Two years follow-up after a concordant benign breast biopsy result. How are we doing?

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Authors: V. Rueda Narvaez¹, J. M. Moreno Salcedo¹, N. Lopez-Galiacho Heras², F. Caceres Cwiek¹, B. Rodriguez Martin¹, F. J. Polo Romero¹; ¹Hellin, CM/ES; ²Albacete, CM/ES
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Purpose

Core-needle biopsy (CNB) is a less expensive, equally accurate alternative to excisional biopsy. Key to the diagnostic success of the core-needle approach is routine consensus evaluation of radiologic-pathologic concordance.

The major limitation of CNB is sampling error. Any CNB procedure may fail to sample cancer, resulting in a benign pathologic diagnosis, despite optimization of technique. To detect such missed cancers at CNB, pathologic results must be correlated with de imaging findings. Regarding concordant benign lesion which is initially thought to be benign radiologically (BI-RADS category 3 or 4A) and also demonstrate benign pathology at CNB, imaging follow-up is recommended to confirm stability and avoid any delay in diagnosis of a possible false-negative.

Nowadays, no standard follow-up guideline for concordant benign lesion has been established, especially the time when the follow-up imaging should begin. Recently, Salkowski et al. have reported that a 6-month follow-up imaging for benign concordant image-guided CNB results did not aid detection of breast cancers of influence recommended rebiopsy rates, suggesting that yearly follow-up might be more appropriate.

The purpose of this study was to evaluate the evolution of the patients who underwent a CNB with benign or nonspecific histologic findings.
Methods and Materials

The prospective study was conducted with institutional review board approval and a waiver of patient informed consent.

Inclusion criteria

From March 2007 through October 2011, consecutive US-guided 14-gauge core needle biopsies of breast masses diagnosed of BI-RADS category 3 and 4A performed at our institution were collected. Among these lesions, breast masses that had benign concordant pathologic results and underwent a two years follow-up were included in this study. Histologic results of malignancy and atypia were excluded.

Biopsy technique

At our institution, US-guided 14-gauge CNB is initially performed for sonographically visible breast masses that were prospectively assigned to the BI-RADS category 4 or 5. Patients with BI-RADS category 3 masses underwent US-guided 14-gauge CNB depending on radiologist criteria or patient's request.

Biopsies were performed by one of 3 radiologists with fellowship training (n=2) or clinical experience (n=1), each of whom had more than 10 years of experience in breast imaging and biopsy with US guidance.

Imaging-pathology correlation and postbiopsy management

The imaging and pathologic finding were considered to be concordant when the pathologic finding provided an acceptable explanation for the imaging features and discordant when did not.

For concordance benign lesions, US follow-up at 6 months after biopsy and annually thereafter for at 2 years was recommended, but follow-up time decision was finally taken depending on radiologist criteria. During the follow-up period for concordant benign lesion, the development of suspicious clinical finding or progression at follow-up US (i.e., increase in size or developing suspicious imaging features) leaded to the patient being subjected to a surgical excision or a rebiopsy depending on the physician's or patient's preference.

Statistical analysis

Main data collected were: age at the time of the biopsy, pathologic result, number of US imaging examination, follow-up interval, need of further surgery or rebiopsy, as well as the concordance between the obtained results and prior biopsy.
For statistical analysis, the results were divided into 3 categories (1\textsuperscript{st} follow-up, 2\textsuperscript{nd} follow-up and > 2 follow-ups). The follow-up intervals were categorized into 6 months (# 11 months), 12 months (> 11 months). These cut-off values were determined discretionally form our data.

Progression at follow-up were performed by using a Kaplan-Meier survival function, and represented by using a time-series graph.

Data were analysed by using statistical software STATA\textsuperscript{©} version 11.2 for Mac OS X\textsuperscript{©} 10.7.2
Results

A total of 129 patients were included, all of whom were women with an mean age of 44.3 years 95% confidence interval (CI), [42.1 - 46.5], and ranged form 16 - 79 years. Pathology of concordant benign lesion is represented in Fig. 1.

The total number of US follow-ups was 217 with a mean of 1.7 follow-ups per patient 95% CI, [1.5 - 1.9]. The mean time-interval and range between CNB and follow-ups is summarized is table 1.

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>mean</th>
<th>95% CI</th>
<th>range</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st follow-up</td>
<td>110</td>
<td>11,6</td>
<td>10,15 - 13</td>
<td>0 - 35</td>
</tr>
<tr>
<td>2nd follow-up</td>
<td>76</td>
<td>10,6</td>
<td>9,5 - 11,7</td>
<td>3 - 27</td>
</tr>
<tr>
<td>&gt; 2 follow ups</td>
<td>31</td>
<td>8,2</td>
<td>6,8 - 9,8</td>
<td>1 - 15</td>
</tr>
</tbody>
</table>

Patients completed a minimum follow-up time of 24 months ranged from 24 to 42 months. Follow-ups are detailed in Fig. 2.

During follow-up, 15 (11.6%) imaging changes were observed. Surgery was carried out in 11 cases (73.3%) and rebiopsy in 4 (26.7%) with a 100% of pathological concordance. No malignant lesions were found in any cases.

Imaging changes were found with an average elapsed time since the original biopsy of 1.6 years 95% CI, [1.1 - 2.2]. Fig. 3 shows in a time-series graph, how patients' US imaging change occur during de follow-up.

At our institution, the actual cost of a breast US follow-up is detailed in table 2.

<table>
<thead>
<tr>
<th></th>
<th>Nº</th>
<th>18 per day</th>
<th>cost per US</th>
<th>US number:</th>
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<td>DAILY ACTIVITY</td>
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<tr>
<td>RADILOG COST</td>
<td>315,74</td>
<td>315,74</td>
<td>17,54</td>
<td>2.017,20</td>
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<tr>
<td>TECNICIAN COST</td>
<td>146,06</td>
<td>146,06</td>
<td>8,11</td>
<td>933,16</td>
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<tr>
<td>CAP II COST</td>
<td>5,27</td>
<td>94,86</td>
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<td>REPERCUSSION COST</td>
<td>4.29</td>
<td>77.22</td>
<td>4.29</td>
<td>493.35</td>
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<tr>
<td>-------------------</td>
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<td>--------</td>
</tr>
<tr>
<td>TOTAL COST</td>
<td>633.88</td>
<td>35.22</td>
<td>4.049.77</td>
<td></td>
</tr>
</tbody>
</table>

The total number of imaging examinations carried out less than a 12-month interval follow-up was 115 (53%). Therefore, a prior 12-month follow-up involves an additional cost estimated in our institution at 4049.77 €.
Fig. 1: Pathological results.

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**Fig. 2:** Follow-up’s distribution Blue: 6-months. Green: 12-months

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Fig. 3: Kaplan-Meier survivor function. Time-serie which shows changes in imaging follow-up

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Conclusion

Imaging changes were found only in 15 patients. Vast majority of these changes appeared after a 12-month interval follow-up with a 100 % histological concordance after surgery or rebiopsy. Therefore, a prior 12-month follow-up might be unnecessary and would involve an additional cost estimated in our patients at 4049.77€.
References


