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BREAST IMAGING
ORIGINAL ARTICLE

Short-term imaging follow-up of patients with concordant benign breast core needle biopsies: is it really worth it?

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PURPOSE
Women with histologically proven concordant benign breast disease are often followed closely after biopsy for a period of two years, and they are considered to be at high-risk for cancer development. Our goal was to evaluate the utility of short-term (six-month) imaging follow-up and determine the incidence of breast cancer development in this population.

METHODS
Retrospective review of concordant benign breast pathology was performed in 558 patients who underwent multimodality breast core biopsy. A total of 339 patients (60.7%) with 393 biopsies qualified for the study. The six-, 12-, and 24-month incidence rates of breast cancer development were estimated with 95% confidence intervals (CI), using the exact method binomial proportions.

RESULTS
No cancer was detected in 285 of 339 patients (84.1%) returning for the six-month follow-up. No cancer was detected in 271 of 339 patients (79.9%) returning for the 12-month follow-up. Among 207 follow-up exams (61.1%) performed at 24 months, three patients were detected to have cancer in the ipsilateral breast (1.45% [95% CI, 0.30%–4.18%]) and two patients were detected to have cancer in the contralateral breast (0.97% [95% CI, 0.12%–3.45%]). Subsequent patient biopsy rate was 30 of 339 (8.85%, [95% CI, 6.05%–12.39%]). Three ipsilateral biopsies occurred as a sole result of the six-month follow-up of 285 patients (1.05%, [95% CI, 0.22%–3.05%]).

CONCLUSION
Short-term imaging follow-up did not contribute to improved breast cancer detection, as all subsequent cancers were detected on annual mammography. Annual diagnostic mammography after benign breast biopsy may be sufficient.

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According to the American Cancer Society, an estimated 232 340 new cases of breast cancer are expected to occur in women in the year 2013, making breast cancer the most commonly diagnosed cancer in women (1). A few of the factors which increase a woman's risk of breast cancer include age, menopausal status, family history, age at first live birth, and history of benign breast disease diagnosed on core needle biopsy or at surgical excisional biopsy (2, 3).

Approximately 1.5 million breast biopsies are performed annually (4, 5), and approximately 75% of these biopsies yield benign histology (6). Percutaneous image-guided core needle biopsy is routinely performed as an accurate alternative to surgical biopsy for obtaining a histological diagnosis of breast lesions (7). Many concordant benign lesions on core biopsy are closely followed after biopsy to evaluate for stability and to avoid any delay in diagnosis of a possible false-negative biopsy (7–11). This follow-up incurs additional cost, radiation, and patient anxiety, with questionable added clinical benefit.

Follow-up imaging protocols after concordant benign breast biopsy vary by institution, and no standard follow-up imaging guidelines for concordant benign lesions have been established (12, 13). The 2010 and 2013 consensus guidelines published by the National Comprehensive Cancer Network (NCCN) recommend follow-up diagnostic imaging and physical exam every 6–12 months for 1–2 years following a concordant benign core needle biopsy, prior to releasing these women back into the general screening population (14). It remains unclear what the appropriate clinical breast exam/imaging schedule should be during those two years, and more importantly, whether this intensive two-year follow-up protocol is of clinical benefit. The goal of this study was to retrospectively examine the utility of our institutional protocol of six-, 12- and 24-month imaging follow-up after concordant benign breast biopsy. We examined the incidence of interval development of bilateral breast cancer in women with histologically proven, concordant benign breast disease with and without atypia. We also evaluated the number of subsequent benign biopsies performed on these women in either breast during the two-year follow-up period, and those that occurred solely as a result of additional follow-up.

Methods

Inclusion criteria

An Institutional Review Board-approved retrospective chart review of a single institution research database was performed during the time period of January 1st, 2007 and July 13th, 2010. Informed consent was waived in this retrospective analysis. Patients were identified for this study if they were recommended for biopsy of a BI-RADS 4 finding. Three additional women with BI-RADS 3 abnormalities were also iden-

tified because the referring physician or patient requested a biopsy. Inclusion criteria were successful completion of the biopsy with benign results and imaging/clinical follow-up during the two-year follow-up period. If a patient returned for any imaging during the two years, she was included in the study. A total of 339 of 558 patients (age range, 20–88 years) had a successful biopsy with benign results and had some type of imaging follow-up in the first two years, and thus qualified for the study. The remaining 219 ineligible patients were excluded either because they were lost to follow-up, failed to have their initial biopsy at our institution, or had discordant biopsy results on radiologic-pathologic review. Six cases were excluded due to radiologic-pathologic discordance, and went on to surgical excision. One malignancy was revealed in this group at surgical excision. Additional exclusion criteria included male patients, patients who underwent magnetic resonance imaging (MRI)-guided biopsy, patients with a prior history of breast cancer, and any BI-RADS 5 lesions. MRI-guided biopsies were excluded due to the difference in follow-up recommendations and consensus management documented in the literature (15–18), as well as the inability to verify adequate sampling of the lesion, as lesions targeted for MRI-guided biopsy enhance *in vivo*, and specimen MRI cannot confirm lesion sampling (17).

Biopsy procedure

A total of 393 core-needle biopsies were performed using either ultrasonography (US) or stereotactic guidance. A total of 286 biopsies were performed under US-guidance using a high-resolution US unit with a 12 or 17 MHz linear-array transducer (iU22, Philips Healthcare, Best,, the Netherlands). Stereotactic guidance was utilized for 107 biopsies using a stereotactic table (Lorad, Hologic, Bedford, Massachusetts, USA). Biopsy devices included a 14-gauge spring-loaded device (Achieve, Care Express Products, Inc., Cary, North Carolina, USA, and Monopty, Bard Biopsy Systems, Tempe, Arizona, USA), as well as 9- and 11-gauge vacuum-assisted devices for US cores (Mammotome, Cincinnati, Ohio, USA). A 9-gauge vacuum-assisted (SenoRx, Inc., Tempe, Arizona, USA or Suros Eviva, Hologic) core needle was utilized for stereotactic biopsies. Specimen radiographs were obtained after all procedures targeting calcifications to confirm adequate sampling. A radiopaque localizing clip was uniformly placed after all biopsies. Two view mammograms were obtained after biopsy to document clip position.

Radiologic-pathologic concordance and recommendations after biopsy

Subsequent to US-guided or stereotactic core biopsy, upon receipt of pathology, the board certified radiologist who performed the biopsy reviewed the pathology reports in conjunction with the mammographic and/or US images to determine concordance. Pathology was determined to be concordant when the reported findings provided an acceptable explanation for the imaging features. In cases where the histologic results were not sufficient to explain the imaging findings, the results were deemed discordant. A total of nine radiologists participated during the study timeframe as the interpreting radiologist. All interpreting radiologists were either fellowship trained in breast imaging or had greater than 15 years of practice experience. The range of practice experience was 1–35 years (mean, 9.6 years; median, 4 years). The positive predictive value for all BI-RADS 4 cases at our institution is approximately 26%. A formal addendum was placed on the original biopsy report stating concordance or discordance and further treatment recommendations. Treatment recommendations included surgical excision for discordant or high-risk lesions, short-term or six-month follow-up for concordant benign breast disease, and definitive surgical treatment for malignancy. Six-month imaging follow-up with concomitant clinical breast examination in our Diagnostic Breast Clinic is routinely and uniformly recommended for concordant benign breast disease at our institution.

Data collection and statistical analysis

Data points collected at presentation included demographic information, risk factors for breast cancer, clinical-pathologic findings on clinical breast examination, imaging findings and pathology at biopsy. The follow-up evaluation after a concordant benign breast biopsy was extensively recorded, including any changes during follow-up in self breast exam, family history or risk factors for breast cancer, follow-up clinical breast examination and imaging results, and the results of any new percutaneous core biopsy or excisional biopsy, if applicable. The six-month, 12-month, and 24-month incidence rates of bilateral cancer development were estimated with 95% confidence intervals (CI), using the exact method binomial proportions. Utilizing the same method, 24-month incident rate of additional benign biopsies in either breast was also calculated. Statistical significance was assigned to P values < 0.05.

Results

The medical records of 558 women were reviewed for eligibility into this study; 339 women had a successful concordant benign biopsy and at least one follow-up imaging exam during the two-year follow-up period, comprising the study cohort. Of the women included in the study, 232 were Caucasian (68.4%), 81 were Hispanic (23.8%), 19 were African American (5.6%), five were Asian (1.5%), and two women marked other (0.6%). The mean age of the study population was 51 years (range, 22–94 years). A total of 110 women (32.4 %) reported a history of a prior benign core or excisional breast biopsy. The majority of the prior biopsies had unknown benign pathology; however, four had atypia on histology (1.2%). Of these atypical biopsies, two were atypical ductal hyperplasia and two were atypical hyperplasia, not otherwise specified (Fig. 1). These lesions were removed by surgical excision.

At the time of the initial diagnostic exam and presentation to our facility, 148 women were symptomatic. Of the symptomatic women, 61 complained of breast pain, 43 felt a painless palpable abnormality, 32 complained of a painful palpable abnormality, eight complained of nipple discharge, and four had multiple complaints. On diagnostic exam, 55 women were given BI-RADS 4 not otherwise specified, 222 were given BI-RADS 4A, 45 were given BI-RADS 4B, and 14 were given BI-RADS 4C. Three women were given a BI-RADS 3, but requested biopsy. Of the 339 women, 44 were recommended to have more than one area biopsied. This resulted in a total of 393 biopsies.

Of the biopsied findings, 250 were described as masses, 95 as calcifica-

tions, 12 as one-view asymmetries, 11 as complex cystic masses, eight as masses with calcifications, seven as areas of architectural distortion, three as focally dilated ducts, and three merely as densities. The four remaining biopsy targets were not recorded. The majority of the benign biopsies revealed benign breast histology (Table 1). Results of the concordant benign biopsies revealed 64 high-risk lesions (16%), which were recommended for surgical excision. Due to patient preference, surgical excision was not performed in one case of flat epithelia atypia and one case of atypical ductal hyperplasia. These patients did not develop malignancy or require additional biopsies during the follow-up interval of two years. The remaining high-risk lesions, including 32 cases of atypical ductal hyperplasia and six cases of atypical lobular hyperplasia, were recommended for and completed surgical excision. None of these lesions were upstaged to cancer on excision. Of the concordant benign breast biopsies without atypia, five patients went on to have surgical excision, secondary to patient preference, often due to the palpable nature of the abnormality.

Table 1. Pathology of initial benign breast biopsies, n=393

Adenosis	2
Atypical ductal hyperplasia[a]	32
Atypical lobular hyperplasia[a]	6
Atypical papilloma[a]	3
Atypia[a]	3
Benign breast tissue	122
Cellular fibroadenoma[a]	3
Cyst wall	28
Dilated duct	2
Fibroadenoma	98
Fibrocystic changes	47
Flat epithelial atypia[a]	5
Fibroepithelial lesion[a]	10
Fat necrosis	3
Lipoma	2
Papilloma	13
Phyllodes[a]	1
Pseudoangiomatous stromal hyperplasia	6
Radial scar[a]	1
Tubular adenoma	2
Usual ductal hyperplasia	4

[a]Histology prompting recommendation for surgical excision.

Table 2. Follow-up diagnostic exams that occurred during the two-year surveillance period

Diagnostic exam	6-month follow-up	12-month follow-up	24-month follow-up
Mammography	84	92	93
US	60	37	18
Mammography and US	123	127	81
MRI	3	5	2
Mammography, MRI, and US	8	7	5

US, ultrasonography; MRI, magnetic resonance imaging.

During the two-year follow-up interval, 285 of 339 women returned at six months (84.1%), based on a six-month follow-up window spanning from >2 months to <9 months, with an average follow-up time of 6.1 months. At the 12-month follow-up interval, 271 of 342 women returned (79.2%), based on a follow-up window spanning from ≥9 months to <20 months, resulting in an average follow-up time of 12.7 months. At the 24-month follow-up interval, 207 of 339 women returned (61.1%), based on a follow-up window spanning from ≥20 months to <35 months, with an average follow-up of 24.2 months (Table 2). Variation in the timing of follow-up was due to different preferences of the interpreting radiologist, as well as patient compliance.

The six-month follow-up resulted in 255 additional diagnostic exams in women over the age of 40, and 31 additional diagnostic exams in women under the age of 40. Subsequently, the 12- and 24-month follow-ups resulted in 34 additional diagnostic exams for women under the age of 40. During the follow-up period, 30 of 339 women (8.8%) had additional breast biopsies, with five women having more than one additional biopsy during the follow-up period, generating a total of 35 additional biopsies. Of these biopsies, 17 occurred in the ipsilateral breast, and 18 in the contralateral breast. A total of 11 biopsies occurred at the six-month mark, three in the ipsilateral breast and eight in the contralateral breast. Contralateral breast biopsies were recommended for the following reasons; two were follow-up of BI-RADS 3 abnormalities, two were palpable, four patients were due for contralateral breast imaging, two were follow-ups after benign biopsy and one was a follow-up for an MRI finding. Additionally, two of the initial benign biopsy sites required re-biopsy due to interval change during the follow-up period, both revealing benign pathology on re-biopsy. This resulted in a re-biopsy rate of 0.5% (2 of 393 biopsies).

Of the 18 contralateral breast biopsies which occurred on routine examination during the surveillance period, two revealed malignancy (11.1%). Total number of malignancies detected in

patients at 24 months was five out of 207 (2.42% [95% CI, 0.79%–5.55%]). The remaining 30 breast biopsies were benign, including benign lesions with and without atypia (Table 3). Surgical excisional biopsy was recommended for histology revealing atypia, resulting in four surgical excisions.

No breast cancers were detected at six or 12 months. Three cancers were detected in the ipsilateral breast at 24-month follow-up (1.45% [95% CI, 0.30%–4.18%]). None of the cancers detected occurred at the site of prior biopsy. Two cancers were also detected in the contralateral breast at 24-month follow-up (0.97%, [95% CI, 0.12%–3.45%]) (Figs. 1, 2). For those women with at least one follow-up exam, subsequent patient biopsy rate was 30 of 339 (8.85% [95% CI, 6.05%–12.39%]) with a total of 35 additional biopsies preformed on 30 patients. Of the three malignancies that occurred in the ipsilateral breast during the two-year follow-up surveillance period, all occurred in women over the age of 40, with an average age of 55.3 years, and all were found on diagnostic mammography. All three malignancies occurred at locations separate from the initial biopsy site in the ipsilateral breast and were discovered by biopsy that was prompted by the 24-month follow-up (Table 4).

Table 3. Histology results of subsequent recommended core biopsies during the 24-month surveillance period

Benign breast tissue	8
Fibroadenoma	7
Cyst wall	3
Papilloma	3
Fibrocystic changes	2
Pseudoangiomatous stromal hyperplasia	2
Ayptical ductal hyperplasia[a]	2
Ductal carcinoma in-situ[b]	3
Invasive ductal carcinoma[b]	2
Atypical lobular hyperplasia[a]	1
Atypical papilloma[a]	1
Usual ductal hyperplasia	1

[a]Histology prompting recommendation for surgical excision.
[b]Malignancy.

Table 4. Histology and location of ipsilateral malignancies diagnosed in three patients during the two-year follow-up of benign core biopsies

BI-RADS	Benign core histology	Tumor histology	Tumor location relative to benign biopsy
4A	Fibroadenoma	Low grade DCIS with ADH	Ipsilateral breast, different quadrant
4A	Fibroadenoma	IDC with DCIS	Ipsilateral breast, same quadrant
4A	Sclerosing adenosis (right)	DCIS, intermediate grade	Ipsilateral breast, different quadrant
4A	Fibroadenomatoid change (left)	N/A	Contralateral breast

DCIS, ductal carcinoma in situ; ADH, atypical ductal hyperplasia; IDC, invasive ductal carcinoma; N/A, not applicable.

Discussion

It is generally accepted that a woman who has undergone breast biopsy with benign pathology is at increased risk for future development of breast cancer (1, 2). Although imaging protocols vary among institutions, many consider these women "high-risk" and image them more frequently, referencing the NCCN guidelines that recommended either six- or 12-month imaging and clinical follow-up after benign biopsy (14). The length of follow-up and whether or not to use the same follow-up pattern of imaging and clinical breast examination as a high-risk patient with other risk factors remains debated. To address some of these questions, we examined our data on women with a concordant benign breast biopsy with subsequent short-term (six-month) follow-up imaging. Based on reported literature, our follow-up protocol for concordant benign breast biopsy is a clinical breast examination every six months with imaging (19). Our data failed to support our institutional policy regarding the need for additional or short-term six-month imaging follow-up in patients with concordant benign breast disease above routine examination, as all additional cancers detected during the follow-up period were found on annual diagnostic mammography at two years. All imaging was performed as a digital diagnostic examination and read by a board certified breast radiologist at our institution. Whether or not those additional findings of biopsies and cancer diagnoses would have been detected on screening mammography in the community setting, which includes mobile mammography units is unclear. Another difference in our retrospective analysis was that radiologic-pathologic concordance was not re-reviewed by a dedicated review committee; rather, the original pathology interpretation and radiologic-pathologic concordance recommendations were accepted (performed by a board certified radiologist, either fellowship trained in breast imaging or with greater than 15 years of practice experience, mean of 9.6 years of practice experience). To our knowledge, our study is unique in this regard, as other publications report the utility of short-term imaging follow-up after concordance is determined by a committee (13, 20). This may be similar to practices throughout the country without a dedicated radiologic-pathologic review committee, and may provide more widely applicable support for eliminating short-term imaging follow-up after concordant benign breast biopsy. Additionally, six-month follow-up imaging is routinely and uniformly performed at our institution on

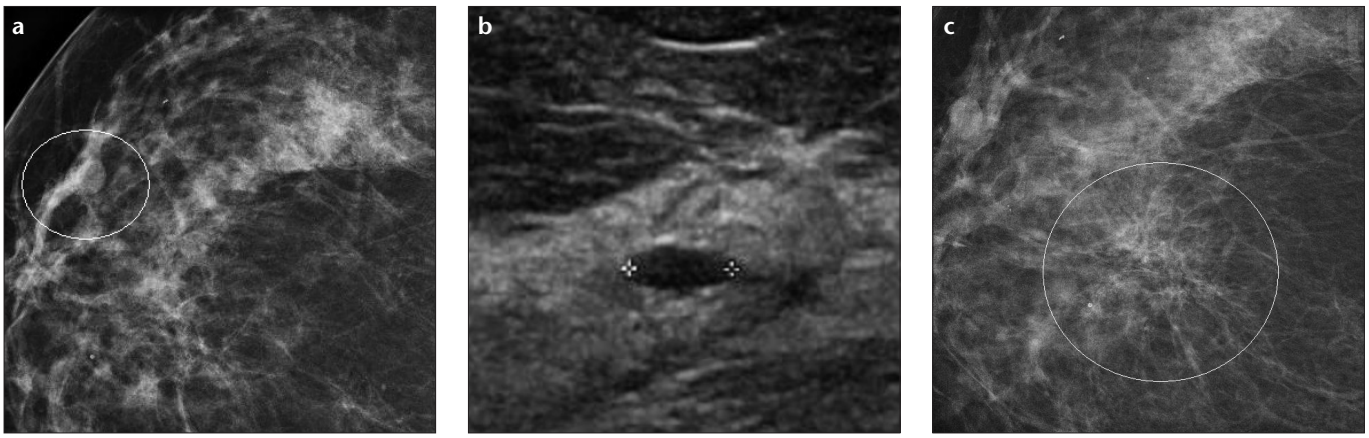

Figure 1. a–c. A 53-year-old high-risk female with strong family history presented on diagnostic exam with a 9 mm oval mass **(a)** with obscured margins in the right breast at 9 o'clock, anterior depth. Ultrasonography **(b)** demonstrates a corresponding oval complicated cyst versus solid mass at 9 o'clock 5 cm from the nipple, measuring 5 mm (BI-RADS 4A). Ultrasonography-guided biopsy revealed sclerosing adenosis with microcalcifications. At 23 months, right diagnostic mammogram magnification view **(c)** demonstrates architectural distortion with associated amorphous calcifications in the right breast at 12 o'clock (BI-RADS 4A). Stereotactic core biopsy revealed intermediate grade ductal carcinoma in situ with calcifications.

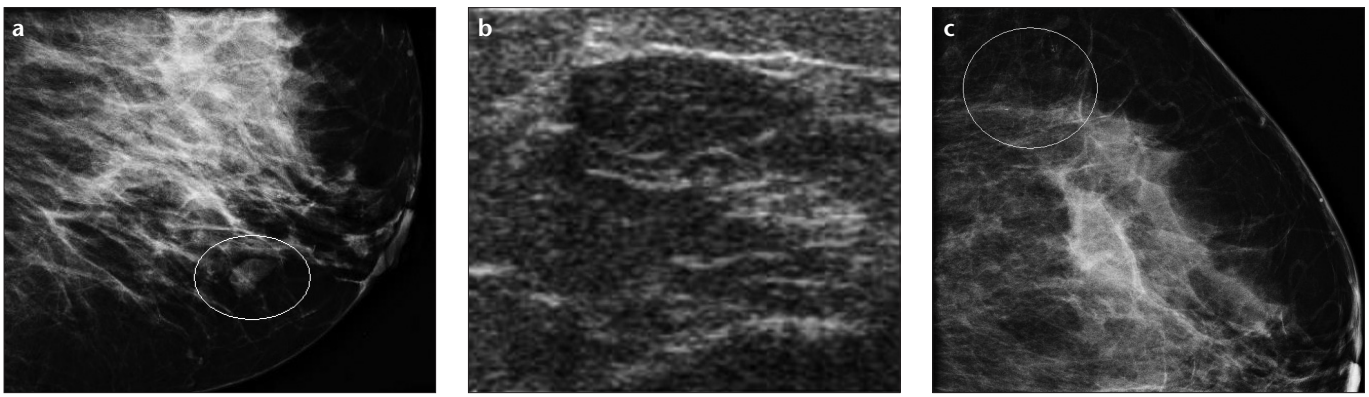

Figure 2. a–c. A 52-year-old female with abnormal screening mammogram. Diagnostic mammogram **(a)** demonstrates a 12 mm lobular mass with circumscribed margins in the left breast at 4 o'clock, mid-depth. Ultrasonography of the left breast **(b)** demonstrates a 12 mm oval hypoechoic solid mass at 4 o'clock, 3 cm from the nipple measuring 10 mm (BI-RADS 4A). Ultrasonography-guided biopsy revealed a fibroadenoma. Patient returned 23 months later with new microcalcifications in the upper outer quadrant of the left breast **(c)**. Stereotactic core biopsy revealed intermediate grade ductal carcinoma in situ with solid features.

all concordant benign biopsies regardless of pathologic diagnosis, strengthening the validity of the six-month follow-up results.

Close follow-up of concordant benign breast disease diagnosed on core biopsy may also stem from a fear of false negative biopsy results and an increased cancer risk in this patient population (21). Long-term follow-up data reveals few false negative concordant core needle biopsies documented in the literature. Acheson et al. (22) produced one false negative in 312 patients during a 55-month follow-up of benign large-core needle biopsies (negative predictive value, 0.997). Similarly, multiple studies have proven core needle biopsy to be comparable to surgical biopsy in accuracy of diagnosis for both benign and malignant lesions. For example, Parker et al. (23) demonstrated a 99% agreement between core needle biopsy and surgical biopsy, in their review of 1363 cases. Additionally, most false-negative diagnoses are detected by radiologic-pathologic discordance and warrant re-biopsy or surgical excision, to avert delayed diagnosis (7–11). Similar studies that did detect false-negatives during a 24-month surveillance period, describe such findings in cases of symptomatic patients with palpable abnormalities or nipple discharge far more commonly than in asymptomatic patients. Youk et al. (13) reported seven such cases out of eight false negative biopsies detected, and calculated a probability of malignancy in their symptomatic patients to be 2.4% within the 1309 women followed (13). Our patient population included 148 symptomatic patients (43.7%), with at least 43 patients complaining of a discrete palpable finding (12.7%). Perhaps this discrepancy is due in part to the difference in sample size, biopsy technique, or differences in determination of radiologic/pathologic concordance. Of note, the average positive predictive value for all BI-RADS 4 lesions at our institution is 26%.

We detected no malignancies in six-month or 12-month follow-up examinations, and five malignancies (2.4% of 207) (three ipsilateral and two contralateral) were found at 24-month follow-up. All malignancies occurred in women over the age of 40; they were all detected on mammography and would have been detected during routine annual diagnostic mammography. Furthermore, the additional six-

month follow-up evaluation resulted in 285 additional diagnostic exams, 31 of which occurred in women under the age of 40. Also, there were 34 additional 12- and 24-month follow-up exams for women under the age of 40. A total of 30 additional benign breast biopsies occurred following recommendation during the 24-month surveillance interval. These factors contribute to an increase in overall cost and increased patient anxiety. Our findings are similar to results produced by Salkowski et al. (20), who detected no malignancies at six- or 12-month follow-up of 1465 concordant benign breast biopsies. That study produced similar re-biopsy rates at six- and 12-month follow-up, of only 0.8% and 0.9%, respectively, suggesting that imaging performed at six months does not affect subsequent treatment outcomes (20). Our re-biopsy rates were 0% at six months and 0.5% during the 12-month interval.

There are limitations to this study. First, many patients were excluded from the study because they did not return for additional imaging at our institution. This may result from the fact that our institution serves as a tertiary referral center for many patients throughout the state, who often desire follow-up closer to home. Of the 342 women with concordant benign breast biopsies, many did not adhere to the complete follow-up regimen of six-, 12-, and 24- month intervals. Patient adherence to the follow-up recommendations varied between 84.1% at six months to 61.6% at 24 months, for patients who did return. This is in-line with documented patient adherence rates in the literature ranging between 51%–72% (13). Second, imaging modalities specified at follow-up were not standardized. Rather, follow-up recommendations were individualized based on the nature of the presenting abnormality and then deciding which imaging modality was most appropriate given the findings. For that reason, abnormalities presenting as calcifications were predominantly followed by mammography, while masses were followed by both mammogram and US. MRI follow-up was predominantly utilized in complicated or high-risk patients. Lastly, our data included pathology from both spring-mounted core biopsy devices and vacuum-assisted core biopsy devices, which are often separated in the literature.

In conclusion, the low incidence of ipsilateral breast cancer detected during the 24-month follow-up period among the 393 concordant benign breast biopsies may obviate the need for additional imaging surveillance during the first two years, specifically the ipsilateral six-month follow-up imaging and clinical examination. Annual follow-up with diagnostic mammography may be sufficient, as our results do not support that short-term (six-month) imaging follow-up contributed to improved breast cancer diagnosis. Patients with a history of benign breast biopsy, with and without atypia, remain at increased risk (perhaps with different future duration of risk) for subsequent development of malignancy and thus specific risk factors should be taken into account when determining an appropriate screening protocol and overall risk stratification (21).

Conflict of interest disclosure

The authors declared no conflicts of interest.

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