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Stereotactic core biopsy: Comparison of 11 gauge with 8 gauge vacuum assisted breast biopsy☆

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ABSTRACT

Purpose: The compare the performance and ability to obtain a correct diagnosis on needle biopsy between 11 gauge and 8 gauge vacuum assisted biopsy devices.
Materials and methods: Hospital records of all consecutive stereotactic core biopsies performed over five years were retrospectively reviewed in compliance Health Insurance Portability and Accountability Act (HIPPA) policy and with approval from the hospital institutional review board (IRB). Pathology from core biopsy was compared with surgical pathology and/or imaging follow-up. A histological underestimation was defined if the surgical excision yielded a higher grade on pathology which changed management.
Results: 828 needle core biopsies (47.5%, 393/828 with 11 gauge and 52.5%, 435/828 with 8 gauge) yielded 471 benign, 153 high risk and 204 malignant lesions. 30/193 (15.5%) 11 gauge lesions and 16/185 (8.6%) 8 gauge lesions demonstrated higher grade pathology on surgical excision. The difference in the rates of the number of correct diagnoses on core needle biopsy between 11 gauge (363/393, 92.4%) and 8 gauge (419/435, 96.3%) based on either surgical or clinical/imaging follow up and the difference in the number of discordant benign core biopsies between 11 (17/217, 7.8%) and 8 gauge (4/254, 1.6%) necessitating a surgical biopsy was significant ($P = 0.013$; $P = 0.001$). Although there were more underestimations with the 11 gauge (25/193, 13.0%) than 8 gauge (15/185, 8.1%) needle, this was not significant.
Conclusion: Our study demonstrates improved performance and increased diagnostic ability of 8 gauge needle over 11 gauge in obtaining a correct diagnosis on needle biopsy.

1. Introduction

Stereotactic breast biopsy is a safe and accurate alternative to surgical biopsy for nonpalpable mammographically visible lesions. Initially performed with 14 gauge automated needles it is now increasingly performed with vacuum assisted biopsy (VAB) device. The advantages of vacuum assisted biopsy include improved retrieval of calcifications, ability to obtain contiguous samples with a single probe insertion, lower rebiopsy rates and fewer histological underestimations from atypical ductal hyperplasia (ADH) to ductal carcinoma in situ (DCIS) or DCIS to invasive carcinoma [1–4].

Accurate percutaneous diagnosis of benign breast disease spares unnecessary surgical biopsy and accurate preoperative diagnosis of malignancy can decrease the number of operations needed for removal and treatment of a lesion [1,5,6]. However, histological underestimation has been reported with ADH in 10–27% and DCIS in 5–21% [7–11] of cases. Underestimation in ADH necessitates a surgical excision to exclude the presence of DCIS or invasive cancer. Likewise, underestimation of DCIS, when an invasive component is identified at surgery needs a second surgical procedure to assess axillary lymph nodes.

Numerous clinical investigations of 11 gauge vacuum assisted biopsy have been conducted demonstrating increased accuracy over 14 gauge automated needle biopsy [2,3,12], but there is very little published data comparing 11 gauge to an 8 gauge vacuum assisted biopsy. Two studies have found no difference in accuracy of breast cancer diagnosis between 8 and 11 gauge devices [13,14]. In one of these studies, underestimation of ADH was not assessed [13] and in the other, only benign lesions that did not need excision were analyzed. Similarly no difference between 11 and 9 gauge biopsy devices have been determined [8,9].

The purpose of our study was to compare the performance and ability to obtain a correct diagnosis on needle biopsy between 11 gauge and 8 gauge vacuum assisted biopsy devices.

2. Materials and methods

The study was approved by the hospital institutional review board and was conducted in compliance with the Health Insurance Portability and Accountability Act policy. Waiver for informed

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Table 1
Differences between 11 and 8 gauge needle.

	8 gauge	11 gauge
Compression	32.5 mm	25 mm
Z differential	0	−4
Sampling	4 samples	10–12 samples
Aperture	23 mm	19 mm
Sample weight	300 mg	100 mg

consent was obtained from the institutional review board. All stereotactic core biopsies performed between January 2003 and December 2008 were retrospectively reviewed. The hospital's online medical records were accessed to obtain radiology, pathology, surgical and clinical notes.

2.1. Biopsy technique

In our institution, stereotactic biopsy is preferred over surgical biopsy for tissue diagnosis of a non palpable, sonographically occult and mammographically visible breast lesion (calcifications, mass, architectural distortion). The threshold and criteria to recommend biopsy made at the time of diagnostic mammogram interpreted by fellowship trained radiologist were the same for stereotactic or surgical biopsy. A surgical biopsy instead of a stereotactic biopsy was recommended only if the lesion was felt not to be amenable to stereotactic core biopsy (breast compression was insufficient; the calcifications were too faint or located too superficial or too deep; or if the patient was unable to cooperate with the procedure). Our department policy requires aspirin and other non steroidal anti-inflammatory drugs to be discontinued five days prior to biopsy. Coumadin was withheld for 48–72 h, and plasma INR levels were obtained prior to biopsy. An INR level of 1.5 or less is considered acceptable at our institution for large core vacuum assisted biopsies. This is the cut-off, used for most interventional radiology procedures in our department.

All the biopsies were directly supervised and performed by an experienced staff radiologist, who is either fellowship trained in breast imaging and/or has greater than 10 years experience in breast imaging, and spends at least 50% of his/her time practicing in breast imaging. A dedicated prone stereotactic biopsy table (Lorad, Danbury, CT) and a vacuum assisted biopsy device (Mammotome; Ethicon Endo - surgery) were used. All biopsies performed in 2003 and 2004 were with an 11 gauge device. The 8 gauge was introduced in our institution in mid 2005. Both 11 gauge and 8 gauge were available and used to perform biopsies from August 2005. The choice of needle size was made by the radiologist performing the biopsy. The factors that influenced the choice of needle were (a) the thickness of compressed breast tissue; (b) location of calcifications and (c) individual radiologist choice and comfort level. Due to differences in targeting and needle specifications, an 11 gauge was preferred if the breast compression was less than 32 mm and the calcifications were either too superficial or too deep in the breast (Table 1).

Informed consent for biopsy was obtained and a pre-procedure time out was performed for each patient. The biopsy protocol remained the same throughout our study period. Standard sterile skin preparation was used. 1% Lidocaine for superficial and 1% lidocaine with 1:10,000 epinephrine for deeper anesthesia was used in all patients with the exception of those with a contraindication to epinephrine or allergic reaction to Lidocaine. 1% Pilocaine was used in patients with known allergic reaction to Lidocaine. The lesion was targeted using Cartesian coordinates. Needle position was confirmed with paired stereotactic images before and after firing. Any changes in targeting were made appropriately and reconfirmed by imaging before sampling the lesion. The center of the lesion was targeted in most cases. With calcifications that were greater than 1 cm in distribution, the most suspicious area was targeted for biopsy.

The needle and probe were inserted such that the aperture was placed at the 12 o'clock position. Core biopsy specimens were obtained with complete 360° rotation with the directional instrument. Multiple samples were obtained per manufacturer's guidelines (Table 1), in order to provide at least 1000 mg of total tissue for pathological analysis. A specimen radiograph was obtained regardless of whether the target was calcifications, mass or distortion. The radiologist assessed the specimen radiograph for adequacy of sampling. More samples were obtained if felt necessary by the radiologist. A radio opaque marker clip (Micromark, Mammomark) was placed at the biopsy site. A post biopsy image was obtained with the patient still on the biopsy table to confirm clip placement. A two view mammogram was obtained immediately following the biopsy to confirm accuracy of clip position.

Direct compression was placed at the biopsy site for 5 min by the radiologist. The incision was closed with steri strips. Detailed verbal and written post procedure instructions were provided. A standard two view mammogram was obtained in all patients at the completion of the procedure to assess clip placement (Fig. 1).

All core needle biopsies were placed into 10% neutral buffered formalin immediately after the procedure and submitted to pathology. For lesions with calcifications, the biopsy specimens were separated by the radiologist into those containing the calcifications and those without based on the specimen radiograph. These were sent in formalin in separately labelled containers. For mass lesions, specimens were not separated.

Histopathological evaluation was performed by dedicated breast pathologists. Concordance between imaging and pathology and follow up recommendations were determined by the radiologist. Core biopsy lesions with no surgical or imaging follow up were excluded in the final statistical analysis. Many patients were referred to our institute only for the biopsy and chose to have their mammograms at their primary institute.

3. Pathological analysis

The cores were placed into tissue processing cassettes (1–2 cores per cassette) and underwent standard overnight processing. Five micron sections were cut at two different levels of the paraffin block and stained with hematoxylin and eosin then reviewed by the attending pathologist. Additional levels from the block were examined if the core needle biopsy was performed for calcifications and none were seen in the original levels or if the biopsy was performed for a mass lesion and one was not identified histologically.

3.1. Post biopsy management

The core and excision biopsies were categorized as benign, high risk and malignant lesions. Lesions such as fibroadenoma, usual ductal hyperplasia and sclerosing adenosis which do not need surgical excision were categorized as benign. Concordant benign results were followed mammographically. Follow up ranged from six months up to four years. Core biopsy lesions felt to have discordant pathology were referred for surgical excision.

The high risk lesions include atypical ductal hyperplasia (ADH), flat epithelial atypia (FEA), lobular neoplasia (LN), papillary lesions (PN) and radial scar (RS). In our institute the standard of care is to surgically excise such high risk lesions diagnosed on core biopsy, due to possibility of associated malignancy.

Malignant lesions include both ductal carcinoma in situ (DCIS) and invasive carcinoma (IC). Surgical excision was recommended in all malignant core biopsy lesions.