Stereotactic Biopsy Results of a Series of Patients with Nonpalpable Breast Lesions in Our Hospital

Hastanemizde Nonpalpabl Meme Lezyonlu Bir Hasta Serisinde Stereotaktik Biyopsi Sonuçları

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Abstract

Aim: Although screening mammography has a high sensitivity in the clinical detection of nonpalpable breast cancer, most mammographically suspicious lesions referred to biopsy are seen to be benign. The rate of malignancy in such lesions that are biopsied with needle–wire localization ranges from 10 to 36%. In this study, we aimed to compare with the literature the pathological results and Breast Imaging Reporting and Data System (BI-RADS) scores of lesions subjected to mammography and excisional biopsy after ultrasonography-guided needle–wire localization and calculate a positive predictive value for each category.

Materials and Methods: By electronically reviewing patient files and using the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes, we identified patients who underwent excisional biopsy after stereotactic marking at the General Surgery Clinic of the Istanbul Sisli Hamidiye Etfal Training and Research Hospital between January 2003 and March 2009. A total of 64 patients were included in the study, of whom 43 had benign and 21 had malignant lesions on postoperative histopathological examination. Data on patient demographic characteristics, indications for marking, and histopathological diagnoses were recorded. The patient BI-RADS scores were determined based on the mammography and breast ultrasonography reports. The BI-RADS classification and histopathological examination results were compared in percentages.

Results: The mean patient age was 48.9 (32–76) years. Based on the mammography reports, the most common indications for stereotactic marking and excisional biopsy were microcalcification cluster and spiculated mass. Histopathological examination results revealed malignancy in 8%, 51%, and 100% of the patients whose BI-RADS scores were mammographically determined to be BI-RADS 3, BI-RADS 4, and BI-RADS 5, respectively.

Discussion and Conclusion: The BI-RADS-based classification of lesions detected by mammography and ultrasonography can help in predicting malignancy. While BI-RADS 4 and BI-RADS 5 lesions are referred to biopsy primarily, short-term follow-up of BI-RADS 3 lesions as an alternative to biopsy could reduce unnecessary biopsies.

Keywords: BI-RADS; malignancy; mammography; stereotactic marking

Öz

Amaç: Tarama mamografisi nonpalpabl meme kanserinin klinik tespitinde yüksek sensitivite göstermekle birlikte, mamografide saptanan ve biyopsi önerilen şüpheli lezyonların çoğunun benign olduğu görülmektedir. Tel lokalizasyonu ile biyopsi yapılan bu lezyonlarda malignite oranı %10–36 aralığında değişmektedir. Bu çalışmada mamografi ve ultrasonografi eşliğinde tel lokalizasyonu sonrasında eksizyonel biyopsi yapılan lezyonların patolojik sonuçlarının ve Meme Görüntüleme Raporlama ve Veri Sistemi *(the Breast Imaging Reporting and Data System—BI-RADS)* skorlarının literatür ile karşılaştırılması ve her kategori için pozitif öngörü değerinin hesaplanması amaçlanmıştır.

Gereç ve Yöntemler: Elektronik ortamda hasta dosyaları incelenerek ve Hastalıkların ve İlgili Sağlık Sorunlarının Uluslararası İstatistiksel Sınıflaması *(ICD-10)* kodları kullanılarak, Ocak 2003—Mart 2009 döneminde Şişli Hamidiye Etfal Eğitim ve Araştırma Hastanesi Genel Cerrahi Kliniği'nde stereotaktik işaretleme sonrasında eksizyonel biyopsi yapılan hastalar belirlendi. Toplamda (postoperatif histopatolojik inceleme sonucuna göre 43'ü benign, 21'i malign lezyonlu) 64 hasta çalışmaya dahil edildi. Hastaların demografik özelliklerine, işaretleme nedenlerine ve histopatolojik tanılara dair veriler kaydedildi. Mamografi ve meme ultrasonografi raporları incelenerek hastaların *BI-RADS* skorları belirlendi. *BI-RADS* sınıflaması ve histopatolojik inceleme sonuçları yüzde (%) üzerinden karşılaştırıldı.

Bulgular: Ortalama hasta yaşı 48,9 (32–76) yıldı. Mamografi raporlarına göre, stereotaktik işaretleme ve eksizyonel biyopsi için en sık neden mikrokalsifikasyon kümesi ve spiküler kitle idi. Histopatolojik inceleme sonuçlarına göre, *BI-RADS* skoru mamografide *BI-RADS* 3, *BI-RADS* 4 ve *BI-RADS* 5 olarak tespit edilen hastaların sırasıyla %8'inde, %51,8'inde ve %100'ünde malignite saptandı.

Tartışma ve Sonuç: Mamografi ve ultrasonografide saptanan lezyonların *BI-RADS* temelinde sınıflandırılması malignitenin öngörülmesine yardımcı olabilir. *BI-RADS* 4 ve *BI-RADS* 5 lezyonlarda ilk planda biyopsi yapılırken, *BI-RADS* 3 lezyonlarda biyopsiye alternatif olarak kısa dönem takip yapılması gereksiz biyopsileri azaltabilir.

Anahtar Sözcükler: *BI-RADS*; malignite; mamografi; stereotaktik işaretleme

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INTRODUCTION

Breast cancer (BC) is the most common type of cancer in women and ranks second after lung cancer among cancer-related causes of death. According to the World Health Organization figures, 1.2 million new cases worldwide are reported each year, with more than 500,000 deaths. According to recent statistics, a woman's lifetime risk of developing BC is around 13% (1). Although the BC incidence has long been on the rise, the mortality rates have been reduced by 30% since 1990 (2). This decrease has largely been a result of the early diagnosis of BC due to the widespread use of screening mammography and advances in treatment. Studies show that regular mammography screening after the age of 40 reduces BC mortality by 30 to 40% (3).

Although screening mammography has a high sensitivity in the detection of clinically hidden BC, most mammographically suspicious lesions referred to biopsy are seen to be benign. Apart from such lesions, needle–wire localization biopsy is also performed for low-grade suspicious lesions which require tissue diagnosis and benign lesions such as fibroadenomas upon the request of the patient or clinician (4). The malignancy rate in lesions subjected to needle–wire localization biopsy ranges from 10 to 36% (4,5).

Before the widespread use of mammography, the most common indication for breast biopsy was the presence of a palpable mass. Mammography is commonly used in the screening of asymptomatic women as it can detect most cancers before becoming palpable. Stereotactic marking is performed to ensure the detection of impalpable lesions. The term "stereotactic" refers to the third dimension toward the depth of the lesion beyond the two dimensions used in regular direct X-rays, allowing precise spatial localization of the lesion (6).

Previously, terminological differences in mammography reports caused confusion in the clinical evaluation and interpretation of mammography findings. In 1992, the American College of Radiology (ACR) developed the Breast Imaging Reporting and Data System (BI-RADS) for terminological uniformity (7). This common system allows lesions subjected to needle–wire localization biopsy to be classified in terms of BI-RADS categories, providing better prediction of malignancy in each category. The BI-RADS also constitutes a quality control tool that allows monitoring of biopsy results while the defined data collection system allows evaluation of the clinical success of each radiologist or breast imaging unit (7).

In this study, we aimed to compare with the literature the pathological results and BI-RADS scores of lesions subjected to mammography and excisional biopsy after ultrasonography-guided needle–wire localization and calculate a positive predictive value for each category.

MATERIALS AND METHODS

By electronically reviewing patient files and using the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes, patients who underwent stereotactic breast biopsy at the General Surgery Clinic of the Istanbul Sisli Hamidiye Etfal Training and Research Hospital between January 2003 and March 2009 were identified. The data were also cross-verified with the electronic records of the radiology unit for mammography and other findings. A total of 64 patients (of whom 43 had benign and 21 had malignant lesions on postoperative histopathological examination) with a mean age of 48.9 (32–76) years were included. The BI-RADS scores were determined based on the mammography and breast ultrasonography reports. Data on patient demographic characteristics, indications for marking, and histopathological diagnoses were obtained from the electronic records. The BI-RADS classification and histopathological examination results were compared in percentages.

Study ethics

The study protocol was approved by the Ethics Committee of the Bagcilar Training and Research Hospital (approval no: 2020.01.1.08.008).

RESULTS

Based on the mammography reports, the most common indications for stereotactic marking were microcalcification cluster and spiculated mass (Table 1).

Histopathological examination revealed malignancy in 8%, 51%, and 100% of patients whose BI-RADS scores were determined to be BI-RADS 3, BI-RADS 4, and BI-RADS 5, respectively (Table 2).

Table 1. Mammographic indications for stereotactic marking

Mammography findings	n (%)
Microcalcification	34 (54)
Spiculated mass	10 (16)
Mass without clear margins	8 (12)
Round mass with sharp margins	8 (12)
Structural deformity	2 (3)
Asymmetric density	2 (3)

DISCUSSION AND CONCLUSION

The BI-RADS-based classification of lesions detected by mammography and ultrasonography helps in predicting malignancy. The rate of cancer with stereotactic biopsy using the needle–wire marking method in our clinic was calculated to be 32.9%. Our results lend support to the recommendation that a biopsy should be performed in BI-RADS 4 and BI-RADS 5 lesions. BI-RADS 3 lesions, on the other hand, are predominantly benign and their-short term follow-up as an alternative to biopsy can reduce unnecessary biopsies.

One in eight women develops BC in her lifetime, which makes the disease the most common malignancy in the female population. Early diagnosis is crucial to reducing the morbidity and mortality rates. The widespread use of mammography and increased awareness among women of periodical examinations have led to a parallel increase in the detection of nonpalpable breast lesions (8). The standard technique for localization of nonpalpable lesions today is marking with wire. Suspicious foci of microcalcification and nonpalpable lesions are among the most common indications for needle–wire localization biopsy, which can detect malignant lesions at earlier stages, with better chances of cure and improvement in quality of life (9).

The use of the marking method began with the placement of a simple needle in the breast. The first relevant report was published by Dudd in 1966 (10). In 1976, Eegan used a staining method with methylene blue injection for making the hidden lesion visible to the surgeon. In the same year, Frank et al. described a combined method using needle and hooked-end wire (10), which was modified by Kopans in 1980. Since no mammography technology allowed computer-aided three-dimensional analyses at that time, the success rate at the first attempt was low. When the analysis needed to be repeated, withdrawal of the hooked-end wire was not possible. Accordingly, Homer developed a new needle–wire system in 1984, in which the tip of the wire is curved and the wire is retractable (10). The advantage of this system is that the needle could be

Table 2. The BI-RADS classification based on mammography findings and the histopathological results

	Benign	Malign		Total (n)
Mammography findings	**n (%)**	**n (%)**		
BI-RADS 2	7 (100)	— (0)		7
BI-RADS 3	23 (92)	2 (8)		25
BI-RADS 4	13 (48.1)	14 (51.9)		27
BI-RADS 5	— (0)	5 (100)		5
Total	**43 (67.1)**	**21 (32.9)**		**64**
Histopathological findings (n)				
Non-proliferative disease without atypia	**28**	**Noninvasive tumor**	**3**	
Fibroadenoma	18	DCIS	3	
Fibrocystic variation	7	**Invasive tumor**	**18**	
Proliferative disease without atypia	**15**	IDC	11	
Focal hyperplasia	7	ILC	7	
Sclerosing adenosis	2			
Intraductal papilloma	2			
Others	4			

DCIS: ductal carcinoma *in situ*; IDC: invasive ductal carcinoma; ILC: invasive lobular carcinoma

localized during the image taking and, if needed, the hooked-end wire could be retracted inside the needle. It has been reported that the marking success rate in nonpalpable lesions before excision is 90 to 100% (7–9). When the radiographic contrast between the lesion and the surrounding tissue is clear, a specimen X-ray is necessary after biopsy to ensure that the target area is excised. The wire must be left in place in the specimen sent for pathological examination, and the pathologist and surgeon should work together on the diagnosis of nonpalpable BC (9,11).

The reported rates of malignancy detection vary between 10% and 50% in lesions examined by the stereotactic method. However, these are average values for all lesions, and differences are observed when the cancer prediction rates are calculated using the BI-RADS categories based on mammographic findings of the lesions (5). The rate of benign lesions ranges from 69.0 to 87.5% in various series in the literature. Such rates are not considered diagnostically decisive as very high rates could mean unnecessary biopsies while low rates could mean failure to detect the malign lesions (12). In our study, the benign lesion detection rate was 67.1%. Three of the malignant lesions detected were *in situ* carcinomas while 18 were invasive carcinomas. The frequencies for these lesions were similar to those reported in the literature (5,12).

The BI-RADS terminology and classification constitute a useful system for measuring the likelihood of malignancy and reducing unnecessary biopsies and provide a clear guidance for physicians as lesions marked by wire are classified in terms of BI-RADS categories and positive predictive values (PPV) could be calculated for each category. About 30 to 50% of nonpalpable lesions manifest themselves only as microcalcifications, which constitute the most commonly reported radiomorphological indication for a biopsy (13). This ratio was reported by Hasselgreen et al. (14) as 51% and by Hall et al. (15) as 53%. In accordance with the literature, most (54%) of the lesions marked with wire in our study consisted of microcalcifications (Table 1). The higher frequency of malignancy in marked calcifications in our series compared to the literature could be attributed to the characteristics of our patient population (patients with suspicious calcifications are referred from other centers to our clinic) and to the good performance of our evaluators.

Analyses of microcalcifications should be done carefully as sometimes malignant and benign microcalcifications may be similar. Although many radiological criteria have been developed to distinguish between malignant and benign calcifications, a complete standardization of these criteria has been possible only after the development of the BI-RADS evaluation categories (16).

If there is no accompanying mammographic abnormality or palpable mass, asymmetric densities are very likely to be considered benign. In general, the proportion of malignancy in asymmetric densities is less than 1% and follow-up rather than a direct biopsy is recommended. Ultrasonography is helpful as an additional modality in the evaluation of these cases. Percentage of focal asymmetric densities in nonpalpable lesions for which biopsy is recommended ranges from 3 to 32% in different studies (17). In our series, 3% of the nonpalpable lesions for which biopsy was requested were asymmetric densities, and all of their pathological results turned out to be benign.

Structural deformity is one of the indirect manifestations of cancer. Among biopsy indications, the frequency of structural deformation of the parenchyma alone was reported to be 1.5 to 9.4% in different studies (18). Those who had lesions for which marking was performed for structural deformation constituted only 3% of our patient group, and all of their pathology evaluations turned out to be benign. However, caution should be taken in lesions in which structural deterioration is detected. They should be evaluated with spot compression, and biopsy should be performed in case of serious suspicion of malignancy (18,19).

Although clear-margined masses are more common in benign lesions, it has been noted that malignant lesions may also have clear margins, and even the halo sign commonly observed in mammography may not indicate benign nature. There have been reports of case series where ductal carcinoma *in situ* (DCIS) was detected in about 2% of the cases with clear-margined masses (5). In our study, it was observed that clear-margined round masses (except for the presence of suspicious conditions in terms of other breast tumors) did not constitute indications for stereotactic biopsy alone.

The effect of BI-RADS categorization alone on biopsy indication was investigated in the literature. There has been debate about BI-RADS 3 lesions. The cases that are most likely to be considered in the benign category constitute 1.4 to 7.7% of all cases. Mostly, a short-term follow-up program is recommended for this patient group. The reliability and effectiveness of monitoring benign lesions by mammography instead of biopsy are mostly based on the results of two major prospective studies involving 80,000 cases, which reported a cancer rate of <2% in benign lesions (16,21). The practice of mammographic monitoring of benign lesions is mostly based on the fact that the malignancy rate in these lesions is low, that their prognosis is good since they can be identified at early stages, and that interval progression of truly malignant lesions could be detected by mammography (22). An important point to note is that all the necessary images are compared to previous images before the BI-RADS 3 diagnosis is made. In some cases, follow-up rather than biopsy could be suitable for BI-RADS 3 lesions after the necessary examinations are carried out. These cases include patients with cancer in the ipsilateral or contralateral breast, pregnant patients, patients for whom augmentation or reduction is planned, and patients not on regular follow-up.

It was reported that cancer or atypia was found in 7 to 9% of clustering microcalcifications which were subjected to stereotactic biopsy and categorized as BI-RADS 3 (8,22). A similar percentage (8%) was observed in the present study. These results indicate that particular attention should be paid in patients categorized as BI-RADS 3, and that it would even be appropriate to resort to biopsy (22). Malignant lesions initially thought to be benign could be diagnosed without delay with short-term follow-ups. At the time of diagnosis, these lesions have good prognosis, as in malignancies detected with screening. However, it is important to use the diagnostic criteria appropriately for the identification of lesions in this category and for the evaluation of their stability (23). Some studies dealing with the pathological results of cases which were categorized as BI-RADS 3 but had a cancer diagnosis showed that short delays in the diagnosis of lesions in this group had negligible effects on the prognosis (24).

In studies evaluating the results of probably benign lesions which showed progression during follow-up and were biopsied, a biopsy was performed for all lesions which showed changes in size, number, and morphology during the follow-up period (22,25). It was not shown in any of these studies that the selective efficiency of biopsy was high in lesions with morphological changes only. The current literature recommends that all changes in probably benign lesions should be evaluated with biopsy. When used appropriately, BI-RADS category 3 helps to reduce unnecessary biopsies and patient anxiety (23). However, this category should not be used for lesions the importance of which is uncertain. Only the lesions that are considered most likely benign after adequate evaluation and additional imaging are performed should be included in this category. The radiologist should decide only after a thorough evaluation of the available data.

While BI-RADS category 5 is almost always used to describe malignant lesions, BI-RADS 4 is a category with more heterogeneous lesions. The lesions in this category do not have a typical malignant appearance as those in category 5, but they have a higher risk of malignancy compared to those in category 3. Most of the lesions that marking studies in the literature dealt with belong to this group. Similarly, marking in the present study was mostly made for lesions in this group (42.7%). With the ACR's new arrangement of the BI-RADS, this broad and heterogeneous category has been divided into the subgroups 4a, 4b, and 4c. Thus, biopsy-suggested lesions have been able to be assessed based on the likelihood of malignancy (23,26). The BI-RADS 5 category include lesions that are most likely (>95%) malignant. In the present study, the pathological result was malignant in 51.9% and 100% of the BI-RADS 4 and BI-RADS 5 calcifications, respectively. When the biopsy result of a lesion in this class is reported to be benign, attention should be paid to the compatibility of the radiology and pathology results, and, if necessary, the biopsy should be repeated (5,26).

The limitations of our study include its retrospective design, the small sample size, and the single-center evaluation. In conclusion, the marking and biopsy-based evaluation of nonpalpable breast lesions with suspicion of malignancy at mammography or

ultrasonography is a common approach for the early detection of BC. The BI-RADS-based classification of such lesions can help in predicting malignancy. While BI-RADS 4 and BI-RADS 5 lesions first require a biopsy, short-term follow-up of BI-RADS 3 lesions as an alternative to biopsy could reduce unnecessary biopsies. However, prospective, larger-sample studies are needed for better conclusions.

Conflict-of-Interest and Financial Disclosure

The authors declare that they have no conflict of interest to disclose. The authors also declare that they did not receive any financial support for the study.

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