Original Article

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How Many of the Biopsy Decisions Taken at Inexperienced Breast Radiology Units Were Correct?

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ABSTRACT

Objective: In this study, we aimed to determine the need for biopsy in patients referred from other clinics for the performance of biopsy with the suspicion of breast cancer.

Materials and Methods: 112 patients were included in the study. It was decided that their biopsies be performed following examinations in other clinics and they presented to the breast radiology unit of our hospital for a second opinion. The demographic characteristics, diagnostic studies completed in the other centers, properties of lesions, decision made as a result of examinations and BI-RADS (Breast Imaging Reporting and Data Systems) categorizations were recorded on the registration forms of the study patients. In addition, the quality of examinations, reasons of repeat tests, additional tests features and the last decision of our clinic were documented. The obtained data were analyzed in terms of re-examination, additional tests and change in the biopsy decision. Changes in the biopsy decisions for patients were specifically inquired.

Results: The biopsy decisions were cancelled in our breast radiology unit for 63 out of 112 patients (56.3%) whose biopsy decisions were made at an external institute. For 42 patients, examinations made by the other clinics were deemed adequate, yet there was no need for biopsy in 22 of them. The biopsy decisions were cancelled for 27 out of 47 patients (57.4%) with repeat examination and 18 out of 28 patients (64.3%) with additional tests because of the insufficient test quality.

Conclusion: Incorrect, inadequate breast screening and false positivity were higher at inexperienced institutes.

Keywords: Breast Radiology, biopsy, experience

Introduction

Breast cancer is the type of cancer with the highest incidence among women apart from skin cancer and it ranks the second among cancer-related deaths (1). Since mid-1980s, regional or national breast cancer screening programs have been carried out to reduce cancer-related mortality by increasing early diagnosis rates for breast cancer (2). Many studies performed have shown that screening via mammography brings about a decrease in breast cancer-related deaths (3-6). However, changes in screening guides and false positive mammography results increased frequency at which other diagnostic tests are applied. Therefore, Ultrasonography (US) in dense breasts, which is a safe and affordable method reducing false negative rates in breast cancer screening regimen, and Magnetic Resonance Imaging (MRI), which is a more reliable study for high-risk patient populations, came to be used in the screening process (7, 8). The abnormal findings obtained as a result of all these radiological assessments have led to a worrying level of increase in the use of breast biopsy utilization rates (9-11). Every year, 1 million women undergo breast biopsy in the USA and 80% of them have a benign pathological result (12-14). The negative pathological results of these false positive tests result in anxiety and morbidity in patients while they also cause an increase in healthcare costs (15, 16). In fact, it is reported that false positive results lead to an unnecessary healthcare expenditure of 1 billion USD every year in the USA (17). On the other hand, a benign breast biopsy result may be histologically good; however, it creates negative effects on the patient from psychological and emotional points of view and results in anxiety (18-20). In this study, we investigated the ratio of patients who really needed biopsy among the patients referred to our clinic for biopsy performance from external centers with the suspicion of breast cancer.

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Materials and Methods

Patients, who had studies were carried out at an external center, were decided to undergo biopsy and presented for consultation purposes to receive a second opinion to the Breast Radiology Unit of our Hospital between March-December, 2015, were consecutively included in the study. Study inclusion criteria: having a radiological study performed outside of our hospital for breast symptoms and screening purposes and having a decision for biopsy taken as a result of this study. All the patients that presented in this way were included in the study. Study exclusion criteria: Not having the DICOM CD image of the radiological study or digital study such as mammography, tomosynthesis or MRI; for US examination, not having the typical images showing the lesion. The patients who did not have a CD or US image were asked to obtain these data. However, the patients who failed to provide any CDs or US images were excluded from the study. Finally, 112 patients were included in the study. All of the patients that took part in the study were women and the median age was 52 (27-85).

A registration form was kept for the patients included in the study. In the registration form: The demographic data of the patient, features of the studies performed at an external center on the patient, characteristics of the lesion detected and decisions taken as a result of the study and the BI-RADS category given, if any, were recorded. After that, the adequacy of the study quality as judged by our unit, reason for repetition if the study was repeated, features of the additional study if additional studies were conducted and information on the final decision taken by us were recorded.

The studies were assessed at our unit by a single radiologist, who had 18 years of experience in breast radiology and the recommendations made were noted. The records obtained were analysed in terms of repeated studies, additional studies and changes in decision. Regarding the changes in decision, the number of patients whose biopsy decision was changed as a result of this assessment was specifically inquired.

Our study was retrospective and it was conducted in line with the Helsinki Declaration (2008).

Statistical analysis

For statistical analyses, the Statistical Package for the Social Sciences version 17.0 (SPSS Inc.; Chicago, IL, USA) was used. For assessing the biopsy requirements of groups, the independent sample t-test was used. For comparing the groups with one another, the variance analysis was used. The value of ≤0.05 was considered significant.

Results

The studies performed on patients referred to our unit with the indication for biopsy from external centers and their numbers are summarized in Table 1. For 42 (37.5%) of the patients that presented to our unit with a biopsy indication, the existing studies were considered adequate and no additional or repeated studies were required. In 22 (52.4%) of these cases, the decision for biopsy was cancelled.

In 47 (41.9%) of the patients, the studies were repeated since the existing studies were not sufficient in quality. The data regarding the studies that were repeated are summarized in Table 2. Forty seven patients underwent 50 studies in total and the number of studies per patient was calculated as 1.06. The decision for biopsy was cancelled in 27 (57.4%) of these patients.

Table 1. Studies performed at external centers on patients referred to our hospital for biopsy

	Mammography	Breast US	Breast MRI
Single Study (39.3%)	31 (27.7%)	6 (5.4%)	7 (6.7%)
Multiple Studies (60.7%)	66 (25.2%)	49 (18.7%)	44 (16.8%)
All Patients	97 (86.6%)	55 (49.1%)	51 (45.5%)

Acronyms: US: ultrasonography; MRI: magnetic resonance imaging

Table 2. Rates of re-imaging performed at our hospital

	Repeat rates	Ratesof imaging at an external center	Rates ofre-imaging at our unit
Mammography	21.6%	97	21
Breast US	25.5%	51	14
Breast MRI	31.4%	51	16

US: ultrasonography; MRI: magnetic resonance imaging

Table 3. Biopsy cancellation rates per study in patients that were referred after a single study

	Study performed	Biopsy decision confirmed	Biopsy decision cancelled
Mammography	16 (51.6%)	15 (48.4%)	
Breast US	3 (50%)	3 (50%)	
Breast MRI	5 (71.4%)	2 (28.6%)	

US: ultrasonography; MRI: magnetic resonance imaging

The number of cases that underwent additional studies was 28 (25%). The additional studies were as follows: MRI in 18 patients, MI in 3 patients and US in 9 patients. Two patients underwent multiple additional studies and the number of additional studies per patient was calculated as 1.07. The decision for biopsy was cancelled in 18 (64.3%) out of 28 patients who received additional studies.

While the decision for biopsy was approved in 49 (43.8%) of the patients that presented to our unit, the decision for biopsy was cancelled in 63 (56.3%) of them and a significant difference was obtained between the two groups (p=0.047). The decision for biopsy was cancelled in 23 (52.3%) out of 44 patients who had only one of the studies of breast US, mammography or breast MRI techniques at an external center and presented to our unit. According to the studies performed, the biopsy cancellation ratios are presented in Table 3. The decision for biopsy was cancelled in 40 (58.8%) out of 68 patients who underwent multiple techniques and were referred for biopsy.

Discussion

The decision for biopsy was cancelled in more than half of the patients who were referred to our unit for the performance of biopsy because of its status as a reference hospital. Today, the increasing use of imaging methods, radiological studies with poor quality and lack of experience of radiologists result in false positive radiological results and unnecessary biopsies performed (21-23). According to the principles

for quality assurance in breast cancer diagnosis reported by the European Society of Breast Cancer Specialists (EUSOMA), a breast cancer unit should have sufficient quality control in place, employ experienced personnel and be able to keep proper records (24). There are no supervisory mechanisms in Turkey that investigate the quality of breast imaging centers and their compliance with the requirements. A study assessing 54 breast units in Istanbul reported that 38% of the devices in mammography units provided images with insufficient quality (25). We also had to repeat the studies in 42% of the patients presenting with the decision for biopsy since the studies were of insufficient quality. Additionally, we cancelled the decision for biopsy in 57.4% of the patients who underwent repeat studies.

Concerning the effects of benign breast biopsies performed to rule out cancer on the patient, the interventional procedure performed may lead to complications such as hematoma, infection, cosmetic deformity and anxiety (26). All the patients that undergo breast biopsy state that they experience biopsy-related stress even though the results are benign. Once the decision for biopsy is made, the procedure being conducted and the time that elapses until the results are received raises the stress levels of patients (27). Furthermore, the anxiety that patients experience due to biopsy are much higher than the anxiety that develops after the request for an additional study or due to follow-up mammography examinations (28, 29). In our study, 25% of the patients underwent additional studies. In this way, the decision for biopsy was cancelled in 64.3% of the patients that underwent additional studies. In 45.5% of the patients, we had to repeat the already performed studies due to artifacts, dosing errors, positioning errors founds on the studies, MRI studies performed without contrast, deficient or wrong application of sequences in MRI and reports that were missing or not compatible with other reports in breast US results. This way, biopsies were cancelled in 52.9% of the patients.

The only negative result of false positive study results and increasing number of benign breast biopsies is not the stress experienced by patients, but also the damages it does to the economy with the rising healthcare expenditures. Coupled by the existing technical incapacities, lack of experience of radiologists and the worry about providing false negative results caused by malpractice laws, the rates of performing additional studies alongside mammography are rising. In the year 2005, the cost of bilateral breast US was 70.11 USD and the cost of MRI study was 1037 USD (eight times the cost of mammographic examination) (30). The economic loss is further increased taking into account the costs of these studies. Furthermore, it is also open to discussion how necessary these additional studies are. For example, it is used to acquire further information when there is a palpable mass in the breast examination, a mass is identified in mammography or the breast is dense (31). However, it has today come to be used as a screening tool; there is a conception that cystic lesions are mostly considered benign whereas solid masses require additional studies (32). In conclusion, MRI is being used at a paramount frequency for the diagnosis of breast cancer (33). In our study, 45.5% of the patients presenting to our unit had undergone MRI studies. On the other hand, a review of our biopsy cancellation ratios shows that no significant differences could be identified between the cancellation rates of patients that had one study performed (52.3%) and those that had multiple studies performed (58.8%) before presenting to our hospital. This way, the rate of false positive diagnosis remains unchanged regardless of whether one study or multiple studies was/were wrongly or inadequately performed or assessed by inexperienced persons. Based on these results, the following is concluded: even if the study was performed in an inexperienced center, one should not proceed to additional studies in that center. Multiple studies performed by inexperienced units that do not perform breast radiology results in unnecessary costs, loss of time and worry on the part of patients. Naturally, we also had to perform additional studies on the patients presenting to our unit (25%). However, the additional studies we performed ensured that we cancelled the unnecessary biopsies in 18 (64.3%) out of 28 patients. These data we have obtained emphasize the importance of experience on the part of the radiologist.

Our study has some limitations, as well. All of the patients presenting to our unit were assessed by a single radiologist and the radiologist saw the location where the study was performed and the patients' names. Therefore, there may have been a biased attitude in the assessment. Furthermore, the patients for whom the decision was taken to cancel their biopsies were not followed. This prevents us from reaching a conclusion about the accuracy of the decision we made. However, our unit has been working as a reference clinic for more than 15 years. Because of the fact that the evaluating specialist has long experience in BI-RADS for breast radiology, we believe in the accuracy of the categorical decisions made (34). As a matter of fact, the studies performed have shown that factors influencing correct decision-making in BI-RADS include the experience of radiologist, his/her interest in dense breast radiology and the high number of studies s/he evaluates on an annual basis (35-37).

Radiological studies with insufficient quality and lack of experience of radiologists evaluating them increases the number of false positive results. The increasing false positive results bring about benign breast biopsies. Unnecessary breast biopsies have positive effects on the patients and the country's economy. Judging by these results, we believe that studies for screening and diagnosis purposes in breast cancer should only be performed by experienced physicians engaged in breast radiology in units with adequate radiological equipment and that the additional studies should not be continued at an inadequate center if the initial study was performed there and the patient should be referred to the reference clinic.

In conclusion, this study has shown that the rates of inaccurate and insufficient studies and false positivity in studies performed at inexperienced centers are very high.

Ethics Committee Approval: Authors declared that the research was conducted according to the principles of the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", (amended in October 2013).

Informed Consent: Written informed consent was not received due to the retrospective nature of this study.

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