Clinical Imaging 55 (2019) 148–155

Contents lists available at ScienceDirect

Clinical Imaging

journal homepage: www.elsevier.com/locate/clinimag

Breast Imaging

Focal breast pain: imaging evaluation and outcomes

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ARTICLE INFO

Keywords:
Focal breast pain
Breast cancer
Mammography
Breast ultrasound

ABSTRACT

Objectives: To determine the number and characteristics of cancers detected and the optimal imaging evaluation in women presenting with focal breast pain (FBP).

Materials and methods: We performed a retrospective review of 4720 women who underwent imaging for FBP from 2001 to 2013. Women 18 and over with one or two foci of breast pain and no concurrent breast symptoms were included. 944 patients met criteria.

We recorded the imaging work-up, presence and type of finding at the site of pain, BI-RADS® assessment, and pathological outcomes. Subsequent imaging and clinical follow up was recorded.

Results: Imaging evaluation consisted of sonogram alone in 286 women, mammogram alone in 231 women, and both in 427 women. 113 women had an imaging finding at the site of pain; 103 were designated benign or probably benign. 12 biopsies of corresponding findings were performed: 9 benign, 1 invasive lobular carcinoma, 1 invasive ductal carcinoma, 1 ductal carcinoma in situ. All three malignancies were seen mammographically; 2 had an ultrasound correlate.

At initial evaluation, 4 incidental breast cancers were diagnosed remote from the site of FBP. All were seen on mammogram and 2 of 4 had an ultrasound correlate. On follow up evaluation, 9 cancers were diagnosed at the site of pain and 13 incidental cancers were diagnosed.

Conclusion: FBP is rarely associated with malignancy. Targeted ultrasound may be deferred in women 40 and older with FBP, no other clinical findings, and a negative mammogram.

1. Introduction

Breast pain is a common symptom in women, with general and focal breast pain together accounting for up to 50% of breast-related health care visits [1–4]. Most instances of breast pain are benign and may be safely managed clinically. However, an early study of focal breast pain (FBP) – pain that is localized to a single quadrant and is non-cyclic in nature – found 7% of women with operable breast cancer presented with breast pain alone [5]. Subsequent research studies examining the incidence of breast cancer in women presenting with breast pain demonstrate much lower cancer rates, ranging from 0 to 3.2% [2,4,6–11]. These suggest that focal breast pain, while common, is rarely a sign of breast cancer.

The American College of Radiology Appropriateness Criteria® for initial evaluation of FBP suggests that ultrasound (US) may be appropriate in patients under 30 years of age, and that both mammography (MG) and US may be appropriate in women over 30 years of age [12]. These recommendations are based on risk benefit analyses that do not support mammography in women under the age of 30 due to a lower incidence of breast cancer, decreased sensitivity of mammography due to dense breast tissue, and increased risk of ionizing radiation.

The goal of this study was to evaluate our experience with the imaging evaluation of FBP with retrospective chart review. We assessed the incidence of breast cancer in our patient population and reviewed the clinical and imaging features of these cancers. We evaluated the relationship between age, breast density, imaging modalities utilized,

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https://doi.org/10.1016/j.clinimag.2019.02.008
Received 16 August 2018; Received in revised form 15 January 2019; Accepted 11 February 2019

Table 1
Demographic and imaging characteristics of women with isolated focal breast pain (n = 944).

Mean age (range)	46.9 years (18.1–89.6)
Race	
Caucasian	626 (66.0%)
Black	273 (28.8%)
Asian	15 (1.6%)
Hispanic	4 (0.4%)
Other or unknown	31 (3.3%)
Side of pain	
Bilateral	50 (5.3%)
Right	375 (39.5%)
Left	522 (55.0%)
Unknown	2 (0.2%)
Imaging	
Ultrasound	291 (30.7%)
Mammogram	231 (24.3%)
Mammogram and ultrasound	427 (45.0%)
Mammographic density (n = 658)	
Almost entirely fatty	58 (8.8%)
Scattered fibroglandular densities	285 (43.3%)
Heterogeneously dense	269 (40.9%)
Extremely dense	44 (6.7%)
BI-RADS® category after initial imaging	
1	713 (75.5%)
2	196 (20.8%)
3	17 (1.8%)
4	16 (1.7%)
5	1 (0.1%)
0	1 (0.1%)

and the relative utility of each modality. We also assessed follow up imaging to evaluate for long-term implications of FBP.

2. Materials and methods

2.1. Study population

We performed a keyword search of our radiologic database spanning January 1, 2001 through December 31, 2013 to identify women who underwent imaging for FBP: patients with pain in a single quadrant or two separate quadrants were included. Patients were excluded if they had any other concurrent breast symptoms, including a palpable area of concern, nipple discharge or retraction, skin changes, erythema, or fever. Lactating patients and patients with a history of breast cancer, breast trauma, or recent breast surgery in the preceding three months were also excluded.

2.2. Data collected

For each patient clinical and demographic data were collected, including age, race, family history of breast cancer, and location of FBP. Each patient's imaging evaluation was then assessed, including imaging modalities used and mammographic density.

The imaging protocol for FBP at our institution calls for MG in women over 40 if the most recent mammogram is > 3 months old with targeted US performed at the interpreting radiologist's discretion. Women under age 30 are worked up with US; MG is only performed in the setting of a suspicious US finding or significant family history. In women 30 to 39, the imaging workup is based on radiologist preference.

All mammograms and breast ultrasounds were prospectively interpreted during the course of routine clinical care using the Breast Imaging Reporting and Data System® (BI-RADS®) guidelines and lexicon. During this time period, our department transitioned from film screen to digital mammography. Tomosynthesis was used for diagnostic mammograms performed from 2011 to 2013. Targeted ultrasound was performed using 13.5 MHz linear transducers. All interpreting radiologists were specialized in breast imaging, with either fellowship-training or more than a decade of breast imaging experience. The location of focal imaging findings was compared to the location of FBP; the two were considered to correlate if the imaging finding was within a 90-degree arc centered at the site of FBP. Final BI-RADS® assessment, pathology, and/or imaging follow-up through December 31, 2014 were recorded.

2.3. Statistical analysis

All data were entered into a Microsoft Excel spreadsheet (Microsoft

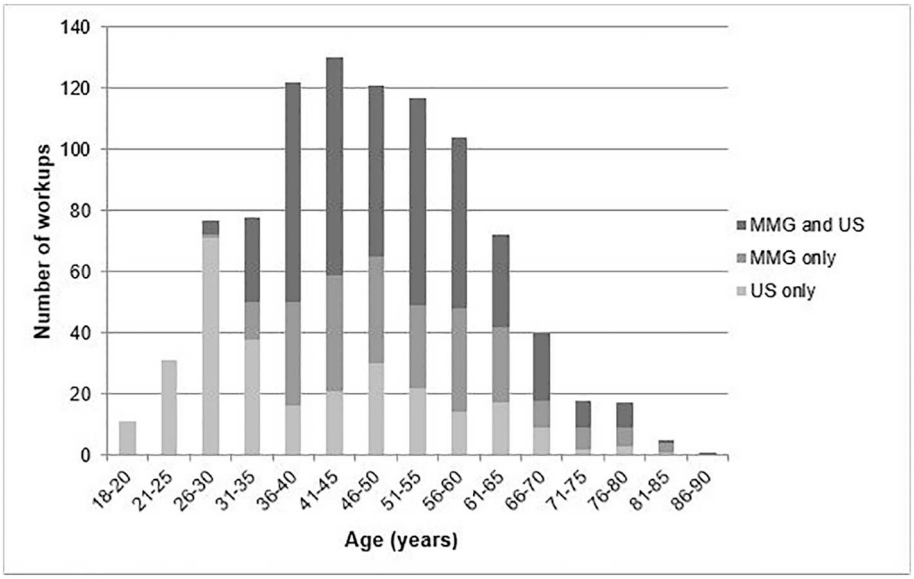

Fig. 1. Imaging evaluation and age.
Stacked column chart demonstrating the imaging evaluation of patients presenting with focal breast pain. Evaluation was with ultrasound, mammogram, or both. The use of mammography increases with age.

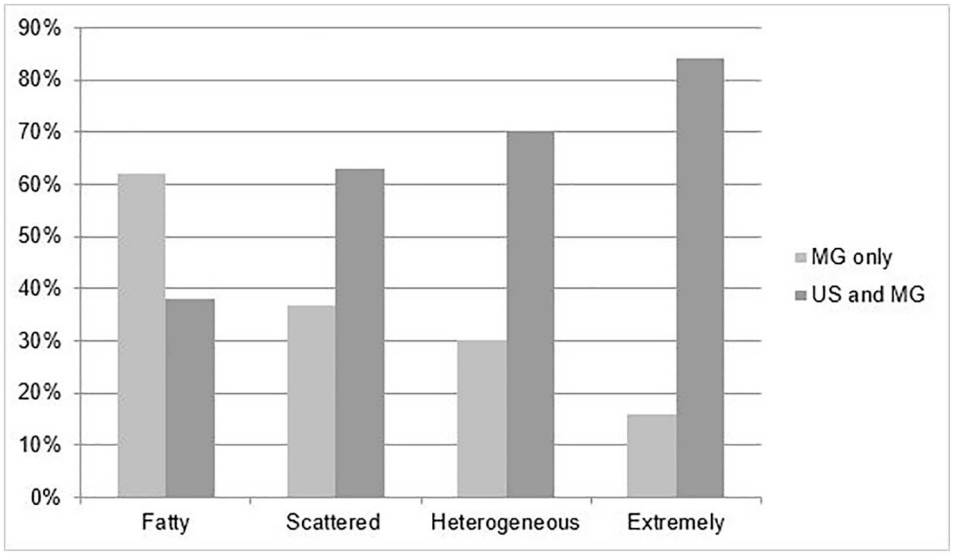

Fig. 2. Imaging evaluation based on breast density.
Clustered column chart demonstrating imaging evaluation based on mammographic density. There is increased utilization of targeted ultrasound in women with denser parenchyma.

Table 2
Biopsies performed at site of initial presentation of FBP.

Corresponding finding for FBP	Modality lesion seen	BI-RADS®	Biopsy modality	Pathology
N	NA	1	Surgical excision	Benign
Y	US	2	Surgical excision	Benign
Y	US	3	Surgical excision	Benign
Y	US	4	US	Papilloma
Y	US	4	US	Benign
Y	MG	4	Stereotactic	Fibroadenoma
Y	US	4	US	Fibroadenoma
Y	MG/US	4	US	Fibroadenoma
Y	US	4	Surgical excision via needle localization	Foreign body reaction
Y	MG/US	4	US	Invasive lobular carcinoma, grade 1/3
Y	MG	4	Stereotactic	Ductal carcinoma in situ (DCIS)
Y	MG/US	5	US	Invasive ductal carcinoma, grade 1/3

FBP focal breast pain, MG mammogram, N no, US ultrasound, Y yes.

Corp, Redmond, WA). Descriptive statistics were used to analyze patient demographics. Chi square test was used to compare the age of the study population to the general population (represented by the Breast Cancer Surveillance Consortium (BCSC) data) [13]. Fisher's exact test was used to compare race and breast density of the study population to the general population. Chi square test was used to analyze difference in imaging evaluation based on breast density. A p-value of 0.05 was used to determine significance. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) were calculated in patients who underwent biopsy or at least 1 year of imaging follow up. Patients with a negative workup at the time of presentation who had a cancer detected at the site of FBP > 12 months after initial presentation were treated as true negatives.

This retrospective chart review was approved by our institutional review board, which waived requirements for informed consent. The study was compliant with the Health Insurance Portability and Accountability Act.

3. Results

Database search for patients with breast pain resulted in 4720 patients. Applying exclusion criteria resulted in 974 patient visits. Thirty of these visits were patients being seen a second or third time for FBP. These repeat visits were excluded from analysis; thus, 944 patients were evaluated.

Patient demographics, imaging workup, site of pain, and final BI-RADS® assessment are summarized in Table 1. Our study population was significantly younger than the average screening population of the

Table 3
Cancers detected over the course of the study, at initial or subsequent evaluation.

					Initial imaging		Subsequent imaging			
	Patient	Age[a] (years)	Breast density[a]	Imaging description	MG	US	Time[b] (months)	MG	US	Pathology
Site of FBP on initial evaluation	1	61	H	M, C	+	+	NA	NA	NA	IDC
	2	56	H	M, C	+	+	NA	NA	NA	ILC
	3	57	S	C	+	−	NA	NA	NA	DCIS
Incidental at initial evaluation	4	70	S	C	+	−	NA	NA	NA	DCIS
	5[c]	63	E	M, C	+	+	NA	NA	NA	DCIS
	6	53	H	C	+	−	NA	NA	NA	DCIS
	7	48	S	M, C	+	+	NA	NA	NA	IDC
On subsequent imaging, at site of FBP	8[c]	50	F	M	−	−	49	+	+	IDC
	5[c]	63	E	C	+	−	24	+	−	DCIS
	9	45	E	M	−	−	19	+	+	IMC, ILC
	10	42	H	M	−	−	75	+	+	IDC
	11	50	E	C	−	−	121	+	NP	DCIS
	12	58	H	AD	−	−	13	+	−	ILC
	13	43	S	C	−	−	21	+	−	DCIS
	14	35	NA	MR: NME	NP	−	66	−	−	IDC
	15[c]	38	S	MR: NME	−	−	13	−	−	DCIS
On subsequent imaging, not at site of FBP	16	47	H	M	−	NP	69	+	+	IDC
	17[c]	72	S	M	−	−	51	+	+	IDC
	18	62	NA	M	NP	−	70	+	+	IDC
	19	47	NA	C	NP	−	23	+	NP	DCIS
	20	57	H	M	−	−	68	+	+	IDC
	8[c]	50	F	M	−	−	38	+	+	IDC
	21	42	S	M	−	NP	52	−	+	IDC
	22	72	F	M	−	NP	67	+	+	IDC
	15[c]	38	S	MR: NME	−	−	15	−	−	IDC
	23	57	S	M	−	NP	87	+	+	IDC
	24	80	H	M	−	−	48	+	+	IDC
	25	80	E	M	−	NP	64	+	+	IDC
	17[c]	72	S	C	−	−	63	+	NP	DCIS

AD architectural distortion, *C* calcification, *DCIS* ductal carcinoma in situ, *E* extremely dense, *F* fatty, *H* heterogeneously dense, *IDC* invasive ductal carcinoma, *ILC* invasive lobular carcinoma, *IMC* invasive mammary carcinoma, *LCIS* lobular carcinoma in situ, *M* mass, *NA* not applicable, *NME* non-mass enhancement, *NP* not performed, *S* scattered areas of fibroglandular density.

[a] At time of initial presentation to breast imaging clinic with isolated FBP.

[b] Interval of time between initial presentation to breast imaging clinic with isolated FBP and cancer diagnosis.

[c] Individual patient who had two separate breast malignancies.

BCSC data with a mean patient age of 47 years (range, 18–90). The distribution of breast density was similar to that of women in the BCSC data ($\chi^2 = 0.596$, $p = 0.9636$). There was a higher percentage of black women and a lower percentage of Asian and Hispanic women in our study relative to the general population (Fisher's exact test, $p < 0.0001$). Family history was unavailable in approximately 2/3 of cases and lacking detail in the remaining patients and was thus not included in the analysis.

Imaging evaluation consisted of ultrasound alone in 286 women (mean age 39 years, range 18–81), mammogram alone in 231 women (mean 51 years, range 29–84), and both mammogram and ultrasound in 427 women (mean 50 years, range 27–90). As illustrated in Fig. 1, in women age 30 years or younger, 95% (113/119) underwent only ultrasound. The use of mammography increased with age: the majority of patients older than 35 received a mammogram (81.9%) either with or without ultrasound. Imaging evaluation also varied based on mammographic density, with increased utilization of targeted ultrasound in women with denser parenchyma ($\chi^2 = 29.0$, $p < 0.0001$) (Fig. 2).

Twelve percent of women (113/944) had a focal imaging finding corresponding to the site of pain. Of these 113 women, 94 were deemed normal or benign. The majority of the benign findings were cysts (67/94). Other benign findings included lymph nodes, stable probable fibroadenomas, and duct ectasia, findings of infection, Mondor's disease, and others. Nine examinations were given a BI-RADS® 3. One patient with a BI-RADS® 3 lesion underwent excision with benign pathology and one was lost to follow up. The remaining 7 patients with BI-RADS® 3 lesions were stable at follow-up imaging and subsequently deemed benign. One BI-RADS® 1 and one BI-RADS® 2 patient underwent surgical excision with benign findings at pathology.

Tissue sampling was recommended in 10 women based on imaging findings: 9 with BI-RADS® 4 lesions and 1 with a BI-RADS® 5 lesion. Table 2 summarizes biopsy results (1 patient with a BI-RADS® 4A lesion did not undergo biopsy and was lost to follow up). From these biopsies, three cancers were detected. Thus, incidence of breast cancer in our population at the site of FBP was 0.3% (3/944). The remaining biopsies demonstrated benign findings.

Table 3 summarizes all the malignancies diagnosed in this population over the span of the review. The three malignancies diagnosed at the site of FBP at initial evaluation were diagnosed in women aged 56–61. Two of the women reported having a mother with breast cancer. All three women were evaluated with both mammogram and ultrasound. All malignancies were evident on mammogram; the two invasive cancers were apparent on ultrasound, but the ductal carcinoma in situ was not as it manifested as microcalcifications. Figs. 3 and 4 show the

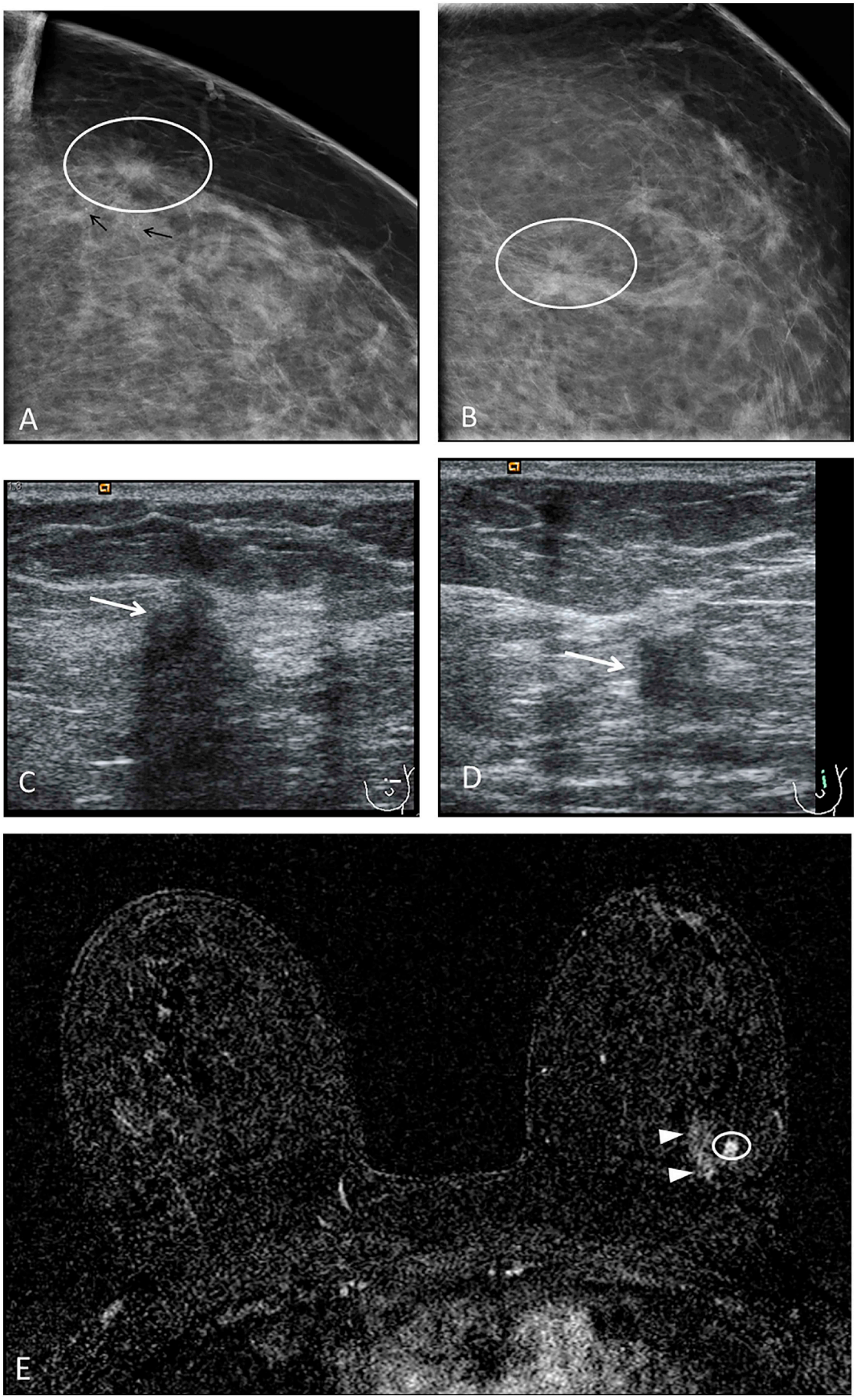

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Fig. 3. Images of a patient presenting with FBP in the upper outer left breast who was diagnosed with IDC at the site of pain (Patient 1 from Table 3). Magnification Craniocaudal (CC) (A) and Lateromedial (LM) (B) views of the left breast demonstrate an irregular, equal density, spiculated mass (white circles) in the area of focal pain in the upper outer left breast and subtle associated microcalcifications (Black arrows).Transverse (C) and Sagital (D) greyscale images of the 1'oclock position of the left breast show an irregular, hypoechoic, mass (white arrows) with indistinct margins and posterior acoustic shadowing in the area of FBP. Single axial subtraction MR image (E) shows an enhancing, irregular mass with irregular margins that corresponds to the IDC in the area of focal pain in the upper outer left breast (white circle). There is some adjacent non-mass enhancement which corresponds to the calcifications seen on the mammogram (white arrows).

imaging findings and work up for the two patients diagnosed with invasive malignancy at the site of pain. Both patients presented with an irregular mass with associated calcifications.

At the time of initial imaging evaluation for FBP, 4 additional cancers were diagnosed remote from the site of the FBP: 3 cases of ductal carcinoma in situ and 1 invasive ductal carcinoma. Three of these occurred in the contralateral breast, while one occurred in the ipsilateral breast but did not co-localize with the site of FBP. All 4 of the incidental cancers were detected on mammography; sonographic correlates were identified in 2 cases.

During follow up 9 women (9/561, 1.6%) were diagnosed with breast malignancy in the same quadrant as a prior episode of FBP. The mean time between initial presentation with FBP and cancer diagnosis was 3.7 years (range 1.1–10.1 years). At the time of subsequent cancer diagnosis, one patient who presented 19 months after FBP evaluation with a new palpable lump still reported breast pain in the same quadrant. Five of the nine patients diagnosed with cancer in the same quadrant as a prior episode of FBP were diagnosed by screening mammogram and reported no symptoms at diagnosis. An additional patient presented with a new palpable, painless lump in the same quadrant 75 months after evaluation for FBP. All 7 of these cancers were detected mammographically. The two cancers that were not detected on mammogram were found in young patients (ages 35 and 38). These cancers were both diagnosed surgically: one by duct excision prompted by bloody nipple discharge, and the other at ductal lavage performed as part of a research study.

An additional 13 cancers developed in 12 women distant from the site of FBP on subsequent imaging evaluation. A mean of 4.6 years occurred between initial presentation and cancer diagnosis remote from the site of FBP (range 1.3–7.3 years).

561/944 women (59.4%) had either a breast biopsy or breast imaging follow up at least 1 year after the initial evaluation. Average follow up by the conclusion of the review was 5.1 years (range, 1.0–13.7 years). Of the 383 women without imaging follow up, 52% (205/383) were under age 40, and 0.5% (2/383) were older than 80.

Among the 561 patients with breast biopsy or at least 1 year of breast imaging follow up, there were 3 true positives, 6 false positives, 0 false negatives, and 552 true negatives. The sensitivity of the imaging work up was 100% (95% CI 29.2%–100%) and the specificity was 98.9% (95% CI 97.7%–99.6%). The NPV was 100% (CI 99.3%–100%) and the PPV was 33.3% (CI 7.5%–70.1%). None of the cancers detected at the site of FBP on follow up were detected at or before one year from the initial evaluation.

4. Discussion

As in several prior studies [2,4,6–10], we found a low incidence of breast cancer in patients presenting with FBP. Of 944 women evaluated in our series, a corresponding cancer was identified at the site of pain in 3 cases. An additional 4 cancers were identified remote from the site of FBP, suggesting that breast cancer is equally as likely to be diagnosed incidentally.

Cancers detected on subsequent imaging were as likely to occur incidentally (9 cancers at and 13 cancers remote from the site of FBP). Prior studies have described similar findings, with a near-equal distribution of cancer both at and remote from the site of FBP [4,6,9].

Imaging evaluation of FBP varied at our institution based on mammographic density and age. As expected, sonography was more commonly utilized in women ≤30 and in women with dense breasts. The most variability in the imaging work up occurred in women between 31 and 35 years old.

None of the cancers detected in our study population at the site of FBP were detected by ultrasound alone, while 3 of the 7 cancers diagnosed at the initial presentation had no sonographic findings. Sonographic findings alone, however, resulted in an additional four negative biopsies and an additional six BI-RADS® 3 designations requiring imaging follow up. Given the high NPV of mammography demonstrated in this and other studies [4,6,10,11], the role of ultrasound in the evaluation of FBP can be reconsidered. Ultrasound remains an appropriate first-line imaging modality in women under 40, given the low likelihood of malignancy, typically dense breast parenchyma, and high sensitivity of ultrasound [14]. However, in women 40 and older, our findings suggest that a targeted ultrasound is not necessary in the evaluation of focal pain if the mammogram is negative. Targeted ultrasound could be added at the discretion of the radiologist if the mammogram is difficult to interpret due to dense breast tissue at the site of FBP.

This study was limited by several factors. Our patient population, although one of the largest series to date, may preclude broad generalization of our findings. As there is no agreed upon definition of FBP, our population may differ from those in previous studies in which different criteria were used. Moreover, follow up was unavailable in a portion of our patients, in part because many were too young to be imaged routinely. We were unable to perform a detailed analysis of the characteristics of FBP due to the retrospective nature of reporting. Similarly, family history was often not included in reports, and when included, did not indicate whether the affected family member was a first degree relative.

5. Conclusions

We found that breast cancer is an infrequent etiology of FBP in the absence of other clinical findings. Patients presenting with FBP are equally as likely to be diagnosed with cancer remote from the site of FBP as at the site of FBP at initial evaluation and on follow up imaging. Additionally, all cancers detected at initial evaluation were seen mammographically, suggesting that targeted ultrasound may be deferred in women 40 and older with FBP, no other clinical findings, and a negative mammogram.

Disclosure

Catherine M. Appleton is a member of the Scientific Advisory Board, Hologic, Inc. and receives Royalties from Oxford University Press. Susan O. Holley receives Royalties from Oxford University Press. The rest of the authors have no disclosures.

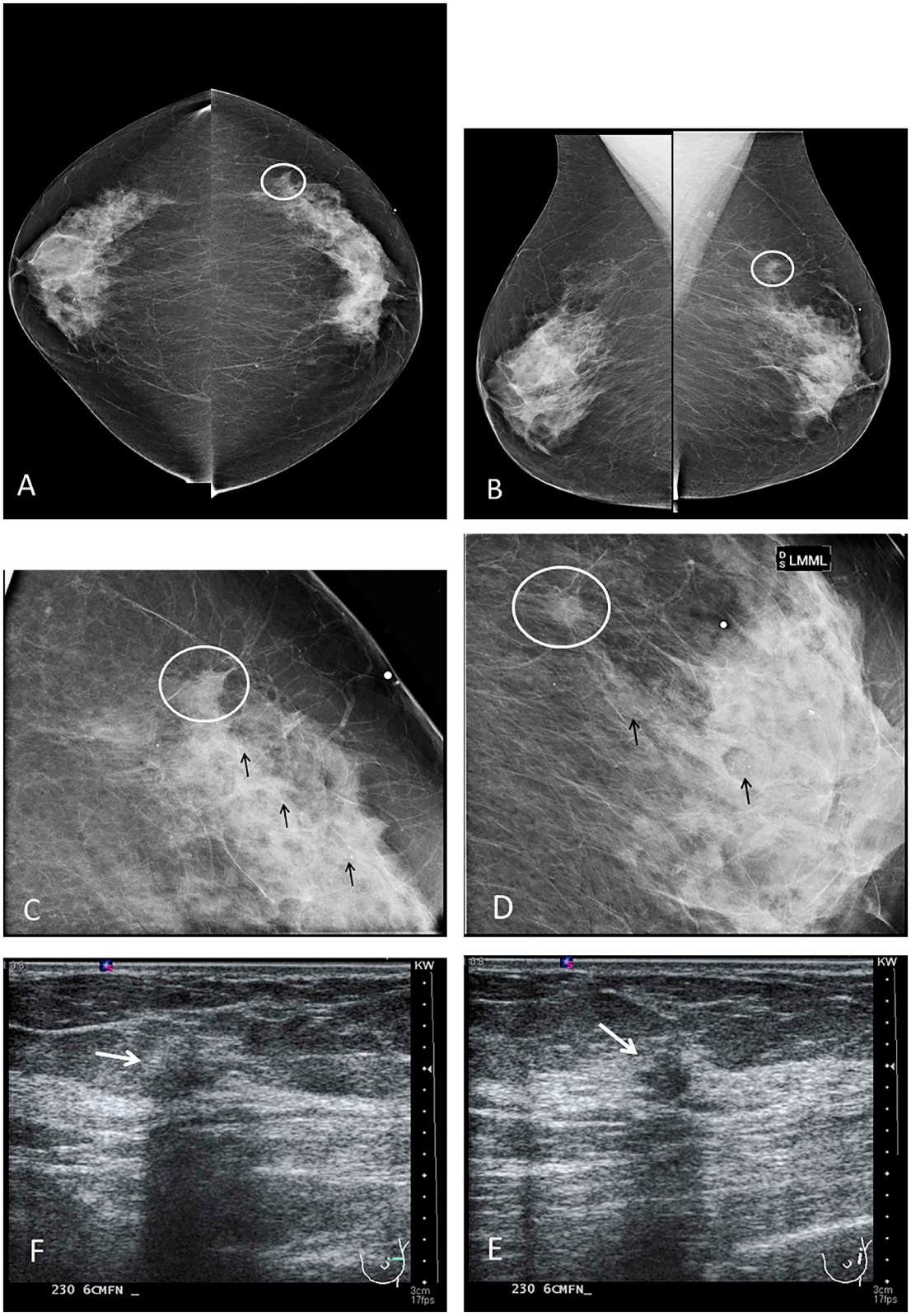

Fig. 4. Images of a patient presenting with FBP in the upper outer left breast who was diagnosed with ILC at the site of pain (Patient 2 from Table 3). Bilateral CC (A) and Mediolateral oblique (MLO) (B) views of both breasts demonstrate an irregular, equal density, mass with indistinct margins (white circles) in the area of focal pain in the upper outer left breast and associated microcalcifications in a linear distribution anterior to the mass. Magnification CC (C) and LM (D) views of the left breast demonstrate a persistent irregular, equal density, mass with indistinct margins (white circles) in the area of focal pain in the upper outer left breast and associated microcalcifications in a linear distribution anterior to the mass (black arrows). Sagital (E) and Transverse (F) greyscale images of the 2:30 position of the left breast show an irregular, hypoechoic, mass (white arrows) with angular margins and posterior acoustic shadowing in the area of FBP compatible with ILC.

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