Surgical Excision for B3 Breast Lesions Diagnosed by Vacuum-assisted Core Biopsy

S. REEFY[1], H. OSMAN[2], C. CHAO[1], N. PERRY[1] and K. MOKBEL[1,2]

[1]*The London Breast Institute, The Princess Grace Hospital, W1U 5NY, London, U.K.;*
[2]*St. George's University of London, SW17 0QT, Tooting, U.K.*

Abstract. *The aim of this retrospective study was to assess whether open surgical excision is required following a B3 diagnosis on 11-gauge vacuum-assisted core biopsy (VACB) of radiologically indeterminate breast lesions. Patients and Methods: Twenty-four women with a histological diagnosis of the B3 category on VACB of radiologically indeterminate breast lesions were identified over a 3-year period. The VACB procedure was performed under stereotactic (n=21), ultrasound (n=2) or magnetic resonance imaging (MRI) (n=1) guidance using the Suros system. Nineteen patients underwent open surgical excision. The remaining 5 patients who had 'complete' removal of the radiological abnormality using VACB under ultrasound (n=2, papilloma) or stereotactic (n=4, atypical ductal hyperplasia) guidance were followed up clinically and radiologically. Results: The median patient age was 49 years. The disease status in three patients was upgraded to ductal carcinoma in situ at open surgical excision. The VACB showed atypical lobular hyperplasia in these 3 patients, associated with microcalcification (n=2) or mass lesion (n=1). No single case of upgrading to invasive breast cancer was identified in our series. The remaining patients (16 out of 19) had a benign biopsy. The upgrade to malignancy was significantly associated with the presence of atypical lobular hyperplasia, a BI-RADS category of 4 and incomplete removal of the radiological abnormality by VACB. After a mean follow-up of 18 months, no malignancy was detected in the 5 patients who did not undergo open surgical biopsy. Conclusion: Open surgical excision is strongly recommended for atypical lobular hyperplasia identified in VACB specimens. VACB can be a safe alternative to surgery in the treatment of B3 lesions in selected cases, providing thorough multidisciplinary discussion has taken place.*

Correspondence to: Professor K. Mokbel, MS, FRCS, London Breast Institute, The Princess Grace Hospital, 45 Nottingham Place, London W1U 5NY, U.K. E-mail: kefahmokbel@hotmail.com

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The core needle biopsy (CNB) represents an essential component of the triple assessment process of breast lesions. Following a thorough history taking, clinical examination and radiological assessment, the results of fine-needle aspiration cytology (FNAC) and/or CNB help the physician to accurately diagnose and plan management of patients with breast pathology. Indeterminate breast lesions reported as B3 (uncertain malignant potential) or B4 (highly suspicious of malignancy) on automated 14-gauge CNB usually require further evaluation in the form of an open surgical biopsy in order to accurately establish the diagnosis prior to the development of a firm management plan. Such procedures are more expensive and invasive usually involving a hospital admission and general anaesthesia. Labelling a core biopsy as B3 would include the finding of: atypical intraductal epithelial proliferations, lobular neoplasia, radial scar, papillary lesion, fibroepithelial lesion with cellular stroma and/or spindle cell proliferations (1). The recent introduction of vacuum-assisted core biopsy (VACB) technology has enhanced the accuracy of tissue diagnosis of breast lesions (2). This study aimed to determine the need for open surgical biopsy in cases of B3 diagnosis on VACB.

Patients and Methods

We retrospectively reviewed the medical records of 24 women who had an 11-gauge VACB yielding a B3 diagnosis at our centre during 2006-2009. All lesions were screen detected.

Each member of the case series underwent clinical examination, digital mammography and ultrasound scanning of both breasts. The mammographic abnormality was categorised as M3 in 21 patients and M4 in three patients. Nineteen patients underwent open surgical excision following radiological localisation. The remaining 5 patients who had 'complete' removal of the dominant radiological abnormality using VACB under ultrasound (n=2, papillomas) or stereotactic (n=3, atypical ductal hyperplasia) guidance were followed up clinically and radiologically. Microcalcification (MCC) was evident on specimen radiographs and microscopic slides in all cases of mammography MCC undergoing open surgical excision (n=20). All patients included in this study had percutaneous VACB using Suros technology. The demographic data and the histology reports of the VACB of the surgically excised specimens were tested for correlation. For those patients who had a B3 lesion on core

biopsy but had no open surgical excision, the clinical follow-up consultations and subsequent breast imaging were also reviewed. All cases were subjected to a thorough multidisciplinary discussion.

Results

The median patient age was 49 (range=36-70) years. Histological analysis of the surgically excised specimens showed low-grade ductal carcinoma *in situ* (DCIS) of the cribriform type in 3 patients. The VACB in these three patients (aged 46, 50 and 60 years) was reported as showing atypical lobular hyperplasia (ALH). The remaining patients (16 out of 19) had a benign biopsy. The open surgical biopsy in these patients showed benign intraductal papilloma in 2, atypical ductal hyperplasia in 7 and benign MCC without atypia in 7 patients. Five patients were followed up without open surgical intervention. Their VACB showed columnar cell hyperplasia with atypia (n=3), benign papillary proliferation with (n=1) or without atypical (n=1). The radiological abnormality was completely removed in three cases and in one patient the dominant cluster of MCC was completely removed with some traces of less worrying MCC remaining. Their follow-up imaging showed no changes over a mean follow-up period of 18 (range=6-30) months. There was no upgrade of the disease to invasive cancer in any of the 19 patients who had open surgical biopsy.

On reviewing the radiological data of the 24 patients included in this study, we observed that 20 patients had indeterminate MCC on screening mammography and 4 patients had mass lesions on breast imaging. The three patients whose disease was upgraded to DCIS following surgical excision had their mammograms reported as M4, showing suspicious microcalcifications or mass lesion. Furthermore, the VACB showed ALH and the lesion was not completely removed by VACB. The clinical and histological data are summarized in Table I.

Discussion

The current system of core biopsy categorization results in a diversity of lesions predicted to have uncertain malignant potential, reported by the pathologist as B3 lesions, namely, lobular neoplasia, atypical ductal or epithelial proliferation, radial scars and papillary lesions (1). Approximately one third of breast lesions categorised as B3 on automated 14-gauge CNB are subsequently found to be malignant (2). The recent introduction of 9- and 11-gauge VACB systems, which allow a more extensive tissue sampling than automated 14-gauge CNB, has enhanced the accuracy of preoperative tissue diagnosis of breast lesions (3). This method of tissue sampling has significantly reduced the rate of underestimation of malignancy determined by automated 14-gauge CNB. However, a B3 diagnosis with VACB is still commonly encountered. This raises the question whether to suffice with clinical observation or to proceed with open surgical intervention in such cases. It is the current standard of care to proceed to open surgical excision following a B3 diagnosis on core biopsy in order to make a definite diagnosis of benign or malignant lesions. However, several studies have demonstrated that as long as there is no atypia in the VACB, it is safe to follow up patients clinically and radiologically (3). In our series, we observed no single case of upgrade to invasive cancer. Only three patients had DCIS, which was of low-grade nature. A similar study recruiting 47 patients with B3 lesions reported a higher incidence of upgrade to invasive malignancy, with two patients being diagnosed with invasive breast cancer (4.7%). These patients had atypia on VACB and therefore the authors concluded that the use of VACB is safe in B3 lesions with no atypia (4). We observed from our small number of patients who had DCIS at open surgical excision that the BI-RADS category of the mammograms in these patients was M4 as compared to M3 in remaining cases; the VACB showed ALH and the mammographic abnormality was not completely removed by VACB in these cases. The finding of ALH in standard CNB specimens was previously shown to be a strong predictor of malignancy at open biopsy (5). In a study of 97 patients with ALH on standard CNB or VACB who underwent surgical excision, 21 out of 97 (22%) were found to have malignancy (6). This finding led the authors to conclude that B3 lesions associated with ALH diagnosed by standard CNB or VACB should be surgically excised. Our observations are in accordance with those of Eby *et al*. who reported an upgrade rate of 15.6% in a series of 115 lesions showing ALH on VACB (7).

Darling and colleagues showed that for lesions diagnosed initially as ALH (B3), underestimation of DCIS and invasive ductal carcinoma was significantly less frequent using the 11-gauge directional vacuum-assisted biopsy device compared with the 14-gauge directional vacuum-assisted device (19% as opposed to 39%, p=0.025) and with the automated 14-gauge needle (19% as opposed to 44%, p=0.01) (8).

Houssamie *et al*. showed the overall underestimation of CNB was 27.7% [95% confidence interval (95% CI), 24.5-30.9%]. When category-specific rates were used: B3 underestimates were 36.2% (95% CI, 30.6-41.8%); B3 underestimates excluding atypical proliferations were 17.9% (95% CI, 10.8-24.9%); atypical ductal hyperplasia underestimates were 29.0% (95% CI, 21.4-36.6%; upgraded to DCIS) (9). The authors also reported that B3 underestimates did not differ between masses (27.9%) and MCC and were significantly lower for VACB (11-gauge) than for automated CNB (14-gauge; p=0.001). Underestimation rates, when sampling MCC, decreased with increasing number of cores collected, but this was mainly for DCIS underestimates.

In a study from the MD Anderson Cancer Centre in the USA, the authors reported their seven-year experience with

Table I. *Radiological, clinical and histological data of recruited patients.*

Patient	Mammography/ US	Serous biopsy	Excision result	Surgical excision pathology
1	M3	B3 Atypical columnar cell change	Residual calcification	Atypical columnar hyperplasia with benign calcification
2	M3	B3 Atypical columnar cell change	Completely excised	Atypical columnar hyperplasia with benign calcification
3	M3	B3 Atypical intraductal hyperplasia	Completely excised	Atypical columnar hyperplasia with benign calcification
4	M4, suspicious of DCIS	B3 Atypical intraepithelial proliferation	Residual calcification	Atypical columnar hyperplasia with apocrine metaplasia
5	M3	B3 Atypical columnar cell change	Completely excised	Atypical columnar hyperplasia and benign microcalcification
6	M3	B3 Atypical columnar cell change	Completely excised	No surgical excision. Follow-up mammograms showed no recurrence.
7	M3	B3 Atypical ductal hyperplasia	Completely excised	Atypical ductal hyperplasia with benign microcalcification
8	M3	B3 Atypical epithelial hyperplasia	Residual calcification	No surgical excision
9	M3	B3 Atypical lobular hyperplasia		DCIS
10	M3	B3 Atypical epithelial hyperplasia	Completely excised	Atypical intraepithelial hyperplasia with benign calcification
11	M3	B3 Atypical epithelial hyperplasia	Completely excised	Florid epithelial hyperplasia with benign calcification
12	M3	B3 Atypical columnar hyperplasia	Residual atypical calcification	Focal columnar hyperplasia with benign calcification
13	M3/ repeated after the biopsy M1	B3 Atypical ductal hyperplasia	Complete excision	No surgical excision. Follow-up mammograms showed no residual calcification M1
14	M4	B3 Atypical lobular hyperplasia		Extensive fibrocystic change with two foci of low-grade DCIS
15	M4	B3 Atypical columnar cell change	Residual calcification	Residual area remained required wire localization and excision. Benign cystic and columnar cell changes with sclerosing adenosis
16	M3	B3 Atypical epithelial hyperplasia	Residual calcification	Benign microcalcification
17	M3	B3 Ductal papilloma	Complete excision	No surgery (papilloma with no atypia)
18	M4	B3 Atypical lobular hyperplasia		Low-grade DCIS
19	M3, U/S papilloma U2	B3 Ductal papilloma with epithelial hyperplasia	Completely excised	Intraductal papilloma with epithelial hyperplasia
20	Benign micro-calcification M3	B3 Ductal hyperplasia	Residual calcification	Ductal hyperplasia with benign microcalcification
21	? papilloma on MRI scan M3	B3 (Benign ductal papilloma)	Completely excised	Follow-up scans showed no residual lesion
22	M3, U/S papilloma U3	B3 Ductal papilloma with epithelial hyperplasia	Completely excised	Benign papillary hyperplasia
23	U/S papilloma	B3 Ductal papilloma	Completely excised	No surgery. Complete excision by Suros, Follow-up scans showed no residual lesion
24	U/S papilloma	B3 Benign ductal papilloma	Completely excised	No surgery. Complete excision by Suros, Follow-up scans showed no residual lesion

U/S: Ultrasound; DCIS, ductal carcinoma *in situ*.

radial sclerosing lesions, reported as B3 on VACB using Suros technology. They observed no single case of upgrade to malignancy (10). In a series of radial scars diagnosed by standard stereotactic CNB, Cawson *et al*. reported upgrade to malignancy in 5.7% (3 out of 53 cases) of cases (11). In their study, 3 out of 53 patients had DCIS at open surgical biopsy and ADH on CNB. Furthermore, the authors concluded that it was safe to manage such lesions conservatively with clinical and radiological monitoring instead of surgical excision, as long as there was no atypia or DCIS. Similarly, Tennant *et al*. demonstrated that VACB was a safe alternative to surgery in the treatment of breast lesions of uncertain malignant potential (B3), particularly radial scars and papillary lesions in which no atypia was present on automated needle core biopsy (4). The patients who had a B3 diagnosis and were treated conservatively in our series had the radiological abnormality completely removed by VACB in 4 cases (2 cases of atypical columnar cell change, 1 case of atypical papillary proliferation and 1 case of benign papillary hyperplasia) and in the remaining case, the dominant radiological abnormality was completely removed. All patients treated conservatively were subjected to a thorough multidisciplinary discussion. Although we detected no malignancy during clinical and radiological surveillance, our follow-up period is relatively short (mean: 18 months) and a longer period of observation is required. Nevertheless, the risk of progression of such lesions to invasive cancer appears to be exceedingly low (12). However, it is strongly recommended that surgical excision be undertaken in cases of ALH where the risk of upgrade to malignancy seems to be significantly higher (13).

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