Non-surgical management of B3a lesions diagnosed at core needle biopsy: can associated malignancy and atipia be ruled out safely with tomosynthesis?

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Aims and objectives

BACKGROUND: conventional two-dimensional (2D) mammography is used for most mammographic examination. A major limitation of this technique is the potential overlap tissue. This overlap occurs because detection of the digital signal depends on the total attenuation of the x-ray beam by the intervening tissue. Overlapping tissue can consequently obscure an area of interest and lead to a false-negative finding. In addition, the overlap of normal structures in the breast can create a pseudolesion, often termed as summary artifact, which prompts a false-positive result. DBT is a new imaging technology that addresses the limitation caused by overlapping structures by acquiring a series of low-dose projection images. Computer reconstruction allows the reader to examine 1-mm single section images from the volumetric dataset on workstation. This technique has shown improved sensitivity and specificity compared with digital mammography.

Although the management of the majority of breast lesions diagnosed at imaging-guided core-needle-biopsy (CNB) is straightforward, a small group of lesions - B3 lesions - pose a dilemma when diagnosed at percutaneous biopsy. These lesions - papilloma, radial scar, lobular neoplasia, atypical ductal hyperplasia, and flat epithelial atypia - are benign, but have an increased risk of upgrade to malignancy when the entire lesion is evaluated after surgical excision. However, it is increasingly being recognized that some B3 subtypes are only associated with a very low risk of malignancy, and, therefore, surgical excision for all represents overtreatment. Because B3 lesions essentially fall into two categories with a lesser and greater risk of associated malignancy, some Authors suggest subdividing the category into B3a for benign lesions potentially associated with malignancy and B3b for more worrisome atypical epithelial proliferations. The purpose of subtyping B3 lesions is to tailor the definitive management, being more aggressive in case of B3b lesions and more conservative for B3a lesions.

B3a lesions include benign papillomas (BP) and radial scars (RS).

Papilloma is a branching epithelial tumor originating from the wall of the milk duct. There are two types of intraductal papillomas, the central and the peripheral type. The central type develops in the large milk ducts near the nipple (solitary intraductal papilloma) and often arises in the period of menopause. It is usually felt as a small lump near the nipple and may cause nipple discharge or bleeding. The peripheral type are often multiple papillomas arising in the ducts farther away from the nipple at the peripheral breasts, and are usually detected in younger women. The peripheral type are associated with a higher risk of malignancy. Intraductal papillomas are the most common cause of bloody nipple discharge in women age 20-40 and generally do not show up on mammography. Anyway mammography is typically recommended for any patient presenting with abnormal nipple discharge. Some studies have reported that mammography has a low positive predictive value of only 16.7%, and low sensitivity of 59% in the diagnosis of malignant duct pathology associated with nipple discharge. In this
case, DBT plays an important role in the detection and characterization of subtle findings that can range from distended retroareolar ducts, a developing asymmetry, architectural distortion, periductal microcalcifications to initial nipple retraction.

Radial scar (RS) of the breast are benign breast lesion characterized by a central fibroelastotic core with ducts and lobules radiating outward, giving the lesion its characteristic stellate appearance. They are classified as complex sclerosing lesion (CSL) when their size on pathology exceeds 10 mm and are classically non palpable. In addition, pathologic examination of a radial scar often reveals a diverse array of pathologic findings including typical epithelial hyperplasia, adenosis, papillomatosis, atypical epithelial hyperplasia, ductal carcinoma in situ (DCIS), and early stage invasive carcinomas. Reports in the literature suggest that radial scar is associated with surrounding malignancy in 0-40% of the cases. Although most radial scars are found incidentally at microscopic evaluation of biopsy specimens of another lesion, the widespread use of mammography has led to identification of features characteristic of this lesion. The most typical mammographic appearance of RS is characterized by an area of architectural distortion and according to the criteria of Tabar and Dean, by the presence of a central radiolucency, radiating long thin spicules, varying appearance in different projections and radiolucent linear structures parallel to the spicules. The relative low density of the centre plays an important role in the differential diagnosis between radial scar and carcinoma, in which the centre tends to be more dense and the translucent area is characteristically absent. On ultrasound, a radial scar, which disturbs the architecture of surrounding breast parenchyma, is often ill-defined round, oval or lobulated lesion with variable internal echoes. In our experience, MR appearance of RS is variable, ranging from non-enhancing architectural distortions to strongly enhancing mass lesions mimicking carcinoma.

The purpose of our study was to evaluate whether digital breast tomosynthesis (DBT) can be used to rule out malignancy and atypia in patients with B3a lesions [benign papillomas (BP) and radial scars (RS)] diagnosed at imaging-guided core needle biopsy (CNB).
Methods and materials

Study population: we retrospectively evaluated 34 high-risk lesions in 32 women (age: mean, 58 years; range: 44 - 78 years) categorized as B3a (RS or BP) at CNB performed from January 2015 to March 2016. According to our management protocol, all lesions were surgically excised and evaluated on the entire surgical specimen.

Biopsy procedures: all CNB were performed by three radiologist with large experience in breast imaging and intervention (10-20 years).

- US-guided CNB - automated biopsy gun (Magnum Biopsy Instrument, Bard) or semiautomated biopsy gun (Precisa, HS Hospital Service), both with 14-gauge needle diameter, 15 cm needle length and needle throw length of 23 mm were used. A mean of 5 core samples per lesion (range 3-8) were obtained. In case of small lesion (less than 6 mm) an amagnetic US visible clip (SenoMark) was left in place to mark the biopsy site.

- MMG-guided CNB - in case in which mammographically detected lesion was not identified on US examination, mammography guidance was used. CNB was then performed on a digital prone table (Mammobed Giotto, IMS)) with a directional vacuum-assisted biopsy device (Mammotome) with 11-gauge needle diameter. A mean of 12 core samples per lesion (range 9-18) were obtained. In case of mammographically detected microcalcifications a radiography of core biopsy specimens were obtained in order to confirm the presence of calcifications. A clip (HydroMark) was left in place to mark the biopsy site.

- MR-guided CNB - MRI-guided VAB (Atec MRI) using a 9-gauge needle was performed in case of lesions visible only at MRI. At least 24 cores were acquired. A clip marker (Atec TriMark) was placed after biopsy and two-view mammograms was acquired to document the clip position.

DBT examination: all women underwent DBT examination which was performed with a dedicated system (Giotto Tomo, IMS) in a single compression episode for each projection, craniocaudal and mediolateral-oblique.

Image analysis: all images were retrospectively reviewed on a dedicated workstation by two experienced radiologists in breast imaging (more than 10 years). Opinion discrepancies - were discussed and were resolved by consensus. The readers were aware of lesion location and the histological diagnosis at CNB. Lesion assessment and categorization were based on the BI-RADS MMG lexicon [American College of Radiology (ACR) Breast Imaging Reporting and Data System Atlas (BIRADS ® Atlas) 5th Edition 2013]
Al lesions identified on DBT and assessed as BI-RADS category 1-3 were considered as negative for malignancy/atypia while all lesions categorized as BI-RADS 4 and BI-RADS 5 were considered suspicious for malignancy /atypia.

**Reference standard:** Final histopathological result (classified into benign, atypical or malignant) after surgical excision was retrieved from our information system and was the reference standard. Histopathological examinations were performed by breast pathologist with more than 10 years of experience.

**Data analysis:** for statistical analysis, the positive predictive values (PPV) and the negative predictive values (NPV) of DBT for malignancy/atypia were calculated for the entire set of lesions and for each histological subtype.
Results

Thirty-four B3a lesions in 32 women were identified; two women had 2 synchronous (bilateral) B3a lesions. Out of 34 lesions, 23 were RS and 11 BP. Twenty-nine over 34 (85%) lesions were identified/visible on DBT, corresponding to 20 (69%) RS and 9 BP (31%).

Of 29 lesions, 5 (17%) were assessed as BI-RADS 3 and 24 (83%) as BI-RADS 4.

Of 20 RS, 2 (10%) were classified as BI-RADS 3 and 18 (90%) as BI-RADS 4 (Fig.1). Of 9 BP, 3 (33%) were classified as BI-RADS 3 and 6 (67%) as BI-RADS 4 (Fig.2).

According to final pathologic examination, 4 lesions (corresponding to 2 RS and 2 BP) were malignant (3 low-grade DCIS and 1 intermediate-grade DCIS) and 1 (corresponding to a RS) was atypical (atypical ductal hyperplasia) (Fig.3). Overall underestimation rate was 17%; underestimation rate for RS was 15% and for BP was 22%.

Of 24 lesions assessed as positive at DBT (all BI-RADS 4), 5 (21%) lesions proved malignant (true-positive) at surgical excision, with an overall PPV of 21% [IC 95%: 6.2%-35.8%].

Of 5 lesions assessed as negative at DBT, all resulted to be benign at surgical excision, corresponding to an overall NPV of 100% [IC 95%: 100%].

The PPV and NPV of tomosynthesis for BP group were 33% [IC 95%: 2.3%-63.7%] and 100% [IC 95%: 100%] while for RS group 17% [IC 95%: 0.5%-33.5%] and 100% [IC 95%: 100%].
Fig. 1

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Fig. 2

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Fig. 3

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CONCLUSION:

According to the literature, conservative management options as radiologic follow-up as an alternative to surgical excision should be considered in case of high-risk lesions associated with a low risk of malignancy (B3a lesions). Tomosynthesis is a widely-available, cheap and powerful tool with high NPV in the setting of B3a lesions. If our results will be confirmed in larger study populations, tomosynthesis might be used to safely address patients diagnosed with these lesions to follow-up instead of surgical treatment.
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