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Effectiveness of Assigning BI-RADS Category-3 to Breast Lesion with Respect to Follow-up

Imrana Masroor

ABSTRACT

Objective: To determine the effectiveness of assigning BI-RADS category-3 to breast lesion with respect to follow-up.
Study Design: A cohort study.
Place and Duration of Study: Radiology Department, the Aga Khan University Hospital, Karachi, from January 2002 to December 2004.
Patients and Methods: Women undergoing X-ray mammography and assigned BI-RADS category-3 and recommended short-term (6-monthly) follow-up were included. Out of these, 44 patients were lost to follow-up and were excluded from the study. The lesions that remained stable after short-term follow-up were recommended routine (annual) follow-up. Needle localization and open surgical biopsy was performed, if the lesion progressed or calcifications increased in number/size and/or on physician or patient preference. The effectiveness of this approach was analyzed by determining the sensitivity, specificity, positive and negative predictive value for BI-RADS category-3.
Results: Of the 65 lesions, 55 remained stable. Of the remaining 10 lesions, two showed increase in number of micro-calcification prompting biopsy. Both turned out to be ductal carcinoma *in situ*. Eight biopsies were performed on clinician or patient preference which turned out to be benign. The sensitivity, specificity, positive and negative predictive values were 100%, 87%, 20% and 100% respectively.
Conclusion: Assessment with short-interval mammographic follow-up is useful to confirm the nature of most non-palpable breast lesions considered probably benign and permits detection of a small number of breast cancers at an early stage. The local setup, patient compliance is a major limitation for performing a follow-up study, as the available numbers can have a profound effect on the determined accuracy value.

Key words: BI-RADS. Category 3. Non-palpable. Breast. Benign.

INTRODUCTION

Mammography can detect non-palpable abnormalities in over 30% of examined women.[1] According to BI-RADS lexicon mammograms fall into six categories.[2] Category-3 mammograms are considered probably-benign lesions and may either be followed-up[3] or subjected to biopsy.[4] The rate of carcinoma being diagnosed in non-palpable lesions, detected by mammography, is 11-36%.[5] Most biopsies performed on mammographically detected lesions turn out to be benign. Attempts, therefore, should be directed to increase the diagnostic accuracy of mammography to make the procedure more cost-effective. Many radiologists will recommend periodic short-term follow-up of category-3 lesions to reduce the number of biopsies with negative results, knowingly running the risk of overlooking 0.5-4% of cancers.[6-8] The scientific evidence establishing the safety and efficacy of substituting periodic mammographic surveillance for

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prompt tissue diagnosis is based on two longitudinal studies of prospectively identified consecutive cases, collectively involving more than 80,000 mammography examinations.[9] Results from all over the globe showed that the frequency of cancer among probably benign lesion is less than 2%.[1,5,6,8,10-12]

There are several reasons to recommend short-term follow-up of category-3 lesions instead of obtaining tissue diagnosis. The positive predictive value of biopsy (whether fine needle aspiration, core and surgical biopsy) increases with decrease in number of biopsies for benign lesions.[1,5,8,9,13] Follow-up mammography is associated with reduced morbidity, when compared to open surgical biopsy,[14] as well as image-guided percutaneous biopsy.[15] The cost is also less than open surgical or image guided biopsy.

Since, there is scarce data regarding the follow-up of breast lesions in local setting, this study was conducted to determine the effectiveness of assigning BI-RADS category-3 to breast lesion with respect to follow-up in this study group.

PATIENTS AND METHODS

It was a cohort study conducted at the Radiology Department of the Aga Khan University Hospital,

Karachi, from January 2002 to December 2004. Medical records of 4667 consecutive patients undergoing mammography for a period of two years were reviewed. Inclusion criteria were all patients assigned BI-RADS category-3. Exclusion criteria were non-compliance for follow-up examination or refusal for biopsy if the lesion progressed on follow-ups. Mammograms were performed on Senograph 500 T Senix H.F and Mammomat 3000 Nova (Siemens). For screening mammograms, standard cranio caudal and oblique views were performed. For diagnostic mammograms in addition to two standard views, additional views such as spot compression or magnification views, as and when required, were done. Short-term follow-up was defined as follow-up with X-ray mammography at six monthly interval and cases were followed for a maximum period of 1-1/2 years. All cases in which findings progressed on 6 months follow-up mammograms underwent biopsy. Gold standard was either stable morphology on maximum follow-up, or biopsy. If the findings regressed or remained stable after 6 months, short-term follow-up was discontinued and patient was advised screening after one year as routine, that would be 1 year after the initial mammograms corresponding to the time for scheduled screening study after one year.

Definite diagnosis of the finding on all mammograms, given category-3, was based on stability or regression on follow-up mammography after one year, the histopathological diagnosis of lesions that showed mammographic progression, and the lesions that were recommended for observation but instead underwent biopsy owing to preference of patients or the referring physician.

RESULTS

A total of 4667 mammograms were performed from 2002 to 2004. Out of those, 116 mammograms were assigned category-3. Follow-up was available in 65 (56.04%) patients. In 41 patients, no follow-up was available. Patients who did not turn-up for the 6 monthly recommended mammograms were excluded from the study. The mean age of patients was 50.2 years ranging from 25-74 years.

Among the 65 patients, 55 were true negative as evidenced by follow-up mammograms in which the lesion remained stable or regressed. Forty-five out of 55 patients had partly well-defined nodules of 1-2 cm in size, which remained stable or further regressed in size. A total of 18 patients had 2 or 3 specks of micro-calcifications, which either became macro-calcification or coarse on 6 months follow-up or remained stable. Remaining 2 patients had scattered and clustered micro-calcification in both breasts suggestive of sclerosing adenosis.

Out of 65 patients, 10 underwent biopsy 2-4 weeks after the mammograms. Of these 10, 2 patients had

indeterminate punctate type of calcifications, which had increased in number, and these cases turned out to be malignant. The remaining 8 patients underwent biopsy because of clinician or patient's preference. All 8 had 2-3 punctate micro-calcifications type, which remained stable mammographically and were histopathologically reported as benign. The two mammograms, which were reported to be malignant histopathologically, turned out to be of ductal carcinoma *in situ*. Of the 8 benign cases, 5 were reported as sclerosing adenosis, one each as fibrocystic change, epithelial hyperplasia, and fibrosclerosis with calcifications, Table I. The overall sensitivity, specificity, positive and negative predictive value of assigning category 3 lesions were 100%, 87%, 20% and 100% respectively.

Table I: Final outcome of patients according to follow-up/biopsy results (n=65).

No. of patients	No. of mammograms	Final BI-RADS category	Biopsy/ follow-up results
N=65	Initial examination		
	Masses/asymmetrical density n= 45	B-3	6-month follow-up
	Suspicious micro-calcifications n=20	B-3	6-month follow-up
N=65	6-month follow-up		
	Masses/asymmetrical density (stable/regressed) n= 45	B-3	1 year follow-up
	Suspicious micro-calcifications (stable) n= 18	B-3	8* -Benign
	Suspicious micro-calcification n=2 (progressed)	B-4	Cancer
N=55	3rd follow-up		
	Masses/asymmetrical density (stable) n= 45	B-2	Routine 1 year follow-up
	Suspicious micro-calcifications (stable) n= 10	B-2	Routine 1 year follow-up

*= biopsy performed on referring physician or patient request.

DISCUSSION

The value of mammography to reduce cancer mortality in a study population is mainly based on detection of non-palpable breast lesions. In the Western world, there is considerable patient awareness regarding breast cancer and medical expenses including the cost of mammography are borne by the State. In Pakistan, no screening programme for breast cancer is being offered in the public sector. Patients have to self-bear the mammography cost. In addition, there is lack of public awareness and education regarding breast cancer. Therefore, most of the patients, assigned short-term follow-up of probably benign breast lesion, do not turn up for recommended short interval follow-up examinations. A radiologist assigning category-3 is in a diagnostic dilemma regarding the outcome on follow-up mammography, instead of recommending biopsy. Mammographic follow-up of non-palpable probably benign lesions detected on mammography, known as Breast Imaging Reporting and Data System (BI-RADS) category-3 lesions is a known strategy to reduce the

number of unnecessary or negative biopsies in the western world. This category is used for lesions that are not definitely benign according to current standards.[16]

Recommending biopsies in all non-palpable lesions detected on mammograms, increases cost and anxiety to patient. This can be reduced by decreasing the number of biopsy procedures and instead, performing short-term mammographic follow-up.

Localization biopsy is not a procedure devoid of complications, and there remains a 2-5% rate of failure in surgically removing the abnormality.[1]

Sickles[8] reported cancer development in 0.5% of patients after a 3-3.5 years minimum follow-up period. In this study, the incidence of development of cancer was 3%, for an interval observation period of 12-18 months.

Forty one (43.96%) patients lost to follow-up were excluded from the study. This compliance rate of only 56.04% shows that patients or physician compliance is a major limitation of recommending follow-up. Compliance rate of 88% has been reported from Western world.[6] The lower compliance rate in this study is likely to be due to cost factor and lack of education and awareness regarding breast cancer in the local population of patients.

In this study of 65 patients who underwent follow-up, 3% demonstrated a biopsy proven cancer whereas Varas has reported a rate of 1.7%.[1] This is probably due to small sample size. The sensitivity, specificity and negative predictive values of this study are similar to that of Vizcaino *et al.*, who reported a sensitivity, specificity and negative predictive values of 100%, 99% and 100% respectively.[17] Still, the availability of the non-complaint group could have changed the present results.

The overall biopsy yield (29%) was higher than that of Sickles[8] (11%), Helvie *et al.*[6] (10%) and Masroor[18] (5%) but lower than that of Varas *et al.*[1] (56%). All biopsies performed for lesion progression (2 of 10) were because of changes in micro-calcification regarding number and appearance on short-term follow-up. Both turn out to be malignant. That was slightly less than reported by Vizcaino *et al.*[17] who found a cancer yield of 20% with micro-calcifications, which progressed. In all other lesions, biopsy was performed on either referring physician's or patient's request. When a referring physician is requesting, it is usually either because of strong family history of breast cancer in patient, or any other associated risk factor. Some women prefer surgical biopsy rather than living with uncertainty of having a potentially malignant lesion with low probability. In this study, where the rate of adherence to follow-up was 56.04%, some cancer cases may have been lost or conversely, a number of benign stable cases may have been lost, affecting the over all results. Follow-up compliance in assessment of category-3 lesions

remains a significant problem. The numbers lost to follow up might have materially affected the computed values. This factor was, however, beyond control.

CONCLUSION

In conclusion, assessment with short-term interval mammographic follow-up is useful to confirm the benign nature of most non-palpable, probably benign, breast lesions and permits detection of a small number of breast cancers at an early stage. In the local setup, patient compliance is a major limitation for performing a follow-up study, as almost half of patients do not turn-up for follow-up mammography because of lack of awareness and cost factor.

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