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ORIGINAL ARTICLE / ÖZGÜN MAKALE

POSITIVE PREDICTIVE VALUES OF THE SONOGRAPHIC BI-RADS FINAL ASSESSMENT CATEGORIES FOR BREAST LESIONS

MEME LEZYONLARINDA SONOGRAFİK BI-RADS SONUÇ KATEGORİLERİ İÇİN POZİTİF ÖNGÖRÜ DEĞERLERİ

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ABSTRACT

Objective: To evaluate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of sonographic Breast-Imaging Reporting and Data System (BI-RADS) final assessment categories for nonpalpable breast lesions.

Materials and Methods: Between January 2008 and 2011, a total of 245 nonpalpable breast lesions (223 patients) that had undergone excisional biopsy after ultrasound-guided wire needle localization in our clinic were evaluated retrospectively. Eight patients excluded from the study because we could not find the pathology results for them. Two hundred and thirty-seven lesions in 215 patients were included in the study. Lesion evaluation was done with a high resolution Logiq 7 USG device (General Electrics) by using a 10–14 MHz linear probe before ultrasound-guided wire needle localization. Static image records were evaluated by two expert radiologists on breast imaging without the knowledge of clinical information, mammographic images and pathologic results of the patients. The radiologists determined the most appropriate BI-RADS category for each lesion. The diagnostic performance of BI-RADS category was compared with the final pathology of the patient by using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV).

Results: Of the 237 lesions, 49 (20.6%) were malignant, 43 (18.1%) were high-risk atypical lesions and 145 (61.1%) were benign. Sensitivity and NPV were 100% for both radiologists, while specificity was 20.7% and 30.3%; PPV was 24.7% and 27.2%, respectively. When evaluation was done for BI-RADS subcategories; PPV for BI-RADS 4 was 15.6% and 22.8% (5.6% and 9.3% for 4; 17.6% and 24.3% for 4b; 40.6% and 66.7% for 4c); for BI-RADS 5 PPV was 66.7% and 84.6%.

Conclusion: Although BI-RADS classification is useful for predicting malignancy for breast lesions found by ultrasound, more education is needed for precise understanding and usage by radiologists.

Key words: BI-RADS, sonographic BI-RADS, positive predictive value

ÖZET

Amaç: Nonpalpable meme lezyonlarında, sonografik Breast Imaging Reporting and Data System (BI-RADS) sonuç kategorilerinin duyarlılık, özgüllük, pozitif öngörü değeri (PÖD) ve negatif öngörü değeri (NÖD)'ni hesaplamaktır.

Yöntem ve Gereçler: Ocak 2008-Ocak 2011 tarihleri arasında kliniğimizde Ultrasonografi (US) ile işaretleme sonrası eksizyonel biyopsi yapılan 223 hasta ve 245 nonpalpabl meme lezyonu retrospektif olarak değerlendirildi. 8 hastanın patoloji sonucuna ulaşılamadığı için çalışma dışı bırakıldı. 215 hastada 237 lezyon çalışmaya dahil edildi. İşaretleme öncesinde lezyon değerlendirilmesi yüksek rezolusyonlu Logiq 7 (General Electric) US cihazı ile 10-14 MHz lineer prob kullanılarak yapıldı. İşaretleme öncesi alınan statik görüntüler, meme görüntüleme konusunda deneyimli iki uzman radyolog tarafından hastaların klinik bilgileri, mamografi görüntüleri ve patoloji sonuçları bilinmeden değerlendirildi. Radyologlar değerlendirmelerinin sonunda her lezyon için en uygun BI-RADS kategorisini belirledi BI-RADS kategorisinin tanısal performansı duyarlılık, özgüllük, pozitif ve negatif öngörü değerleri ile doğruluk oranları hesaplanarak değerlendirildi.

Bulgular: İkiyüz otuz yedi lezyonun 49'u malign (%20,6), 43'ü yüksek riskli atipili lezyon (%18,1) ve 145'i benign (%61,1) idi. Sonografik BI-RADS için duyarlılık ve NÖD her iki gözlemcinin değerlendirmesinde de %100 iken, özgüllük %20,7-%30,3 ve PÖD %24,7-%27,2 arasında değişmekteydi. BI-RADS alt gruplarına göre değerlendirme yapıldığında ise PÖD, BI-RADS 4 için %15,6-22,8, (4a için %5,6-9,3, 4b için %17,6-24,3, 4c için 40,6-66,7), BI-RADS 5 için %66,7-%84,6 saptandı.

Sonuç: Ultrasonografide saptanan lezyonları BI-RADS kategorilerine göre sınıflandırmak, malign lezyonların öngörülmesinde oldukça yardımcıdır. Ancak BI-RADS sonografi terminolojisinin herkes tarafından daha net anlaşılması ve kullanılması için daha fazla eğitime ihtiyaç vardır.

Anahtar sözcükler: BI-RADS, sonografik BI-RADS, pozitif öngörü değeri

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Breast cancer is the most common cancer in women and accounts for 23% of female cancers worldwide (1). Similarly, it is the most common female cancer in Turkey and accounts for 35% of all cancers in women (2). Breast cancer is also the most common cause of cancer-related deaths worldwide (3).

Various imaging techniques are used for early diagnosis of breast cancer. Mammography (MG) is accepted as the gold standard technique for breast imaging. With the help of ultrasonography, the specificity of MG increases. Especially with the help of ultrasound (US), the numbers of false negative lesions in dense breasts and false positive lesions that result in biopsy are reduced. It also helps to identify cystic-solid, and benign-malignant differentiation. US is also useful for interventions (4).

The American College of Radiology (ACR) developed Breast Imaging, Reporting and Data System (BI-RADS) to provide a common language and reliable results to clinicians. BI-RADS was first established for MG in 1993; then, with the frequent usage of US in breast lesions, it was also described for US in 2003. With the BI-RADS classification, shape, orientation, boundaries, echo pattern, posterior acustic features and the surrounding tissue changes are evaluated. Each feature of every lesion is categorized from one to five (5). BI-RADS classification helps to diagnose and maintain objectivity in follow-ups of breast lesions (6).

The purpose of our study is to evaluate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of non-palpable breast lesions that underwent ultrasound guided wire needle localization for excisional biopsies.

Materials and Methods

We retrospectively evaluated 223 patients with 245 non-palpable breast lesions who underwent ultrasound guided wire needle localization for excisional biopsy between January 2008 and January 2011. Eight patients were excluded because we could not retrieve their pathological diagnosis. As a result, 215 patients with 237 non-palpable breast lesions were included in the study. Ethical approval of the study was obtained from Ankara Numune Education and Research Hospital Ethical Committee of Scientific Studies (Reference number 2011-147).

The evaluation of the lesions was performed with ultrasound (General Electric Medical Systems; Logic 7, Milwaukee, USA) using 10-14 MHz linear probe. At least two static images of the lesions in two orthogonal positions were obtained by an experienced radiologist on thermal papers. The static images were retrospectively evaluated by two experienced radiologists on breast imaging. The observers were blind to the clinical data, mammography images and pathology results of the cases.

The observers chose the most suitable BI-RADS category at the end of the evaluation. The lesions were classified as BI-RADS 3 (most probably benign), BI- RADS 4a (low suspicion of malignancy), BI-RADS 4b (intermediate suspicion of malignancy), BIRADS 4c (moderate suspicion of malignancy) or BIRADS 5 (high suspicion of malignancy).

Data analysis was carried out using the SPSS for Windows 11.5 pocket program. Descriptive statistics are shown as percentages (%). The diagnostic performance of the BI-RADS category was compared with the final pathology of the patient for sensitivity, specificity, positive and negative predictive values.

Results

The mean age of the patients was 48.6 (23-77). All lesions were non-palpable, the mean length of their long axis was 9.6 mm (3-30 mm), and the mean lenght of their short axis was 5.9 mm (1.5-16 mm). The most common localization of the lesions was in the upper-outer quadrant of right breast, in 63 out of 245 (25.7%) lesions.

Histopathological diagnosis of 237 lesions could be obtained, of which 49 (20.6%) were malignant, 43 (18.1%) were high risk lesions and 145 (61%) were benign lesions. The most common benign pathology was columnar cell lesion (CCL), observed in 38 lesions (26.2%). Other pathologies were fibrocystic changes (24.1%), ductal epithelial hyperplasia (DEH) (18.6%), and fibroadenoma (9.6%), respectively. In one benign lesion, more than one pathological diagnosis was reported; for this reason, we could not specify the detailed classification.

The most common malignant lesion was invasive ductal carcinoma (63.2%) and the most common high-risk lesion was atypical CCL (53.4%). The distribution of the malignant lesions is summarized in Table 1.

Sensitivity, specificity, PPV, and NPV

Sensitivity was 100% for both observers, but specificity ranged between 20.7% and 30.3% in ultrasonographic evaluation. While NPV was 100% for all assessments, PPV ranged between 24.7% and 27.2%. When assessments were made for BI-RADS subgroups, PPVs for BI-RADS 4 were 15.6% - 22.3% (5.6-9.3% for 4a, 17.6-24.3% for 4b, 40.6-66.7 for 4c); and 66.7%-84.6% for BI-RADS 5 lesions. The results are summarized in Table 2.

Discussion and Conclusions

BI-RADS classification was first described for mammography in 1993. Since 1993 many studies have demonstrated that it was useful for clinicians in differentiating benign from malignant (7, 8).

Table 1. The distribution of malignant lesions.

Pathological Diagnosis	*Number*	%
Invasive ductal carcinoma	31	63.2
Ductal carsinoma in situ	8	16.3
Tubular carsinoma	3	6.1
Metastasis	2	4.08
Cribriform carcinoma	1	2.04
Invasive micropapiller carcinoma	1	2.04
Tubulolobular carsinoma	1	2.04
Invasive mixed carsinoma	1	2.04
Medullary carcinoma	1	2.04

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Table 2. Sensitivity, Specificity, PPV, NPV.

	1. Observer	*2. Observer*
Sensitivity	100%	100%
Specificity	20.7%	30.3%
PPV B4+5	24.7%	27.2%
B4	15.6%	22.8%
B4a	5.6%	9.3%
B4b	17.6%	24.3%
B4c	40.6%	42%
B5	84.6%	66.7%
NPV	100%	100%

Although mammography is accepted as the best imaging protocol for breast cancer screening, many studies have demonstrated US is valuable in differentiating malignant from benign (9-11).

With the increasing use of US for breast lesions, ACR described BI-RADS classification for US in 2003 to provide a common language and determine a more accurate description for clinician.

Sensitivity and NPVs in our study were convergent or a little better when compared to other studies. Park et al. (12) reported a sensitivity of 96-100%, and NPV of 95-100% in their study. In a study conducted by Lee et al. (13), sensitivity was reported as 97-98% and NPV as 94-96%. Constantini et al. (14) reported their sensitivity was 98.2% and NPV was 95.2% in the study. In their study, Stavros et al. (10) reported a sensitivity of 98.4% and NPV of 99.5%. Lai et al. (15) reported a lower degree of sensivity and NPV as 91-95% and 81-93%, respectively. Graf et al. (16) reported similar values of NPV like our study, as 100%. The higher levels of sensitivity and NPVs confirm that a patient who has breast cancer can be diagnosed positively with BI-RADS (BI-RADS 4-5 lesions). ACR indicates malignancy rates should be less than 2% in BI-RADS 3 lesions. In our study, none of the BI-RADS 3 lesions were defined as malignant (with an NPV of 100%).

The specificity of BI-RADS US was found to be 20.7%-30.3% in our study. Though the false positive results were high in our study, there are several studies in the literature in accordance with our findings. Park et al. (12) reported their specificity results ranged between 8 and 43%. This level was 26-40% in the study of Lee et al. (13); and 45-77% in the study of lai et al. (15).

The other parameter interpreted in our study was PPV. PPV is an important measure of BI-RADS US, showing how accurately it can identify the malignancy. In our study, PPVs ranged between 24.7 and 27.2%. This parameter was found to be 30-40%; 38%; and 72% in the studies of Stavros et al. (10); Park et al. (12); and Constantini et al. (14), respectively. When the prevalance of malignancy increases, PPV also increases. The pathology results established a malignancy rate of 20.6% in our study. When we search the literature, in the reports showing higher levels of PPVs, we saw malignancy rates were also higher. Malignancy rates were 32%, 51.3%, 57.5%, and 53.3% in the studies of Lazarus et al. (17), Lee et al. (13), Constantini et al. (14), and Lai et al. (15), respectively. In the study of Constantini et al. (18), the malignancy rate was 58.98%; however they included lesions with atypia in the malignant group. In our study, we reported cases with atypia as a separate group and the ratio was 18.1%. If these lesions were included in the malignancy group, it would increase the ratio of both malignancies and PPVs in our study. Menteş et al. (19) reported similar rates as in our study; their malignancy rate was 22.3%. There are similar reports with malignancy rates of 10-30% in non-palpable breast lesions that underwent ultrasound guided wire needle localization for excisional biopsy (20, 21).

In our study, we calculated the PPVs of BI-RADS 4, 4a, 4b, 4c, and 5 lesions. ACR states the malignancy probability of BI-RADS 4 lesions ranges from 2% to 95% (5). Many studies have claimed that PPV for BI-RADS 4 lesions ranges from 4% to 71% (8, 17, 22-24). We found PPV for BI-RADS 4 lesions to be 15.6-22.8%. The PPV results of BI-RADS 4 lesions were 18.6%, 17%, 16.2%, 21% in the studies of Yoon et al. (25), Heining et al. (26), Raza et al. (27), and Wiratkapun et al. (28), respectively. These results are comparable with our study.

When PPVs for subgroups of BI-RADS 4 lesions were calculated, they were determined to be 5.6-9.3%, 17.6-24.3%, and 40.6-42% for BI-RADS 4a, 4b, and 4c lesions, respectively. Our results are again similar to other studies. The PPVs for BI-RADS 4a, 4b, and 4c lesions were 6%, 15%, and 53% in the study of Lazarus et al. (17). In the study of Wiratkapun et al. (28), PPVs for these lesions were reported as 9%, 21% and 57%, respectively. It can be said that subgrouping of BI-RADS 4 lesions helps clinicians in differentiating malignant lesions. But it is also known that clearer criteria descriptions are needed for this purpose.

ACR states the malignancy probability of BI-RADS 5 lesions as over 95%. There have been many studies focused on this subject. While some studies confirmed the rates of ACR, some studies reported slightly lower rates for PPV of BI-RADS 5 lesions, ranging between 80 and 97% (7, 13, 14, 16, 17, 23, 24, 26). In our study, PPV for BI-RADS 5 lesions were calculated as 66.7-84.6%. Our rates for BI-RADS 5 lesions are lower than stated by ACR, but Tan et al. (29) also reported an 84% rate of PPV, similar to our study. In their study, Raza et al. (27) reported a PPV rate of 93.4% for BI-RADS 5 lesions; but, when they discriminated their lesions as either non-palpable or palpable, their rate decreased to 88.8% in non-palpable lesions. We must indicate that our study was conducted on non-palpable breast masses, so this might be one of the reasons for the lower rates in our study for this group. Supporting this evidence, Hamy et al. (30) reported a PPV of 78.7% for non-palpable BI-RADS 5 lesions in their study. One other reason for the lower rate in our study might be the design of this study. We only evaluated ultrasonographic images for BI-RADS classification, but in real time, mammographic images should also be interpreted.

We found a slightly lower level of malignancy in this study, but the rate of lesions with atypia was quite high (18.1%). Hamy et al. (30) reported malignancy rates of 32.9% and atypia rates of 8.8% in their study. Many studies indicate that lesions with atypia have increased risk of malignancy. Degnim et al. (31), and Hartmann et

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al. (32) reported the relative risk ratio for malignancy in lesions with atypia as 3.88 and 4.24, respectively. In another study, conducted by Kabat et al. (33), the odds ratio for breast cancer was found to be 8.17 for ipsilateral breast, and 5.98 for contralateral breast.

Our study has some limitations. Observers had the opportunity to evaluate static images of the lesions; they did not perform the real time US. This might cause suboptimal evaluation of BI-RADS descriptives and as a result final BI-RADS categories. Second, only non-palpable lesions were included in the study. Third, this study was conducted with ultrasonography only.

The malignancy rate of non-palpable lesions that underwent ultrasound guided wire needle localization for excisional biopsy was 20.6% in this study. The rate of lesions with atypia was found to be 18.1%. While the PPV of BI-RADS 4 and subgroups was similar to the rates of ACR, it was a little lower in BI-RADS 5 lesions than the rates of ACR. Our results support the importance of pathological evaluation of BI-RADS 4 and 5 lesions. BI-RADS classification of lesions noticed in US evaluation is helpful in predicting malignant lesions. Instead of excisional biopsy, strict follow-up for BI-RADS 3 lesions will decrease the biopsy rates for benign lesions.

In conclusion, with routine use and precise understanding of sonographic BI-RADS terminology, the final classification of breast lesions would be done more correctly. Further training and periodic performance evaluations would likely help to achieve better agreement among the radiologists.

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

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