

Frequency of Discordant Lesions and False-negative Cancers at Stereotactic Vacuum-assisted Biopsy

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Abbreviations

SVAB

stereotactic vacuum-assisted biopsy

BI-RADS

Breast Imaging Reporting and Data System

9G

9-Gauge

11G

11-Gauge

Rationale and Objectives: This study aimed to determine frequency of discordant lesions and discordant false-negative cancers at stereotactic vacuum-assisted biopsy (SVAB).

Materials and Methods: Institutional database was searched for discordant SVAB results between January 1, 2005 and December 31, 2012, in this retrospective institutional review board-approved Health Insurance Portability and Accountability Act-compliant study. Patient age, indication for initial mammogram, breast density, lesion size, Breast Imaging Reporting and Data System categorization, operator experience, biopsy needle gauge, biopsy histology, and final surgical histology of discordant lesions were collected and entered into a Microsoft Excel spreadsheet. Discordant rate and false-negative rates were calculated. Fisher exact test was used to assess prevalence of discordance using 11-Gauge needles versus 9-Gauge needles. Patient age, lesion Breast Imaging Reporting and Data System, operator days of experience, mammographic density, and lesion size were evaluated for association with false-negative discordant lesions using an exact Mann-Whitney *U* test.

Results: A total of 1861 SVABs were performed, 224 (12%) with an 11-Gauge VAB device and 1637 (88%) with a 9G Suros or Eviva device. Majority (1409 of 1861; 76%) of SVABs targeted calcifications. Twenty-three of 1861 (1.2%) discordant lesions were identified in 23 women. Seven of 23 (30%) discordant lesions were found to be cancers after final surgical pathology. Needle gauge was not associated with discordance. Operator experience was not associated with false-negative discordance.

Conclusions: A relatively low discordance rate (1.2%) was observed. However, a high percentage (30%; range in literature 11.7%–53.8%) of our discordant lesions were false negatives. This study emphasizes the need for careful radiological-pathologic review after SVAB and for repeat biopsy or surgical excision in the setting of discordance.

Key Words: Stereotactic vacuum-assisted biopsy; discordance; mammography; false negatives.

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INTRODUCTION

The majority of the literature reviewing stereotactic vacuum-assisted biopsy (SVAB) and addressing discordance arises from the late 1990s and early 2000s when SVAB was an emerging technology. Early studies served to validate the efficacy of SVAB and demonstrated that SVAB was statistically less likely to lead to radiological-pathologic

discordance and undersampling compared to stereotactic core biopsy (1–4). SVAB has now become a standard tool for tissue sampling of breast lesions, particularly lesions without a sonographic correlate, most frequently calcifications.

Recognition and documentation of discordance by the radiologist after tissue sampling is a key element of SVAB and is mandated by the American College of Radiology (5). Discordance suggests a lesion has not been sampled adequately and therefore raises the possibility of a missed cancer.

The purpose of this study is therefore to determine and provide an update on the frequency and characteristics of discordant lesions and false-negative cancers at SVAB in an era where SVAB is a standard percutaneous biopsy tool. We also aim to identify those factors that led to discordance in our study sample.

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MATERIALS AND METHODS

Data Collection

This study was an Institutional Review Board-approved Health Insurance Portability and Accountability Act-compliant retrospective single-institution review. Our institutional database was searched for all records of SVABs performed between January 1, 2005 and December 31, 2012, yielding discordant pathology results. Stereotactic-guided vacuum biopsy pathology results yielding high-risk lesions or atypia were excluded from analysis. Patient age, risk factors for breast cancer, indication for initial mammogram, and mammographic breast density were recorded, as was lesion type, lesion size, and Breast Imaging Reporting and Data System (BI-RADS) categorization. Operator days of experience in breast imaging (ie, number of days the individual radiologist had been practicing breast radiology at the time the biopsy was performed), needle gauge employed in SVAB, initial biopsy histology, and final surgical histology records were collected from institutional database and entered into a Microsoft Excel (Microsoft, 2010, Redmond, Washington) spreadsheet.

Stereotactic Vacuum Biopsy Techniques

SVABs were performed with either a Mammotome 11G needle (Devicor Medical Products, Inc., Cincinnati, OH) between January 2005 and March 2007, a Suros ATEC 9G needle (Hologic, Bedford, MA) from April 2007 to December 2011, or an Eviva 9G needle (Hologic) from January 2012 to December 2012. All biopsies were performed on a Mammotest prone biopsy table (Fischer/Siemens, Norderstedt, Germany). Biopsies were performed by any one of 15 radiologists. Ten to twelve specimens were routinely obtained for each biopsy. In the case of calcifications, specimen radiographs were evaluated by the radiologist performing the procedure as is standard practice at our institution. Non-calcified lesions did not routinely undergo specimen radiography. After biopsy samples were obtained, a postbiopsy marker clip was placed, and evaluation of a postbiopsy mammogram was performed for marker placement to assess for a residual lesion and to evaluate accuracy of targeting by the radiologist who performed the procedure.

Determination of Discordance

Discordance was determined by the radiologist performing the biopsy after review of biopsy pathology and then recorded on the biopsy report as is our institutional practice. Additional retrospective review of biopsy and postbiopsy imaging of all SVAB-discordant cases was performed by a specialist breast radiologist with 14 years of experience to determine lesion type and primary reason for discordance. Discordant cases were categorized according to four lesion types (calcification, mass, asymmetry, or distortion). Cases were also classified according to primary cause of discordance based on the following categories: incorrect needle position,

nondiagnostic biopsy specimen (normal tissue), scant calcifications on specimen radiograph, or biopsy pathology discordant with imaging, nonspecific. All discordant lesions were referred for surgical excision; the final surgical histology report was also reviewed retrospectively by the same breast radiologist to evaluate for false-negative (malignant) discordant cases.

Statistical Analysis

A chi-square goodness-of-fit test was used to assess whether the distribution of BI-RADS scores was uniform for discordant lesions. Fisher exact test was used to assess significant difference in prevalence of discordant cases among 11-Gauge needle versus 9-Gauge needle cases. Fisher exact test was also used to determine if there were significant differences in discordant cases for calcifications versus non-calcifications. Using an exact Mann-Whitney *U* test, we evaluated patient age, lesion BI-RADS, operator days of experience, mammographic density, and lesion size to determine if any features were associated with malignancy on final surgical pathology among discordant lesions.

RESULTS

Stereotactic Vacuum Biopsy Pathology Results

A total of 1861 SVABs were performed over the 7-year study period in 1861 women. Of 1861 biopsies, 224 (12%) were performed with an 11G VAB device and 1637 (88%) were performed with a 9G Suros or Eviva device. The majority (1409 of 1861; 76%) of SVABs targeted calcifications. Overall pathology results for SVAB were as follows: 967 of 1861 (52%) benign lesions; 541 of 1861 (29%) malignant lesions; and 353 of 1861 (19%) high-risk or atypical lesions. Of these biopsies, 23 of 1861 (1.2%) discordant lesions were identified in 23 women (mean age 52 years, range 29–75).

In all cases, the radiologist who performed the SVAB issued an addendum to the stereotactic biopsy report that stated there was a concern for radiological-pathologic discordance. Further management with surgical excision was recommended in 23 of 23 (100%) cases.

Characteristics of Women with Discordant Lesions

Three of 23 (13%) women had recently diagnosed ipsilateral cancers (two in the same quadrant as the discordant lesion); one woman was a BRCA2 gene mutation carrier with a remote personal history of cancer; another woman presented with a palpable lump. The remaining 18 of 23 (78%) women were recalled from routine screening examinations without known risk factors or symptoms. We were not able to identify a patient's menopausal status in our institutional database and therefore used 51 years, the average age of menopause in the United States (6), as a cutoff: 13 of 23 (57%) women were younger than 51 years of age and 10 of 23 (43%) women were older than 51 years of age. Of 23 women with discordant lesions, eight (34.8%) had

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