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Original article

Vacuum-assisted complete excision of solid intraductal/intracystic masses and complex cysts: Is follow-up necessary?

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ABSTRACT

Introduction: Management of complex cysts and benign intraductal/intracystic masses is controversial. The aim of this study was to determine if the complete removal of the complex cyst lesions with ultrasound-guided vacuum-assisted excision (US-VAE) is sufficient for their safe management when the histological diagnosis obtained at biopsy is benign.

Subjects and methods: This is a single institution retrospective study performed on patients who underwent breast biopsy between April 2007 and September 2013. Patients with complete removal of complex cyst lesion of a BIRADS 4 lesion by US-VAE that obtained a benign diagnosis were included. Size, morphology, histological diagnosis, and surgical or imaging follow-up of the lesions were analyzed.

Results: During the study period, 131 lesions met the inclusion criteria. Benign papilloma represented 32% (42/131) of the lesions; the remaining lesions had various benign diagnoses. Mean size of the solid mass or the cysts' thickest septum was 7 mm (range, 2–24). Mean imaging follow-up was 34.9 months (24–99 months) in 115 lesions. No recurrence or malignancy in the post-biopsy bed were observed during follow-up. Eleven lesions (8.4%) underwent surgery as follow-up: no cancer was found, but two lesions demonstrated atypia.

Conclusions: Complex cyst lesion image completely excised with US-VAE and with a benign histology at biopsy might not require further imaging follow-up or surgery and a return to routine screening can be safely recommended. In a world where healthcare delivery and accessibility is important, elimination of unnecessary follow-ups is pertinent given its lower cost and lesser social impact.

1. Introduction

Management of lesions presenting as intraductal or intracystic masses or complex cysts is controversial. While it is recommended that these lesions be classified as "indeterminate", ACR BIRADS category 4, the follow-up of a benign histological biopsy result varies from complete surgical excision [1–3] to image follow-up over a period of 2 years [1,4,5]. Surgery has the advantage of providing a clear and definitive diagnosis, but can be deemed too aggressive and too costly for the majority of the cases which end up having a benign diagnosis. On the other hand, a two-year follow-up leads to patient anxiety [6–8] and creates a burden on healthcare costs [8–10] as well as on imaging schedules.

Vacuum-assisted biopsy (VAB) of the ultrasound image of a lesion (i.e. the abnormal tissue as demonstrated by ultrasound; herein referenced to as "image" in this paper) has been demonstrated to be superior to core-needle biopsy (CNB) for the histopathological diagnosis accuracy of papillary lesions and complex cysts [11–14]. Furthermore, some studies support the use of complete ultrasound-guided vacuum-assisted excision (US-VAE) of the image as an alternative to surgical excision for benign papillomas and complex cysts [11,12,14–20], even if there is no proof that it is the same as the complete histological removal of the lesion, suggesting that follow-up could be unnecessary for proven benign lesions that underwent complete US-VAE. Nevertheless, Chang and al. have demonstrated that there may be some remaining lesional tissue when patient undergo surgery after US-VAE of the image [11]; the clinical outcome of this residual lesional tissue remains uncertain for histologically-proven benign lesions.

The purpose of this study was to determine if complete US-VAE

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Abbreviations

BI-RADS	Breast Imaging- Reporting and Data System
CNB	core-needle biopsy
IRB	institution review board
US-VAB	ultrasound-guided vacuum-assisted biopsy
US-VAE	ultrasound-guided vacuum-assisted excision

of the image of histologically-proven benign complex cysts could be sufficient for their safe management, thereby avoiding an unnecessary surgery or imaging follow-up.

2. Material and methods

2.1. Study design and population

This is an IRB-approved single institution retrospective descriptive study of the follow-up of patients who underwent breast US-VAB from April 2007 to September 2013. The need for individual consent was waived by the IRB because of the retrospective nature of the study. Two senior radiologists from the same institution participated in the study and performed all the biopsies.

This center is a reference center for the provincial breast cancer screening program. Original imaging is performed at government-appointed radiology clinics, and individuals with abnormal images are sent to our center for additional imaging and biopsy, if necessary. This provincial screening program invites women aged 50–69 years on a 2-year basis.

Intraductal and intracystic masses were labeled as intracystic masses, which included all masses, regardless of size, located within a cyst or a breast duct as demonstrated by the ultrasound image. Complex cysts were defined as a cluster of small cysts with a septation of 0.5 mm of more [4,14]. As intracystic masses and complex cysts terms are often used interchangeably in the literature, namely in the previous ACR BI-RADS lexicon edition [21,22], intracystic masses and complex cysts will be grouped under complex cysts in this paper.

Study inclusion criteria comprised all consecutive complex cysts that underwent complete ultrasound-guided vacuum-assisted excision of the image (US-VAE) during the study period. As per the institution protocol, these lesions were either complex cysts or benign papillary lesion diagnosed with a 14G core needle biopsy. For the latter lesions, repeat biopsy with a US-VAE is recommended in our institution to avoid undersampling. The complete excision was defined as the absence of any residual lesional image seen on ultrasound after the completion of the biopsy. Lesion with final biopsy diagnosis of papilloma or any benign histological finding without any atypia or malignancy were included in the study.

BI-RADS 5 lesions or lesions located in a surgical bed of an operated neoplasm were excluded from the study. In addition, any lesion presenting with radiological-pathological discordance after 14G biopsy that required US-VAB for better sampling or any lesions for which complete excision of the image could not be demonstrated were also excluded from the study.

2.2. Data collection

Ultrasound imaging characteristics and 3D location of the lesions were recorded. Lesions' measurements were obtained from ultrasound reports and only the largest dimension was kept in the database. Symptoms at presentation (palpable mass, nipple discharge, or pain), menopausal status, and personal or familial history of breast cancer were also registered. Biopsy procedure data such as biopsy needle manufacturer, gauge, number of specimen collected, complete or incomplete excision, and name of the operator were noted.

2.3. Biopsy procedure

Ultrasound guidance for biopsy was provided by either a GE Logiq 9 (GE Healthcare, Waukesha, WI, USA) using a 13 MHz probe or a Toshiba Aplio (Toshiba Corp., Tokyo, Japan) using a 15 MHz probe. VAB was performed using ATEC 9G system (Hologic, Inc., Bedford, MA, USA) or Encor 7G or 10G system (Bard Biopsy Systems, Tempe, AZ, USA).

For each biopsy procedure, informed consent was systematically obtained by the radiologist as it is the regulation at our institution. After disinfection, local anesthesia was administrated following the routine protocol used at our center: 5 ml of 1% lidocaine for skin and subcutaneous tissue followed by 5 ml of 1% lidocaine with epinephrine, and 5 ml of 0.25% bupivacaine for deeper anesthesia in the biopsy bed. A small skin incision was made with an 11-blade to facilitate the insertion of the biopsy needle. Images showing the aperture of the biopsy needle located immediately underneath the lesion in addition to images of the complete excision of the lesion and the biopsy marker in place were performed for each biopsy. The number of passes varied depending on the size of the lesion but was recorded in the dictation of the case by the radiologist. At the end of the procedure, a biopsy marker was left in place and a post-biopsy mammography was performed to confirm its good positioning.

2.4. Post-biopsy management and follow-up

Patients with benign pathological results were followed up at 6, 12, and 24 months, with ipsilateral ultrasound and mammography. Breast MRI was used for follow-up in the rare occasion where the lesions were seen initially on MRI ($n = 4$ patients), to ensure the complete excision of the suspicious enhancement.

2.5. Study endpoint

The date of the last imaging follow-up was recorded. Stability of the biopsy bed over a 24-month period or more and the absence of any recurrent solid or cystic image in it were considered as the endpoint confirming the absence of malignant transformation.

For clinical reasons, some patients underwent surgery despite benign pathology. For these lesions, the final surgical histology was considered as the endpoint of this study and concordance with the histological diagnosis obtained with US-VAE was obtained. Atypia or neoplasm at the biopsy site was considered as an upgrade. Atypia or neoplasm diagnosed at distance and/or independent from the biopsy site was not considered as an upgrade.

2.6. Statistical analysis

Descriptive analyses are presented. Continuous data were presented as means plus or minus the standard deviation or minimum and maximum, as appropriate. Categorical variables were presented using frequencies.

3. Results

3.1. Characteristics of the patients

Fig. 1 presents the study flowchart. During the study period, 301 complex cyst lesions were biopsied with US-VAB at our center by