The role and histological classification of needle core biopsy in comparison with fine needle aspiration cytology in the preoperative assessment of impalpable breast lesions

A E K Ibrahim, A C Bateman, J M Theaker, J L Low, B Addis, P Tidbury, C Rubin, M Briley, G T Royle

Abstract

Aims—To investigate the role of needle core biopsy (NCB) in the preoperative assessment of impalpable breast lesions, mainly derived from the NHS Breast Screening Programme (NHSBSP) and to assess our own modifications to a suggested system for the classification of breast NCBs.

Methods—The NCB, fine needle aspiration cytology (FNAC), and radiology scores from 298 women with non-palpable breast lesions presenting between January 1997 and December 1998, together with the open biopsy results (where available) were collated and analysed.

Results—The mean follow up period was 15.8 months (range, 5–28). The 298 NCB specimens were categorised as follows: unsatisfactory/non-representative (B1; n = 61; 20.5%), benign but uncertain whether representative (B2r; n = 52; 17.4%), benign (B2; n = 103; 34.6%), lesions possibly associated with malignancy but essentially benign (B3a; n = 9; 3.0%), atypical epithelial proliferations (B3b; n = 10; 3.4%), suspicious of malignancy (B4; n = 7; 2.3%), and malignant (B5; n = 56; 18.7%). Excision biopsy was performed in 43 cases within the B1 (n = 19), B2r (n = 8), B2 (n = 8), and the B3a (n = 8; data unavailable in one case) categories, revealing malignancy in 18 (42.8%) cases and in 65 cases within the B3b, B4, and B5 categories, revealing malignancy in 64 cases (98.5%). The sensitivity of NCB for malignancy was 87.7%, with a specificity and positive predictive value of 99.3% and 98.5%, respectively. FNAC had an inadequacy rate of 58.7%, a complete sensitivity of 34.5% and a specificity of 47.6%.

Conclusions—This study confirms the value of NCB in the preoperative assessment of impalpable breast lesions. Two new categories are suggested for the NCB classification; category B2r for benign breast tissue where representativeness is uncertain, and the subdivision of category B3 into B3a for benign lesions potentially associated with malignancy (for example, radial scars and intraduct papillomas) and B3b for more worrisome atypical epithelial proliferations. These will aid the accurate audit of NCB and identify more clearly the intellectual pathway leading to a particular assessment.

Keywords: needle core biopsy; impalpable breast lesions; fine needle aspiration cytology; NHS Breast Screening Programme

Since Bolmgren et al introduced stereotactic needle biopsy of the breast in the late seventies,1 needle core biopsy (NCB) of the breast has become an increasingly important diagnostic tool in the assessment of both palpable and non-palpable breast lesions.2 3 Although there are well established scoring systems for both the radiological and cytological assessment of breast lesions, there is no such established system for reporting breast NCB specimens.1 5

There is controversy in the literature about the role of combining fine needle aspiration cytology (FNAC) and NCB in the assessment of breast lesions. Some studies favour FNAC over NCB as a less expensive, faster, and more sensitive test.6 7 Others criticise the use of FNAC as the only pathological diagnostic test, particularly in the assessment of non-homogeneous microcalcification containing breast lesions,8 as well as the inability of FNAC to distinguish invasive from in situ malignancy.9 10 Some authors recommend combining the two techniques in selected cases.11

In our study, we assessed the combined role of NCB and FNAC in the preoperative assessment of impalpable breast lesions, most of which presented via the National Health Service Breast Screening Programme (NHSBSP). We have also evaluated our own modification of a suggested scoring system for breast NCB.

Patients and methods

Two hundred and ninety five women presenting mainly via the Southampton and Salisbury NHSBSP service between January 1997 and December 1998 with impalpable mammographic abnormalities, and assessed in the Southampton University Hospitals NHS Trust Breast Unit, were included in our study. The techniques used for NCB and FNAC are described below.

FNEE NEEDLE ASPIRATION CYTOLOGY (FNAC)

A breast FNAC was performed by one of two radiologists involved with the study (CR and MB) under ultrasonographic or conventional
We included biopsies showing normal/benign tissue within the B1 category if the biopsy was performed because of atypical features and strongly associated with malignancy, such as atypical ductal hyperplasia (ADH). The breast NCB results were discussed at one or both of two weekly meetings attended by the breast radiologists, the histopathologists, the cytopathologists, and the surgeons. Surgical excision biopsy was performed, where indicated, in a proportion of the cases.

DATA ANALYSIS

The data were entered into a Microsoft Excel® V5.0/95 database and analysed using the SPSS® V6 statistical program and Stata® V 6.0.

To calculate the sensitivity and specificity of breast NCB, the individual cases were categorised into positive and negative groups. Positive breast NCBs were defined as those within the B3b, B4, and B5 categories. The true positive cases were those confirmed as malignant on subsequent open biopsy. Negative breast NCBs were defined as those within the B2r, B2, and B3a categories; false negative breast NCBs were defined as those cases within the B2r, B2, and B3a categories in which malignancy was identified on subsequent excision biopsy.

The complete sensitivity of breast FNAC was defined as the number of cases scored as C3, C4, or C5 expressed as a percentage of the total number of cases subsequently confirmed as malignant on NCB and/or excision biopsy. The specificity of FNAC was defined as the number of correctly identified benign cases (that is, scored as C2) expressed as a percentage of the total number of benign lesions aspirated.

Sensitivity, specificity, and complete sensitivity are all presented together with their respective 95% confidence intervals (CI). Spearman rank correlation coefficients were obtained to assess the strength of the linear association between the breast NCB score and the radiology and cytology scores, respectively.

**Results**

The results from 298 consecutive breast NCBs from 295 women (mean age, 56 years; range, 46–80) were analysed along with the corresponding FNAC, radiological, and excision biopsy data. The mammographic indications for NCB, listed by NCB result category, are shown in Table 2. The mean follow up period was 15.8 months (range, 5–28).

The breast NCB specimens were categorised as follows: unsatisfactory/non-representative (B1; n = 61; 20.5%), benign but uncertain whether representative (B2r; n = 52; 17.4%), benign (B2; n = 103; 34.6%), atypical benign lesions (B3a; n = 9; 3.0%), atypical epithelial proliferations (B3b; n = 10; 3.4%), suspicious of malignancy (B4; n = 7; 2.3%), and malignant (B5; n = 56; 18.7%).

Excision biopsy was performed in 43 cases within the B1–B3a categories (B1, n = 19; B2r, n = 8; B2, n = 8; B3a, n = 8) (data unavailable in one case) because of radiological or cytological concerns, revealing malignancy in 18 cases (table 3). Of these 18 cases, the radio-

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**Table 1** Classification system for the categorisation of breast needle core biopsy (NCB)

<table>
<thead>
<tr>
<th>Biopsy category</th>
<th>Description of NCB</th>
</tr>
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<tbody>
<tr>
<td>B1</td>
<td>Unsatisfactory or normal tissue†</td>
</tr>
<tr>
<td>B2r*</td>
<td>Benign but uncertain whether representative</td>
</tr>
<tr>
<td>B2</td>
<td>Benign representative lesion</td>
</tr>
<tr>
<td>B3a*</td>
<td>Essentially benign lesions that may be associated with malignancy—for example, radial scar/complex sclerosing lesion, intraductal papilloma</td>
</tr>
<tr>
<td>B3b*</td>
<td>Lesions showing atypical features and strongly associated with malignancy, such as atypical ductal hyperplasia (ADH)</td>
</tr>
<tr>
<td>B4</td>
<td>Malignant, but diagnosis cannot be categorically made owing to a technical artefact or the small size of the biopsy</td>
</tr>
<tr>
<td>B5</td>
<td>Malignant, either in situ or invasive</td>
</tr>
</tbody>
</table>

*Our modifications to the suggested classification system from St Bartholomew’s Hospital. The B2r (benign but requires clinical/radiological review) category is an additional category and the B3 category has been subdivided into B3a and B3b.
†We included biopsies showing normal/benign tissue within the B1 category if the biopsy was performed because of atypical features and strongly associated with malignancy, such as atypical ductal hyperplasia (ADH).

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**Table 2** Mammographic indications for breast needle core biopsy by category

<table>
<thead>
<tr>
<th></th>
<th>B1</th>
<th>B2r</th>
<th>B2</th>
<th>B3a</th>
<th>B3b</th>
<th>B4</th>
<th>B5</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microcalcification</td>
<td>49</td>
<td>34</td>
<td>89</td>
<td>3</td>
<td>10</td>
<td>7</td>
<td>42</td>
<td>234 (78.5%)</td>
</tr>
<tr>
<td>Asymmetrical density</td>
<td>5</td>
<td>10</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>9</td>
<td>34 (11.4%)</td>
</tr>
<tr>
<td>Calcified opacity</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>13</td>
<td>13 (4.4%)</td>
</tr>
<tr>
<td>Stellate lesions</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>2 (0.2%)</td>
</tr>
<tr>
<td>Others</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>11</td>
<td>11 (3.7%)</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>52</td>
<td>103</td>
<td>9</td>
<td>10</td>
<td>7</td>
<td>56</td>
<td>298 (100%)</td>
</tr>
</tbody>
</table>
Malignancy was 34.5% (CI, 24.6% to 45.4%), with a specificity of 47.6% (CI, 37.8% to 57.6%) and an inadequacy rate of 58.7%.

Tables 4 and 5 show the association between the breast NCB score and the radiology and cytology, respectively; table 6 shows the association between the radiology and cytology scores. Ignoring all cases in which the NCB score was inadequate (B1 cases), the correlation between the NCB and radiology scores was $r = 0.49$ (n = 237; p < 0.0005). Similarly, ignoring cases with inadequate biopsy or cytology, the correlation between the breast NCB and cytology scores was $r = 0.59$ (n = 102; p < 0.0005). These correlation coefficients demonstrate that there is a moderate association between the breast NCB score and each of the radiology and cytology scores. Ignoring cases with inadequate cytology, the correlation between the cytology and radiology scores was $r = 0.52$ (n = 123; p < 0.0005). This indicates that when an adequate cytology specimen was available, there was a moderate correlation between the cytology and radiology scores.

**Discussion**

We have found the five category classification system for breast NCB to be very useful but have encountered two main drawbacks. First, a considerable proportion of breast NCB specimens show benign changes but the histopathologist cannot be certain whether the tissue is representative of the mammographic lesion. This occurred most frequently in our study when NCBs were performed for microcalcifications but only occasional microcalcifications were identified. However, we also encountered this problem when NCBs were performed for mammographic lesions other than microcalcifications. These NCB specimens could be classified as either B1 (normal/inadequate) or B2 (benign), but we feel that such cases should be highlighted to ensure that the breast team reviews them. Therefore, we have introduced the B2r category for this situation, indicating that benign breast tissue is present but that review is particularly important. Breast NCBs are often obtained in our...
group using a stereotactic method, and therefore one can be relatively confident in such cases that the tissue is truly representative of the mammographic lesion.

The second problem that we encountered was that the B3 group includes a heterogeneous group of breast diseases, some of which are essentially benign, although possibly associated with an increased frequency of malignancy (for example, radial scar and intraduct papilloma). However, also included in the B3 category are atypical epithelial proliferations, which are strongly associated with the presence of malignancy on excision biopsy. This would include the presence on NCB of single ducts containing atypical epithelial proliferation, but in which a firm diagnosis of either atypical ductal hyperplasia or ductal carcinoma in situ was not possible because the extent of the abnormal proliferation could not be assessed from the NCB alone. A review of the literature found 66 cases of “atypical ductal hyperplasia” identified on breast NCBs, which on subsequent excision were diagnosed as ductal carcinoma in situ in 27 cases and invasive ductal carcinoma in seven cases. Other studies have reported the identification of malignancy at open biopsy in 33–88% of cases in which atypia was identified.

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However, our sensitivity for NCB in diagnosing atypical ductal hyperplasia or ductal carcinoma in situ was not possible because the extent of the abnormal proliferation could not be assessed from the NCB alone. A review of the literature found 66 cases of “atypical ductal hyperplasia” identified on breast NCBs, which on subsequent excision were diagnosed as ductal carcinoma in situ in 27 cases and invasive ductal carcinoma in seven cases. Other studies have reported the identification of malignancy at open biopsy in 33–88% of cases in which atypia was identified. However, our sensitivity for NCB in diagnosing atypical ductal hyperplasia or ductal carcinoma in situ was not possible because the extent of the abnormal proliferation could not be assessed from the NCB alone. A review of the literature found 66 cases of “atypical ductal hyperplasia” identified on breast NCBs, which on subsequent excision were diagnosed as ductal carcinoma in situ in 27 cases and invasive ductal carcinoma in seven cases. Other studies have reported the identification of malignancy at open biopsy in 33–88% of cases in which atypia was identified.

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important prognostic factors, essential for planning future treatment. Other studies have suggested that combining the two techniques is particularly important in certain situations—for example, cases of microcalcifications where the differential diagnosis lies between phyllodes tumour and fibroadenoma, because FNAC is unable to distinguish phyllodes tumours from fibroadenoma. However, we believe that phyllodes tumours at the benign end of the spectrum cannot be reliably distinguished from cellular fibroadenomas using breast FNAC or NCB, and therefore recommend excision biopsy in this situation.

In conclusion, our study highlights the importance of a multidisciplinary approach in the preoperative assessment of impalpable breast lesions. We have also suggested two modifications to an otherwise very useful classification system for breast NCBs. We fully accept that the clinical decision facilitated by breast NCB in these patients relates solely to their further management and, in particular, to whether a mammographic abnormality requires surgical excision. However, we believe that it is essential that the intellectual pathway leading to patient management decisions is clearly identifiable, particularly for audit purposes, and hope that our refinements to the classification system will enable this to be achieved with greater accuracy.

We are very grateful to Dr C Wells for supplying the breast NCB classification system upon which much of this study was based.