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Factors Associated with Optimal Follow-up in Women with BI-RADS 3 Breast Findings

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Abstract

Objective: Assess rate of and factors associated with optimal follow-up in patients with BI-RADS 3 breast findings.

Methods: This Institutional Review Board-approved, retrospective cohort study, performed at an academic medical center, included all women undergoing breast imaging (ultrasound and mammography) in 2016. Index reports for unique patients with an assessment of BI-RADS 3 (retrieved via natural language processing) comprised the study population. Patient-specific and provider-related features were extracted from the Research Data Warehouse. The Institutional Cancer Registry identified patients diagnosed with breast cancer. Optimal follow-up rate was calculated as patients with follow-up imaging on the same breast 3–9 months from the index exam among patients with BI-RADS 3 assessments. Univariate analysis and multivariable logistic regression determined features associated with optimal follow-up. Malignancy rate and time to malignancy detection was recorded.

Results: Among 93,685 breast imaging exams, 64,771 were from unique patients of which 2,967 had BI-RADS 3 findings (4.6%). Excluding patients with off-site index exams and those with another breast exam <3 months from the index, 1,125 of 1,511 patients (74%) had optimal follow-up. In univariate and multivariable analysis, prior breast cancer was associated with optimal follow-up; younger age, Hispanic ethnicity, divorced status, and lack of insurance with not having optimal follow-up. Malignancy rate=0.86%; mean time to detection=330 days.

Discussion: Follow-up of BI-RADS 3 breast imaging findings is optimal in only 74% of women. Further interventions to promote follow-up should target younger, unmarried women, those with Hispanic ethnicity, and women without history of breast cancer and without insurance coverage.

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Summary Statement:

In this study at a large health system conducting over 90,000 breast examinations annually, only 74% of women assessed to have BI-RADS 3 on an index breast examination had optimal follow-up as recommended.

Keywords

Breast imaging; BI-RADS; Follow-up; Mammography; Health disparities

Introduction

Optimal diagnostic follow-up is critical in order to address the National Academy of Medicine's mandate for health care professionals to improve the diagnostic testing process.(1) A published study analyzing litigation cases from 2009–2013 showed that 20% alleged a diagnosis-related error as the primary reason for a lawsuit.(2) Thirty-one percent of diagnosis-related errors involve a failure or delay in ordering, scheduling and executing diagnostic tests,(2) including 45% involving diagnostic imaging.(3) Cancer is one of the leading missed diagnoses resulting from this failure or delay in diagnostic imaging.(3)

Breast cancer screening is a mainstay of public health in the United States. Over 33 million women a year receive mammograms, representing an estimated 60% of all women age 40 and over.(4) Previous studies have demonstrated a 20–30% reduction in breast cancer mortality with regular screening that results in further management. At a study performed between 1995–1997 at an academic medical center, the most common Breast Imaging Reporting and Data System (BI-RADS) assessment leading to a breast lesion biopsy was a BI-RADS category 3.(5) Recommendations for category 3 breast findings on mammography typically include 6-month follow-up imaging, followed by 12- and then 24-month follow-up imaging.(6–8) However, follow-up imaging has been sub-optimal in many women with breast imaging not performed to follow-up BI-RADS 3 lesions in the recommended time frame.(9–12) Since BI-RADS 3 breast lesions have up to 2% likelihood of malignancy (BI-RADS lexicon 5th ed), it is imperative that optimal follow-up of BI-RADS 3 test results be addressed to avoid this potential source of diagnostic imaging failure. We define optimal follow-up as having a follow-up breast exam completed 3–9 months from an index exam with a BI-RADS 3 assessment, as described previously.(13)

Factors that have been assessed that hinder optimal breast imaging follow-up include low patient income and lack of insurance coverage.(14) Patient demographics and referring provider characteristics (e.g., referring provider specialty) have contributed to enhancing timely management of abnormal test results and screening recall rates.(15, 16) However, no studies that comprehensively assessed patient- and provider-related factors have focused on optimal BI-RADS 3 follow-up, including time to malignancy detection. Therefore, we assessed the rate of optimal follow-up and patient- and provider-related factors associated with optimal follow-up in patients with BI-RADS 3 breast findings.

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Methods

Setting and Population

The Institutional Review Board approved this HIPAA-compliant, retrospective cohort study and waived the requirement for informed consent. We conducted a 12-month study (January 1, 2016 – December 31, 2016) at a tertiary academic medical center, with an affiliated community hospital and a cancer institute, and an outpatient network that spans 183 practices and 1,200 physicians. The entire study site conducts over 500,000 diagnostic imaging examinations annually. The study population included all adult patients who completed a breast imaging examination, both screening and diagnostic, during the study period, including ultrasound (US) and 3D digital mammography. Index reports performed at the study site with an assessment of BI-RADS 3 and belonging to unique patients comprised the study population.

Data Collection

All radiology reports corresponding to eligible breast imaging during the study period were retrieved from the imaging data repository populated by Epic (Epic Systems Corporation, Madison, WI). The Institutional Research Data Warehouse was used to extract: (1) patient-specific features including age, race, marital status, previous breast cancer and other concurrent malignancies, as well as insurance coverage; and (2) provider-related features, including referring provider site (i.e., urban academic medical center, community teaching hospital, cancer institute, or outpatient facilities), and referring provider specialty (e.g., medicine, surgery, obstetrics). Referring provider site was coded as “other” for referring providers with no listed affiliations. In addition, diagnostic exams performed at outside facilities and documented in physician notes were noted. Other information extracted from the imaging data repository included presence of follow-up breast imaging within one year from the index report date, performed on the same breast. Modality was classified into mammography (with or without ultrasound) and ultrasound alone. The Institutional Cancer Registry was used to identify patients diagnosed with breast cancer at the study institution. BI-RADS 3 assessment and breast density were retrieved using a natural language processing application that has been previously validated.(17, 18) Breast density was analyzed as a binary variable (dense vs. non-dense).(19)

Outcome Measures and Data Analysis

The unit of analysis included unique patients who had eligible breast imaging exams with BI-RADS 3 findings. The primary outcome measure - rate of *optimal follow-up* - was calculated as all patients with follow-up breast imaging 3–9 months from the index exam out of all patients with BI-RADS 3 findings in an index exam within the study period. Patients with follow-up performed after 9 months. and those with no-follow-up up to one year from the index exam. were counted as not having optimal follow-up (i.e., suboptimal follow-up). Patients with breast imaging within 3 months from the index case were excluded from analysis because these examinations may have been performed for other reasons, given that they are earlier than recommended for BI-RADS 3 findings.

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A secondary outcome - malignancy rate - was recorded for the study cohort as all patients diagnosed with breast cancer as of December 31, 2017. Time to malignancy detection was recorded, including the mean time for all patients in the study cohort as well as the mean time for those with optimal follow-up and those without (i.e., suboptimal follow-up).

Univariate analysis was performed on all patient-related and provider-related factors collected, using chi-square statistic for categorical variables and logistic regression for continuous variables. Multivariable logistic regression was used to assess optimal follow-up by modeling patient- and provider-related factors. T-test was used to assess time to malignancy detection. We used the presence of optimal follow-up as the outcome variable for our model. SAS software version 9.3 was used for all statistical analyses (SAS Institute Inc, Cary NC). Significance level was defined as a p-value less than 0.05.

Results

Study Cohort

In 2016, a total of 93,685 breast imaging exams were performed for 64,771 unique women. Of these, 5,229 exams (5.6%) were given a BI-RADS 3 assessment, 2,967 (4.6%) of which were from unique patients. Excluding those with index exams performed elsewhere, 1,721 imaging reports belonging to unique women were included. Of these 1,721 reports, 135 (8%) were excluded as they had another breast imaging examination performed less than 3 months from the index exam and another 75 were excluded because they were breast MRI, leaving 1,511 imaging reports belonging to unique women (2.4%) in the study cohort.

Optimal Follow-up

1,125 of 1,511 women (74%) had optimal follow-up. 305 (20%) had no follow-up, and 103 (7%) had late follow-up that occurred 9+ months after the index exam.

Factors Associated with Optimal Follow-up

Patient and provider factors associated with optimal follow-up of BI-RADS 3 findings in univariate analysis are shown in Table 1. Breast density was not significantly associated with optimal follow-up and was omitted from the multivariable model (p=0.81). Mean age was older for women who had optimal follow-up. Married women also had more optimal follow-up compared to those who were single or divorced. Finally, women with prior breast cancer and those seen at the affiliated cancer institute received more optimal follow-up.

On multivariable analysis (Table 2), prior breast cancer and having a cancer institute as the referring provider site were significantly associated with more optimal follow-up. Younger patient age and divorced status were associated with less optimal breast imaging follow-up. Analysis considering race and ethnicity showed Asian women had more optimal follow-up while Hispanic women had less optimal follow-up, compared to White women. Finally, lack of insurance coverage was associated with less optimal follow-up.

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Malignancy Rate

Malignancy rate was 13/1,511 (0.86%), concordant with the BI-RADS lexicon (BI-RADS lexicon 5th ed). 13 patients were detected to have cancer with at least one year of follow-up for the entire cohort. Mean time to detection was 330 days; 316 days for patients who had optimal follow-up, and 401 days for those with suboptimal follow-up (p=0.28).

Discussion

In this study at a large health system conducting over 90,000 breast examinations annually, only 74% of women assessed to have BI-RADS 3 on an index breast examination had optimal follow-up as recommended.(20) The suboptimal follow-up rate, 26%, is consistent with others reported, ranging between 12–33%.(9–12, 14) This finding is significant given the large number of women who undergo breast imaging annually.(4) Mean time to malignancy detection was 85 days longer for patients who did not receive optimal follow-up compared to those that did. However, this result was not statistically significant, likely due to small number of detected cancers in our cohort (n=13).

Prior breast cancer, older patient age, and married status were associated with optimal follow-up on univariate analysis and remained significant on multivariable analysis. Patients seen at a cancer institute and those who had insurance coverage also had more optimal follow-up. Previous studies have also noted more optimal follow-up in a group of women with prior history of breast cancer.(9) Perhaps the low rates of breast cancer among those with BI-RADS 3 findings(12) contribute to the less optimal follow-up in women who have never previously been diagnosed with breast cancer. Marital status appears to confer an advantage in having optimal follow-up. In a prior study of breast cancer patients, married women had better 5-year cancer-free and overall survival, compared to unmarried women.(21) The same improved survival advantage is seen in married women who have duodenal adenocarcinoma.(22) Finally, married woman are also more likely to be up-to-date with their colorectal cancer screening.(23) Perhaps, more attention should be focused on improving follow-up in unmarried women.

There is optimal follow-up for patients seen by referring providers at a cancer institute, likely because these patients already had cancer and are receiving closer follow-up. In addition, a cancer institute typically provides care coordination services to improve communication and care coordination for cancer patients.(24) A few providers did not have listed affiliations and their patients had less optimal follow-up on univariate analysis. However, this was not significant after adjusting for other variables.

Older age was associated with optimal follow-up, perhaps because younger women are less frequently diagnosed with breast cancer (6% in women aged 40–44, compared to 12% in women aged 50–54),(25) which may lead to lesser follow-up. However, addressing optimal follow-up in younger women is meaningful given that the risk of progression to invasive cancer in women with ductal carcinoma in situ is higher for younger women.(26) In addition, recommendations for breast screening begin at 40 to 45 years of age.(27)

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Finally, Asians had more optimal breast imaging follow-up and Hispanic women had less optimal follow-up, even adjusting for all other confounders. Hispanic women have been noted previously to have less optimal mammography follow-up compared to non-Hispanic white women.(28) In all of our practice sites, we send letters to all patients with BI-RADS 3 reminding them to come for follow-up. However, all letters are sent in English and not translated to Spanish or any other language, even for patients who self-report as Hispanic. Anticipating that language may be an issue, we plan to send Spanish-translated letters in the future to women who self-report as Hispanic.

Lack of insurance coverage is also associated with less optimal follow-up, as reported previously.(14) Lack of insurance coverage is a key factor that impacts access to healthcare in addition to low income and low literacy. These social determinants of health have been estimated to account for 20% of premature deaths in the United States.(29) The effect of social determinants on cancer prevention is evident when examining disparities in mammography use. Sabatino et al noted that Hispanic women were less likely than non-Hispanic women to report to screening mammography (58.1% vs 69.0%), and low income, uninsured women continued to have the lowest rates of breast cancer screening.(30) We note both factors to be associated with less optimal follow-up as well. A care coordination system has been proven to enhance health processes, including facilitating screening for colorectal cancer and cervical cancer.(31) Perhaps a care coordination system that incorporates analytics and risk-estimation to identify persons at high risk for suboptimal follow-up could reduce follow-up disparities. In addition, more active management of unresolved BI-RADS 3 using electronic audit tools, commonly available in breast imaging practices, could be utilized. Future studies should focus on follow-up disparities so that effective interventions may be designed and implemented.

Limitations to our study include the retrospective nature of our data analysis. We did not assess indication for the exam. In addition, this study was performed in an academic medical center which may limit its generalizability. This study was limited to modalities of 3D digital mammography and ultrasound, as 3D mammography is being increasingly implemented as a screening tool to improve the sensitivity and specificity of screening mammography.(32, 33) In a previous study, the use of 3D mammography was associated with a higher odds of receiving a BI-RADS 3 assessment.(32)

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Take-Home Points:

- Optimal follow-up of women assessed to have BI-RADS 3 breast imaging findings occur in only 74% of cases but adherence is influenced by patient factors.
- Social determinants of health, including lack of insurance coverage, younger age, divorced status and Hispanic ethnicity are associated with lack of optimal follow-up for BI-RADS 3 breast imaging findings.
- There is optimal follow-up in patients seen by referring providers at a cancer institute. Factors that facilitate care coordination in such sites likely enhance patient follow-up care.

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Table 1:

Univariate analysis of patient- and provider-related factors on optimal follow-up of BI-RADS 3 breast findings (n=1,586)

Factors	Optimal Follow-up n=1,125 (%)	Late or No Follow-up n=386 (%)	Odds Ratio (95% CI)
Age (mean)	52	49	1.02 (1.01– 1.03) *
Race			
White	797 (70.8)	259 (67.1)	Reference
African-American	105 (9.3)	40 (10.4)	0.85 (0.58– 1.27)
Asian	58 (5.1)	12 (3.1)	1.57 (0.86 −3.11)
Hispanic	92 (8.1)	47 (12.2)	0.64 (0.44 −0.94) *
Other	73 (6.5)	28 (7.3)	0.85 (0.54– 1.36)
Insurance Status			
Private	765(68.0)	217(56.2)	Reference
Public	197(17.5)	65 (16.8)	0.86 (0.63–1.18)
None	163 (14.5)	104 (26.9)	0.45 (0.33– 0.59) *
Marital Status			
Married	707 (62.8)	208 (53.9)	Reference
Single	270(24.0)	113 (29.3)	0.70 (0.54– 0.92) *
Divorced	60 (5.3)	33 (8.5)	0.54 (0.34– 0.84) *
Other	88 (7.6)	32 (8.3)	0.81 (0.53– 1.25)
Prior breast cancer	152 (13.5)	30 (7.8)	0.54 (0.36– 0.82) *
Prior other cancer	261 (23.2)	88 (22.8)	0.98 (0.74 −1.28)
Provider site			
Academic medical center	668 (59.3)	245 (63.5)	Reference
Community teaching hospital	32 (2.8)	12 (3.1)	0.98 (0.45– 1.93)
Cancer institute	53(4.7)	7 (1.8)	2.76 (1.25– 6.19) *
Outpatient facilities	152 (13.5)	43 (11.1)	1.29 (0.89– 1.86)
Unaffiliated	191 (16.9)	59 (15.3)	1.18 (0.85– 1.65)
Other	29 (2.5)	20 (5.2)	0.53 (0.29– 0.96) *
Provider specialty			
Medicine	615 (54.7)	219 (55.7)	Reference
OB-GYN	168 (14.9)	55 (14.2)	1.09 (0.77– 1.53)
Surgery	90 (8.0)	34 (8.8)	0.94 (0.62 −1.44)
Other	252 (22.4)	78 (20.2)	1.15 (0.86– 1.55)
Modality			
Mammography	955 (84.9)	281 (72.8)	Reference
Ultrasound	170 (15.1)	105 (27.2)	0.48 (0.36–0.63) *
Breast Density			

Factors	Optimal Follow-up n=1,125 (%)	Late or No Follow-up n=386 (%)	Odds Ratio (95% CI)
Dense	240 (21.3)	75 (19.4)	1.05 (0.72–1.52)

*Statistically Significant

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Table 2:

Multivariable analysis of patient- and provider-related factors on optimal follow-up of BI-RADS 3 breast findings

Effect	Odds Ratio	95% Confidence Interval	
Age	1.011 *	1.000	1.021
Race			
White	Reference		
Asian	2.249 *	1.193	4.581
African-American	0.864	0.574	1.322
Hispanic	0.645 *	0.430	0.975
Other	1.022	0.637	1.684
Marital Status			
Married	Reference		
Divorced	0.527 *	0.331	0.849
Unknown	0.863	0.552	1.377
Single	0.916	0.680	1.239
Insurance Status			
Private	Reference		
Public	0.816	0.567	1.183
None	0.503 *	0.368	0.689
Provider Site			
Academic medical center	Reference		
Community teaching hospital	1.253	0.624	2.676
Cancer institute	4.925 *	1.698	15.696
Other	0.535	0.288	1.013
Outpatient facilities	1.442	0.952	2.217
Unaffiliated	2.159	0.956	4.889
Provider Specialty			
Medicine	Reference		
OB-GYN	0.998	0.677	1.484
Surgery	1.058	0.668	1.706
Unaffiliated	0.535	0.248	1.154
Cancer			
Prior breast cancer	1.685 *	1.022	2.779
Prior other cancer	0.754	0.546	1.041
Modality			
Mammography	Reference		
Ultrasound	0.550 *	0.400	0.758

* Statistically Significant