The Effect of Imaging on the Clinical Management of Breast Pain

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BACKGROUND: Breast pain is a common complaint to primary care and breast specialists. Literature recommends imaging to provide reassurance of benign etiology. The effect of imaging on reassurance and subsequent healthcare utilization has not been described.
OBJECTIVE: To determine if initial imaging for breast pain reduces subsequent utilization.
DESIGN: Retrospective cohort study at a hospital-based breast health practice.
PATIENTS: Women referred for breast pain from 2006–2009.
MAIN MEASURES: Imaging ordered at initial provider visit; clinical utilization, defined as the number of follow-up visits, diagnostic imaging studies, and biopsies completed within 12 months following initial visit.
KEY RESULTS: Sixty-percent of women were age 40 or younger, 87% were from racial/ethnic minority groups. Twenty-five percent had imaging ordered at initial visit. Of those who received initial imaging, 75% had normal radiographic findings, yet 98% returned for additional evaluation. In adjusted analyses, women with initial imaging had increased clinical services utilization (OR 25.4, 95% CI: 16.7, 38.6). Women with normal clinical breast exams who received initial imaging exhibited increased odds for subsequent clinical services utilization (OR 23.8, 95% CI: 12.9, 44.0). Six cancers were diagnosed; imaging in the absence of clinical breast exam abnormalities did not result in any cancer identification.
CONCLUSIONS: Initial imaging for women with breast pain increased the odds of subsequent clinical utilization and did not increase reassurance in ruling out malignancy.

KEY WORDS: breast pain; mammography; breast cancer.
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BACKGROUND

Women often seek medical attention for breast pain due to concerns of breast cancer.[1–3] Breast pain accounts for 45–70% of breast-related complaints in the primary care setting.[4–6] Given that breast pain as a sole complaint has low risk of breast cancer (0-3%),[7–9] reassurance of non-malignancy is appropriate.[2,10,11] Nevertheless, reaching definitive diagnosis in patients with breast pain represents a dilemma, as the causes and treatments of breast pain are inadequately defined.

Current guidelines recommend imaging for breast pain if clinically indicated, such as in conjunction with a palpable mass.[12] Previous research has also recommended imaging in patients in need of reassurance,[9,11,13,14] and suggested that after initial imaging, the majority of women require no intervention following reassurance that evaluation findings are normal.[1,15] No studies have examined the effect that initial imaging for evaluation of breast pain has on provider or patient assurance in ruling out malignancy, as well as subsequent clinical management in women with breast pain.

The aim of the present study was to determine how imaging impacts clinical management of breast pain. We assessed whether initial imaging increases reassurance in ruling out breast cancer, as measured by subsequent clinical utilization. We posited that reassurance in ruling out breast cancer would be reflected in reduced subsequent clinical utilization.

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METHODS

Study Setting and Population

We conducted a retrospective chart review of women referred for breast pain to internists practicing in a hospital-based diagnostic breast health practice at an academic medical center from January 1, 2006 to December 31, 2009. This specialty practice includes internists trained in breast health and a triage protocol that results in the majority of benign referrals triaged to internists.[16] Referrals are scheduled with a provider who follows a woman longitudinally through subsequent breast care received. Data were abstracted from the electronic medical record (EMR) or scheduling system. This study was approved by the Institutional Review Board of Boston University School of Medicine.

Measures

Initial imaging was defined as the completion of a physician-ordered diagnostic mammogram, ultrasound, or magnetic resonance imaging (MRI) within 3 months of initial clinical visit. Screening mammograms were distinguished from diagnostic mammograms through provider-input orders in the EMR. Screening mammograms were excluded from this and our outcome metric.

The outcome of interest was clinical services utilization. Clinical services utilization served as a proxy for reassurance, and was quantified as the number of subsequent diagnostic services completed in the 12 months following initial provider visit. The following discrete clinical variables were included in defining clinical utilization: (1) additional imaging tests completed (diagnostic mammograms, ultrasounds, or MRIs) (2) biopsies completed (fine needle aspiration, core needle, and excisional biopsies), and (3) additional clinical visits to a breast specialist over 12 months of follow-up. These three variables were summed to yield a summary "clinical services utilization score." This summary measure was categorized into 3 levels: 0: no further clinical utilization, 1: one additional follow-up measure, and 2: two or more additional follow-up measures, all over 12 months of follow-up. The components of clinical utilization were also analyzed individually as dichotomous variables: any receipt of additional diagnostic imaging, any biopsy completed, and categorical number of additional visits (no additional visits, one additional visit, and two or more additional visits), all over 12 months of follow-up.

The number of cancers diagnosed during 12 months of follow-up was descriptively analyzed, including clinical presentation, clinical evaluation and diagnostic testing, and timing of diagnostic testing and diagnoses. Cancer diagnoses were confirmed from pathology reports in the EMR. All women in the study were cross-referenced with the Boston Medical Center Cancer Registry to ensure no cancer diagnoses were missed.

Since abnormal clinical breast exam results could confound analyses by clinical indication, the study population was stratified based on the following categories of clinical exams: (1) normal clinical breast exam, (2) mass on clinical breast exam and (3) abnormality other than mass on clinical breast exam (including breast skin changes, nipple changes, nipple discharge). Stratification in this way allowed for restricted analyses on women with normal clinical breast exams.

Covariates in analyses included demographics and risk factors for breast cancer: age ($\geq$ 40 or <40 years), language (English or non-English speaking), race/ethnicity (White, Black, Hispanic, or Other), insurance (private, public, or no insurance), family history of breast cancer, current hormone therapy use, and current oral contraceptive use. Race/ethnicity minority status was included as it has been associated with delays in cancer screening,[17] diagnosis,[18,19] and treatment.[19–21] Year of referral was included in analyses to account for potential secular trends in imaging and diagnostic utilization.

Statistical Analyses

Demographic differences between women with and without initial imaging were identified using the chi-square test or t-test. Subsequent clinical services utilization was compared between the women who received initial imaging and those who did not. These associations were examined within each of the three strata of clinical breast exam results. Unadjusted logistic regressions determined the odds of each measure of clinical utilization in women who received initial imaging compared to those who did not receive initial imaging.

Multivariate ordinal logistic regression models assessed the effect of initial imaging on subsequent clinical utilization, controlling for demographic and clinical variables. Multivariate models were applied to the study population as a whole and the three clinical breast exam result strata. Variables that were not associated with the outcome at the $p<0.05$ level and variables that did not change effect estimates by greater than 10% were removed from the model.

Sensitivity analyses were conducted to rule out alternative explanations of findings. For women with normal clinical breast exams, we compared the subgroup with no initial imaging to the subgroup with normal initial imaging results (Breast Imaging-Reporting and Data System (BIRADS) 1 or 2). Using age as a proxy for menopausal status, we conducted a stratified analysis of women less than and equal or greater than 50 years of age. Provider seen at initial visit was included in analyses to account for provider-specific practices in managing breast pain. Because of the small number of patients seen by some providers, cluster analysis was not possible. Instead, we stratified the analyses by one outlier provider with a higher rate of initial imaging compared to the other providers. All data were analyzed using Statistical Analysis System version 9.1 (SAS Institute, Cary, NC).

RESULTS

Breast pain accounted for 32% of new patient referrals seen by internal medicine breast providers from January 2009–December 2009. The mean age was 39 ±13 years with 60% of women under age 40, 87% were of minority race/ethnicity, 55% were English speaking, and 73% had no insurance or public health insurance (Medicaid or Medicare) (Table 1). Twenty percent of women reported current oral contraceptive use, and 2% reported current postmenopausal

Table 1. Association of Demographic and Clinical Variables Associated with Receipt of Initial Imaging for Breast Pain

	Total	Imaging within 3 months of referral		
	N (%)	Yes, *N* (%)	No *N* (%)	
	N=916	*N*=229 (25.0)	*N*=687 (75.0)	*P*-values
Age				
<40 years	548 (59.8)	142 (62.0)	406 (59.1)	
≥40 years	368 (40.2)	87 (38.0)	281 (40.9)	$p=0.44$
Race/Ethnicity				
White	121 (13.2)	43 (18.8)	78 (11.4)	
Black	298 (32.5)	76 (33.2)	222 (32.3)	
Hispanic	376 (41.1)	85 (37.1)	291 (42)	
Other	121 (13.2)	25 (10.9)	96 (14)	$p=0.023$
Language				
English speaking	507 (55.4)	144 (62.9)	363 (53)	
Non-English speaking	409 (45.7)	85 (37.1)	324 (47)	$p=0.0081$
Insurance				
None	177 (19.3)	45 (19.7)	132 (20)	
Public	492 (53.7)	125 (54.6)	367 (53)	
Private	247 (27.0)	59 (25.8)	188 (27)	$p=0.89$
Clinical Breast Exam Results				
Mass	111 (12.1)	75 (32.8)	36 (5)	
Abnormality other than mass	293 (32.0)	79 (34.5)	214 (31)	
Normal	512 (55.9)	75 (32.8)	437 (64)	$p<0.0001$
Family History of Cancer				
Yes	195 (21.3)	61 (26.2)	134 (20)	
No	721 (78.7)	168 (73.4)	553 (80)	$p=0.02$
Oral Contraceptives				
Yes	197 (21.5)	59 (25.8)	138 (20)	
No	719 (78.5)	170 (74.2)	549 (80)	$p=0.07$
Hormone Therapy				
Yes	16 (1.7)	7 (3.1)	9 (1)	
No	900 (98.3)	222 (96.9)	678 (99)	$p=0.11$
Year of referral				
2006	225 (24.6)	40 (17.5)	185 (26.9)	
2007	215 (23.5)	53 (23.1)	162 (23.6)	
2008	198 (21.6)	52 (22.7)	146 (21.2)	
2009	278 (30.3)	84 (36.7)	194 (28.2)	$p=0.31$
Provider				
1	156 (17.0)	27 (11.8)	129 (18.9)	
2	187 (20.4)	105 (45.9)	82 (11.9)	
3	228 (24.9)	26 (11.4)	202 (29.4)	
4	12 (1.3)	7 (3.1)	5 (0.7)	
5	19 (2.1)	8 (3.5)	11 (1.6)	
6	21 (2.3)	2 (0.9)	19 (2.8)	
7	60 (6.6)	18 (7.9)	42 (6.1)	
8	233 (25.4)	36 (15.7)	197 (28.7)	$p<0.0001$

hormone therapy use. Over half had a normal clinical breast exam (55%); 12% had a palpable mass noted on clinical breast exam.

Receipt of Initial Imaging

Twenty-five percent of women were referred for diagnostic imaging at initial provider visit (Table 1). Women who received initial imaging were more likely to be white race/ethnicity ($p=0.02$), English-speaking ($p=0.008$), have a mass on clinical breast exam ($p<0.0001$), and have a family history of breast cancer ($p=0.02$) than women who did not receive initial imaging. Receipt of initial imaging was associated with provider seen at initial visit ($p<0.0001$). When the association between provider and initial imaging was stratified by clinical breast exam results, this association was not significant in women with a mass on clinical breast exam ($p=0.06$), but remained in women with normal clinical breast exams ($p<0.0001$).

Subsequent Clinical Services Utilization

Women who received initial imaging were more likely to have subsequent imaging, biopsies, additional visits, and higher clinical services utilization than women who do not receive initial imaging (Table 2). Ninety-eight percent of women who received imaging initially had additional clinical services utilization, versus 26% of women who did not receive imaging ($p<0.0001$). After adjusting for clinical breast exam results, age, family history, and provider, the odds of having a higher level of clinical services utilization for women who received initial imaging were 25.4 (95% CI: 16.7,38.6). While race and language were significantly associated with receipt of initial imaging

Table 2. Association of Initial Imaging for Breast Pain with Subsequent Clinical Utilization

	Imaging within 3 months of referral			Unadjusted OR *(95% CI†)	Adjusted‡ OR(95% CI)
	Yes, *N*=229	No *N*=687	*p*-value*		
	n (%)	*n* (%)			
Follow-up imaging within 12 months					
Yes	126 (55.0)	79 (11.5)	$p<0.0001$	8.8 (6.2,12.5)	7.9 (5.1, 12.2)
No	103 (45.0)	608 (88.5)			
Follow-up biopsy within 12 months					
Yes	38 (16.6)	27 (3.9)	$p<0.0001$	6.0 (3.4, 10.7)	2.1 (1.1, 4.1)
No	191 (83.4)	660 (96.1)			
Sum of visits over 12 months					
0	90 (39.3)	514 (74.8)	$p<0.0001$	4.1(3.1, 5.6)	2.5 (1.8, 3.6)
1	93 (40.6)	119 (17.3)			
2+	46 (20.0)	54 (7.9)			
Clinical services utilization score§					
0	6 (2.6)	509 (74.1)	$p<0.0001$	35.3 (24.1, 51.6)	25.4 (16.7, 38.6)
1	62 (27.1)	121 (17.6)			
2+	161 (70.3)	57 (8.3)			

** OR Odds ratio*
† CI Confidence interval
‡ Adjusted for clinical breast exam results (normal, mass, or other abnormality), age, family history, and provider.
§ Clinical services utilization score: sum of diagnostic follow-up imaging, biopsies, and visits over 12 months of follow-up

(Table 1), these variables did not change the estimate of the effect size in the models and therefore were not included in final models.

When the study population was stratified by clinical breast exam results, the adjusted association between initial imaging and subsequent clinical services utilization remained (Tables 3, 4, and 5). Women with normal clinical breast exams who received initial imaging had 23.8 (95% CI: 12.9, 44.0) times the odds of increased clinical utilization than women who did not receive initial imaging, controlling for age, family history, and provider. Looking at the specific components of utilization (diagnostic imaging, biopsies, and visits), these women had 10.4 (95% CI: 5.5, 19.2) times the odds of receiving additional imaging, 3.7 (95% CI: 1.1, 12.2) times the odds of receiving a biopsy, and 2.3 (95% CI: 1.4, 3.9) times the odds of having additional visits.

Eight providers delivered care to women in the study sample. Four providers saw the majority (87%) of women

Table 3. Association of Initial Imaging for Breast Pain with Subsequent Clinical Utilization in Women with Mass on Clinical Breast Exam, *n*=111

	Imaging within 3 months of referral		Unadjusted OR* (95% CI†)	Adjusted‡ OR (95% CI)
	Yes, *n*=75	No, *n*=36		
	n (%)	*n* (%)		
Follow-up imaging within 12 months				
Yes	45 (60.0)	11 (30.5)	3.1 (1.3, 7.10)	8.5 (2.5, 28.8)
No	30 (40.0)	25 (69.5)		
Follow-up biopsy within 12 months				
Yes	26 (34.7)	13 (36.1)	3.7 (2.3, 6.0)	1.2 (0.5, 3.3)
No	49 (65.3)	23 (63.9)		
Sum of visits over 12 months				
0	21 (28.0)	25 (69.4)	4.4 (2.0, 10.0)	6.5 (2.5, 16.7)
1	34 (45.3)	5 (13.9)		
2+	20 (26.7)	6 (16.7)		
Clinical services utilization score§				
0	2 (2.7)	22 (61.1)	31.7 (11.5, 87.3)	37.6 (12.2, 116.0)
1	11 (14.7)	8 (22.2)		
2+	62 (82.7)	6 (16.7)		

** OR Odds ratio*
† CI Confidence interval
‡ Adjusted for age, family history, and provider
§ Clinical services utilization score: sum of diagnostic follow-up imaging, biopsies, and visits over 12 months of follow-up

Table 4. Association of Initial Imaging for Breast Pain with Subsequent Clinical Utilization in Women with Abnormalities Other than Mass on Clinical Breast Exam, *n*=293

	Imaging within 3 months of referral		Unadjusted OR* (95% CI†)	Adjusted‡ OR (95% CI)
	Yes, *n*=79	No, *n*=214		
	n (%)	*n* (%)		
Follow-up imaging within 12 months				
Yes	41 (51.9)	23 (10.7)	8.5 (4.6, 15.8)	7.6 (3.3, 17.1)
No	38 (48.1)	191 (89.3)		
Follow-up biopsy within 12 months				
Yes	7 (8.9)	5 (2.3)	4.1 (1.3, 13.2)	1.8 (0.4, 7.6)
No	72 (91.1)	209 (97.6)		
Sum of visits over 12 months				
0	39 (49.4)	163 (76.2)	3.3 (1.9, 5.6)	2.1 (1.1, 4.2)
1	27 (34.2)	39 (18.2)		
2+	13 (16.5)	12 (5.6)		
Clinical services utilization score§				
0	1 (1.3)	162 (75.7)	39.3 (19.8, 77.9)	28.4 (13.2, 61.3)
1	30 (38.0)	39 (18.2)		
2+	48 (60.7)	13 (6.1)		

** OR Odds ratio*
† CI Confidence interval
‡ Adjusted for age, family history, and provider
§ Clinical services utilization score: sum of diagnostic follow-up imaging, biopsies, and visits over 12 months of follow-up

during the study. The variability in imaging ordering behaviors varied among both the low- and high-volume providers. The percent of patients receiving initial imaging ranged from 5–31% among providers. Since the subjects seen by Provider 2 made up 46% of the population that received imaging, we performed a sensitivity analysis separating this provider from the other seven providers. The odd ratios of adjusted subsequent imaging was 6.3 (adjusted for age and family history, 95%CI: 2.8, 14.3) compared with the adjusted OR for all other providers (7.7, 95% CI: 4.6, 13.1), suggesting that the findings were not attributable to this provider.

We did not control for imaging results in our analyses, as BIRADS results were significantly associated with all outcome measures. Of the 229 women who received initial imaging, 25% had results that required follow-up (BIRADS

Table 5. Association of Initial Imaging for Breast Pain with Subsequent Clinical Utilization in Women with Normal Clinical Breast Exams, *n*=512

	Imaging within 3 months of referral		Unadjusted OR* (95% CI†)	Adjusted‡ OR (95% CI)
	Yes, *n*=75	No, *n*=437		
	n (%)	*n* (%)		
Follow-up imaging within 12 months				
Yes	40 (53.3)	45 (10.3)	9.4 (5.5, 16.3)	10.4 (5.5, 19.2)
No	35 (46.7)	392 (89.7)		
Follow-up biopsy within 12 months				
Yes	5 (6.7)	9 (2.1)	3.4 (1.1, 10.4)	3.7 (1.1, 12.2)
No	70 (93.3)	428 (97.9)		
Sum of visits over 12 months				
0	30 (40.0)	326 (74.6)	3.7 (2.3, 6.0)	2.3 (1.4, 3.9)
1	32 (42.7)	75 (17.1)		
2+	13 (17.3)	36 (8.2)		
Clinical services utilization score§				
0	2 (2.7)	325 (74.4)	27.4 (15.4, 48.6)	23.8 (12.9, 44.0)
1	23 (30.7)	74 (16.9)		
2+	50 (66.7)	38 (3.7)		

** OR Odds ratio*
† CI Confidence interval
‡ Adjusted for age, family history, and provider
§ Clinical services utilization score: sum of diagnostic follow-up imaging, biopsies, and visits over 12 months of follow-up

Table 6. Initial Clinical Management of Women with Cancer in Cohort of Women with Breast Pain

Case	Age at initial visit	Patient-reported reason for referral	Clinical breast exam results	Initial Imaging	Imaging results	Days from initial visit
1	59	Bilateral breast pain	Mass, left breast	Bilateral diagnostic mammogram	BIRADS* 4	2
2	47	Left breast pain	Mass, left breast	Bilateral diagnostic mammogram and Ultrasound	BIRADS 5	0
3	58	Right breast pain	Mass, right breast	Diagnostic mammogram		0
4	33	Left breast pain	Mass, left breast	Bilateral diagnostic mammogram and Ultrasound	BIRADS 4	77
5	58	Left breast pain	Tenderness, left breast	Unilateral Diagnostic mammogram	BIRADS 1	6
6	59	Bilateral breast pain	Normal	None		0

** BIRADS Breast imaging-reporting and data system*

0, 3, 4, or 5), while 97% went on to receive subsequent diagnostic evaluation (clinical, radiographic, or biopsy). When comparing the 437 women with normal clinical exam and no initial imaging to the 58 women who had a normal exam and initial imaging that revealed normal findings (BIRADS 1 or 2), the adjusted OR remained high at 18.0 (95%CI: 9.4, 59.0), indicating that with normal imaging results, increased subsequent utilization remains. Stratifying women by age greater than 50 years (adjusted OR=12.3, 95% CI: 5.2, 36.8) or less than 50 years (adjusted OR 5.4, 95% CI: 3.3, 8.821) did not show major differences in subsequent additional imaging.

Breast Cancer Diagnoses

Six (0.6%) breast cancers were diagnosed in this study population during the study timeframe, four ductal carcinoma in situ (DCIS) and two invasive ductal carcinoma (IDC, Tables 6 and 7). Cross-referencing with the hospital cancer registry revealed no additional cancer diagnoses in the study cohort. Five of the 6 women initially presented with an abnormal clinical breast exam; 4 with a mass and one with focal tenderness. Four of these women were diagnosed through imaging that was initiated as result of a mass found on clinical breast examination. Table 6 and 7 shows that three of them had timely diagnostic services as a result (Cases 1, 2, 3), while one had almost one year delay due to development of cellulitis and two missed appointments (Case 4). One of these cancers (Case 3) was diagnosed in the breast contralateral to the pain, so that only three of these four cancer diagnoses were concordant with the presenting symptoms. One woman presented with focal tenderness (Case 5) but no discrete mass on initial clinical breast exam and had diagnostic imaging that was read as normal. At a follow-up visit 92 days later, a mass was found on the breast contralateral to the initial site of pain. The patient declined a breast biopsy twice and did not keep one appointment, resulting in a delay in her diagnosis. Only one cancer was diagnosed in a woman who presented with a normal clinical breast examination (Case 6). This case

Table 7. Follow-Up Care of Women with Cancer in Cohort of Women with Breast Pain

Case	Follow-up recommended	Follow-up diagnostic testing	Days from initial visit	Follow-up diagnostic testing results	Cancer site concordant with pain?
1	Right stereotactic biopsy	Right breast stereotactic biopsy	12	DCIS†, right breast	No
2	Referral to breast surgeon	Ultrasound guided core biopsy, left breast	18	IDC‡, left breast, stage 1	Yes
3	Diagnostic Mammography	Unilateral Diagnostic Mammogram, right breast	14	BIRADS 4	
		Right breast stereotactic biopsy	21	IDC, right breast, stage 2	Yes
4	Referral to breast surgeon	Left breast needle localization	223	DCIS, left breast	Yes
5	Follow up with provider in 2 months	Left breast Ultrasound	92	BIRADS 1	
		Bilateral diagnostic mammogram	224	BIRADS 4	
		Bilateral Ultrasound	224	BIRADS 4	
		Right stereotactic needle core biopsy	245	Patient declined biopsy	
		Right breast needle localization	330	DCIS, right breast	No
6	Screening Mammography	Unilateral Mammogram, right breast	16	BIRADS 4	
		Core breast biopsy, right	34	DCIS, right breast	No

** BIRADS Breast imaging-reporting and data system*
† DCIS Ductal carcinoma in situ
‡ IDC Invasive ductal carcinoma

presented with bilateral pain and an age-appropriate screening mammogram (not considered initial imaging in this study) was performed which revealed an incidental finding of Stage 2 IDC. In summary, three of the women had incidental cancer diagnoses (the cancer site did not correspond with the patient-reported area of pain or clinical findings); three had a cancer concordant with their clinical presentation and exam findings.

DISCUSSION

This is the first study to date that measures outcomes in addition to cancer diagnoses in women with breast pain. Our results indicate that initial imaging in the evaluation of breast pain increases subsequent clinical utilization, regardless of clinical breast exam findings. Women who received initial imaging were significantly more likely to undergo additional diagnostic evaluation. Most importantly, women with normal clinical breast exams had increased odds of clinical utilization if they received initial imaging, with no benefit of increased cancer detection. The findings did not change when the data was stratified by age as a proxy for menopausal status, or stratified by one provider with higher rates of initial imaging.

These results support existing data demonstrating a low probability of malignancy in women presenting with breast pain as a primary complaint.[9–11] The number of cancers diagnosed represents 0.6% of the study population, within the range of 0-3% previously documented in the medical literature.[7–9] Three of the 6 cancers were detected with initial imaging showing a lesion that corresponded with a mass at the site of breast pain; one had a negative initial mammogram with imaging three months later finding a contralateral DCIS, while two were detected through screening mammography (not considered diagnostic imaging in analyses). Diagnostic imaging in women with breast pain and normal clinical exams yielded no cancer diagnoses.

Previous studies in women with breast pain have sought to describe the causes, prevalence, and treatment of breast pain. Studies analyzing imaging in evaluation of breast pain have focused on cancer diagnosis as the outcome, and have demonstrated low yield of imaging in the setting of normal findings on clinical examinations.[8–11,14,22] Nevertheless, imaging has been recommended for reassurance purposes,[9] with no data describing its effect on the management of breast pain. By looking at clinical utilization outcomes, we measured the effect imaging has on clinical management of breast pain. Our data show that imaging in the initial evaluation of breast pain leads to increased clinical utilization without increased breast cancer detection. While initial imaging in women with breast pain has been recommended for reassurance purposes, there is significant increased subsequent utilization in women who receive initial imaging, without increased diagnostic yield.

Overutilization of diagnostic imaging is a concern, particularly as healthcare reform demands efforts to curtail overutilization.[23,24] In addition, normal test results do not necessarily lead to reassurance, and in some cases can increase anxiety levels and do harm.[25–27] With efforts to improve health care quality while decreasing costs, it is important to determine if imaging for patients with breast pain is of value in reassuring patients and providers, as reflected in subsequent utilization. The fact that individual provider behaviors vary within the same clinic in the management of women with breast pain and normal clinical breast exams (this variation was absent in women with mass on clinical breast exam), suggests a need for establishment of guidelines for women with breast pain.

Past studies have posited that the goal of imaging in breast pain is to provide reassurance of benign etiology to the patient and provider. This implies that diagnostic certainty of non-malignancy should increase. Previous research has demonstrated a link between diagnostic certainty and provider clinical actions, such that reduced test-ordering behaviors are directly influenced by providers' increased certainty regarding diagnoses.[28–30] Applying this association to our study, with reassurance and diagnostic certainty, subsequent testing should decrease. The increased utilization observed in this study suggests the opposite, that initial imaging does not provide reassurance or increase diagnostic certainty.

Several limitations should be considered when interpreting study findings. Study data did not allow for breast cancer risk adjustment. Using a tool such as the Modified Gail Model[31] was not age-appropriate for all women and there was incomplete data for variables in the tool, including age at first pregnancy, menarche, and menopause. Clinical services provided outside of the institution were not included in analyses. Systematic data to categorize non-malignant diagnoses (i.e. fibroadenoma, cyst) were not available and therefore not included in analyses. Clinical services and additional visits during 12 months of follow-up attributed to complaints other than breast pain could not be ascertained, and therefore we were not able to exclude these visits from analyses.

A potential referral bias exists in this population in that only women with breast pain referred to a specialty practice were included. Providers in this practice have expertise in clinical breast exams and are likely to have a higher sensitivity and specificity of their exams than most primary care providers. Markers of patient concern or anxiety were not collected and therefore could not be controlled for in analyses. Using clinical utilization as a proxy for diagnostic certainty does not elucidate whether the patient or provider is driving increased utilization. Patients who received diagnostic imaging following initial provider visit may have demonstrated a higher level of anxiety or concern than patients who did not. Similarly, providers themselves may

be uncertain about the underlying etiology of breast pain and therefore order additional diagnostic tests. Future studies that prospectively assess anxiety and reasoning for subsequent imaging are needed to address these concerns.

While past studies have indicated the main value of breast imaging in women with painful breasts to be that of reassurance, our results show that initial imaging leads to additional evaluation. Our results support previous research demonstrating that the prevalence of cancer in patients with breast pain is low and suggest that following normal clinical exam, diagnostic imaging is not required to either rule out cancer or provide reassurance in ruling out cancer. As importantly, these results support the critical role of clinical breast exam skills in the evaluation of breast pain.

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