Cost Minimization Analysis of Ultrasound-Guided Diagnostic Evaluation of Probably Benign Breast Lesions

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Abstract: The objective of this study was to compare direct health care costs for two competing diagnostic strategies for probably benign breast lesions detected by ultrasound in young women. We developed a decision analytic model and performed a cost minimization analysis comparing ultrasound-guided vacuum-assisted core biopsy and conservative short-term diagnostic ultrasound follow-up. Relative probabilities for diagnostic outcomes were derived from pooled analysis of the medical literature. Direct health care costs were estimated using United States national average figures from calendar year 2010. Deterministic sensitivity analyses were conducted, as well as a first-order Monte Carlo simulation to confirm cost differences between the two strategies. The conservative short-term imaging follow-up strategy ($639.55 average cost per patient) was the most economical strategy compared to immediate vacuum-assisted core biopsy ($879.55 average cost per patient). Sensitivity analyses demonstrated that the preferred strategy is most dependent on the probabilities of detecting change in appearance on follow-up ultrasound, having a benign finding on immediate core biopsy, and finding cancer on a biopsy triggered by an interval change in ultrasound appearance. The model was also sensitive to the costs of vacuum-assisted core biopsy and diagnostic ultrasound. Conservative imaging follow-up of BIRADS 3 breast masses by ultrasound is cost saving compared to immediate vacuum-assisted core biopsy, with a potential of saving more than one-third of overall costs associated with the diagnostic work-up of such lesions. Watchful waiting with short-term interval follow-up ultrasounds will spare women from unnecessary procedures and spare the United States health care system from unnecessary direct health care costs.

Key Words: BIRADS 3, breast ultrasound, cost minimization analysis, probably benign breast mass, ultrasound-guided breast biopsy

There is much debate regarding the best approach for the diagnostic imaging work-up of (BIRADS 3) probably benign breast lesions evaluated by ultrasound (US) (1). Although some radiologists are comfortable recommending short-term interval follow-up imaging to demonstrate stability over time, others are more aggressive and recommend immediate US-guided tissue biopsy to obtain a definitive diagnosis (2,3). The former entails no adverse risks associated with the biopsy procedure, but may contribute to patient anxiety associated with waiting for follow-up imaging results at 6, 12, and 24 months. The latter not only entails the physical and emotional risks associated with undergoing a minimally invasive procedure but also is associated with a high likelihood of rapid, reliable tissue diagnosis with no further follow-up imaging necessary.

Recent advances in image-guided biopsy technology have brought renewed interest to this continuing conundrum. Specifically, vacuum-assisted image-guided biopsy devices now allow for improved tissue sampling, vastly reducing and possibly eliminating the risk of false negatives from inadequate tissue sampling (4). These devices have gained favor in most imaging centers in lieu of the traditional, more operator-dependent core biopsy needles. In fact, as the technology
becomes more user-friendly, its use continues to expand to include the outpatient office setting of many breast surgeons (5). Given the increased ease of use and diagnostic yield of vacuum-assisted ultrasound-guided breast biopsy, physicians that were previously tentative about recommending biopsy for probably benign lesions are becoming more confident in suggesting immediate biopsy (6).

For premenopausal women with dense breasts, focused breast US remains the primary modality for the evaluation of new palpable findings (7,8). The most common solid tumor in young women is a fibroadenoma with sonographic features of circumscribed borders, round/oval shape, three or fewer gentle lobulations, and homogeneous echotexture (9). Such benign entities have no risk of malignancy and reassuring the patient of their benign nature is the standard of treatment (10).

For many presumed benign breast masses, however, the BIRADS descriptors of benignity are not all present upon initial US evaluation. These lesions that cannot be characterized as definitely benign (BIRADS 2 category) are instead described as “probably benign” and require further diagnostic evaluation (BIRADS 3 category) (11–13). Furthermore, about 2% of breast lesions initially categorized as probably benign are eventually diagnosed as malignant lesions, frustrating both patients and physicians (14). With the purported higher diagnostic yield of vacuum-assisted core biopsy devices, there is increasing adoption of this technology. However, with increasing use are increasing concerns that the breast imaging community may be performing too many unnecessary biopsy procedures in lieu of conservative imaging follow-up.

The specific aim of this cost minimization study is to develop a decision analysis model for comparing the direct health care costs associated with these two alternative imaging-based diagnostic strategies for the US-detected BIRADS 3 category breast mass. Currently, there is no formal cost comparison for the US-based diagnostic management of probably benign breast lesions in a premenopausal population. Specifically, it would be of great interest to the breast care community and to health systems and organizations to quantify the direct health care cost differential between these two competing ultrasound-based diagnostic strategies. This analysis is of increasing importance in an era of health care reform and a movement toward minimizing unnecessary, costly medical procedures. Our study works under the premise that the difference in direct costs (or savings) between the two strategies is equivalent to the value of one diagnostic protocol over the other. We hypothesize that choosing conservative short-term interval follow-up has a substantial direct health care cost savings over immediate US-guided vacuum-assisted core biopsy and, thus, currently represents the diagnostic strategy of greatest value for society.

MATERIALS AND METHODS

We used standard decision analysis software (Tree Age Pro; TreeAge Software, Williamstown, MA) to construct and analyze our model. Decision analysis uses information available from the medical literature to produce a model of possible outcomes associated with a particular condition to help determine the most economically advantageous strategy between competing alternatives. A cost minimization analysis assumes that these competing alternatives have equivalent outcomes, allowing direct comparison of the two in terms of direct health care dollars spent.

Reference Case

The model assumes that a 30-year-old female with no past medical history or risk factors for breast cancer has been found to have a new breast lesion during her initial diagnostic imaging work-up. This “probably benign” breast mass, categorized as BIRADS 3, is best seen by ultrasound (the modality of choice in this age group).

Alternative Strategies

We compare two widely accepted diagnostic strategies for management of ultrasound-detected BIRADS 3 lesions. First, the patient may choose to undergo immediate vacuum-assisted US-guided percutaneous biopsy to obtain a definitive histologic diagnosis. Second, the patient can undergo watchful waiting with short-term interval follow-up diagnostic ultrasounds at 6, 12, and 24 months. If the mass shows no sonographic change at 24 months, the mass is considered benign and no further imaging is necessary. If there is interval change during any follow-up imaging study, then the patient undergoes a vacuum-assisted US-guided breast biopsy for definitive histologic diagnosis.
Perspective and Time Horizon

This analysis is from the societal perspective in regard to the direct health care expenditures associated with two competing diagnostic strategies. We consider direct health care costs associated with the diagnostic evaluation of our reference case either until histologic diagnosis by vacuum-assisted US-guided core biopsy or a total of 24 months of diagnostic US follow-up imaging (equated with benign histologic diagnosis). All costs after tissue diagnosis are considered to be treatment-related and, therefore, irrelevant to our cost minimization analysis for the diagnostic work-up of BIRADS 3 breast lesions.

Effectiveness Measure

Patient anxiety and quality of life for the two alternatives will be assumed equal, allowing for comparison of health care dollars associated with direct costs. Intuitively, the anxiety and suffering associated with the first scenario (an immediate biopsy procedure, a possible second surgical excision if atypia is found, and awaiting definitive histology results) is likely similar to the anxiety experienced by patients who endure 2 years worth imaging follow-up without any invasive procedures. Furthermore, the levels of anxiety associated with these scenarios have not been examined or quantified in the medical literature, which would allow for an alternative outcome measure and a cost-utility analysis. Therefore, our endpoint measure for this cost minimization analysis is limited to direct health care costs rather than a cost-utility measure such as quality-adjusted life years (QALYs).

Decision Branches

A schematic of the decision tree is provided in Fig. 1. The decision node for our base case is represented by the two options for US-based diagnostic evaluation of a probably benign mass: immediate vacuum-assisted US-guided core biopsy or 6-month short-term interval diagnostic ultrasound.

If an immediate biopsy is chosen, possible histology findings are placed into one of three categories: carcinoma, atypia, or benign. The carcinoma category includes ductal carcinoma, lobular carcinoma, and ductal carcinoma in situ (DCIS). If carcinoma is found by biopsy, the diagnostic evaluation is complete. If atypia is found, such as atypical ductal hyperplasia or lobular carcinoma in situ, these findings are considered to be reliable criteria to prompt US-guided needle localization with surgical excisional biopsy, after which the histologic diagnosis is complete (15). If a benign histology is found, such as fibroadenoma, then the diagnostic evaluation is also considered complete.

In contrast, if the decision is made to follow a BIRADS 3 lesion by short-term interval follow-up imaging, any interval change at 6, 12, or 24 months prompts a vacuum-assisted US-guided core biopsy and the decision defaults into the branch described above. If the lesion remains stable on diagnostic ultrasound for 24 months, then the diagnostic evaluation is complete and equated with benign histologic findings.

Assumptions

In addition to the assumptions aforementioned, others that help simplify our model are listed here. The following assumptions are biased toward the null hypothesis to further strengthen any significant study findings. In other words, assumptions were made to create the best case scenario for the ultrasound-guided vacuum-assisted core need biopsy strategy.

1. All diagnostic ultrasounds and vacuum-assisted US-guided core biopsies are performed and interpreted by experienced breast radiologists.
2. Diagnostic ultrasound, although operator-dependent, has been shown to have up to 100% sensitivity.
in identifying palpable breast lesions and up to a 100% negative predictive value in experienced hands (16,17). Therefore, the best case scenario of 100% sensitivity and negative predictive value are assumed here.

3. The diagnostic yield with US-guided vacuum-assisted core biopsies has been shown to approach 100% (e.g., there are no inadequate tissue samples) (16). Therefore, the best case scenario of no false negative biopsy results is assumed here.

4. There are no false positive biopsy results (e.g., cancer detected when there is none in reality).

5. Patients undergoing vacuum-assisted core biopsy or surgical excisional biopsy do not experience any costly adverse events. Infection, for instance, occurs in less than 1% of cases, and generally responds to antibiotics. The most common adverse event, a hematoma, is normally treated conservatively without intervention (18).

6. Once a patient begins short-term interval follow-up ultrasounds, she is not switched to the vacuum-assisted core biopsy decision branch due to patient or physician preference. In other words, a significant change in ultrasound appearance is required to proceed to biopsy.

7. If a breast lesion shows any interval change (suspicious characteristics) on follow-up ultrasound and therefore the patient undergoes vacuum-assisted biopsy, these breast lesions have the same probability of malignant, atypical, or benign histology at any interval follow-up stage (6, 12, or 24 months) (19). These values, however, are different from those of patients undergoing immediate US-guided vacuum-assisted core biopsy (no suspicious characteristics) instead of proceeding down the short-term interval follow-up imaging decision branch.

8. Finally, any costs, morbidity, and mortality of subsequent therapeutic or palliative measures are considered treatment-related and therefore beyond the scope of our diagnostic work-up evaluation.

Model Parameters

The performance characteristics for each diagnostic procedure for the reference-case analysis were derived from the medical literature. Peer-reviewed studies and meta-analyses published from 2000 through 2010 were considered for inclusion. For several values, weighted averages were calculated based on the available literature. The costs of specific medical procedures were obtained from assigned Current Procedural Terminology (CPT) codes from calendar year 2010, the relative value scale, and the national conversion.

### Table 1. Baseline Values for Performance Characteristics

| Parameter | Baseline probability (Range) (%) | References |
|-----------|---------------------------------|------------|
| Probability of carcinoma on immediate vacuum-assisted US-guided core biopsy | 2 (2–4) | (19,22,23) |
| Probability of benign histology on immediate vacuum-assisted US-guided core biopsy | 92 (87–98) | (16,19,23,24) |
| Probability of atypia on immediate vacuum-assisted US-guided core biopsy | 6 (0–13) | (16,22,23,24) |
| Probability of carcinoma on US-guided core biopsy due to interval change | 6 (4–10) | (19,24) |
| Probability of benign histology on US-guided core biopsy due to interval change | 91 (83–96) | (19,24) |
| Probability of atypia on US-guided core biopsy due to interval change | 3 (0–7) | (19,24) |
| Probability of no change in appearance on 6-, 12-, or 24-month follow-up US | 80 (79–97) | (16,19,25) |
| Probability of interval change in appearance on 6-, 12-, or 24-month follow-up US | 20 (3–21) | (16,19,25) |

### Table 2. Medicare-Based Reimbursement Rates

| Procedure(s) | CPT Code(s) | Total Cost |
|--------------|-------------|------------|
| US-guided vacuum-assisted core biopsy + biopsy + placement of marker + pathology evaluation | •19103: Biopsy of breast; percutaneous, automated vacuum-assisted or rotating biopsy device, using imaging guidance  
•19295: Image-guided placement, metallic localization clip, percutaneous, during breast biopsy/aspiration  
•88307: Level V—Surgical pathology, gross, and microscopic examination | $827.36 |
| Single grayscale and color Doppler diagnostic breast US | •76645: Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation | $91.44 |
| Surgical excision = US-guided needle localization + surgical biopsy procedure + pathology evaluation | •19290: Preoperative placement of needle localization wire, breast  
•19125: Excision of breast lesion identified by preoperative placement of radiologic marker, open; single lesion  
•88307: Level V—Surgical pathology, gross, and microscopic examination | $866.44 |
factor ($36.87) obtained from the American Medical Association for calendar year 2010 (20). Note that costs for both the vacuum-assisted US-guided core biopsy and the surgical excisional biopsy include placement of a metallic clip (standard practice after breast biopsy) and pathology evaluation of the biopsy specimen. The cost of surgical excision includes needle localization under US-guidance prior to the procedure (standard of practice for surgical excision). Our final reference-case model parameters are outlined in Tables 1 and 2.

Sensitivity Analysis

As we could not rely solely on the probabilities found in the available literature, we performed sensitivity analyses to determine whether changing the probability of an event caused a change in the favored decision strategy. One-way sensitivity analyses were performed for all the model parameters. Individual variables were deemed sensitive when changing it led to the alternative strategy becoming less costly. We varied all probabilities using the full range of possible values (0–100%) and a range of costs from zero to at least twice the current national average price for all procedures to account for potential variation among different populations. Parameters that affected the preference for one strategy over another were combined in two-way sensitivity analyses.

We also performed a Monte Carlo analysis, which is a form of multiway analysis. Specifically, we performed 1,000 first-order Monte Carlo simulation trials where each trial randomly selects a single path through the decision tree, following a single branch at each chance node, with higher probability events being more likely. As all individual trials are run through the decision tree, an overall average outcome is calculated that should approach the regular expected value. Monte Carlo analysis results are reported as an expected mean value, standard deviation (SD), minimum value, and maximum value.

RESULTS

Reference-Case Analysis

For our reference-case patient, the conservative short-term imaging follow-up strategy was the most economical strategy compared to immediate US-guided vacuum-assisted core biopsy. Patients undergoing short-term interval US follow-up had average associated direct health care costs of $639.55. In comparison, patients undergoing an immediate US-guided vacuum-assisted core biopsy had average associated direct health care costs of $879.35.

Sensitivity Analysis

One-way sensitivity analyses demonstrated that the model was sensitive to the probability of benignity on immediate US-guided vacuum-assisted core biopsy (Fig. 2), probability of cancer on biopsy triggered by interval US change (Fig. 3), and probability of change on follow-up US (Fig. 4). The model was also sensitive to the cost of US-guided vacuum-assisted core biopsy (Fig. 5) and the cost of diagnostic breast US (Fig. 6).

Specifically, conservative short-term interval follow-up imaging remained the least costly strategy as long as the probability of benign finding on immediate core biopsy stayed above 60%, the probability of cancer on biopsy triggered by an interval change in US appearance stayed below 60%, and the probability of change detected on short-term interval follow-up US stayed below 30%. The short-term interval follow-up strategy remained the strategy of choice if the cost of vacuum-assisted US-guided core needle biopsy stayed above $359.00 and the cost of a single diagnostic breast US stayed below $189.70. Two-way sensitivity analysis results did not yield any additional insights.

The Monte Carlo analysis with 1,000 model simulations yielded a mean cost for immediate US-guided vacuum-assisted core biopsy of $872.41 (SD $192.37) with a minimum value of $827.36 and maximum value of $1,693.80. For conservative interval imaging follow-up, the mean cost was $643.02 (SD $398.30) with a minimum value of $274.32 and a maximum value of $1,968.12.

DISCUSSION

Conclusion

Under current parameters, conservative imaging follow-up of BIRADS 3 breast masses is cost saving compared to immediate vacuum-assisted US-guided core biopsy by about 37.5% using our patient model. Serial imaging follow-up remains the cost-minimizing strategy as long as, all else held equal, the national average cost of vacuum-assisted US-guided core biopsy exceeds $359.00 and the national average cost of a
diagnostic ultrasound remains less than $189.70. However, diagnostic ultrasound is unlikely to increase from its current national average cost of $91.44, and the cost of vacuum-assisted biopsy devices may decrease as the technology becomes more widely used, but likely not to the threshold value of $359.00.
While our model is sensitive to the probability of benignity on immediate US-guided vacuum-assisted biopsy, probability of cancer on US-guided biopsy triggered by a change on interval US, and probability of change found on interval follow-up US, these threshold values are unlikely to be met in practice. On the basis of the available literature, we are confident that probability of benignity on immediate biopsy of a BIRADS 3 lesion will remain above 60% (92% current weighted average). Likewise, the threshold probability of cancer on biopsy triggered by interval change of 60% appears much too high to ever be encountered (6% current weighted average). However, the threshold probability of finding change on interval follow-up US of 30% is possible given the current best estimate of 20%. Additional larger scale observational studies should be conducted to increase the power associated with the event probability of detecting interval changes of BIRADS 3 lesions used in our decision model.

**Limitations**

For purposes of our analysis, we assume equal anxiety and patient quality of life for both decision branches. In reality, the amount of anxiety experienced by women for the two strategies may be significantly different. Moreover, individual women may feel more anxious about undergoing one of the decision branches over the other. Nevertheless, patient anxiety about diagnostic evaluations remains difficult to quantify and are beyond the scope of our cost minimization study.

Other limitations include the fact that there are currently only a handful of studies that describe the probabilities for management of BIRADS 3 category “probably benign” breast lesions by ultrasound. Specifically, our sensitivity analysis demonstrates that the probability of detecting interval change on follow-up imaging may significantly influence the decision analysis. We ameliorate this limitation by conducting Monte Carlo simulation trials. However, results from larger multi-institution observational studies would make the results of our analysis more reliable. Our assumptions state that there is 100% yield from vacuum-assisted core biopsies which may not be the case for all institutions, as the technology is user-dependent and yield may be commensurate with experience level of the radiologist. We assume that there are no adverse events from either surgical excision or vacuum-assisted biopsy, but there may be minor adverse events in less than 1% of cases, and their associated costs are not included in our model. Finally, although these are well-documented diagnostic protocols for BIRADS 3 breast lesions, there is some variation nationally in regard to length of interval follow-up and referring physician or patient preferences for earlier biopsy that preclude strict adherence to the conservative follow-up imaging branch of our decision tree.

**Policy Implications**

There are many in the breast imaging community who are concerned that the new vacuum-assisted US-guided core biopsy technologies are being overutilized. The high direct costs associated with this technology may not warrant its immediate use when a “probably benign” solid breast mass is found on diagnostic ultrasound. Instead, many in the breast imaging community are espousing that watchful waiting with short-term interval follow-up ultrasounds will spare women from unnecessary procedures with little change in patient outcome and spare society from unnecessary health care costs.

Our study is the first to quantify the cost saving between the two diagnostic strategies and clearly shows that conservative short-term imaging follow-up of BIRADS 3 lesions costs society significantly less in
terms of direct health care dollars. This is assuming that there are no additional lives saved by one or the other diagnostic protocols, and that the level of anxiety (patient quality of life) is not significantly different between the two decision branches.

**Future Research**

There is a current paucity of observational data for the diagnostic evaluation and follow-up results for BIRADS 3 breast lesions discovered using ultrasound in premenopausal women. Data from large registries would be helpful for future analysis of the effectiveness of vacuum-assisted US-guided core needle biopsy versus alternative diagnostic strategies. The Athena Breast Health Network is one such research consortium that plans to enroll 150,000 women in California for a longitudinal observational study in breast cancer screening, diagnosis, and treatment (21). Results from studies such as Athena may help breast cancer experts determine the most cost-effective measures for the diagnostic evaluation of BIRADS 3 breast masses.

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