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# Breast Cancer Detection with Short-Interval Follow-up Compared with Return to Annual Screening in Patients with Benign Stereotactic or US-guided Breast Biopsy Results<sup>1</sup>

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## Purpose:

To compare the cancer detection rate and stage after benign stereotactic or ultrasonography (US)-guided core breast biopsy between patients with short-interval follow-up (SIFU) and those who return to annual screening.

## Materials and Methods:

The Breast Cancer Surveillance Consortium (BCSC) registry and the BCSC Statistical Coordinating Center received institutional review board approval for active and passive consent processes and a waiver of consent. All procedures were HIPAA compliant. BCSC data for 1994–2010 were used to compare ipsilateral breast cancer detection rates and tumor characteristics for diagnoses within 3 months after SIFU (3–8 months) versus return to annual screening (RTAS) mammography (9–18 months) after receiving a benign pathology result from image-guided breast biopsy.

## Results:

In total, 17631 biopsies with benign findings were identified with SIFU or RTAS imaging. In the SIFU group, 27 ipsilateral breast cancers were diagnosed in 10715 mammographic examinations (2.5 cancers per 1000 examinations) compared with 16 cancers in 6916 mammographic examinations in the RTAS group (2.3 cancers per 1000 examinations) ( $P = .88$ ). Sixteen cancers after SIFU (59%; 95% confidence interval [CI]: 39%, 78%) were invasive versus 12 after RTAS (75%; 95% CI: 48%, 93%). The invasive cancer rate was 1.5 per 1000 examinations after SIFU (95% CI: 0.9, 2.4) and 1.7 per 1000 examinations (95% CI: 0.9, 3.0) after RTAS ( $P = .70$ ). Among invasive cancers, 25% were late stage (stage 2B, 3, or 4) in the SIFU group (95% CI: 7%, 52%) versus 27% in the RTAS group (95% CI: 6%, 61%). Positive lymph nodes were found in seven (44%; 95% CI: 20%, 70%) invasive cancers after SIFU and in three (25%; 95% CI: 5%, 57%) invasive cancers after RTAS.

## Conclusion:

Similar rates of cancer detection were found between SIFU and RTAS after benign breast biopsy with no significant differences in stage, tumor size, or nodal status, although the present study was limited by sample size. These findings suggest that patients with benign radiologic-pathologic-concordant percutaneous breast biopsy results could return to annual screening.

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**B**iopsy of breast lesions is increasingly being performed by using minimally invasive image-guided percutaneous needle techniques (1). Although the exact number of percutaneous breast biopsies performed annually in the United States is unknown, estimates range from 500 000 to as many as 1 000 000 (2). The number of percutaneous breast biopsies performed in the United States continues to increase, replacing surgical excisional biopsies for cancer diagnosis of a breast abnormality detected with mammography or ultrasonography (US) (3). Compared with surgical excisional biopsies, image-guided percutaneous breast biopsies have the benefit of lower complication rates and lower cost and have an equal accuracy rate (4–8).

Conflicting results and recommendations in the literature regarding recommendations for follow-up of benign breast biopsy findings are likely responsible for the wide range of practices for these patients. Some U.S. centers recommend that patients return for a 4- to 6-month follow-up unilateral mammographic and/or US examination to ensure that there has been no change at the biopsy site, in accordance with a consensus statement for stereotactically guided vacuum-assisted biopsies (9). Other centers return patients to routine annual screening on the basis of a survey of core breast biopsy practices in the United States (9–12). Currently, there are no evidence-based guidelines for follow-up imaging in patients whose benign biopsy findings show radiologic-pathologic concordance.

In three single-institution studies, investigators have specifically evaluated the utility of short-interval follow-up (SIFU)

for patients after receiving a benign breast biopsy finding. Lee et al recommended follow-up imaging at 6 months for nonspecific benign histopathologic findings and an annual screening examination for specific benign histopathologic findings, such as a fibroadenoma (13). Shin et al recommended follow-up imaging at 6, 12, and 24 months (2). However, in a more recent single-institution retrospective study, investigators explored the benefit of SIFU imaging from 4 to 9 months compared with 9 to 15 months for radiologic-pathologic-concordant benign biopsy findings (14). The more recent study demonstrated no benefit in SIFU imaging at 6 months versus the longer follow-up interval, implying that SIFU may not be necessary (14). The elimination of routine SIFU imaging would decrease unnecessary healthcare use and costs and could also decrease patient anxiety (15).

To our knowledge, no large multi-institutional studies have been specifically conducted to evaluate the benefit of SIFU compared with return to annual screening (RTAS) for patients with benign concordant breast biopsy findings. The goal of our study was to compare the cancer detection rate and the stage of cancers detected after benign stereotactic or US-guided core breast biopsy between patients with SIFU and those with RTAS.

## Materials and Methods

### Study Design

This study is a retrospective, multi-institutional study based on biopsy data from 1994 to 2010. Each Breast Cancer Surveillance Consortium (BCSC) registry and the BCSC Statistical Coordinating Center received institutional review board approval for either active

or passive consenting processes or a waiver of consent to enroll participants, link data, and perform analytic studies. All procedures were Health Insurance Portability and Accountability Act compliant, and all registries and the Statistical Coordinating Center received a Federal Certificate of Confidentiality and other protections for the identities of women, physicians, and facilities that were subjects of this research.

### Data Source

We used retrospective data from five breast imaging registries that participate in the BCSC: Carolina Mammography Registry, Chapel Hill, NC; New Hampshire Mammography Network, Lebanon, NH; New Mexico Mammography Project, Albuquerque, NM; Vermont Breast Cancer Surveillance System, Burlington, Vt; and Group Health Cooperative, Seattle, Wash. The registries, comprising 226 radiology facilities, collected information on all mammographic and breast US examinations performed at radiology facilities in the community and all breast pathology interpretations performed at the affiliated laboratories. Patient characteristics and clinical information were

### Advance in Knowledge

- Short-interval follow-up imaging after a benign concordant biopsy finding did not result in detection of additional cancers or improvement in the stage, tumor size, or nodal status of invasive cancers detected when compared with a population who returned to routine annual screening.

### Implication for Patient Care

- Our multi-institutional study suggests that patients can return to routine annual screening after receiving a benign concordant imaging-guided breast biopsy finding.

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#### Abbreviations:

BCSC = Breast Cancer Surveillance Consortium

CI = confidence interval

RTAS = return to annual screening

SIFU = short-interval follow-up

#### Author contributions:

Guarantors of integrity of entire study, J.M.J., A.K.J., E.S.O., E.N.H.; study concepts/study design or data acquisition or data analysis/interpretation, all authors; manuscript drafting or manuscript revision for important intellectual content, all authors; approval of final version of submitted manuscript, all authors; literature research, J.M.J., A.K.J., B.M.G., E.N.H.; clinical studies, J.M.J., A.K.J., D.L.M.; experimental studies, A.K.J.; statistical analysis, E.S.O., D.L.M., E.N.H.; and manuscript editing, all authors

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Conflicts of interest are listed at the end of this article.

collected for each imaging examination. Radiologist assessments and recommendations were based on the American College of Radiology Breast Imaging Reporting and Data System (16). The selected registries also collected data on benign breast pathology findings. After the diagnosis of invasive breast cancer or ductal carcinoma in situ, breast cancer diagnoses and stage of breast cancers were obtained by linking BCSC data to hospital-based pathology services; regional Surveillance, Epidemiology, and End Results programs; and state tumor registries. Data were pooled and analyzed at the Statistical Coordinating Center. A full list of BCSC publications can be found at <http://breastscreening.cancer.gov/publications/>.

### Percutaneous Image-guided Core-Needle Breast Biopsy

All biopsies included in this study were performed by using either US or stereotactic mammography. Magnetic resonance-guided breast biopsies were excluded because of the small number performed and the challenge of concordance. Owing to the nature of the data collection, specific data on biopsy variables (eg, needle size, number of samples, clip placement, and postbiopsy imaging) were not available.

### Histologic Classification of Lesions

Benign categories included epithelial tumors, mixed connective tissue and epithelial (fibroepithelial) neoplasms, mesenchymal tumors, mammary dysplasia or fibrocystic changes, and tumorlike lesions. All other lesions were considered high risk or cancerous. High-risk lesions, including lobular carcinoma in situ or lesions with atypia (atypical lobular hyperplasia, atypical ductal hyperplasia, papilloma with atypia, and flat epithelial atypia), were excluded because these lesions are handled differently than purely benign findings.

### Participants

From 1994 to 2010, data were collected from 142,514 benign core breast biopsies that had been performed with US or stereotactic guidance with known laterality. Biopsies were

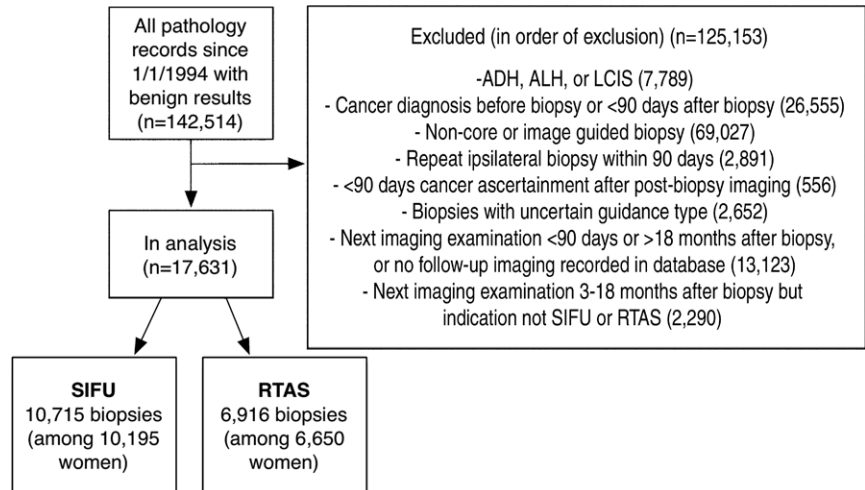


Diagram shows the patient selection workflow. The algorithm used to select appropriate cases for the analysis is outlined. The number of biopsies at each step appears in parentheses. The number of women in the final group for analysis is also shown. *ADH* = atypical ductal hyperplasia, *ALH* = atypical lobular hyperplasia, *LCIS* = lobular carcinoma in situ.

excluded if the result indicated a high-risk lesion.

### Determination of Radiologic-Pathologic Concordance

To determine the radiologic-pathologic concordance, we applied the following algorithm: Biopsies followed by a repeat ipsilateral biopsy (of any type) within 90 days or before a follow-up imaging study (if any) were excluded, owing to the likelihood of representing a discordant radiologic-pathologic result (Figure). We examined biopsies that resulted from both screening and diagnostic evaluations. The first breast imaging examination (mammography or US) after each selected biopsy was identified. These postbiopsy images were classified as SIFU (obtained 3–8 months after biopsy, with an indication of SIFU or routine screening) or RTAS (obtained 9–18 months after biopsy, with an indication of SIFU or routine screening). We excluded biopsies for which the first subsequent imaging examination occurred less than 3 months or more than 18 months after biopsy or if there was no imaging after biopsy. We then determined whether breast cancer (invasive or ductal carcinoma in

situ) was diagnosed in the same breast within 3 months after postbiopsy SIFU and RTAS imaging. At least 3 months of follow-up after postbiopsy imaging was required for adequate cancer ascertainment. Three months was chosen because approximately 97% of patients return for additional imaging, biopsy, or surgical consultation within 90 days, on the basis of a large BCSC multicenter retrospective analysis (17).

### Data Analysis

We enumerated the cases of incident ipsilateral breast cancer diagnosed within 90 days in the SIFU and RTAS groups and estimated the rate and 95% confidence interval (CI) per 1000 postbiopsy imaging examinations. We described the frequency and percentage of invasive cancers among all cases and of node-positive, late stage (defined as stages 2B, 3, or 4), and large tumors ( $\geq 20$  mm) among invasive cancers. We estimated 95% CIs by using the exact method for a binomial distribution. Differences were tested by using the Fisher exact test. All statistical tests were two sided. Analyses were performed by using Stata software, release 12 (StataCorp, College Station, Tex).

**Results**

We identified 33044 eligible biopsies with benign findings among 30604 women with a mean age of 52 years. The SIFU ( $n = 10715$ ) and RTAS ( $n = 6916$ ) groups had no clinically meaningful differences in the distributions of age, race or ethnicity, body mass index, menopausal status, current hormone therapy use, family history of breast cancer, breast density, or indication for prebiopsy imaging (Table 1). The remaining 15413 biopsies were excluded because they were followed by an imaging examination less than 3 months ( $n = 934$ ) or more than 18 months ( $n = 3368$ ) after biopsy, had no follow-up imaging recorded in the BCSC database ( $n = 8821$ ), or showed an imaging examination 3–18 months after biopsy but the indication was not SIFU or RTAS ( $n = 2290$ ).

Twenty-seven ipsilateral breast cancers were diagnosed within 3 months after 10715 SIFU imaging examinations, for a rate of 2.5 cancers per 1000 examinations (95% CI: 1.7, 3.7 per 1000 examinations) compared with 16 cancers within 3 months after 6916 RTAS imaging examinations, for a rate of 2.3 cancers per 1000 examinations (95% CI: 1.3, 3.8 per 1000 examinations) ( $P = .88$ ) (Table 2, Table E1 [online]).

Among the breast cancers detected after SIFU, 59% (16 of 27 cancers; 95% CI: 39%, 78%) were invasive (rate, 1.5 cancers in 1000 examinations; 95% CI: 0.9, 2.4) compared with 75% (12 of 16 cancers; 95% CI: 48%, 93%) after RTAS (rate, 1.7 cancers in 1000 examinations; 95% CI: 0.9, 3.0). Among invasive cancers, positive lymph nodes were found in seven (44% of 16 cancers with node data; 95% CI: 20%, 70%) in the SIFU group and three (25% of 12 cancers; 95% CI: 5%, 57%) in the RTAS group. Late-stage cancer was diagnosed in four cancers in the SIFU group (25% of 16 invasive cancers with stage data; 95% CI: 7%, 52%) and three cancers in the RTAS group (27% of 11 cancers; 95% CI: 6%, 61%). Large tumors were diagnosed in four cancers in the SIFU group (25% of 16 invasive cancers

**Table 1**

**Patient Characteristics at the Time of Postbiopsy Breast Imaging according to Follow-up Interval for Women with Benign Concordant Biopsy Findings**

Characteristic	SIFU ( $n = 10715$ )	RTAS ( $n = 6916$ )	P Value*
<b>Age (y)</b>			.001
<40	633 (5.9)	317 (4.6)	
40–49	3651 (34.1)	2276 (32.9)	
50–59	3401 (31.7)	2252 (32.6)	
60–69	1800 (16.8)	1233 (17.8)	
70–79	983 (9.2)	665 (9.6)	
≥80	247 (2.3)	173 (2.5)	
<b>Race or ethnicity</b>			.004
White, non-Hispanic	9075 (90.0)	5862 (89.1)	
Black, non-Hispanic	259 (2.6)	224 (3.4)	
Asian or Pacific islander	163 (1.6)	119 (1.8)	
Hispanic	348 (3.5)	194 (2.9)	
Other or mixed	241 (2.4)	178 (2.7)	
Missing (%)	5.9	4.9	
<b>Body mass index (kg/m<sup>2</sup>)</b>			.70
<25	3438 (43.8)	1889 (43.7)	
25 to <30	2273 (29.0)	1285 (29.7)	
30 to <35	1274 (16.2)	672 (15.5)	
≥35	861 (11.0)	479 (11.1)	
Missing (%)	26.8	37.5	
<b>Premenopausal status</b>			.42
Yes	3105 (33.5)	2096 (32.9)	
No	6159 (66.5)	4275 (67.1)	
Missing (%)	13.5	7.9	
<b>Current use of hormone therapy</b>			.43
Yes	1166 (15.0)	910 (14.5)	
No	6617 (85.0)	5363 (85.5)	
Missing (%)	27.4	9.3	
<b>Family history of breast cancer in a first-degree relative</b>			.007
Yes	1832 (18.2)	1307 (19.9)	
No	8223 (81.8)	5261 (80.1)	
Missing (%)	6.2	5.0	
<b>Mammographic breast density (BI-RADS category)</b>			<.001
Almost entirely fat	489 (5.2)	291 (4.9)	
Scattered fibroglandular densities	3551 (38.1)	2126 (35.8)	
Heterogeneously dense	4516 (48.4)	2873 (48.4)	
Extremely dense	765 (8.2)	647 (10.9)	
Missing (%)	13.0	14.2	
<b>Type of breast imaging</b>			<.001
Mammography	9859 (92.0)	6744 (97.5)	
US	856 (8.0)	172 (2.5)	
<b>Prebiopsy breast imaging conducted for routine screening</b>			<.001
Yes	7422 (76.6)	4790 (79.2)	
No	2261 (23.4)	1257 (20.8)	
Missing (%)	9.6	12.6	

Note.—Numbers in parentheses are percentages. BI-RADS = Breast Imaging Reporting and Data System.  
\* P value was calculated with the  $\chi^2$  test to compare nonmissing values of the characteristic.



Table 2

## Incident Ipsilateral Breast Cancer Cases Diagnosed within 90 Days after Postbiopsy Imaging

Tumor Characteristic	SIFU (10 715 Postbiopsy Imaging Examinations among 10 195 Women)		RTAS (6916 Postbiopsy Imaging Examinations among 6650 Women)		P Value <sup>‡</sup>
	No. of Cancers*	Rate <sup>†</sup> or Percentage	No. of Cancers*	Rate <sup>†</sup> or Percentage	
Total cancers, rate per 1000 postbiopsy imaging examinations	27	2.5 (1.7, 3.7)	16	2.3 (1.3, 3.8)	.88
Total cancers, rate per 1000 women with at least one postbiopsy imaging examination	27	2.6 (1.7, 3.9)	16	2.4 (1.4, 3.9)	.88
Invasive cancers, rate per 1000 postbiopsy imaging examinations	16	1.5 (0.9, 2.4)	12	1.7 (0.9, 3.0)	.70
Invasive cancers, rate per 1000 women with at least one postbiopsy imaging examination	16	1.6 (0.9, 2.5)	12	1.8 (0.9, 3.1)	.70
Invasive cancers, percentage of total number of cancers (%)	16	59 (39%, 78%)	12	75 (48%, 93%)	.34
Percentage of total number of invasive cancers (%)					
Late stage (stage 2B, 3, or 4) (nonmissing)	4 (16) <sup>§</sup>	25 (7%, 52%)	3 (11) <sup>§</sup>	27 (6%, 61%)	>.99
Node positive (nonmissing)	7 (16) <sup>§</sup>	44 (20%, 70%)	3 (12) <sup>§</sup>	25 (5%, 57%)	.43
Large size (≥20 mm) (nonmissing)	4 (16) <sup>§</sup>	25 (7%, 52%)	5 (12) <sup>§</sup>	42 (15%, 72%)	.43

Note.—Numbers in parentheses are 95% confidence intervals, unless indicated otherwise.

\* Data represent the number of cancers and the number of women—that is, each cancer was unique to one woman.

<sup>†</sup> Rate per 1000 postbiopsy imaging examinations.

<sup>‡</sup> P values were calculated with the Fisher exact test, used to compare SIFU and RTAS rates or percentages.

<sup>§</sup> Numbers in parentheses are percentages.

with size data; 95% CI: 7%, 52%) and in five cancers in the RTAS group (42% of 12 cancers; 95% CI: 15%, 72%).

## Discussion

Image-guided percutaneous breast biopsy has been shown to be highly accurate for cancer detection (11,18–20). Stereotactic biopsies have demonstrated a false-negative rate averaging 2.8% (range, 0.3%–8.2%) (5). For US-guided core-needle biopsy, the false-negative rates range from 0% to 1.7% (19). Approximately 20%–33% of image-guided breast biopsy specimens prove to be cancer (21,22). Thus, most biopsy findings are truly benign (10,23). The physician who performs the breast biopsy should perform a radiologic-pathologic concordance check to minimize false-negative biopsy results. The cytopathologic or histopathologic sampling results should be reviewed to determine if the lesion has been adequately biopsied and whether the results are concordant or discordant with the imaging findings. These results should be communicated to the referring physician and/or the patient, as appropriate (24–26).

There are currently no evidence-based national guidelines for the follow-up imaging of patients with benign breast biopsy findings. In addition, there are conflicting recommendations in the literature regarding the follow-up imaging of these patients. Some studies recommend SIFU imaging (2,27–29), while others found no benefit to SIFU imaging (6,30–34). The implied rationale for SIFU is earlier detection of cancers missed during image-guided biopsy, hopefully when the cancers are still at an early stage, thus leading to less delay in treatment and less effect on the treatment needed. In the previous studies, investigators did not specifically evaluate differences in breast cancer detection rates or severity of tumors detected after benign stereotactic or US-guided core breast biopsy when comparing SIFU breast imaging to RTAS. In our study, the rates of cancer detection between SIFU and RTAS after a benign breast biopsy finding were similar and comparable to the rate of cancers expected in a standard screening population. The proportion of invasive cancers with late stage, large size, and positive nodal status were also similar in the two groups. Our results

are supported by a recent retrospective analysis of radiologic-pathologic-concordant benign biopsy findings which showed no benefit in SIFU imaging at 6 months, as demonstrated by similar positive predictive values for detection of malignancy in groups with repeat imaging at 6 and 12 months (14).

SIFU imaging was recommended by the authors of two single-institutional studies specifically designed to evaluate follow-up recommendations for benign breast biopsy findings. Lee et al followed up 298 patients with benign breast biopsy findings and recommended a 6-month follow-up for non-specific pathology findings and annual screening for benign specific pathology findings on the basis of the one cancer detected during SIFU at 6 months compared with one cancer detected at 24-month follow-up (13). In a 2006 study, Shin et al followed up 156 patients and recommended 6-month, 1-year, and 2-year follow-up on the basis of the one cancer detected at 6 months and two cancers detected between 12 and 24 months (2). The low number of cancers diagnosed in these studies makes it difficult to detect differences in cancer detection rates or

distributions of stage, tumor size, or nodal status between the follow-up intervals.

The large and diverse BCSC population allowed us to compare the cancer detection rates and the distributions of stage, tumor size, and nodal status between the SIFU group at 6 months (3–8-month range) and the RTAS group at 12 months (9–18-month range). We found that the rate of cancers detected per 1000 SIFU examinations (2.5 cancers per 1000 examinations) was similar to and not statistically different than 2.3 cancers detected per 1000 RTAS examinations. It is also important to note that there were no statistically significant differences between invasive cancer rates or distributions of stage, tumor size, or nodal status of invasive cancers detected in the SIFU group compared with the RTAS group. The presence of cancers in the SIFU imaging population may not justify the recommendations of SIFU imaging if there is no improvement in cancer stage, size, or nodal status.

The main strength of our study is the large sample of both patients and radiologists that is representative of diverse community-based radiology practices in the United States. To our knowledge, this is the first multi-institutional study designed to assess differences in cancer detection rates and tumor characteristics between SIFU and RTAS after a benign concordant breast biopsy finding.

The major limitation of this study was the inability to determine the spatial relationship between the finding that prompted the initial biopsy and the site of the subsequent diagnosis of cancer. If the site of subsequent breast cancer development and prior biopsy coincide, this indicates that the biopsy finding was a false-negative result and, thus, the SIFU would serve to identify false-negative biopsy findings at an earlier time. If the cancer occurs in the ipsilateral breast at a site distinct from the biopsy site, then the biopsy finding would be considered a true-negative result and may indicate that the breast has a potentially increased biological risk of cancer formation, as described

in published epidemiologic data (35–38). In this scenario, the SIFU would provide earlier diagnosis for women that could be described as higher risk. Regardless of which paradigm is being used to justify SIFU, our population-based study of breast cancer screening in this group of patients, similar to prior research, failed to show benefits in either differential rates of cancer detection or improved cancer characteristics in the SIFU group.

An additional limitation of this study was the modest number of cancers detected at postbiopsy imaging, which limits the statistical power to detect differences in cancer stage, size, or nodal status and precludes analysis of differences in outcome characteristics between subgroups of women (eg, by age, race, hormone therapy use, and breast density). Another potential limitation of our methods was the lack of details relating to biopsy guidance type (needle size and US vs stereotactic guidance). These biopsy methods are not only different in terms of techniques, but the mammographic findings and histologic entities can differ greatly. It is possible that trends in outcomes after these different types of biopsies are different, and a pooled analysis may null these effects.

In summary, we found no evidence of a benefit to performing routine SIFU for benign concordant radiologic-pathologic biopsy results. Our study suggests that patients may return to annual screening after receiving a concordant benign breast biopsy finding without risk of developing later-stage cancer. This practice may reduce unnecessary healthcare use and cost and minimize mental duress for the patient.

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