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Original Article

Diagnostic effectiveness of wire-guided localization for non-palpable breast lesions and its importance in breast cancer management

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Abstract

Objective: Breast cancer represents the most prevalent malignant disease among women globally, accounting for approximately 30% of all female cancers. Wire-guided localization is now a commonly utilized method for diagnosing breast lesions that are not palpable on clinical examination but can be identified through the use of mammography (MG) and/or ultrasound (US). The objective of the study was to determine the cancer prediction rate of the method in patients with non-palpable breast lesions who underwent excisional biopsy with wire guided localization and to evaluate the diagnostic significance of the method by comparing age, size, family history, radiomorphologic type, Breast Imaging and Data System (BI-RADS) category, location, and histopathologic features. Furthermore, the objective was to elucidate the advantages of the method in breast cancer treatment by determining the re-excision rates and types according to the surgical margin status of malignant lesions.

Methods: The study was planned retrospectively. A total of 228 histopathologically examined lesions that underwent US or MG-guided wire-guided excisional biopsy for non-palpable breast lesions between June 2006 and December 2011 were included in the study.

Results: Of all lesions, 58 (25.4%) were diagnosed as malignant, while 170 (74.6%) were diagnosed as benign pathologies. The cancer prediction rate of the method was determined to be 25.4%. The malignancy rate demonstrated a statistically significant correlation with age, with an increasing trend observed with advancing age (p=0.006). No statistically significant differences were observed between malignant and benign lesions with respect to size, localization, or family history. With regard to lesion type, the malignancy rate was higher in lesions comprising microcalcification clusters (p=0.005). Malignancy rates were significantly higher in the BI-RADS 4b (OR:6.06) and BI-RADS 4c (OR:6.77) groups compared to the other BI-RADS categories. In cases where the surgical margins were positive for malignancy (28/58), the rate of mastectomy was significantly higher than in cases where the margins were negative (p=0.006). The majority of malignant lesions (79.3%) were classified as stage 0 or 1 cancers.

Conclusion: Wire-guided localization is still an effective method for early diagnosis of breast cancer and identification of suspicious non-palpable lesions. Developing new techniques in pathology, radiology, and surgery to better localize suspicious non-palpable lesions and reduce surgical margin positivity rates will facilitate the fight against breast cancer.

Keywords: Breast cancer, mammography, reexcision, surgery, ultrasound, wire guided localization.

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INTRODUCTION

According to the Global Cancer Observatory (GLOBOCAN) data published by the International Agency for Research on Cancer (IARC), breast cancer is the most common cancer in women worldwide, with 2.3 million new diagnoses in 185 countries worldwide in 2020 and approximately 685,000 women dying from the disease. This represents one in eight cancer diagnoses and a mortality rate of 6.9% (1,2). Due to the high incidence of breast cancer, mammography (MG) screening programs have become widespread throughout the world. As a result of the widespread use of MG screening programs, more women are undergoing MG examinations, and non-palpable breast lesions are being detected more frequently (3). Between 25-35% of breast cancers are non-palpable lesions at the time of diagnosis. Localization and biopsy methods are used to diagnose these lesions (4). Although more than 50 years have passed since its first application, wire-guided localization biopsy (WGL) is stil widely used for non-palpable breast lesions and is considered the gold standard (5). Although there have been extensive studies of radio-guided occult lesion localization with injection of 99 technetium (ROLL), radioactive seed of 125 iodine (RIS), radiofrequency identification with microprocess or tag (RFID), scout radar, paramagnetic-based particle methods as alternatives to this method (6-10), their use has not become as widespread as wire localization biopsy.

This study aimed to investigate the diagnostic efficacy and reliability of the wire localization biopsy method in non-palpable breast lesions.

MATERIALS AND METHODS

A total of 228 lesions of 224 patients who underwent excisional biopsy after wire localization under MG and/or ultrasound (US) guidance for non-palpable BI-RADS (Breast Imaging and Data System) categories 3-5 breast lesions between June 2006 and December 2011 at the General Surgery Clinic of Gazi University Faculty of Medicine (GUFM) were included in the study. This study was conducted with the approval of GUFM Research Ethics Committee number 382 dated 11-28-2012. Demographic characteristics, histopathological and radiological reports of the patients were retrospectively reviewed from the hospital information system. MG and US examinations were reported using the BI-RADS classification. Lesions detected by either MG or breast US were localized by that radiologic method, and lesions detected by both were localized by US guidance. For both methods, localization was considered successful if the wire tip was within or within 1 cm of the lesion. During surgery, the direction of the wire, its relationship to the lesion, and the depth of the lesion from the skin were reported by the radiologist to inform the surgeon.

After with a needle-wire system, the cases were sent to the general surgery clinic and operated on the same day. Under general anesthesia, the wire-marked area was excised together with 1 cm of surrounding intact tissue, according to the radiologist's marking report. The directions of the excised area were marked with silk sutures. This specimen was checked by US or MG and sent to the pathology department after the complete removal of the lesion was confirmed by the radiologist. Subcutaneous tissue and skin were closed without placing a drain in the cavity. Lesions were evaluated for age, BI-RADS category, size, family history, location, lesion type, and surgical margin. These characteristics were compared with histopathologic findings. The cancer-predictive value of the method was determined.

In addition, re-excision rates in cases with histopathologically detected malignancy and comparisons of these rates by histopathologic subtype were performed. For malignant lesions, a positive surgical margin was defined as a tumor that was closer than 2 mm to the clean surgical margin or a tumor that showed continuity at the surgical margin.

Statistical Analysis

In this study, statistical analyses were performed using the SPSS 15.0 package program. Descriptive statistics, mean (±) standard deviation, median (min-max), and frequency distribution were presented as percentages. Fisher's exact test, chi-squared test with Yates correction, and chi-squared significance test were used for categorical data in inter group comparisons. Mann-Whitney U test was used to compare malignant versus benign age. Odds ratio (OR) values are presented with a 95% confidence interval (CI). The statistical significance level was set at $p<0.05$.

RESULTS

The study was conducted between June 2006 and December 2011 in a total of 224 female patients between the ages of 18 and 77. The total number of lesions was 228. The mean age of the patients was 48.93±10.05 years, 52.03 in malignant cases, and 47.85 in benign cases. While 61 (27.2%) of the patients were younger than 45 years, 163 (72.8%) were older than 45 years. Of the 228 lesions, 58 (25.4%) were malignant and 170 (74.6%) were benign on histopathologic examination. The positive predictive value (PPD) of the method was 25.4%. When benign-malignant lesions were compared according to age, the mean age of malignant lesions was significantly higher (p=0.006) (Table 1).

Table 1. Distribution of benign or malignant lesions by age

	N	Age (Mean±SD)	P value
Benign	170 (74.6%)	47.85±9.78	
Malign	58 (**25.4%**)	52.03±10.33	**0.006**

A total of 15 patients had a family history of breast cancer, while 209 patients had no family history of breast cancer. The risk of malignancy was 1.51 times higher in patients with a family history compared to those without a family history. However, no statistically significant difference was found. There was no statistically significant difference between lesion size and malignancy. When the relationship between radiomorphologic lesion type and malignancy was analyzed, it was observed that the malignancy rate was higher and statistically significant in lesions consisting of microcalcification clusters (Table 2) (p=0.005). According to US and/or MG reports, 19 lesions (8.3%) were BI-RADS 3, 136 lesions (59.6%) were BI-RADS 4a, 45 (19.7%) were BI-RADS 4b, 26 lesions (11.4%) were BI-RADS 4c, and two lesions (0.9%) were BI-RADS 5.

Table 2. Distribution of benign/malignant lesions by radiologically defined (MG/US) lesion type

	Malign	Benign
Lesion type (n=228)	**n (%)**	**n (%)**
Solid mass	13 (22.4%)	83 (48.8%)
Microcalcification cluster	37 (63.8%)	58 (34.1%)
Microcalcification+mass	5 (8.6%)	13 (7.6%)
Hypoechoic area	2 (3.4%)	8 (4.7%)
Complicated cyst	-	5 (2.9%)
Nodular density	1 (1.7%)	2 (1.2%)
Parenchyma distortion	-	1 (0.6%)
	p=0.005	

While the histopathology of all BI-RADS 3 lesions was benign, 20 (14.7%) of 136 BI-RADS 4a lesions were malignant, 23 (51.1%) of 45 BI-RADS 4b lesions were malignant, 14 (53.8%) of 26 BI-RADS 4c lesions were malignant, and one (50%) of two BI-RADS 5 lesions were malignant. Statistically, there was a significant presence of malignancy in the BI-RADS 4b and BI-RADS 4c groups (p=0.001) (Table 3). The risk of malignancy was 6.06 times higher in BI-RADS 4b and 6.77 times higher in BI-RADS 4c.

Table 3. Distribution of histopathologic results by BI-RADS

BI-RADS category (n=280)	**Malign n**	**%**	**Benign n**	**%**	**OR**	**95% CI**	**P value**
BI-RADS 3	-	-	19	100	0.001	0.001-1.66	0.135*
BI-RADS 4a	20	14.7	116	85.3	1		
BI-RADS 4b	23	**51.1**	22	48.9	**6.06**	2.68-13.84	**0.0001****
BI-RADS 4c	14	**53.8**	12	46.2	**6.77**	2.51-18.50	**0.0001****
BI-RADS 5	1	50	1	50	5.80	0.01-223.26	0.282*
							p=0.0001***

Abbreviations: BI-RADS: Breast Imaging and Data System, CI: Confidence Interval, OR: Odds Ratio. *Fisher's exact test, **Chi-squared test with Yates correction, ***Chi-squared significance test.

Table 4. Distribution of surgical margin positivity rates based on benign and malignant lesions

	Surgical margin negative		**Surgical margin positive**		**OR**	**%95 CI**	**P value**
	Number	**%**	**Number**	**%**			
Benign	144	84.7	26	15.3	5.169	2.66-10.03	**0.0001***
Malign	30	51.7	28	48.3	1		
Total	174	76.3	54	23.7			

Abbreviations: CI: Confidence Interval, OR: Odds Ratio. *Chi-squared significance test.

Table 5. Relationship between surgical margin and breast conserving surgery in malignant lesions

	Malign lesions margin status			
	Negative margin		**Positive margin**	
BCS	18	60%	1	3.57%
Mastectomy procedures	12	40%	27	96.4%
				p=0.006*

Abbreviations: BCS: Breast Conserving Surgery.*Chi-squared significance test.

Of the 58 histopathologically malignant lesions, 30 were invasive carcinomas, and 28 were in situ carcinomas. When the malignant lesions were evaluated according to histopathologic types, 47 (19.7%) were ductal carcinoma, 6 (2.6%) were papillary carcinoma, and five lesions were lobular carcinoma, tubular carcinoma, mixed carcinoma, and mucinous carcinoma subtypes. The most common benign pathology was a fibrocystic change (34.2%), followed by intraductal papilloma (13.6%), ductal epithelial hyperplasia (11.4%), and other pathologies. Looking at the surgical margin positivity rates of the extracted specimens, 30 (51.7%) of the 58 malignant lesions had negative surgical margins, while 28 (48.3%) had positive surgical margins (Table 4). When the 58 patients diagnosed with malignancy were evaluated in

terms of therapeutic approach, 47 (81%) patients underwent additional surgery, while 11 (19%) patients did not require additional surgery. Regarding the relationship between surgical margin and breast-conserving surgery (BCS), only 1 (3.57%) of 28 patients with positive surgical margins underwent BCS, whereas 18 (60%) of 30 patients with negative surgical margins underwent BCS. There was a statistically significant difference between the positive and negative margin groups with respect to BCS (p=0.006) (Table 5).

DISCUSSION

With the widespread use of MG screening programs, detection rates of non-palpable breast lesions have increased. Detection of non-palpable breast lesions and biopsy of these lesions with appropriate methods has led to the detection of breast cancer at earlier stages. Survival of breast cancer diagnosed at earlier stages has increased, and BCS has become more preferred with the development of radiotherapy facilities. WGL is still the most widely used biopsy method for histopathologic diagnosis of these non-palpable breast lesions. This procedure has a number of complications. These include wire displacement, syncope, bleeding, and incomplete lesion removal. In addition to its complications, it has disadvantages such as patient anxiety and time dependency since it is performed on the same day.

Our study found that WGL remains an effective, safe, and applicable method for non-palpable breast lesions. In our study, all lesions were removed using this method and confirmed by the radiologist with US or MG. We did not encounter any known complications of this method, such as syncope, bleeding, wire displacement, wire breakage, and retention in breast tissue. The 228 lesions included in our study were diagnosed histopathologically, which demonstrates the efficacy of the employed methodology. Of the lesions in question, 58 were histopathologically diagnosed as malignant. This result indicates that the cancer prediction value of the method is 25.4%, a figure that varies in different studies in the literature (11,12). It seems plausible to suggest that the higher prevalence of malignant lesions observed in recent studies may be attributable to more selective biopsy indications and the concomitant increase in technical and experiential capabilities of radiology units. The rate observed in our study is consistent with the results reported in the current literature. The relatively low rate of malignancy indicates that some unnecessary biopsies may have been performed, whereas exceedingly high rates suggest that some malign cases may have been overlooked. The mean age of malignant lesions was found to be significantly higher. Upon analysis of the histopathologic distribution according to age groups, it was observed that the likelihood of malignancy increased with increasing age; however, this trend was not statistically significant. An examination of the relationship between the radiomorphologic status of lesions and malignancy reveals that the majority of malignant lesions are comprised of microcalcification clusters (63%). In the existing literature, it is reported that approximately 50% of non-palpable breast cancers consist of microcalcification clusters. In our series, the prevalence of microcalcifications in malignant cases appears to be slightly higher than that reported in the literature (13). This may be attributed to the utilization of different biopsy techniques in lesions without microcalcifications.

The BI-RADS system was developed by the American College of Radiology in 1993 with the objective of providing information to clinicians in a standardized language and facilitating the management of cases (14). In our study, an examination of the relationship between BI-RADS classification and malignant lesions revealed an absence of evidence of malignancy in all BI-RADS 3 lesions (0%). Malignancy was identified in 14.7% (20/136) of BI-RADS 4a lesions, 51.1% (23/45) of BI-RADS 4b lesions, 53.8% (14/26) of BI-RADS 4c lesions, and 50% (1/2) of BI-RADS 5 lesions. In the existing literature, the malignancy rate in lesions classified as BI-RADS 3 is reported to range from 0% to 2%. The appropriate use of this category serves to reduce false positive biopsy rates while maintaining an acceptable cancer detection rate (15). In a recent study, this rate was found to be 0.6%. In the majority of BI-RADS 3 lesions that were diagnosed as malignant, an increase in size or morphologic change was identified during follow-up (16). The BI-RADS 3 malignancy rate in our study was 0%, which is consistent with the current literature. We contend that lesions classified as BI-RADS 3 should primarily be followed up at 6-month intervals.

Additionally, it is recommended that biopsy rates remain high in accordance with the estimated risk of malignancy. It is established that the malignancy rate in BI-RADS 5 lesions exceeds 95%. In our study, the observed rate was approximately 50%. It is hypothesized that this result is due to the low number of BI-RADS 5 patients who underwent a biopsy. The BI-RADS 4 category is more heterogeneous in that it encompasses a wide range of risk levels, with a specified range of 2-95%. The category is further subdivided into 4a (2-10% malignancy risk, low suspicion), 4b (10-50% malignancy risk, moderate suspicion), and 4c (50-95% malignancy risk, high suspicion) categories, thereby providing a more specific prediction and increasing compatibility with radiology pathology (17). In our study, BI-RADS 4 lesions constituted 90% of the lesions. The positive predictive value of BI-RADS 4 lesions for malignancy has been reported to range between 25.7% and 59.2% in the literature (18-20). In the present study, the positive predictive value for BI-RADS 4 lesions was calculated to be 38% (57/150). Our findings are in alignment with the existing literature. The malignancy rates for BI-RADS 4b and 4c were 51.1% and 53.8%, respectively, which were significantly higher than those observed in the other categories. The malignancy rate in lesions classified as BI-RADS 4a was found to be 14.7%. In a recently published study, US and MG in BI-RADS 4 lesions were found to be amenable to interpretation using an improved MRI (magnetic resonance imaging) method with dynamic contrast, thereby facilitating more accurate prediction and the prevention of unnecessary biopsies in this category (21). In a recent study, Xie et al. reported that 59.6% of 458 BI-RADS 4a lesions were downstaged to BI-RADS 3 with advanced MRI methods and that only 1.5% of these lesions exhibited malignant characteristics (22). As a result of these developments in radiology, it is anticipated that a reduced number of biopsy decisions will be made for BI-RADS 4a lesions. The surgical margin is a significant determinant of the surgical management of patients with malignancy following WGL biopsy. In our study, the incidence of positive surgical margins in malignant lesions was 48%. In the existing literature, the reported range for this rate is quite broad, spanning from 10% to 53% (23, 24). In a study of wire-guided breast biopsy, Toth et al. reported a positive surgical margin rate of 10.7% in 214 cases diagnosed as breast cancer. The authors posited that tumor volume, ductal carcinoma in situ (DCIS), and learning curve were independent prognostic factors for positive surgical margins (25). In comparison to studies conducted in previous years, a reduction in the incidence of positive surgical margins has been observed in recent studies (25-27). This decline may be attributed to the growing preference for breast-conserving surgery (BCS) among surgeons with increasing surgical and radiological experience. The widespread use of BCS has led to a shift in focus from the diagnostic to the therapeutic aspects of WGL. In cases where WGL results in negative surgical margins, patients with breast cancer may be treated with sentinel lymph node sampling and radiotherapy, obviating the need for re-excision.

In our study, of the 28 patients with positive surgical margins, only one underwent BCS, while the others underwent mastectomy procedures. It can be attributed to the fact that the majority of surgeons had limited experience with BCS and sought to address the concern of recurrence. In a multicenter study conducted by Fung et al. positive margin was identified in 12% of patients diagnosed with malignant lesions via WGL. Even though mastectomy procedures were performed in only one-third of patients with positive surgical margins, two-thirds of them underwent breast-conserving surgery with re-excision (28). The inclination of surgeons to select breast-conserving surgery for breast cancer, even in instances where positive surgical margins are present, has grown over time. Nevertheless, surgeons will typically opt for BCS in patients with negative surgical margins, given the reduced anxiety levels observed in such cases. To this end, further studies in the fields of radiology and surgery will be beneficial in reducing positive surgical margin rates.

As previously stated, the disadvantages and complications associated with the wire-guided biopsy procedure have prompted the continued development of alternative localization methods for non-palpable breast lesions. To address the issue of wire displacement, wires with varying properties have been developed, and the hook wire method is a commonly utilized approach (12). Furthermore, the utilization of a vacuum-assisted breast biopsy table to facilitate lesion localization has been explored

and documented as a safe and viable approach (29). While various techniques, including the use of methylene blue dye, carbon marking, and cryoprobe-assisted localization, have been described in the literature, their application has not become widespread. Furthermore, ultrasound-guided surgery (UGS) and radioactive material localization methods (ROLLIS, RIS) are regarded as viable alternatives to WGL (30). The necessity of imaging the lesion with US and the requirement for US training of surgeons represent a limitation of the UGS method (31). In a randomized controlled study by Taylor et al. comparing RIS and WGL, no statistically significant difference was found between the two groups in terms of positive surgical margin rate (32). In a recent meta-analysis comparing WGL, RIS, ROLL, and UGS, the benefits of the RIS and ROLL methods, including the lack of impact on the surgical incision site, enhanced patient comfort, and flexibility in surgical planning, were highlighted. However, no significant difference was observed between these methods and WGL in terms of outcomes such as re-excision rates and positive surgical margins. The results of this meta-analysis indicate that UGS is associated with a reduced incidence of surgical margin positivity compared to other methods, which may subsequently result in a lower rate of reoperations. The disadvantages of these techniques include the necessity for precise injection by the radiologist and time dependency in the ROLL procedure, as well as the requirement for trained personnel for radiation safety in the RIS procedure (34). However, in a recent study of 158 cases comparing UGS and ROLL, no statistically significant difference was found between UGS (10.98%) and ROLL (12.16%) in terms of positive surgical margins (35). The UGS method necessitates that surgeons receive training in US techniques. A comparative analysis of our experience with the WGL method and the current literature reveals that a significant superiority of radio localization methods over the WGL method has yet to be demonstrated. The inclusion of a greater number of cases in comparative studies will enhance the level of evidence. The successful and safe excision of non-palpable breast lesions with lower positive surgical margins will result in a reduction in the surgical recurrence rates of the disease and an improvement in breast cancer prognosis.

Limitations: The present study is limited by its retrospective design, the involvement of multiple surgeons, and the absence of a comparative element.

CONCLUSION

WGL is still an effective method for early diagnosis of breast cancer and identification of non-palpable suspicious lesions. It is cost-effective and safe compared to other methods. If supported by strong levels of evidence, new needle-free localization methods may replace this method in the coming years due to lower positive margin rates, less patient anxiety, and no risk of wire displacement.

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