The Role of US Guided Handheld Vacuum Assisted Breast Core Biopsy (VACB) in the surgical management of breast nodules: Preliminary report of KCCC experience

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Abstract

Objective

The purpose of this study was to evaluate the role of US guided hand held vacuum-assisted breast core biopsy (VACB) in the surgical management of breast nodules.

Materials And Methods

Twenty five breast nodules in twenty five women were subjected to US guided 11-gauge vacuum-assisted breast core biopsy over a period 22 months. Biopsies were performed using handheld 11-g VACB needle under US guidance using high-resolution US equipment with a 7.5–10 MHz linear transducer. A median of 12 specimens were obtained per lesion with insertion of a clip marker in place. Pre and post procedure imaging findings, complications, histologic outcome, and medical records were reviewed.

Results

The patient median age was 50.16 years (range, 36- 72 years). Lesion median size was 1.7 cm (range 0.8-3.0 cm). Lesions were categorized using BI-RAD system as follow: 12 (48%) category 3, 11 (44%) category 4 and 2 (8%) as category 5. Six out of 25 (24%) lesions were palpable. The median time required to perform the biopsy was 25 min (range, 20-40 min). Complete removal of the lesion seen at sonography was achieved in 22/25 lesions (88%) and was significantly more frequent in lesions measuring < 1.5 cm than in larger lesions. Accuracy was 100 %. No repeat was asked. Surgical biopsy was spared in 24/25 (96%) patients. One case was referred for surgical excision upon pathologist advice.

Conclusion

In our small series, US guided vacuum-assisted beast core biopsy was a fast, less invasive, accurate method in diagnosing breast nodules. It is a cost effective procedure, accepted by the patient and led to sparing surgical procedure in 96 % of women. VACB has become an integral part in the management of breast nodules and further work is going on to assess the long-term outcome.

Key Words

Breast nodules, core biopsy, VACB, excisional breast biopsy.

Introduction

Breast cancer is the most common cancer and the second leading cause of cancer-related mortality in women [(1)]. When breast cancer is suspected, excisional biopsy (EXB) used to be the recommended diagnostic option, because it provides a sample for histopathologic diagnosis and is often therapeutic in patients with early-stage cancer. Fortunately, 55% – 85% of women who undergo EXB are found to have benign breast lesions [(2)] with no need for further surgery. Additional disadvantages of EXB include its expense and the related morbidity that arises from the surgical procedure itself.

US guided percutaneous large-core breast biopsy using automatic 14-G needle has been performed successfully for more than a decade[(3)]. This technique is efficacious, cost effective, and generally accepted as an alternative to

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excisional biopsy. Although this method usually provides a reliable diagnosis, the technique has shortcomings. The possibility of false-negative diagnoses is the most obvious shortcoming with an overall rate of 2.9-10.9% [4-8]. In addition, all the false-negative results arose from biopsies of small breast nodules <1.5 cm [8] and can theoretically occur also with core biopsy of an ill-defined mass composed largely of fibrosis surrounding a small infiltrating carcinoma.

With the advent of the new Hand Held Vacuum assisted breast core biopsy device (VACB) (Fig. 1) for US guided breast biopsy. This device is expected to bring to US guided breast biopsy advantages similar to those already recognized in stereotactic guided one.

The goal of this study was to show that US guided hand held Mammotome has a recognizable role in the management of breast lesions specially those measuring ≤ 1.5 cm in its greatest dimension.

Material and Methods

Patients characteristics

A total of 25 patients with 25 breast nodules were referred to the radiology department at Kuwait Cancer Control Centre (KCCC), in the State of Kuwait. All patients were subjected to US guided breast biopsies between April 2006 to February 2008. US guided core biopsy was offered as an alternative to open surgical biopsy for palpable and non-palpable breast nodules that could be seen with sonography and that were suspicious or highly suggestive of malignancy, and for occasional lesions with benign or probably benign findings, at the request of the patient and her referring physician (e.g., due to patient anxiety). Patients with a bleeding diathesis and those unable to co-operate with the procedure were excluded.

Relevant mammograms, US and MRI studies were reviewed. The choice of the tissue-acquisition device for sonographically guided biopsy was made by the radiologist performing the biopsy. Breast nodules were categorized using Breast Imaging Reporting and Data System [BI-RADS] [9].

The 11-gauge hand held vacuum-assisted biopsy probe was selectively used for sonographically guided biopsy of the following lesions:

a) Solid lesions that were suspicious (BI-RADS[9], category 4) and measured 2.0 cm or less, to potentially enable complete removal of the lesion found at imaging and clip placement if necessary.

b) Solid lesions that were highly suggestive of malignancy (BI-RADS, category 5) and measured 1.0 cm or less, to facilitate biopsy of small lesions that can be difficult to sample with a 14-gauge automated needle and to enable clip placement.

c) Complex lesions, subtle lesions, and cysts with mural thickening, intramural nodules, or thick septations, regardless of size, to provide a larger volume of tissue to the pathologist for analysis.

d) Other lesions for which it was desired to remove a large volume of tissue (e.g. to remove a palpable lump).

e) Lesions with probably benign (BI-RADS, category 3) findings measuring 2 cm or less, for which biopsy was requested by the patient and her referring physician.

Sonographically Guided Biopsy Technique

The technique of sonographically guided 11-gauge vacuum-assisted biopsy is shown in Figures 2,3. Under aseptic conditions and the patients in the supine or supine oblique position, and through 3-5 mm length skin incision, US guided 11-gauge directional vacuum-assisted biopsies were performed using high-resolution sonography equipment with a 7.5-10 MHz linear array transducer. A localizing clip was placed if the entire lesion seen at US was removed at the end of the procedure. The median number of specimens obtained per lesion was 12 (range 8-20). The larger number of specimens was obtained if complete removal of the lump was desired.

Most lesions that were ≤ 1.5 cm were biopsied with an attempt made to continue the biopsy until no sonographic evidence of the lesion. A

Fig.1: Vacuum Assisted Core Biopsy needle

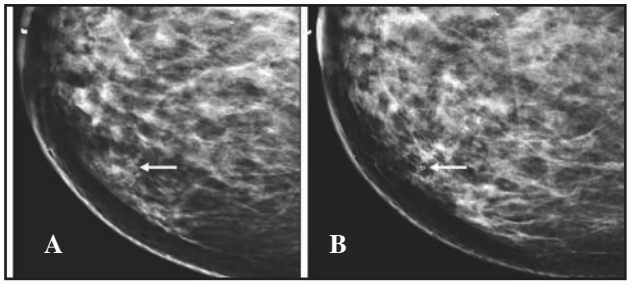

Fig.2: Asymptomatic 45 year woman with a 9 mm non-palpable breast nodule in the right LOQ (arrow head). a. Pre- and b. Post biopsy CC mammograms. Note the marker in place after complete removal of the lesion that proved to be DCIS (arrow).

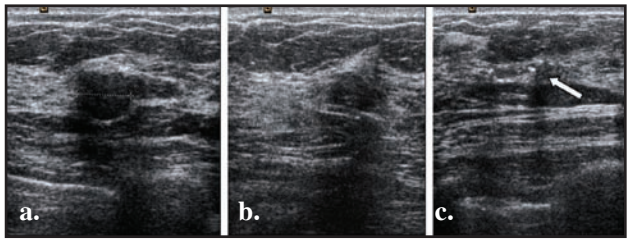

Fig.3: US of the same patient in Fig.2 a) Before insertion of the needle. b) Needle seen in place under the lesion. c) After the VACB with the echogenic marker in place (arrow), note that there is no residual mass or hematoma seen in place.

marking clip was placed at the biopsy site at the conclusion of each biopsy.

A mammogram and US were performed after each biopsy to record the measurements and resultant percentage of any residual portion of the lesion, the architectural changes, hematoma and the place of the marking clip. Complications from the biopsy such as significant bleeding, hematoma, infection, skin discoloration or defect were recorded.

Follow-Up Protocol

Pathologic findings at sonographically guided VAC biopsy were correlated with the imaging findings, and specific follow-up recommendations were made to the referring clinician as per the following protocol:

1) Repeated biopsy (sonographically guided or surgical) was suggested if inadequate tissue was obtained or if there were discordance between imaging and pathologic findings.

2) Diagnostic surgical biopsy was suggested for women in whom US guided biopsy revealed certain specific lesions including atypical ductal hyperplasia, possible phyllodes tumor, radial scar, papilloma with atypia.

3) If the pathologist suggested surgical excision.

4) If sonographically guided biopsy revealed carcinoma, the patient was referred for definitive surgery.

5) If US guided biopsy revealed benign findings concordant with the imaging characteristics for which excision was not deemed necessary, the patient was advised to return for imaging follow-up in 6 months.

After all lumpectomies, we recorded the type of any malignancy remaining and reported any evidence of epithelial displacement. The final histopathology was compared with that from the VACB to determine whether there was an underestimation of disease (e.g. atypical ductal hyperplasia upgraded to ductal carcinoma in situ). Further surgical management of each of the 25 patients was recorded

Data Analysis

Imaging studies, medical records, and histological findings were reviewed. A woman was considered to have been spared a surgical procedure if US guided biopsy yielded benign findings concordant with imaging features for which imaging follow-up was suggested or if the biopsy yielded carcinoma referred for definitive treatment. A woman was considered not to have been spared a surgical procedure if she was referred for diagnostic surgical biopsy after US guided one. The time to perform US guided biopsy procedure was calculated from the time of the prebiopsy US to the time of positioning

a sterile bandage on the skin at the end of the procedure.

Bi-Rads	No. of Lesions	No. Of Malignancy
Category 3	12	0 (0%)
Category 4	11	5 (45%)
Category 5	2	2 (100%)
Total	25	7 (28%)

Table 1: Breast Imaging Reporting And Data System (Bi-Rads) Categories And Frequency Of Malignancy

Results

The classification of the nature of the lesions as classified according to the BI-RADS [9] system is demonstrated in Table 1. Two lesions were classified as BI-RADS category 5, 11 lesions were classified as BI-RADS category 4, and 12 lesions were classified as BI-RADS category 3 [Table 1].

Histologically, 7 lesions were classified as malignant, One lesion was described as epithelial and myoepithelial lesion possibly benign that advised further surgical excision with safety margin that was considered high risk, non was described as (atypical ductal hyperplasia, atypical lobular hyperplasia, or lobular carcinoma in situ). Seventeen lesions were benign (fibroadenoma, adenosis, FCC and pseudoangiomatous hyperplasia).

All lesions (2/2) classified as BI-RADS category 5 were malignant.

Of the BI-RADS category 4 lesions, (5/11) were noted to be malignant or high risk.

Of the BI-RADS category 3 lesions, none (0/12) was noted to be malignant

Nineteen lesions were non palpable.

Histologically, of the 18/25 lesions classified as benign, 10 were fibroadenomas, and 6 were fibrocystic change and adenosis, one pseudoangiomatous hyperplasia, and one though described benign, yet surgery was advised.

The average lesion size was 11 mm, and the average numbers of samples obtained per lesion were 12.

The average distance of the post-biopsy marking clip from the original center of the lesion as measured on the post-biopsy mammogram was 5 mm. The greatest distance of a marking clip from the center of the original lesion was 1.5 cm.

US and mammography performed after biopsy revealed that 22/25 (84.6%) lesions had no imaging evidence of the original lesion remaining. Among the other lesions, 2/25 still had sonographic evidence of the lesion remaining after biopsy and 1 still had some mammographic density remaining after biopsy but no sonographic evidence of the lesion. No significant architectural distorsion was noted.

In 10 patients, the lesion was not seen well or at all on the original mammogram and therefore the judgment as to whether any evidence of the original lesion remained was based solely on sonography.

Two types of minor complications were recorded in three patients. One case developed hematoma and 3 developed skin discoloration that last for 1-2 weeks but no skin defect nor infection were reported. The hematoma measured 1.7 cm and required no further intervention beyond applying pressure to the biopsy site. No residue of this hematoma was noted 2 weeks later.

No repeated biopsies were required because of insufficient tissue or inconclusive results.

Only one discrepancy in diagnosis was, documented in one patient with infiltrating ductal carcinoma at VACB biopsy that turn out to be infiltrating lobular carcinoma observed in the surgical specimen. All other lesions that were surgically excised had complete histologic agreement with the original percutaneous biopsy. No cases of epithelial displacement were observed in any of the surgical excisions.

Surgical procedure was spared in 24/25 (96%) patients. In 17 patients the VACB was not only diagnostic but also curative for benign lesions and in 7 patients it obviated the need for diagnostic surgery.

Fig.4: VACB device

Discussion

Small breast nodules, especially those smaller than 1 cm, are the most difficult to accurately target when performing US guided automated core biopsy because of the possibility of the needle traversing near, but not through the lesion. This is especially true in small deep lesions in a large or fibrotic breast. There are occasions when, even with five or more core passes, one is uncertain if tissue from the lesion has definitely been obtained [10].

When a 15-mm lesion is biopsied using standard automated core biopsy technique and the resultant histology is fibroadenoma, the radiologist's confidence in this specific benign diagnosis is high. However, if at 6-month follow-up the lesion measures 19 mm, that confidence is diminished somewhat and questions arise as a result. Is it safe to continue to follow up this lesion? Should it be rebiopsied with the core technique? Should it be surgically excised? By performing an excisional VACB initially, one can mitigate this dilemma and its corresponding questions [10].

Four factors may primarily account for the better performance of vacuum assisted devices in comparison with automated devices: (a) ease of obtaining a larger number of specimens, (b) higher average specimen weights, (c) higher percentage of breast tissue (versus blood clot) per specimen, and (d) ability to perform contiguous breast tissue acquisitions.

With complete removal of the sonographic evidence of the small mass, there is a reduced chance of sampling error and consequent false-negative diagnosis. Thus, when performing an excisional VACB of a BI-RADS category 4 or 5 small mass, any resultant benign diagnosis can intuitively be relied on more confidently, obviating a re-biopsy in the face of discordant imaging and histologic results [11].

In addition, when we biopsy a small mass with the handheld VACB device, the imaging evidence of the lesion is no longer present. Therefore, it is unlikely that the lesion proven benign at biopsy will grow to a size that would confuse the original diagnosis.

Some may question the high number of BI-RADS category 3 lesions that were biopsied. It is believed that many women with a known mass (e.g. women with lesions designated as BI-RADS category 3 who underwent biopsy in this series) prefer to have an immediate biopsy or VACB removal of that mass rather than undergo 6-month imaging follow-up, in spite of reassurance that there is less than a 2% chance of malignancy. If one considers the patient's mental state as well as her physical state (practicing the art of medicine in addition to the science), it is clear to us that many women with BI-RADS category 3 masses will desire and should be allowed to undergo immediate biopsy. If, on the other hand, one wants to achieve a higher positive biopsy rate, one can deny biopsy to women in this category [10].

Mammographic findings after surgical excisional biopsy of a benign breast lesion include

the following: focal architectural distortion, increased focal density at the site of the biopsy, focal skin thickening or retraction, fat necrosis, and, occasionally, focal calcifications [13].

Insertion of the 11-gauge biopsy device requires an incision that is approximately 3–5 mm length. The incisions typically heal in 1–2 weeks and could not be accurately identified at 6-month follow-up in this study. Post procedure imaging revealed minimal or no architectural distorsion. No clinical changes were recorded at the 6-month follow-up investigation.

Although the breast fibroadenoma is a common benign breast tumor, the treatment and follow-up of these lesions is still debatable. It is recommended to use US guided VACB, not only for diagnosis but also to provide an option for the definitive treatment of breast fibroadenomas [12].

US guided vacuum-assisted 11-gauge needle biopsy of the breast is a largely uncomplicated procedure that is well accepted by patients and does not produce parenchymal scarring, architectural distortion, fat necrosis, or other identifiable changes such as those encountered after surgical biopsy. Thus, the use of this biopsy method does not pose a diagnostic dilemma in the subsequent interpretation of routine screening mammograms and sonograms [15].

US guided 11-gauge vacuum-assisted biopsy obviated a surgical procedure in 96% of lesions in this study, resulting in a decrease in the cost of diagnosis compared with the surgical biopsy [14].

Conclusion

In conclusion we found that the data from our series suggest that sonographically guided hand held vacuum-assisted breast core biopsy is a fast, accurate, generally accepted minimally invasive, cost effective technique for diagnosing breast lesions that affect the surgical management of both benign and malignant breast nodules.

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