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Original article

Outcomes of patients with lobular in situ neoplasia of the breast: The role of vacuum-assisted biopsy

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ABSTRACT

Objectives: To audit the outcomes of patients with non-pleomorphic lobular in situ neoplasia (LISN) of the breast and clarify the role of vacuum-assisted biopsy (VAB), surgical biopsy and conservative management for this condition.

Materials and method: A single-centre retrospective review of hospital databases covering a 14-year period was performed. Patients with LISN as the most pertinent diagnosis on core needle biopsy (CNB), vacuum-assisted biopsy (VABs) or surgical biopsy were identified. The radiological features, histopathological findings and outcome of subsequent annual mammography were recorded.

Results: Between 1998 and 2012 there were 70 patients with LISN as the most pertinent diagnosis at CNB, VAB or surgery. 52 underwent VAB, typically 18 11-gauge samples. The pathology was upgraded from the preceding 14-gauge CNB in 7 cases. Of 11 patients who underwent surgery after VAB, one (who had undergone a low tissue yield VAB) was upgraded. There were no new breast cancers during a mean annual mammographic follow-up period of 53 months in 40 patients who had VAB with complete radiological-histopathological concordance.

Conclusion: Provided there is adequate tissue sampling and radiological-pathological concordance, VAB is a safe alternative to open biopsy in the management of non-pleomorphic LISN.

Introduction

Lobular in situ neoplasia (LISN - also known as lobular neoplasia) is a collective term that encompasses lobular carcinoma in situ (LCIS) and atypical lobular hyperplasia (ALH). With the growing numbers of women undergoing mammographic screening, LISN is encountered with increasing frequency in needle biopsies of the breast. Typically it is an incidental finding on biopsies performed for indeterminate microcalcification. LISN may be multifocal and bilateral, representing a field change. It is, however, often also found in the breast adjacent to an invasive breast cancer, particularly invasive lobular carcinoma (ILC). Newman reported that LCIS was present in 72 of 73 cases of ILC [1]. Because of concerns about sampling error, accepted practice has been to perform an open diagnostic biopsy when LISN is encountered on a needle biopsy in order to exclude associated malignancy.

Vacuum-assisted biopsy (VAB) has been in use in our unit at Royal Bolton Hospital for the last 14 years. It enables a larger volume of tissue to be removed percutaneously than with 14-gauge core needle biopsy (CNB), thus reducing sampling errors which may lead to under-diagnosis of malignancy. It has been used primarily as a second-line technique following 14-gauge CNB, either where the CNB is regarded as inadequate for diagnosis or for the further investigation of lesions categorised pathologically as B3 (lesions of uncertain malignant potential) or, less commonly, B4 (suspicious of malignancy) [2]. Increasingly we have used it in the further investigation of those women who have a B3 diagnosis of LISN on CNB or in cases where VAB has been performed but with a relatively low tissue yield (such as with a 10-gauge Vacora). Our policy has been that if the mammographic abnormality is of low suspicion and the vacuum biopsy is either normal or shows further LISN then, following multidisciplinary team discussion, open biopsy is not performed and the woman is followed up with regular mammography.

This study is an audit of outcomes in patients with LISN managed (1) by VAB with no subsequent surgical biopsy; (2) by surgical biopsy with or without preceding VAB; and (3)

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conservatively with mammographic follow-up following a CNB diagnosis of LISN. The objectives were to assess the role of CNB, VAB and surgical biopsy in the management of LISN. The issues of radiological-pathological concordance and volume of tissue sampled were explored.

Materials and methods

This retrospective single-centre study was registered with the hospital audit department. Ethical approval was not required. Multiple data sources were used to ensure all eligible patients were identified and included. The primary source was the histopathology database which was searched for patients with a diagnosis of lobular carcinoma in situ and/or atypical lobular hyperplasia on CNB, vacuum or surgical biopsy. The breast screening database was searched for B3 diagnoses on core needle biopsy between February 1998 and April 2012 and these were then cross-checked with the pathology database. The records of women under mammographic surveillance for increased breast cancer risk were examined, and finally a cross-check was made with the local database of women registered with the Sloane Project (a UK national audit of screen-detected in situ carcinoma and atypia). Patients whose initial core biopsies contained concurrent invasive carcinoma, ductal carcinoma in situ (DCIS), atypical ductal hyperplasia (ADH) and pleomorphic LCIS were excluded.

For each woman the radiological abnormality along with number of biopsy samples obtained was recorded. Initial biopsy was performed using a 14-gauge Achieve needle (Cardinal Health, Dublin, OH, USA) or 10-gauge Vacora device (Bard Biopsy Systems, Tempe, AZ, USA). Masses were usually biopsied under ultrasound guidance. Microcalcification was biopsied under stereotactic x-ray guidance and calcium retrieval was confirmed with specimen radiography. A marker clip was deployed if the biopsy was anticipated to remove the target lesion.

Following an initial percutaneous needle biopsy diagnosis of LISN, most patients underwent wider sampling with either percutaneous image-guided biopsy or surgical biopsy. Some underwent mammographic surveillance only. Patients were followed up with annual mammography after biopsy.

VAB was performed using an 8 or 11-gauge Mammotome device (Devicor Medical Products, Cincinnati, OH, USA), 7 or 10-gauge EnCor (Bard Biopsy Systems, Tempe, AZ, USA) or 10-gauge Vacora. The devices used and number of samples taken were noted. The study period spans the introduction of VAB to the department. Its increasing utilisation during that period reflects changing multidisciplinary team (MDT) protocols based on increasing evidence and experience with VAB. All cases were discussed at an MDT meeting involving several radiologists, pathologists and surgeons. Sample adequacy, radiological-pathological concordance and subsequent management were determined by MDT agreement. Concordance was defined as a biopsy result that explained the radiological abnormality.

Histopathology results and the presence of radiological-pathological concordance were noted. Details of subsequent radiological surveillance were recorded for patients who did not undergo surgery, and subsequent breast cancer diagnoses and deaths were noted.

Results

70 women with LISN diagnosed between February 1998 and April 2012 were eligible for inclusion. Mean patient age was 55 years (range 42–76). 61 patients were screening cases and 9 symptomatic. The radiological abnormalities comprised 59 cases of microcalcification, 7 masses, 3 masses or densities with microcalcification and 1 deformity. Mean radiological follow up was 39 months (range 0–141 months).

Of these 70 patients, 52 underwent a vacuum biopsy, typically using an 11-gauge Mammotome device. The vacuum devices used for definitive sampling are provided in Table 1. The mean number of vacuum biopsy samples taken was 18 (range 5–30).

Patient group A: patients managed with VAB and radiological follow up ($n = 41$)

41 patients underwent vacuum biopsy of a radiological abnormality, with ($n = 28$) or without ($n = 13$) preceding 14G CNB. Of the 13 patients who had first line VAB, 12 had first line low tissue yield 10G Vacora followed by a second VAB, and one had first line 11G Mammotome taking 12 samples with no further VAB performed. Radiological-pathological concordance was demonstrated in all cases, as detailed in Table 2. The most pertinent pathology demonstrated was LISN. In 9 cases LISN was not present in the definitive VAB; these included 7 cases of M3 calcification (benign calcification, B2), one M3 mass (fibroadenoma, B2) and one M3 mass with calcification (sclerosing adenosis with calcification, B2). These 41 patients did not undergo subsequent surgical biopsy.

Patients were invited for annual mammograms. One patient has not attended for follow up imaging during the 72 months since her diagnosis with LISN. The remaining 40 patients have a mean follow up 53 months (range 12–141 months), during which there were no new diagnoses of breast cancer. Four patients died during follow up; one patient with a previous history of contralateral invasive breast cancer died from metastatic breast cancer 24 months after the diagnosis of LISN and a further three patients died from unrelated causes.

Patient group B: patients managed surgically, with ($n = 11$) or without ($n = 10$) preceding VAB

11 patients with LISN underwent VAB and a subsequent surgical procedure. This comprised three groups of patients: (1) 2 cases where a concordant 14-gauge CNB result was upgraded on subsequent VAB (patients 1 and 2); (2) 6 cases where concordance was first achieved at VAB from which the pathology prompted subsequent surgery (patients 3–8); (3) 3 non-standard cases in whom subsequent open biopsy was also performed (patients 9–11). These included one with comedo necrosis at VAB, one where no microcalcification was retrieved at VAB and one first-line low tissue yield VAB. Further details of these cases are given in Table 3.

Cases 1, 2 and 11 demonstrate that a concordant pathology result can be subsequently upgraded when additional tissue is sampled. Specifically, in case 11 DCIS found at surgery was missed on VAB when 6 samples were taken using a 10-gauge Vacora device, despite seemingly concordant pathology.

10 patients (9 microcalcification, 1 mass) diagnosed with LISN on initial core biopsy underwent subsequent surgical biopsy without preceding VAB (Table 4). Review to establish the reason for proceeding direct to surgical biopsy without VAB revealed papillary fragments on CNB in one patient and comedo necrosis on CNB in

Table 1
Vacuum devices used.

Vacuum device	Probe gauge	Number of patients	Mean number of samples (range)
Vacora	10	5	10 (5–22)
Mammotome	8	7	11 (6–24)
Mammotome	11	38	18 (8–30)
EnCor	7	1	11
EnCor	10	1	18