaxial CNB procedure performed for suspicious MCs detected on mammography. In this way, we aimed to provide a more cost-effective and more easily accessible approach for the evaluation of suspicious MCs detected on mammography.

Materials and Methods

Ethical approval for this retrospective study was obtained from the Non-Interventional Clinical Research Ethics Committee of İzmir Katip Çelebi University (approval no: 0183, date: 25.04.2024).

Patient Selection

Between December 2020 and December 2024, the records of patients with BI-RADS category 4A-C and 5 lesions visible only on mammography who underwent stereotactic coaxial needle-guided CNB were retrospectively reviewed. To identify patients with mammographic MCs, our institutional database was queried. Exclusion criteria included the presence of a mass on imaging, a palpable mass on clinical examination, a mass detectable on ultrasound, an associated opacity on

mammography, and lack of available surgical pathology results at our institution. The gold-standard diagnostic method is surgical excision. For the 76 retrospectively reviewed patients, the following parameters were evaluated: the distribution and morphological characteristics of calcifications detected on mammography, size of the calcifications, BI-RADS category of the lesions, presence of calcifications on specimen mammography, number of biopsy samples obtained, presence of calcifications in pathology results, biopsy pathology findings, surgical excision pathology results, and follow-up findings.

Patients whose biopsy results were benign and radiologic–pathologic concordant were followed for at least 12 months.

Stereotactic Coaxial CNB Procedure on Mammography

The biopsy procedure was performed by a single radiologist with five years of breast radiology experience. Before the biopsy, all patients were informed about the procedure and provided written informed consent. Coagulation parameters were assessed. Mammography and biopsy procedures were performed using an IMS Giotto mammography device (Bologna, Italy). A 14-gauge semi-automatic coaxial biopsy needle (Geotek 14G, 15 cm) was used. After identifying the lesion on mediolateral projection, the biopsy area was cleaned with povidone-iodine (Betadine), locally anesthetized with 3-4 cc of prilocaine, and a small incision was made. Through this incision, under stereotactic guidance, the lesion was marked in the appropriate position using the coaxial needle. After determining the lesion depth with a craniocaudal projection, multiple samples were obtained sequentially from the center of the lesion using a 14-gauge core needle-guided by the coaxial system, with small angular adjustments to the right and to the left. The obtained samples were placed on a slide, and specimen mammography was performed to evaluate the presence of MCs. After assessment, the samples were placed in formalin and sent to the pathology laboratory (Figure 1). Post-surgical pathology results were used as the gold-standard, and specificity, PPV, and NPV were evaluated accordingly.

Data Analysis

The evaluation of findings was performed according to the 5th edition of the BI-RADS classification. On mammography, the distribution (diffuse, regional, linear, segmental, grouped) and morphologic types (amorphous, coarse heterogeneous, fine pleomorphic, and fine linear branching) of MCs were recorded according to BI-RADS criteria.

The histopathological diagnosis was obtained from coaxial CNB and from post-surgical specimens. Histopathological evaluations were performed by experienced breast pathologists. Among the 76 patients, those whose biopsy results revealed invasive carcinoma or DCIS were classified as the malignant group. Patients diagnosed with malignancy were referred for surgical excision. For lesions diagnosed as benign on CNB, radiologic-pathologic concordance was assessed. Cases showing radiologic-pathologic discordance or persistent suspicion of malignancy were also referred for surgical excision. Cases with radiologic-pathologic concordance were followed up for at least 12 months. No lesion showed an increase in size during follow-up. Cases

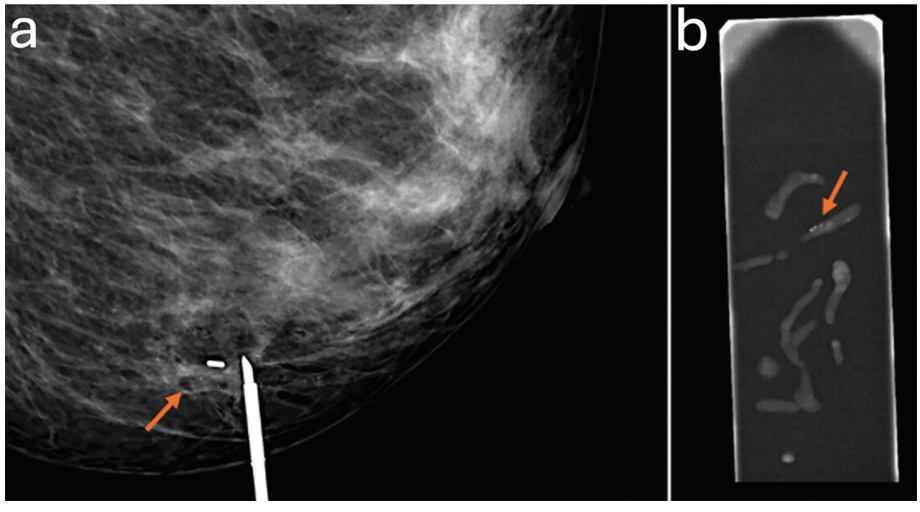

Figure 1. a) Tru-cut biopsy performed with a 14G needle in a case with segmental fine linear calcifications. b) Specimen radiograph (orange arrow indicates the calcification)

Diagnosis: Ductal carcinoma in situ with intermediate nuclear grade

that remained stable during follow-up were classified as benign.

Statistical Analysis

Descriptive statistics for qualitative variables in the study were presented as numbers and percentages. Relationships between qualitative variables were analyzed using the Pearson chi-square test and Fisher's exact test. The performance of the index test was evaluated against the reference standard (gold-standard) using 2×2 contingency tables. Sensitivity, specificity, PPV, and NPV were calculated based on standard definitions, and 95% confidence intervals were calculated.

The agreement between the index test and the gold-standard was assessed using Cohen's Kappa coefficient. A p-value <0.05 was considered statistically significant. All calculations were performed using the SPSS software package (version 28).

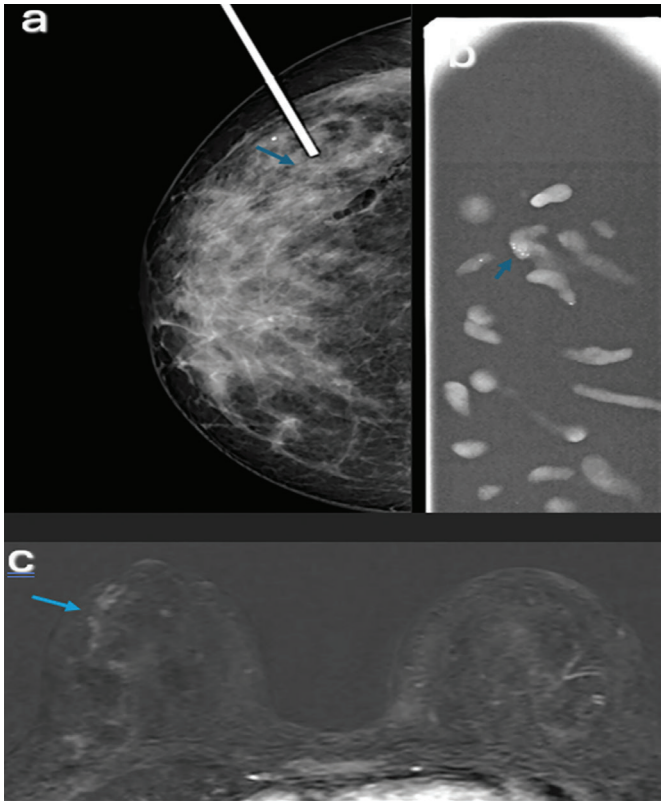

Figure 2. a) Stereotactic coaxial biopsy performed on a BI-RADS 4C calcification area showing fine pleomorphic regional distribution on mammography. b) Detection of calcification on the specimen radiograph. c) Contrast enhancement observed in the same area on MRI

BI-RADS: Breast imaging reporting and data system, MRI: Magnetic resonance imaging

Results

The mean age of the patients was 54.1±8.6 years (range: 40-76 years). Procedures were performed on the right breast in 39 patients (51.3%) and on the left breast in 37 patients (48.6%). Among the 76 cases, 56 (73.7%) were diagnosed as benign, and 20 (26.3%) as malignant. Biopsy results showed 15 cases of DCIS and 5 cases of invasive ductal carcinoma

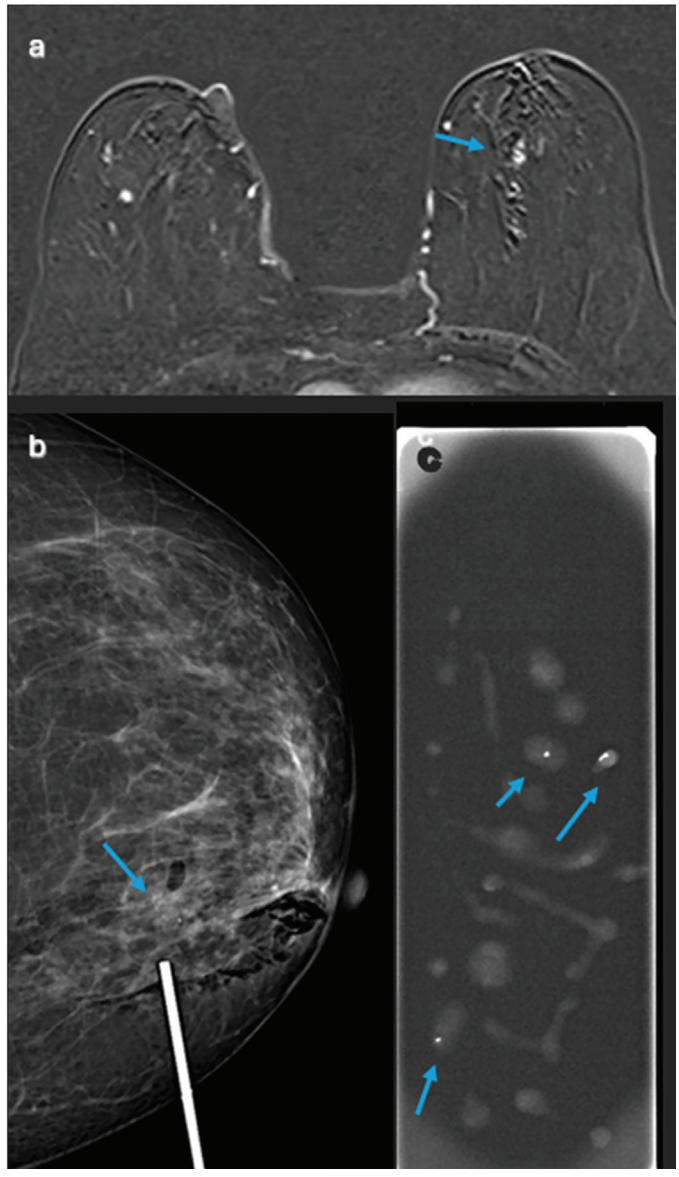

Figure 3. a) Non-mass enhancement observed on MRI. b) Stereotactic coaxial biopsy performed on a BI-RADS 4C calcification area showing fine pleomorphic segmental distribution on mammography. c) Detection of calcification on the specimen radiograph

BI-RADS: Breast imaging reporting and data system, MRI: Magnetic resonance imaging

among the malignant lesions. Among benign lesions, there were 3 cases of sclerosing adenosis (SA), 5 cases of atypical ductal hyperplasia (ADH), 2 cases of lobular carcinoma *in situ* (LCIS), 1 case of fat necrosis, 1 case of intraductal papilloma, and 44 other benign findings (such as fibrocystic changes or benign breast tissue). Surgical pathology results revealed 13 invasive ductal carcinomas, 15 DCIS, 1 calcified fibroadenoma, 3 LCIS, SA, 3 ADH, 1 atypical lobular hyperplasia, 1 intraductal papilloma, and 7 benign lesions. Twenty-eight patients were followed up without surgical intervention. All MCs diagnosed as malignant by CNB were referred for surgical excision (Figures 2 and 3). Among the 56 cases diagnosed as benign, 28 that showed no change in size or morphology during 1-2 years' follow-up were considered stable.

Mammographic and Biopsy Findings

Among the 76 patients included in the study, when biopsy results were compared with the gold-standard, the biopsy sensitivity for detecting malignant lesions was 71.4% and the specificity was 100%. The PPV was 100%, and the NPV was 85.7%. No false-positive cases were identified. The Kappa coefficient was 0.759, indicating strong agreement between the biopsy results and the gold-standard (Tables 1-2).

When calcifications observed in the specimens were compared with those in the pathology results, sensitivity was 100% and specificity was 71.4%. The PPV was 73.9% and the NPV was 100%. These results show that all cases in which calcifications were detected on specimen examination were also confirmed by pathological findings (Table 3).

When calcification size was evaluated in relation to biopsy accuracy, concordance between biopsy and the gold-standard was observed for MCs measuring ≤10 mm (52.9%), whereas discordance was found for MCs measuring 10-20 mm (17.6%) and >20 mm (29.4%) (p=0.004).

When the number of biopsy samples was evaluated, a statistically significant discordance between biopsy and gold-standard results was observed in cases with 10 or more samples: 7.4% (p=0.034). Although not statistically significant, the highest concordance (60.3%) was observed in cases with 5-10 samples. When the presence of calcifications in the specimen was compared with the biopsy (gold-standard) concordance, no significant difference was observed (p=1.000). Similarly, no significant difference was found between detection of calcifications on pathological examination and concordance with the biopsy gold-standard; (p=0.285; Table 4).

According to the gold-standard results, the regional distribution rate of malignant lesions (46.4%) and the grouped distribution rate of benign lesions (72.9%) were statistically significant (p=0.002). Regarding morphological features, malignant lesions showed significantly higher rates of pleomorphic (35.7%) and fine linear (64.3%) calcifications, whereas benign lesions more frequently exhibited coarse (35.4%) and amorphous (41.7%) calcifications (p<0.001). In terms of BI-RADS categories, malignant lesions were significantly more frequently classified as BI-RADS 4C (78.6%) and BI-RADS 5 (21.4%), whereas benign lesions were more frequently categorized as BI-RADS 4A (43.8%) and BI-RADS 4B (29.2%) (p<0.001) (Table 5).

Table 1. The relationship between the biopsy procedure and the gold-standard surgical pathology

Biopsy result	Malignant	Benign	Total
Malignant	20 71.4%	0 0.0%	20 26.3%
Benign	8 28.6%	48 100.0%	56 73.7%
Total	28 100.0%	48 100.0%	76 100.0%

Table 2. Diagnostic performance of the biopsy procedure

Metric	Value	95% CI
Sensitivity	0.714	(0.529-0.847)
Specificity	1.000	(0.926-1.000)
PPV	1.000	(0.839-1.000)
NPV	0.857	(0.743-0.926)
Kappa	0.759	-

CI: Confidence interval, PPV: Positive predictive value, NPV: Negative predictive value

Table 3. The relationship between the detection of calcification in the specimen and the presence of calcification in pathology

Specimen	Pathology: calcification present	Pathology: calcification absent	Total
Calcification present	34 100.0%	12 28.6%	46 60.5%
Calcification absent	0 0.0%	30 71.4%	30 39.5%
Total	34 100.0%	42 100.0%	76 100.0%

Table 4. The relationship between variables and the concordance between biopsy and the gold-standard

Variable	Category	Incorrect (count, %)	Correct (count, %)	p-value
Calcification size	<10 mm 10-20 mm >20 mm	0 (0.0%) 4 (50.0%) 4 (50.0%)	36 (52.9%) 12 (17.6%) 20 (29.4%)	0.004
Number of samples	<5 5-10 >10	1 (12.5%) 4 (50.0%) 3 (37.5%)	22 (32.4%) 41 (60.3%) 5 (7.4%)	0.034
Specimen calcification	Present Absent	5 (62.5%) 3 (37.5%)	41 (60.3%) 27 (39.7%)	1.000
Pathology calcification	Present Absent	2 (25.0%) 6 (75.0%)	32 (47.1%) 36 (52.9%)	0.285

Table 5. The relationship between calcification morphology, distribution, and BI-RADS category with the gold-standard pathology result

Variable	Category	Malignant (count, %)	Benign (count, %)	p-value
Distribution	Diffuse Regional Segmental Linear Grouped	0 (0.0%) 13 (46.4%) 3 (10%) 5 (17.9%) 7 (25.0%)	0 (0.0%) 10 (20.8%) 1 (2.1%) 2 (4.2%) 35 (72.9%)	<0.001
Morphology	Coarse Amorphous Pleomorphic Fine linear	0 (0.0%) 0 (0.0%) 10 (35.7%) 18 (64.3%)	17 (35.4%) 20 (41.7%) 6 (12.5%) 5 (10.4%)	<0.001
BI-RADS	4A 4B 4C 5	0 (0.0%) 0 (0.0%) 22 (78.6%) 6 (21.4%)	21 (43.8%) 14 (29.2%) 13 (27.1%) 0 (0.0%)	<0.001

BI-RADS: Breast imaging reporting and data system

Discussion

Suspicious MCs detected on mammography are an important indicator in the diagnosis of early-stage breast cancer. In this study, the diagnostic performance of coaxial CNB results for BI-RADS 4-5 MCs detected on mammography was compared. The biopsy procedure, with its high specificity and PPV, is considered the gold-standard diagnostic method. In addition, the morphological and distributional characteristics of the MCs were statistically evaluated for correlation with pathological findings. This study demonstrated that coaxial needle CNB, performed under mammographic guidance, is a highly specific technique with strong clinical reliability.

VAB is recommended for the diagnosis of suspicious MCs, given its high diagnostic accuracy[8]. In the study by Göksu et al.[13] pathology results among 53 patients with BI-RADS 3-4 MCs detected on mammography revealed 47 benign and 6 premalignant or *in situ* lesions. A total of 89% of the MCs were reported as benign; two cases developed procedure-related complications[13]. In the study by Thakkar et al.[14] VAB results showed 100% specificity, 96% sensitivity, and a high NPV. Histopathologically, 42% of the lesions sampled by VAB were malignant and 58% were benign. A hematoma developed in 42 patients, but no other major complications were reported[14]. In the meta-analysis conducted by Yu et al.[15] which included 21 studies, the sensitivity and specificity of VAB were reported as 98% and 99%, respectively.

When CNB and VAB are compared in patients diagnosed with ADH and DCIS, the underdiagnosis rate is lower with VAB[8]. The rates of false negatives and radiologic-pathologic discordance are also lower for VAB than for CNB[8]. However,

stereotactic CNB requires a larger number of samples to achieve diagnostic accuracy[15]. Nevertheless, due to the high cost of the VAB unit and vacuum biopsy needles, access remains limited in many centers. In addition, because larger tissue samples are obtained, the risk of complications is higher and regional structural distortion may occur[13].

In our study, the sensitivity of the biopsy procedure was found to be 71.4%, while its specificity was 100%. The PPV was 100%, and the NPV was 85.7%. Therefore, biopsy provides diagnostic certainty when it yields a positive result, as it is considered the gold-standard. However, some malignant cases were not detected by biopsy, suggesting the possibility of false negatives due to sampling error, particularly in cases with MCs. The Kappa value of 0.759 obtained for biopsy results indicates strong agreement between biopsy results and the gold-standard diagnosis.

In cases with MC sizes between 10 and 20 mm or greater than 20 mm, and in cases where 10 or more tissue samples were obtained, the false-negative rate of the biopsy procedure was higher. These findings suggest that although more biopsy samples are taken in cases with more extensive calcifications, the accuracy of the procedure tends to decrease. The procedure achieved a higher success rate for more localized MCs (<10 mm). With respect to the number of samples, the best performance was observed in the group in which 5-10 cores were collected. However, the optimal number of samples required for a reliable histopathological diagnosis remains a matter of debate.

The detection of calcifications in the specimen and on pathology was not significantly associated with the diagnostic accuracy of the biopsy. No procedural complications were observed, and potential complications were similar to those seen with ultrasound-guided core needle biopsy. Compared with VAB, the cost of the procedure is considerably lower. It can be performed at any center equipped with a mammography unit. Since the procedure is performed using a coaxial needle, there is no risk of tissue seeding.

In our study, the distribution of MCs showed that malignant cases were significantly more likely to have a segmental distribution, whereas benign cases were more likely to exhibit a grouped distribution. With respect to MC morphology, coarse and amorphous calcifications were significantly associated with benignity, whereas pleomorphic and particularly fine linear calcifications were significantly associated with malignancy. Similarly, in the study conducted by Rizuana et al.[16] fine linear or branching, pleomorphic, and heterogeneous microcalcification morphologies, as well as segmental, regional, and linear distributions, were shown to be associated with a higher risk of DCIS. Moreover, heterogeneous calcifications with regional distribution were linked to an increased risk of invasive carcinoma[16]. In our study, no calcifications were found in the diffuse category. Diffuse calcifications are most commonly associated with mastopathy.

The rate of BI-RADS categories 4C and 5 was significantly higher in malignant cases. In our study, a higher BI-RADS score and the presence of segmental, fine linear, and fine pleomorphic MCs on mammography were associated with malignancy. According to the BI-RADS classification, fine linear branching calcifications on mammography have a 70% PPV for malignancy, and fine pleomorphic MCs are considered a high-risk feature. Çetin Tunçez et al.[17] reported that morphological and distributional features of MCs are associated with DCIS, consistent with our findings.

Study Limitations

The main limitation of our study is that it is retrospective and conducted at a single center. Studies involving larger patient groups with longer follow-up periods will enable more accurate and reliable analyses.

Conclusion

Our study showed that stereotactic CNB has high specificity and PPV but relatively low sensitivity in the evaluation of BI-RADS 4 and 5 MCs, and that it is an effective, low-cost diagnostic method that can be used in daily clinical practice.

Ethics

Ethics Committee Approval: Ethical approval for this retrospective study was obtained from the Non-Interventional Clinical Research Ethics Committee of İzmir Katip Çelebi University (approval no: 0183, date: 25.04.2024).

Informed Consent: Before the biopsy, all patients were informed about the procedure and provided written informed consent.

Footnotes

Authorship Contributions

Surgical and Medical Practises: S.Ü., Concept: S.Ü., Design: S.Ü., T.İ., H.Ç.T., Data Collection or Processing: S.Ü., Analysis or Interpretation: M.G., Literature Search: Ö.P., Writing: S.Ü.

Conflict of Interest: No conflict of interest was declared by the authors.

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