Smyrna Tıp Dergisi ***Araştırma Makalesi***

Optimizing Biopsy Strategies for Nonpalpable Breast Lesions; Evaluating the Efficacy of Wire-Guided Biopsy: A Retrospective Cohort Study

Nonpalpabl Meme Lezyonları için Biyopsi Stratejilerinin Optimizasyonu; Tel ile İşaretleme Biyopsilerinin Etkinliğinin Değerlendirilmesi: Retrospektif Kohort Çalışması

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Summary

Objective: The increased use of mamography in breast cancer screening programs has resulted in the detection of large numbers of nonpalpable malignant lesions. Eventhough the most frequently preferred technique in these cases is wire localization biopsy, unnecessary biopsy rates are still higher. Aim of the study is to identify the criteria that will help to reduce the unnecessary biopsy rates.

Material and Methods: Fifty-seven patients with BIRADS IV or BIRADS V breast lesions identified on ultrasonography or mammography were included in the study. Study was conducted at the Ankara Numune Education and Research Hospital Department of General Surgery between February 2012 and July 2013. Demographic, radiologic, and histopathologic data of the patients were collected, and the relationship between data groups was statistically analyzed.

Results: The median age of the patients was 50.33±8.632 (min:27-max:76). There were 17 (%29.8) malignant and 40 (%70.2) benign patients. %52 of malign patients were in fifth decade. Malignancy rate was %27.5 in BIRADS IV patients. All the patients with BIRADS V lesion were malignant. The relation between BIRADS score and malignancy was statistically significant (p=0.001). Malignancy rate was %40 in microcalcification group. The success rate of wire needle localization was %96. Being selective in the indications for wire-guided biopsy is beneficial in reducing unnecessary biopsies and the associated medical and financial burdens. In the study, the procedure's ability to detect malignant cases was determined to be 29.8%. Within the existing literature, there are publications that describe cases where wire-guided biopsy was used to identify radiologically suspicious lesions, similar to this study. When examining the subgroups, malignancy rates for each group were identified as 7% for BIRADS IVa, 33% for BIRADS IVb, and 75% for BIRADS IVc. The high rates of malignancy in particularly the BIRADS IVc subgroup and the BIRADS V category suggest a priority indication for wire-guided biopsy in these groups of patients. The age group of 50 to 69 years old represents the predominant demographic for breast cancer in women. In the study, 45.6% of all cases were identified in the age group of 50-59 years, and it was observed that 34.6% of these were malignant.

Conclusion: Wire localization biopsy could be practiced safely for patients aged over 50 years and who have BIRADS IVc or BIRADS V lesions that contain microcalcifications in mammography.

Key words: Breast, nonpalpable breast lesion, wire-guided breast biopsy

Özet

Amaç: Meme kanseri tarama programlarında mamografinin artan kullanımı, palpabl olmayan büyük sayıda malign lezyonun tespit edilmesine neden olmuştur. Bu durumlarda en sık tercih edilen teknik olan tel lokalizasyon biyopsisi olmasına rağmen, gereksiz biyopsi oranları hala daha yüksektir. Bu çalışmanın amacı, gereksiz biyopsi oranlarını azaltmaya yardımcı olacak kriterleri belirlemektir.

Gereç ve Yöntem: Ultrasonografi veya mamografide BIRADS IV veya BIRADS V meme lezyonu olan 57 hasta çalışmaya dahil edilmiştir. Bu çalışma, Şubat 2012'den Temmuz 2013 tarihleri arasında Ankara Numune Eğitim ve Araştırma Hastanesi Genel Cerrahi Bölümünde yürütülmüştür. Hastaların demografik, radyolojik ve histopatolojik verileri toplanmış olup veri grupları ve arasındaki ilişki istatistiksel olarak incelenmiştir.

Bulgular: Hastaların medyan yaşı 50,33±8,632 (min:27-max:76) idi. 17 (%29,8) malign ve 40 (%70,2) benign hasta vardı. Malign hastaların %52'si beşinci on yılda idi. BIRADS IV hastalarında malignite oranı %27,5 idi. BIRADS V lezyonu olan tüm hastalar maligndi. BIRADS skoru ile malignite arasındaki ilişki istatistiksel olarak anlamlıydı (p=0.001). Mikrokalsifikasyon grubunda malignite oranı %40; tel iğne lokalizasyonunun başarı oranı %96 saptandı. Meme biyopsilerinde tel ile işaretleme için endikasyonların seçici olunması, gereksiz biyopsileri ve bunlarla ilişkili tıbbi ve finansal yükleri azaltmada faydalıdır. Çalışmada, işlemin malign vakaları tespit etme yeteneği %29,8 olarak belirlenmiştir. Alt gruplar incelendiğinde, her grup için malignite oranları BIRADS IVa için %7, BIRADS IVb için %33 ve BIRADS IVc için %75 olarak belirlenmiştir. Özellikle BIRADS IVc alt grubu ve BIRADS V kategorisinde malignite oranlarının yüksek olması, bu hasta gruplarında tel rehberli biyopsinin öncelikli bir endikasyon olduğunu önermektedir. Kadınlarda meme kanseri için en yaygın demografik grup 50 ile 69 yaş arasıdır. Çalışmada, tüm vakaların %45,6'sı 50-59 yaş grubunda tespit edilmiş ve bu vakaların %34,6'sının malign olduğu gözlemlenmiştir.
Tartışma: Tel lokalizasyon biyopsisi, 50 yaşın üzerindeki ve mamografide mikrokalsifikasyon içeren BIRADS IVc veya BIRADS V lezyonları olan hastalarda güvenle uygulanabilir.
Anahtar kelimeler: Meme, nonpalpabl meme lezyonu, tel ile işaretli meme biyopsisi

Kabul Tarihi: 23.Nisan.2024

Introduction

Breast cancer in females is the prevailing kind of cancer, with an annual incidence exceeding 2 million cases (1,2). In Turkiye, the occurrence of breast cancer has about doubled in comparison to the preceding decade. The breast cancer screening program in Turkiye targets women aged 40 and above, including annual mammograms (3). The implementation of screening programs and technical advancements has resulted in a rise in the early detection of breast lesions (4).

Accurate localization of non-palpable lesions is essential for achieving an adequate safety margin during excision in early-detected cases, which helps in minimizing local recurrence and precisely identifying the tumor bed in patients undergoing breast-conserving surgery (5,6). Wire-guided localization (WGL) is the conventional technique used to locate nonpalpable breast lesions (7). The existing standard procedure of wire localization (WL) typically involves placing a wire into the breast lesion under radiological supervision, generally on the day the surgery is scheduled (8).

However, it has been reported that the rate of breast cancer detection in cases where wire-guided biopsy of the breast is applied ranges between 10% and 36% (9,10). As can be inferred from this data, it is evident that unnecessary biopsies are performed in 70-90% of benign cases. Additionally, the cost and morbidity associated with the procedure are also high. This situation underscores the necessity of establishing a diagnosis in the preoperative period to prevent unnecessary biopsies.

This study aims to identify criteria that could minimize unnecessary biopsy rates in patients undergoing wire-guided breast biopsy. By determining criteria that can predict which patients are likely to have malignant outcomes, we aim to reduce the number of biopsies performed on benign cases, thereby enhancing the reliability of the technique.

Material and Method

This retrospective study included 57 female patients with nonpalpable BIRADS IV and V lesions who underwent wire-guided biopsy at Ankara Numune Education and Research Hospital's General Surgery Clinic between February 2012 and July 2013. The diagnostic value of biopsies performed after wire localization under mammography (MMG) or ultrasonography (USG) guidance, factors influencing malignancy, pathology results, stages of breast cancer, and treatment outcomes were examined. The study was conducted retrospectively, with data extracted from the SARUS computer system archives, under the approval of the Ankara Numune Education and Research Hospital Scientific Committee, dated 06.11.2013, with application number 686/2013.

Patients' age, lesion size, localization, and radiological characteristics were compared and analyzed in relation to malignancy. The success of specimen mammography and pathology results were evaluated for each patient. Mammography and USG reports were assessed according to the BIRADS classification system established by the ACR. All patients underwent MMG and USG at our hospital's radiology clinic. Lesions identified as suspicious were marked with a wire by the radiology clinic.

The marking was considered successful if the tip of the wire was within or 5 mm close to the lesion. Wire marking was applied to BIRADS IV and BRADS V lesions that contained microcalcifications, solid masses, cystic lesions, or microcalcifications detected during MMG or USG and recommended for biopsy by a radiologist.

For localization procedures, a MatekTM Breast Localization Needle 20 G, 10 cm guide wire was used without local anesthesia. The position of the wire relative to the lesion and the lesion's distance from the skin were checked with MMG, USG, or both, and reported to the surgeon preoperatively by the radiologist. After marking, surgical excision was performed under local or general anesthesia in the operating room on the same day.

Data obtained from the study were analyzed using PASW Statistics Version 18 software. Descriptive statistical methods were used to evaluate the data, along with Fisher's exact test and Pearson's Chi-Square test for comparing qualitative data. Sensitivity, specificity, positive predictive value, and negative predictive value of the variables were calculated. Results were evaluated at a significance level.

Sensitivity refers to the test's ability to correctly identify patients with the disease, i.e., the percentage of positive results in those who are actually sick (True positive / True positive + False negative). Specificity refers to the test's ability to correctly identify healthy individuals, i.e., the percentage of negative results in those who are not sick (True negative / True negative + False positive). Predictive Value compares the likelihood of accurately identifying patients with the disease at any given test time to the likelihood of obtaining a positive result (false positive) in healthy individuals. For example, the odds ratio of a test developed to diagnose a disease would be the likelihood of the test confirming the disease divided by the likelihood of the test producing a positive result in non-diseased subjects.

Results

The study encompassed individuals ranging in age from 27 to 76 years, with an average age of 50.3±8.6. Regarding the pathological distribution of the cases, 17 (29.8%) were diagnosed as malignant and 40 (70.2%) were diagnosed as benign (Table 1).

Table 1. *Classification and percentage of cases as pathological character*

Pathology	**n**	**%**
Malignant	17	29,8
Benign	40	70,2
Total	57	100

Upon analyzing the pathological results, it was found that out of the 17 malignant cases, 12 (21%) were diagnosed as invasive ductal carcinoma, 4 (7%) as DCIS, and 1 (1.8%) as invasive lobular carcinoma. Out of the 40 reported cases classified as benign, 14 were diagnosed as intraductal papilloma, 2 as lobular intraepithelial neoplasia (LIN), 6 as fibroadenoma, 14 as fibrocystic disease, and 4 as atypical hyperplasia (Table 2).

Table 2. *Numerical and percentage distribution of cases according to pathological subtype*

Pathology	**n**	**%**
Intraductal Papilloma	14	24.6
Fibroadenoma	6 10.5	
Fibrocystic Disease	14	24.6
Atypical Hyperplasia	4	7
Lobular Intraepithelial Neoplasia	2	3.5
Invasive Ductal Carcinoma	12	21
DCIS	4	7
Invasive Lobular Carcinoma	1	1.8
Total	57	100

DCIS : Ductal Carcinoma In Situ

The cases were categorized based on age groups: below 40 years, 40-49 years, 50-59 years, and 60 years and above. The correlation between age and malignancy did not reach statistical significance based on the results of the Pearson Chi-Square test. Nevertheless, it was noted that all instances and cancerous individuals were concentrated in the age range of the fifth decade (Table 3).

Table 3. *Differentiation between malignant and benign according to age groups*

Age	**Malignant**	**Benign**	**total**	**P Value**
<40	1	4	5	0,465
40-49	4	16	20	
50-59	9	17	26	
>60	3	3	6	
Total	17	40	57	

Out of the total number of cases, 28 were less than 1 cm in size, 25 were between 1 and 2 cm, and 4 were greater than 2 cm. Out of the malignant cases, 9 had a size smaller than 1 cm. However, there was no statistically significant difference observed between tumor size and malignancy (Table 4).

Table 4. *Distribution of pathological results according to tumor size*

Size	Malignant	Benig	Total	P Value
<1 cm	9	19	28	0,534
1-2 cm	6	19	25	
>2 cm	2	2	4	
Total	17	40	57	

Following analyzing the BIRADS score of the cases, it was observed that 51 patients entered into the BIRADS IV category, while 6 patients got into the BIRADS V category. Eleven cases (21.5%) in the BIRADS IV category were found to be malignant, while all cases in the BIRADS V category were malignant. Upon examining the relationship between BIRADS and malignancy, it was found that this correlation was statistically significant (p-0.001) based on Fischer's Reality test.

Upon examination of the BIRADS IV subgroups, it is evident that the majority of cases belong into the IV a group. However, malignant cases are most commonly found in the IV c group. The BIRADS IV c group exhibited a malignancy rate of 75% (Table 5).

Table 5. *Distribution of lesions according to BIRADS classification*

BIRAD	Malignant	Benign	Total
IV	6	24	30
IVa	1	13 14	
IVb	1	2	3
IVc	3	1 4	
V	6	0 6	
Total	17	40	57

During their examinations, there were 35 cases that exhibited microcalcification, a characteristic associated with malignancy, and 14 cases that were confirmed to be malignant. Within the group of lesions that exhibited microcalcification, the proportion of cases that were determined to be malignant was 40%.

The rate of malignancy among the cases without microcalcification was 13%. Upon investigating the correlation between microcalcification and malignancy, it was determined that this association exhibited statistical significance based on Fischer's Reality test (Table 6). The diagnostic sensitivity of MMG for detecting malignant cases was 82.3%, while its specificity was 86.3%. The positive predictive value was 6.04, and the negative predictive value was 0.2.

Table 6. *Distribution of pathological results according to the presence of microcalcifications on mammography*

Microcalcification	Malignant	Benign	Total
Exist	14	21	35
None	3	19	22
Total	17	40	57

P value: 033

When analyzing the USG characteristics, it was found that nearly half of the cases (42%) had no detectable features. However, in cases where charecteristics were present, there was a high suspicious of malignancy (42%), particularly when solid mass lesions were identified. (Table 7). Based on the results of the Pearson Chi-Square test (p=0.215), this finding was not statistically significant. The USG's sensitivity for detecting malignancy was 58.8%, while its specificity was 77.4%. The positive predictive ratio was 2.61 and the negative predictive ratio was 0.53.

Table 7. *Distribution of pathological results according to USG charecteristics*

USG	Malignant	Benign	Total
Solid	9	12	21
Cystic	0	6	6
Microcalcification	0	1	1
Solid and microcalcification	1	4	5
No features	7	17	24
Total	17	40	57

P value: 0,296

On evaluating the pathology of the cases, it was determined that four patients were in Stage 0, seven patients were in Stage I, and six patients were in Stage 11A. Imaging studies revealed the presence of axillary lymph node in four patients, all of whom had a primary tumor size of less than 1 cm. No cases exhibited distant metastasis.

Surgical margins were considered adequate for excision in 12 patients following wire marking and breast-conserving surgery (BCS). A second surgery was unnecessary. Four patients underwent MRM. One patient underwent simple mastectomy for invasive lobular carcinoma (Table 8).

Table 8. *Stage of cases reported as malignant and surgery performed*

Stage	MRM	BCS	SP
Stage 0	0	3	1
Stage 1	2	5	0
Stage 2A	2	4	0
Total	4	12	1

MRM : Modified Radical Mastectomy, BPS: Breast Conserving Surgery, SP: Simple mastectomy

Discussion

Being selective in the indications for wire-guided biopsy is beneficial in reducing unnecessary biopsies and the associated medical and financial burdens. In the study, the procedure's ability to detect malignant cases was determined to be 29.8%. Within the existing literature, there are publications that describe cases where wire-guided biopsy was used to identify radiologically suspicious lesions, similar to the study. In the study conducted by Mediana Franco et al. (11), the rate of detecting malignancies was 16%, while in the study conducted by Duarte et al. (12), it was 16.9%. To increase these rates and minimize the number of unnecessary biopsies, establishing certain criteria could be useful in preventing the performance of wire-guided biopsies in benign cases. In the study, the proportion of benign cases was identified as 70.2%. This rate corroborates that 30-40% of BIRADS IV cases turn out to be malignant, highlighting the reliability of the radiology unit's BIRADS classification.

Ductal Carcinoma In Situ is identified through mammography rather than a physical examination, and it is estimated to account for 15-20% of all breast cancers (13). The possibility of detecting in situ cancers through wire-guided biopsy has also become feasible. In a study published by Yetkin and colleagues (14), the incidence of malignancy was found to be 19.36%; in the series of Elzohery et al. (6), this rate is 10%.

According to the study data, the proportion of cases diagnosed with DCIS was 7% of the total number of cases. The incidence of Ductal Carcinoma In Situ (DCIS) diagnosis was found to be 12.5% among the cases where malignancy was identified. Within the presented research, there were a total of 13 cases of invasive cancers, specifically invasive ductal carcinoma and invasive lobular carcinoma. These cases accounted for 22.8% of the total number of cases observed. All instances of DCIS detected were smaller than 2 cm in size and were detected at an early stage. The study revealed that , the ratio of in situ to invasive cancer was 30%. When compared to the existing body of literature, this ratio seems to be comparatively low. The lower in situ cancer ratio can be attributed to the smaller number of BIRADS V cases.

Advanced age increases the risk of developing breast cancer. The age group of 50 to 69 years old represents the predominant demographic for breast cancer in women (15,16). In the study, 45.6% of all cases were identified in the age group of 50-59 years, and it was observed that 34.6% of these were malignant. In cases over 50 years of age, wire-guided biopsy can be preferably chosen in the study as well, since it is found to be most commonly associated with malignant cases in the fifth decade, compared to other biopsy techniques.

If the mean lesion sizes of the patients included in the study are evaluated according to the literature, they are seen as 0.9 cm (17), 1,1 cm (18), 2.05 cm (6) and 2.5 cm (19). In the study, lesions under 1 cm constituted 49% of all cases. 52% of the malignant cases were under 1 cm. However, no significant relationship was found between the size of the mass and malignancy. It was concluded that the characteristics identified in mass imaging are more important than size. The need for biopsy with marking in four cases over 2 cm could be attributed to differences in the experiences of different surgeons or difficulties in palpation due to macromastia in patients.

The assessment and interpretation of mammograms, as well as the understanding of the disease, depend on The Breast Imaging Reporting and Data System (BIRADS) established by the American College of Radiology. The report combines diagnostic mammography and sonographic findings, with a final judgment division ranging from 1 to 6 based on the level of suspicion for the lesion (20). The study conducted by Ghaemian et al. examined the diagnostic value of the BIRADS classification for malignancy.

The results showed that in category 4A, there was a sensitivity of 22.6% and a specificity of 22.9%. In category 4B, the sensitivity was 2.8% and the specificity was 99.1%. In category 4C, the specificity was 14.2% and the specificity was 97.2%. The observed sensitivity and specificity for BIRADS 5 were 60.4% and 100% respectively (21). In the study, BIRADS IV cases constituted 89.4% of all cases, with 27.5% of these cases being identified as malignant. The proportion of BIRADS V cases was 10.6%, and all of these were assessed as malignant. The malignancy rate for BIRADS V cases was determined to be 100%. When examining the subgroups, malignancy rates for each group were identified as 7% for BIRADS IVa, 33% for BIRADS IVb, and 75% for BIRADS IVc. The high rates of malignancy in particularly the BIRADS IVc subgroup and the BIRADS V category suggest a priority indication for wire-guided biopsy in these groups of patients.

Approximately 30 to 50% of nonpalpable lesions are only detectable through microcalcifications, which are the most frequently observed radiomorphological sign that prompts a biopsy (22). The ratio was documented by Hasselgreen et al. (23) as 51%, by Hall et al. (24) as 53%, and by Hacim et al. (25) as 54%. Microcalcifications are not very well visualized with ultrasound (USG). Only about 15% of calcifications, which are not associated with a mass seen in mammography, can be visualized with USG (26). In the study, microcalcifications were detected in 61.4% of all cases on mammography. Among the cases where microcalcifications were identified, the malignancy rate was found to be 40%. The relationship between microcalcifications and malignancy was also statistically significant. In the literature, this rate is reported to be between 7,89-47,8% (27,28,29). When microcalcifications are detected in mammography, wire-guided biopsy may be the preferred technique.

This study, focusing on breast cancer diagnosis using mammography and wire-guided biopsy, has several limitations that merit attention. The research was conducted with a limited number of patients from a specific region or demographic group, which may affect the applicability of our findings to different populations with varying ethnicities, ages, and genetic backgrounds. Our methodology primarily involved mammography and wire-guided biopsy, standard methods that may not completely capture the diverse presentations of breast cancer, especially in varied breast tissue densities or at very early stages.

The duration of follow-up post-diagnosis in the study, while providing initial insights, may not be long enough to fully understand the long-term implications, such as recurrence rates or the effectiveness of treatments. The technological aspects, such as the resolution of mammography equipment and biopsy tools, play a significant role in detecting lesions and could vary across medical centers, leading to inconsistent findings. Additionally, the interpretation of radiological data is subject to a degree of subjectivity, potentially leading to inter-observer variability in lesion classification and treatment decisions.

Another aspect to consider is the external validity of the findings, as procedures and protocols are specific to a medical center and may not directly translate to other settings with different medical practices and healthcare systems. Furthermore, the statistical methods used, though appropriate for our data, may have limitations in fully addressing certain biases or confounding variables.

These considerations are crucial for understanding the context and applicability of our results. Future research should aim to include a broader and more diverse population, extend the follow-up period, and incorporate newer diagnostic technologies to validate and expand upon our findings

Conclusion

Screening mammographies have led to an increase in the number of nonpalpable suspicious lesions. The choice of methods for diagnosing nonpalpable lesions forms a crucial part of the patients' treatment protocol. The most commonly used method for this purpose is surgical excision following wire localization guided by mammography (MMG). However, when looking at the diagnostic rates of this method, they are found to be between 10-36%. As in the study, unnecessary biopsies, which can reach up to 70%, are one of the major disadvantages of the procedure. The application of IIAB or tru- cut biopsy techniques does not change these rates, and wire-guided biopsy remains valid for definitive diagnosis and treatment. In conclusion, in women over 50 years of age with BIRADS IV; particularly those in the BIRADS IVc subgroup, and those with BIRADS V lesions and microcalcifications detected in mammography, wire- guided biopsy should be recommended as the preferred method. The success rate is increased by the collaborative work of surgical, radiological, and pathological units, and the full implementation of control steps in this technique.

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