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Minimal invasive complete excision of benign breast tumors using a three-dimensional ultrasound-guided mammotome vacuum device

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KEYWORDS: benign breast tumor; mammotome vacuum-assisted biopsy; scarring; surgical biopsy; three-dimensional imaging; volumetry

ABSTRACT

Objective *The aim of this study was to evaluate the use of three-dimensional (3D) ultrasonography in the complete excision of benign breast tumors using ultrasound-guided vacuum-assisted core-needle biopsy (Mammotome®). A protocol for the management of benign breast tumors is proposed.*

Method *Twenty consecutive patients with sonographically benign breast lesions underwent 3D ultrasound-guided mammotome biopsy under local anesthesia. The indication for surgical biopsy was a solid lesion with benign characteristics on both two-dimensional (2D) and 3D ultrasound imaging, increasing in size over time or causing pain or irritation. Preoperatively, the size of the lesion was assessed using 2D and 3D volumetry. During vacuum biopsy the needle was visualized sonographically in all three dimensions, including the coronal plane. Excisional biopsy was considered complete when no residual tumor tissue could be seen sonographically. Ultrasonographic follow-up examinations were performed on the following day and 3–6 months later to assess residual tissue and scarring.*

Results *All lesions were histologically benign. Follow-up examinations revealed complete excision of all lesions of < 1.5 mL in volume as assessed by 3D volumetry. 3D ultrasonographic volume assessment was more accurate than 2D using the ellipsoid formula or assessment of the maximum diameter for the prediction of complete excision of the tumor. No bleeding or infections occurred postoperatively and no scarring was seen ultrasonographically on follow-up examinations.*

Conclusions *Ultrasound-guided vacuum-assisted biopsy allows complete excision of benign breast lesions that are ≤ 1.5 mL in volume (calculated by 3D volumetry), and thus avoids open surgery and postoperative scarring. Under local anesthesia it is a safe procedure with optimal compliance. 3D ultrasound offers the advantage of better preoperative demonstration of the lesions' margins, resulting in better assessment of volumetry, improved intraoperative needle location and perioperative identification of residual tumor tissue. 3D sonographically guided biopsy should be integrated into breast cancer screening programs as a safe therapeutic option for breast lesions presumed to be benign. Copyright © 2003 ISUOG. Published by John Wiley & Sons, Ltd.*

INTRODUCTION

Intensified breast cancer screening programs have led to an increasing detection rate of benign breast lesions necessitating new diagnostic and therapeutic options. However, an increasing rate of open surgery for benign breast lesions, which is associated with scarring, morbidity, and jeopardized follow-up examinations, must be avoided. Ultrasonography is now widely used as a non-invasive diagnostic technique for the investigation of breast lesions, and can improve the specificity of clinically and mammographically detected abnormalities. This combined approach (mammography and ultrasonography) permits the physician to distinguish benign nodules from malignant nodules with a high diagnostic accuracy[1–3].

Three-dimensional (3D) ultrasonography, by demonstrating the topography and margins of tumors in the coronal plane, represents a new tool for the discrimination

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of benign from malignant breast lesions[4,5]. Additionally, it enables volume assessment that is as accurate as 3D computed tomography (CT) measurements as demonstrated in liver tumors and improves visualization of the needle and guidance during biopsy, thus resulting in a high sensitivity of core-needle results[6,7].

Due to the phenotypic variability of malignant breast tumors, most solid breast lesions, even if they present clinically as benign breast lesions, need histological verification. This is usually achieved with fine-needle aspiration or core-needle biopsy. The sensitivity and specificity of these techniques depend on several parameters, including the quality of the pathological specimen and the biopsy technique used[8,9]. Once the benign nature of a breast lesion has been verified by either histological or cytological biopsy, open breast surgery for complete excision can be avoided by performing follow-up examinations[1,10,11].

Counseling of women with a breast lesion diagnosed benign on core-needle biopsy must include the small possibility of the tumor having malignant potential. To the best of our knowledge, there are no data available on the incidence of carcinomas in sonographically benign breast lesions. In mammographic lesions, categorized as BI-RAD 3 (Breast Imaging Reporting and Data System: Category 3: probably benign, follow-up recommended), the frequency of carcinoma is still 0.5% to 2%[12,13].

In the presence of a presumed benign breast lesion a complete surgical excisional biopsy may still be warranted if: (a) poor compliance for follow-up examinations is anticipated; (b) a pregnancy is planned; (c) the patient is extremely anxious; (d) the lesion is increasing in size during follow-up examination; or (e) the lesion causes irritation or pain.

Therefore, some women opt for complete surgical excisional biopsy of an existing breast lesion even if considered as most probably benign. Open breast surgery with the aim to remove a breast lesion is associated with perioperative morbidity and, above all, with scarring jeopardizing follow-up examinations for breast cancer screening.

The Mammotome® vacuum biopsy allows the removal of several core biopsies without replacement of the needle by performing multiple aspirations following rotation of the mammotome® probe through approximately 90°. The diagnostic accuracy of histological sampling by mammotome vacuum biopsy in malignant tumors has been found to be as high as 98%[14]. The purpose of this study was to develop a management protocol for breast lesions presumed to be benign, using diagnostic two-dimensional (2D) and 3D ultrasonography, 2D and 3D volumetry and perioperative sonographic 3D needle guidance. The current study cohort comprised 20 patients who underwent 2D and 3D ultrasound-guided vacuum biopsy (Mammotome) for benign breast tumors.

METHODS

Over a period of 6 months, all patients who were referred for surgical removal of a clinically benign breast tumor causing either irritation or showing interval growth on follow-up examination were counseled. Twenty patients were enrolled into the study. All met the inclusion criteria of having one solid breast lesion < 2.5 cm in diameter. Preoperative evaluation included 2D ultrasonography (Voluson 730 Expert, GE Ultrasound Germany, Solingen, Germany) to characterize the lesion according to the EUSOMA (European Society of Mastology) and IBUS (International Breast Ultrasound School) guidelines[15,16]. Additionally, all lesions were examined with 3D sonography to exclude a converging pattern on the coronal plane as described by Rotten and colleagues[8]. In the third plane (the so-called C-plane) carcinomas are preferentially associated with a pattern of thick hyperechogenic bands converging according to a stellar pattern towards a hyperechogenic irregular rim surrounding the hypoechogenic central core of the mass. In contrast, benign lesions are characterized by a compressive pattern showing hyperechogenic bands of fibrous tissue peripheral to the mass[8] (Figure 1).

The maximum diameter of the tumor was obtained using 2D ultrasonography. Orthogonal planes were identified and the volume of the lesion calculated using

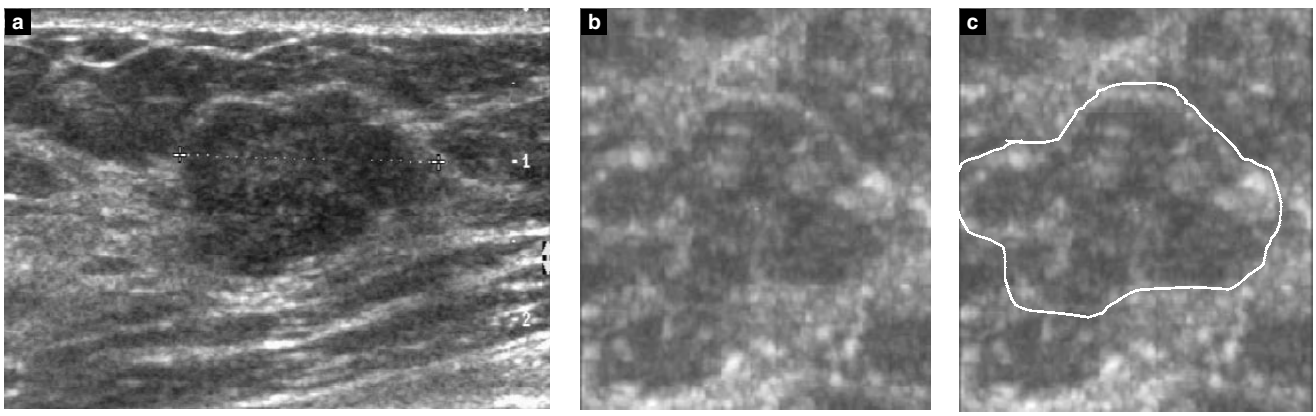

Figure 1 (a) Two-dimensional ultrasound image of a benign breast lesion. (b) Three-dimensional sonographic image of the same lesion in the coronal plane showing the compressive pattern. (c) The same image as (b) but showing the outline of the tumor's margin.

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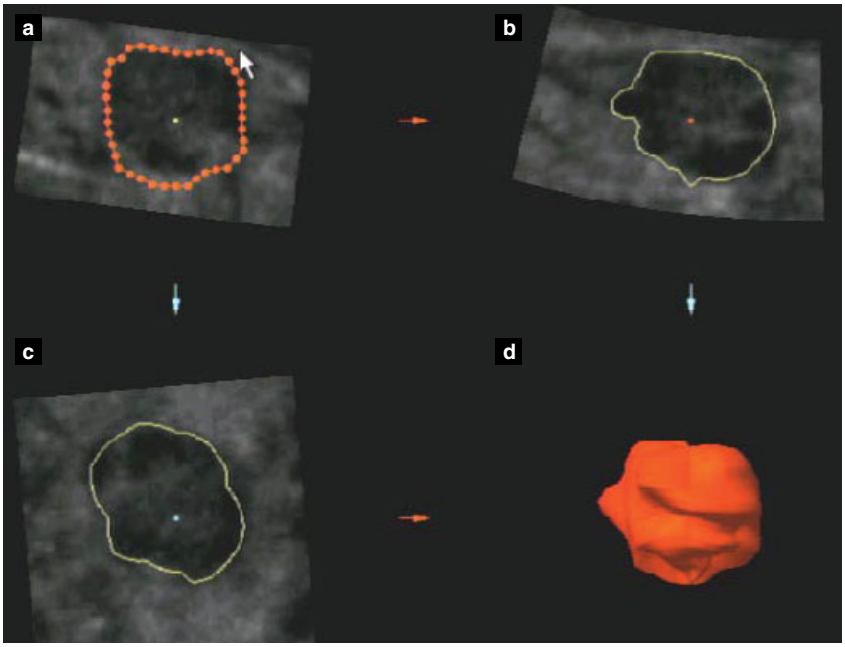

Figure 2 Volumetry was performed with the VOCAL imaging program (Voluson 730 Expert machine). The typical multiplanar display of the lesion in the coronal plane is shown in (a)–(c). The manual mode was used for the contour tracing. (d) A typical three-dimensional model is generated showing the uneven surface of the lesion.

the ellipsoid formula. With 3D imaging of the lesion and manual volume rendering in different planes a 3D reconstructed image was automatically computed (Figure 2).

All patients were given the options of either open surgical biopsy or ultrasound-guided vacuum-assisted excisional biopsy. Patients were included in this study if they opted for ultrasound-assisted biopsy only.

Following intracutaneous injection of initially 1–2 mL 1% lidocaine with a 26-gauge needle, an additional amount (5–7 mL) of local anesthesia was placed under ultrasound guidance just below the lesion to create a space for the mammotome hand-held-device. A 2–3 mm long skin incision was performed and the 11-gauge Mammotome (Ethicon GmbH, Endo-Surgery Deutschland, Norderstedt, Germany) was positioned with the aperture of the needle just caudal of the lesion (Figure 3). During excisional biopsy repeated 3D ultrasound images were obtained to monitor continuously the needle position. The vacuum biopsy resulted in excision of several specimens; the probe was then repositioned according to residual tissue as visualized by 2D and 3D images. In all patients the biopsy was performed with a single insertion and a single placement of the device underneath the tumor. The duration of the procedure itself lasted between 20 and 45 min depending on the size of the tumor, the location and the consistency of the surrounding tissue.

The procedure was terminated if either no remaining tumor could be identified or a residual lesion was obscured by air or blood (Figure 4a) that inadvertently occurred during withdrawal of a series of samples. At the time of removal of the device, compression of the breast was performed either by the patient herself or

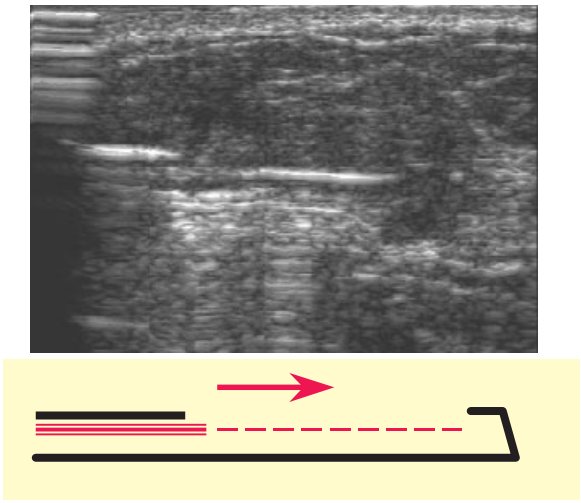

Figure 3 The 11-gauge Mammotome is positioned with the aperture of the needle just below the lesion.

the operator for approximately 5 min. The incision was covered with a sterile plaster and a compression bandage was applied.

Histological examination was performed on all specimens. Ultrasonographic follow-up examinations were performed on the following day and 3–6 months later to assess residual tissues and scarring.

RESULTS

The mean age was 39.2 (range, 20–52) years. Two patients were older than 50 years.

All lesions presented with benign characteristics with sharp margins on 2D sonographic imaging and a

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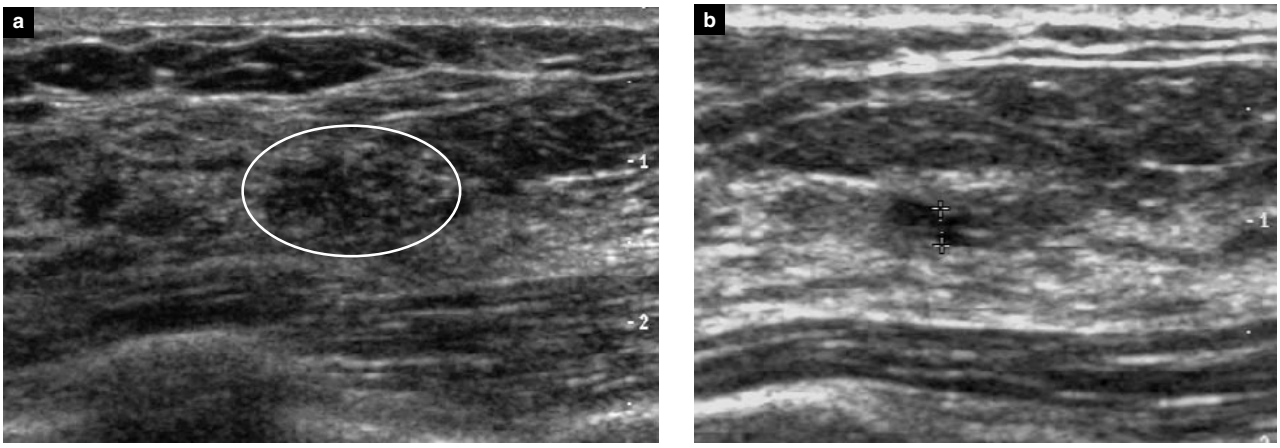

Figure 4 (a) Ultrasound image taken on the first postoperative day showing the site of the lesion as a region of low echogenicity with echogenic foci corresponding to air and hematoma. (b) After 3 months only a small structure can be identified at the site of the former lesion showing no signs of the shadowing that can be expected from scars following open surgery.

compression pattern on the coronal plane (Figure 1). The mean long axis diameter of all lesions was 1.4 (range, 0.7–2.3) cm. The mean volume calculated with 2D and 3D volumetry of all lesions was 0.84 (range, 0.09–2.76) and 0.85 (range, 0.07–2.2) mL, respectively.

Lesions < 1 mL volume had similar volumes calculated from 2D and 3D images; a greater discrepancy occurred for volumes > 1 mL, as demonstrated in Figure 5. The correlation coefficient (Pearson test) was 0.97 and was statistically highly significant.

Under local anesthesia no patients complained of side effects or pain during the procedure or the day after. No patient developed a clinically relevant hematoma.

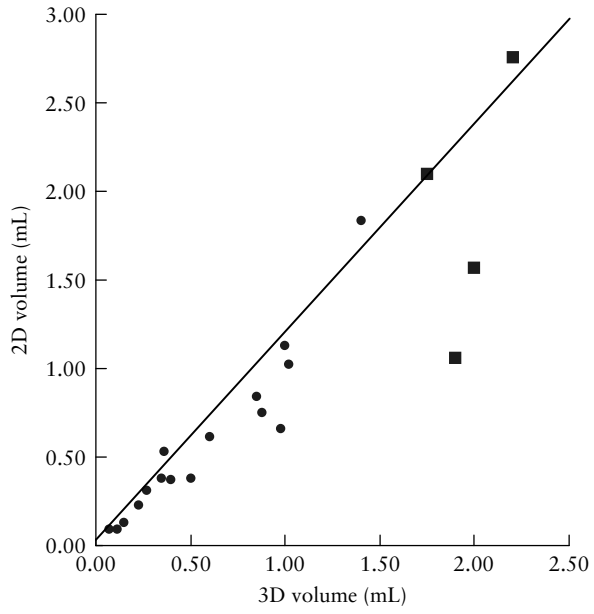

Figure 5 Two-dimensional volume measurements calculated using the ellipsoid formula plotted against volumes obtained with three-dimensional ultrasound using the Kretz Voluson 730. A statistically significant correlation coefficient of 0.97 was obtained by the Pearson test. Note the discrepancy of the volume data of the incompletely excised lesions. ■, incomplete excision; ●, complete excision.

Under sonographic guidance 16 lesions were removed completely. Seven patients had a hypoechogenic mass which was interpreted as a hematoma or seroma on the first postoperative day (Figure 4a) with dimensions similar to those of to the excised lesion. In nine patients no residuum could be discriminated from the surrounding tissue. Of the four patients in whom the lesions could not be completely removed, the volume of the lesion exceeded 1.5 mL (Figure 6). In these four patients sonographic follow-up showed a residual mass smaller in size than the previous tumor and causing no irritation, therefore no further intervention was performed. Of the 20 lesions excised, the histological diagnosis revealed ten fibroadenomas, six cases of sclerosing adenomatosis and four cases of sclerosing mastopathy.

No complications (e.g. pain requiring analgesics, bleeding or hematomata exceeding the size of the primary lesion) were documented.

Of the 20 patients one patient failed to return for follow-up examination. The remaining 19 patients were seen after a mean of 4 months (range, 12–20 weeks). All

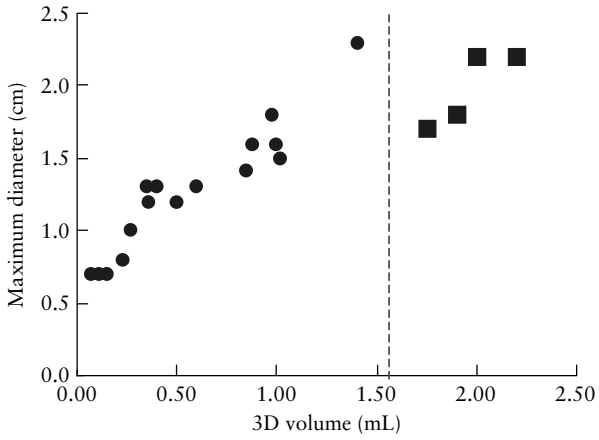

Figure 6 Maximum two-dimensional diameter and three-dimensional volumetry: the diameter has a less accurate predictive value than the volume for complete excision of a lesion with the Mammotome vacuum-assisted biopsy (see dotted line). ●, complete excision; ■, incomplete excision.

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had good cosmetic outcome and were satisfied with the mammotome technique, the hematomata having resolved in all patients. No sonographic scar with shadowing could be demonstrated, the presumed site of the excision could still be detected in 10/15 patients (one patient lost to follow up) as a small (< 2 mm in diameter) hypoechogenic structure (Figure 4b).

DISCUSSION

Although the mammotome device has been integrated into stereotactic and ultrasound-guided breast biopsies[14,17], to the best of our knowledge only few reports have focused on the ultrasound-guided complete excision of benign breast lesions instead of open breast surgery lesions[18,19] none of them using 3D ultrasonography for preoperative and intraoperative assessment.

3D ultrasound offers the opportunity to visualize the architectural distortion of a lesion in the coronal plane[8]. Although 2D ultrasound shows signs of disrupted connective tissue layers in the sagittal and transverse planes, the compressive and retraction patterns seen in the coronal plane obtained by the 3D technique have a high specificity and sensitivity in differentiating benign from malignant masses (0.938 and 0.914, respectively)[8].

We assume that volume measurements of breast tumors with 3D ultrasonography are more accurate than those obtained by 2D ultrasonography. To date, only in liver tumors has a discrepancy between 2D volume and 3D ultrasonographic volume measurements and 3D CT volumetry been proven[5]. As demonstrated in Figure 2, 3D ultrasonography with the Voluson 730 Expert offers the possibility to create a tumor model, thus demonstrating more accurately the margins of the tumor compared to 2D sonography. However, there is currently no model to define and compare the accuracy of different volume measurements using breast ultrasonography. Our data confirm that the new mammotome biopsy device can be safely applied to excise benign breast tumors completely. Whereas Parker and coworkers[19] reported the successful removal of all sonographic evidence of masses $\leq$1.5 cm in greatest dimension, our results showed that tumors with a maximum diameter of 2.3 cm, but a volume of < 1.5 mL can be completely excised. The prediction of complete excision is also shown to be more accurate with 3D volumetry than with 2D measurements (Figure 6).

Reports on the prevalence of mammographic scarring after stereotactic breast biopsy provide varying results, but severe scarring seems to be rare. Schwartzberg *et al.*[20] report minimal scarring in only 16% of 150 patients and Beck *et al.*[17] noted one patient with severe scarring in a cohort of 460 follow-up mammograms. We presume that the prevalence of scarring after sonographic vacuum biopsy is very low. However, there is a lack of uniformity among the observers' use of descriptive terms for breast masses and scarring. In our study group ultrasonographic follow-up presented no difficulty in interpretation because no structural defects with shadowing were noted (Figure 4b).

According to the results of Parker *et al.* 88% of their cases had no ultrasonographic evidence of remaining lesions following biopsy[19]. In our series we can confirm that no residual tumor was left when the lesions were < 1.5 mL in volume. In 20% of our patients (4/20 patients) who had lesions > 1.5 mL incomplete excision was found.

In a breast ultrasound screening group of 3626 patients, Kolb and coworkers detected 204 (5.6%) benign breast masses[1]. Although they believed that, depending on the ultrasound appearance, biopsy need not be performed in all solid masses, 96 patients who were recommended follow-up alone opted for either needle aspiration or surgical biopsy. These data confirm the need for a procedure that provides patients with confidence, has minimal side effects, and costs no more than surgical biopsy performed under general anesthesia. Parker *et al.* discussed the management and patient's confidence if a lesion shows growth on follow-up examination[19]. Parker questioned whether a lesion that had already been biopsied should be re-biopsied. Using initial mammotome excision biopsy this dilemma can be avoided.

However, breast ultrasound and ultrasound-guided invasive procedures require considerable expertise. If a biopsy is suggested, the benefits of an ultrasound-guided biopsy versus primary surgical removal of the whole lesion should be discussed.

Although we recognize that our study is limited by the small number of patients, our intention was to report our early experience with the integration of 3D sonography into the perioperative management of benign breast tumors. Due to our promising initial results on follow-up examinations we would like to encourage more screening centers to integrate the vacuum-assisted mammotome breast biopsy technique, as we have done, into their biopsy protocols. The consequence would be a reduction in the number of open biopsy procedures for benign lesions and a reduction in patients' discomfort, anxiety and postoperative morbidity, including scarring. We believe that the health economy may benefit from widespread use of this device as an alternative to open surgery and that prospective, long-term studies will further underline these advantages. However, improved non-invasive diagnosis and appropriate counseling should remain the main goal to an overall reduction of the number of breast biopsies for benign tumors.

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