National survey of B1 and B2 reporting of breast needle core biopsies

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ABSTRACT

Aim This survey investigated the variation in the use of the breast core biopsy categories B1 normal and B2 benign.

Method A survey with case scenarios was circulated to 701 breast pathologists in the UK.

Results The response rate was 40%. If there was concordance between the radiological and histological findings, then there was a clear consensus on the appropriate B category. However, if there was discordance between the radiological and histological findings, then frequently there was poor agreement on the appropriate category. Analysis of these cases and supplementary questions on the criteria used to make a pathological categorisation showed that some pathologists are influenced by the radiological features or by the multidisciplinary discussion, rather than just using the histological features.

Conclusions This survey shows that pathologists frequently do not follow the National Health Service breast screening guideline that B categories should be based solely on the histological changes.

INTRODUCTION

The National Health Service Breast Screening Programme (NHSBSP) uses five diagnostic categories for needle core biopsies: B1 normal, B2 benign, B3 benign of uncertain malignant potential, B4 suspicious of malignancy and B5 malignant, which is subdivided into B5a for ductal carcinoma in situ and B5b for invasive malignancy.[1] These categories are also recommended for symptomatic lesions.[1] High levels of diagnostic accuracy can be achieved using the triple approach which combines clinical and radiological findings with core biopsy diagnosis.

The NHSBSP guidelines state that the B category should be solely based on the histological features.[1] B1 categorisation "indicates a core of normal tissue whether or not breast parenchymal structures are present. Normal histology may indicate that the lesion has not been sampled." However, "in the case of certain benign lesions, such as hamartomas and lipomas, apparently normal histological features would be expected on core biopsy. Cores with B1 diagnoses may contain microcalcification, for example within involutional lobules. A core is classified as B2 when it contains a benign abnormality … including fibroadenomas, fibrocystic changes, sclerosing adenosis, duct ectasia … abscesses [or] necrosis. In some cases, it may be difficult to determine whether a specific lesion is present, for example if minor fibrocystic changes are seen. It may be appropriate and prudent to classify the lesion as B1, rather than B2, if only very minor changes are present." The judgement of the adequacy of needle biopsy sampling of an imaging-detected lesion should be made by multidisciplinary meeting (MDM) discussion.[1]

The stimulus for this survey was an earlier unpublished survey in the West Midlands region, which showed a wide variation in the proportion of core biopsies reported as B1 or B2. There was evidence that the national guidelines were not always being followed. Some pathologists preferred to use a combined B1/B2 category and some either tried to provide a multidisciplinary opinion before the MDM or changed the B code after the MDM instead of just reporting the histopathology.

The aim of this survey was to assess the way the B1 and B2 categories are used in a larger sample.

METHOD

A questionnaire was drawn up based on clinicopathological scenarios. The link to the questionnaire was circulated to all known breast pathologists in each region by the regional quality assurance reference centres for the NHSBSP. For each scenario, the pathologist was asked to categorise the core biopsy as B1 normal, B2 benign or 'would prefer to use B1/B2'. There was also a box for comments. There were supplementary questions on the criteria used to make a B classification.

RESULTS

A 40% response rate was obtained (279 of 701 known breast pathologists). Fourteen respondents (5%) were monospecialists reporting breast specimens only, 93 (33%) were subspecialists (reporting specimens from two to four cancer sites), 94 (34%) were generalists with a special interest in breast cancer and 77 (28%) were generalists who also report breast specimens. Most pathologists reported specimens from both screening and symptomatic patients (249, 89%) with smaller numbers reporting symptomatic cases only (29, 10%) or screening cases only (1). Most respondents were from England (242, 87%) with few from Scotland (12), Wales (7), Northern Ireland (9) or the Republic of Ireland (8). Almost all reported both surgical and core biopsy specimens and participated in the NHSBSP pathology external quality assurance scheme (97% for both).

The responses to clinical scenarios and the supplementary questions are summarised in tables 1 and 2.

DISCUSSION

The guidelines for non-operative diagnostic procedures and reporting in breast cancer screening give details of how the B core biopsy categories should be used: "These categories are designed to take account purely of the histological nature of the

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Table 1 Responses to the clinical scenarios

Responses—number (%) Question	B1	B2	Prefer B1/B2	Comments, number of responses
1. Core biopsies taken for investigation of a screen-detected abnormality in a 60-year-old woman. Mass on mammogram and ultrasound. Imaging suspect—R3. On histology, unremarkable breast ducts and lobules, with mild stromal fibrosis only. No microcalcification	216 (81%)	12 (4%)	39 (15%)	Does biopsy explain mass? 12 Need MDT discussion 37 Histology does not explain mass 15 Need rebiopsy 7 Need levels 4 Depends on radiology 6
2. Biopsies done for calcification seen on mammogram. On histology, unremarkable breast ducts and lobules, with a mild stromal fibrosis only. No microcalcification	259 (96%)	4 (1.5%)	6 (2.2%)	No calcification 32 Was calcification in specimen X-ray? 13 Need levels 9 Need MDT discussion 9 Repeat biopsy 2 X-ray blocks 3
3. Biopsies done for calcification seen on mammogram. On histology, unremarkable breast ducts and lobules, with a mild stromal fibrosis. Microcalcification present in stromal fibrosis	30 (11%)	202 (76%)	35 (13%)	Need MDT discussion 48 B2 if calcification representative 8 Calcification is not normal—B2 1 Correlate with specimen X-ray 4 Check size of calcification 5
4. Biopsies done for calcification seen on mammogram. On histology, fibrocystic change, with fibrosis, cysts and apocrine change is seen throughout the cores, together with some sclerosing adenosis that has associated microcalcification	3 (1%)	259 (97%)	6 (2%)	Need MDT discussion 28 Check size of calcification 5 Check specimen X-ray has calcs 2 Check calcs in block X-ray 1
5. Biopsies done for calcification that is highly suspect of malignancy seen on mammogram. Histology shows fibrocystic change, with fibrosis, cysts and apocrine change	34 (13%)	179 (68%)	52 (20%)	Need MDT discussion 89 Biopsy may not be representative 47 Repeat biopsy 32 Need levels 5 Check size of calcification 4 B category depends on radiology 10 B1 as not representative 2
6. Biopsies done for a vague mass seen on mammogram. Histology shows mostly normal/mild fibrosis, with one small cyst in one core. No microcalcification	107 (40%)	81 (31%)	77 (29%)	Need MDT discussion 46 B category depends on MDT 22 Biopsy may not be representative 6 Repeat biopsy 1 Need levels 1
7. Biopsies done for calcification seen on mammogram. Histology shows prominent fibrocystic change, with fibrosis, cysts and apocrine change throughout the cores. However, no microcalcification is seen	163 (61%)	75 (28%)	28 (11%)	Need MDT discussion 27 No calcification in biopsy 56 Check calcs in block X-ray 16 Need rebiopsy 11 B1 if no calcification in biopsy 11 Polarise to look for Wedelite 3 X-ray the block 1
8. Biopsies done for a well-defined mass on mammogram and ultrasound. Cores show a fibroadenoma	0	268 (100%)	0	Need MDT discussion 4
9. Biopsies done for a spiculate mass seen on mammogram, highly suspect of a cancer. Cores show prominent fibrocystic change, with fibrosis, cysts and apocrine change	84 (32%)	141 (53%)	41 (15%)	Need MDT discussion 74 Biopsy may not be representative 65 Need repeat biopsy 25 Need levels 4 B1 as not representative 3 B2 if representative 1
10. Biopsies done for a parenchymal deformity on mammogram, suspect of radial scar. Cores show fibrocystic change	58 (22%)	164 (62%)	44 (17%)	Need MDT discussion 42 Biopsy may not be representative 21 Need repeat biopsy 9 Need levels 4 B1 as not representative 2 B2 if representative 1 Depends on the degree of fibrocystic change 2
11. Biopsies done for a lesion, clinically and radiologically suggestive of a lipoma. Cores show mature adipose tissue only	74 (28%)	147 (55%)	45 (17%)	Need MDT discussion 19 Consistent with a lipoma 45 B2 if representative 8 Lipoma cannot be diagnosed on core 2 B classification irrelevant 2

Percentages are rounded so do not always add up to 100%.
Calcs, calcifications MDT, multidisciplinary team.

specimen and not the clinical or imaging characteristics. Similarly, it is not feasible for pathology interpretation to judge independently whether a sample is adequate from the mammographic lesion. This judgement requires multidisciplinary discussion."[1] This survey shows that many pathologists do not follow this guidance.

Table 2 Responses to supplementary questions

Question	Response	
	Yes	No
Would your reply to any of the above case scenarios depend on any other factors?	212 (79%)	55 (21%)
If yes, tick all that apply		
Degree of radiological certainty in sampling/clinical certainty	165 (79%)	
Quality of biopsy	152 (73%)	
Discussion at MDM/triple assessment	188 (90%)	
Is there consistency between pathologists reporting in your department?		
Always	23 (9%)	
Usually	228 (86%)	
Sometimes	11 (4%)	
Not often	2 (0.8%)	
What criteria do you usually use to report WBN biopsies?		
Report the pathology and categorise strictly according to the pathology guidelines	127 (48%)	
Adapt guidelines to suit personal/local team preference and practice	22 (8%)	
Categorise biopsies taking clinical and radiological factors into account	99 (37%)	
Categorise biopsies following MDM triple assessment	17 (6%)	
Do you change the pathology category as a result of discussions at the MDM?		
Never	65 (25%)	
Rarely (once or twice/month)	179 (68%)	
Sometimes (once a week)	16 (6%)	
Often (more than once/week)	2 (0.8%)	
If you change the pathology category following MDM discussion, do you record the pre-MDM and post-MDM categories in the pathology report?		
Yes—record both pre-MDM and post-MDM categories	177 (68%)	
Yes—record post-MDM categories only	12 (5%)	
No—keep original	15 (6%)	
Not applicable	56 (22%)	
If you change the pathology category following MDM discussion, do you record the pre-MDM and post-MDM categories in the MDM minutes/patient notes?		
Yes—record both pre-MDM and post-MDM categories	75 (29%)	
Yes—record post-MDM categories only	21 (8%)	
No—keep original	2 (0.8%)	
Don't know/can't say	106 (41%)	
Not applicable	57 (22%)	

MDM, multidisciplinary meeting; WBN, wide bore needle.

Where there was concordance between the radiological features and pathological findings, there was unanimity (case 8) or near unanimity (case 4) of B category.

Where there was discordance between the radiological and pathological findings, the B category was frequently not consistent with the pathological diagnosis. Case 5 had mammographically suspicious calcification and core biopsy showed fibrocystic change, but only 68% used the recommended B2 category. Case 2 was biopsied for calcification, but the core biopsy showed normal breast tissue with no calcification and 96% appropriately classified this as B1 normal. However, case 3 with the same radiological scenario and core biopsy showing normal tissue, but with calcification, was called B2 benign by 76% suggesting that the fact that calcification was present in the core biopsy resulted in a change in classification. Case 7 was also biopsied for calcification and the core biopsy showed fibrocystic change without calcification. Despite the presence of a benign pathological diagnosis, only 28% used the B2 category. Similarly in cases 9 and 10, despite the presence of a benign pathological diagnosis, B1 was frequently used, probably because the pathology may not explain the radiological features.

Case 11 was radiologically and clinically suggestive of a lipoma. The core biopsy showed adipose tissue, which may be normal breast tissue and is also consistent with a lipoma. The split between B1 (28%) and B2 (55%) is understandable, but according to the guidelines B1 should be used and the multidisciplinary team (MDT) should then apply the triple approach.

The supplementary questions show that pathologists frequently categorise biopsies taking clinical and radiological factors into account, in particular being influenced by the degree of radiological certainty in sampling the lesions. The discussion at the MDM also influences some pathologists and some teams change the diagnostic category after this discussion. A few pathologists adapt the guidelines to suit personal or local team preference and practice. The responses to these supplementary questions support the impression gained in analysing the responses to the clinical scenarios that many pathologists do not follow the guidance that the B category should be based solely on the pathological findings. In particular, the B1 category is sometimes used if the biopsy may not explain the radiological findings even if there are features of a benign diagnosis present.

The B1/B2 category is not an official category, but this survey shows that many pathologists would like to use it. This preference was seen in pathologists from all four degrees of specialisation. It is difficult to know whether the B1/B2 category is used in routine practice as it is not an option when entering data onto the National Breast Screening System computer. The use of the B1/B2 category is not advocated.

Complete unanimity of categorisation of core biopsies is clearly impossible. In particular, there is a degree of subjectivity

over whether a minor degree of fibrocystic change or changes raising the possibility of a sclerosed fibroadenoma are better categorised as B1 or B2.[2]

There is evidence of wide variation in the frequency of B1 and B2 categories in routine breast screening. The rate of B1 varied from 0.4% to 17% and B2 from 26% to 57% in different breast screening units in England.[3] Similar variation is seen for individual pathologists (B1 from 1.3% to 18% and B2 from 26% to 53% for pathologists reporting at least 100 core biopsies).[4] Clearly, the pathologist is not the only contributor to this variation. Other factors such as the accuracy of radiological sampling are also important. Nevertheless, this survey shows a range of approaches to using the B1 and B2 categories consistent with differences between pathologists contributing to the variation in B1 and B2 rates.

Full specificity is one of the measures used to assess the quality of performance of breast screening. It is the number of correctly identified benign lesions (the number of B2 results minus the number of false negatives) expressed as a percentage of the total number of benign lesions biopsied. It assumes that lesions that are called B1 or B3 on core biopsy, but that are not excised, are benign. The full specificity is related to the proportion of biopsies that are categorised as B1 and B2. A low B1 rate is associated with a higher full specificity.[4] Conversely, a high B1 reporting rate results in a unit failing to meet the target for specificity.

More importantly, an inappropriate use of B1 and B2 categories can have a negative impact on patients. If the pathologist categorises minimal changes as B2, this may give false reassurance to the MDT. The MDT may then decide not to investigate the lesion further, when further investigation should have been performed. We are aware of examples resulting in missed cancers: one centre, when audited, had a very low rate of B1 diagnosis and also had a very high rate of missed cancers. There are data from the NHSBSP which show that the frequency of B1 or B2 core biopsies from cancers has reduced with time.[5 6] A review of such cases from one region did not show that the misclassification of normal biopsies as B2 contributed, but only 14 cases were studied.[6] Other contributory causes of core biopsy not detecting carcinoma include a failure to appreciate radiological–pathological discordance and occasionally the pathologist failing to identify a risk lesion or a carcinoma.[7 8] We have found no study looking at the role of misclassifying core biopsies as B2 rather than B1.

The NHSBSP is revising the methodology for auditing potential false-negative assessments which have preceded cancers presenting as either an interval cancer (between screening episodes) or a screen-detected cancer at the following screening episode. A detailed investigation of the assessment process and resulting outcomes (including pathology review and the MDT discussion) will help to reduce harm where operator and/or pathology performance have failed to adhere to national guidance. An improved understanding and dissemination of the expected rates of false-negative assessment will help the NHSBSP to reduce the incidence of false negatives in the programme. The National Pathology Audit reported only 104 cases as B1 or B2 of 49 983 cancers.[5] The MDM decision was that radiological or clinical features were sufficiently suspicious for these cases to proceed to surgical biopsy where malignancy was confirmed.

In conclusion, this survey shows that there is a variation in the use of B1 and B2 categories. Some pathologists are influenced by whether they consider a lesion has been adequately sampled when assigning a B category. The guidelines state that the pathologist should make a diagnosis based on the histological features. The pathologist should comment on whether calcification is present and what the calcification is associated with, if the biopsy was taken for calcification. Similarly, if the biopsy is targeting a mass or distortion, it is reasonable for the pathologist to comment if the pathological changes may not explain the radiological findings. Nevertheless, the MDM should make the judgement on whether the biopsy adequately sampled the lesion.

Take home messages

- The breast screening guidelines state that core biopsy diagnosis should be based solely on the histological features.
- The guidelines also state that the multidisciplinary meeting should decide whether a lesion has been adequately sampled.
- This survey shows that some pathologists when choosing the diagnostic category are influenced by the clinical or radiological features, in particular by whether they consider a lesion has been adequately sampled.

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