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# Screen-detected malignant breast lesions diagnosed following benign (B2) or normal (B1) needle core biopsy diagnoses

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ARTICLE INFO

*Article history:*
Received 17 December 2009
Received in revised form 26 February 2010
Accepted 22 March 2010
Available online 12 April 2010

*Keywords:*
Screen detected breast lesions
Needle core biopsy
False-negative cores

ABSTRACT

Breast needle core biopsy (NCB) is now a standard diagnostic procedure in the triple assessment of screen detected breast lesions. However, unlike fine needle aspiration (FNA) cytology, information on the miss rate including false-negative diagnoses (FN) of malignancy (benign 'B2' or normal 'B1' NCB with a malignant outcome) is limited.

*Methods:* A large series of NCBs (121, 742) performed over a 8-year period has been studied to assess the frequency and causes of missing a malignant diagnosis on NCB and to evaluate their impact on patients' management in the screening service.

*Results:* During the period of this study, 50,691 were diagnosed as B2 and 9599 were diagnosed as B1. Out of those, 779 B2 and 919 B1 were diagnosed as malignant on subsequent surgical specimens respectively giving a FN rate of 3.0%. However when year of diagnosis was taken into consideration, we found that during the period 1999–2001, the FN rate for B2 was 2.7% while the miss rate for B1 was 4.0%. This showed marked improvement over time to reach a figure of 0.5% and 0.5% for B2 and B1 respectively during the period 2005–2007. On detailed review of cases from a single screening region diagnosed during the last 3 years (2005–2008), 14 cases (0.17% of all NCBs) with malignant surgery were diagnosed as B2 (seven cases; FN rate 0.19%) and B1 (seven cases; B1 biopsy rate from cancer 0.19%). In these cases, NCB was unsatisfactory, there was a discrepancy between radiological abnormalities and histological findings with recommendation for excision or suspicious/malignant cytological diagnosis on concurrent FNA material. Therefore, our results indicate that the malignancy miss rate on NCB is rare and FN NCB diagnoses had no impact on patient management.

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## 1. Introduction

Preoperative diagnosis in breast cancer screening is achieved using triple assessment involving multidisciplinary cooperation between radiologists, surgeons, and pathologists. Preoperative pathological diagnosis is made using fine needle aspiration cytology (FNA) or needle core biopsy (NCB). NCB is now considered as the method of choice for the triple assessment and has contributed to an increase of the preoperative diagnosis rate in screen detected breast cancers.[1–3]

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doi:10.1016/j.ejca.2010.03.024

In previous studies, we have demonstrated that the performance of NCB has markedly improved over time and the recent figures showed high measures of performance[4] and that false-positive NCB diagnosis is very rare.[5] In this study, we have examined a large series of NCB of screen detected breast lesions from all screening units in the United Kingdom. In addition, detailed data related to benign/normal NCB diagnoses with a malignant outcome were collected from the East Midlands region, United Kingdom. We aimed to provide data on the frequency, causes, conditions and pitfalls resulting in false-negative or inadequate NCB diagnoses in screening practice and to assess their impact, on breast screening programmes.

## 2. Patients and methods

This is a retrospective study of all women who attended following invitation for breast screening at one of 96 screening services in the United Kingdom between 1st April 1999 and 31st March 2007. During this period, 121,742 women (1.47% of screened) underwent assessment with needle core biopsy (NCB) procedure. Criteria for performing NCB were nearly always mammographic findings which were not definitely benign following further imaging (extra views and ultrasound). A small proportion (<1%) were performed as a consequence of the patient reporting a physical finding or a radiographer detecting a physical abnormality during mammography. All patients diagnosed on NCB were discussed at a multidisciplinary meeting with a breast radiologist, histopathologist and surgeon present and a decision for further action was made.

NCB results were categorised according to United Kingdom guidelines.[6] B1 = normal, B2 = benign, B3 = lesion of uncertain malignant potential, B4 = suspicious of malignancy, B5 = malignant (B5a = *in situ* malignancy, B5b = invasive malignancy, B5c = malignant [*in situ*/invasive status cannot be assessed). Outcomes were determined as malignant (*in situ* and invasive) or benign lesions. False-negative NCB is defined as a case that was given a B2 result and which turns out at open surgery to be a malignant lesion (*in situ* and/or invasive). False-negative rate is defined as the number of false negative results (malignant outcome after a B2 diagnosis) expressed as a percentage of the total number of carcinomas sampled. Inadequate rate is defined as the number of B1 expressed as a percentage of the total number of NCB sampled. B1 core biopsy rate from cancers is defined as the number of cases with malignant outcome after a B1 diagnosis expressed as a percentage of the total number of carcinomas sampled. Core biopsy miss rate from cancers is defined as the sum of false negative rate and B1 core biopsy rate from cancers.[6] Analysis of the results was performed in accordance with the standards specified in the National Health Service Breast Screening Programme (NHSBSP) Publication and European Guideline.[6,7]

In this study, NCBs were identified from the NHSBSP national computer system which records data from all screening units throughout the United Kingdom. Detailed data related to the B1 and B2 cases with a malignant outcome diagnosed in the East Midlands region in the last 3 years (from 1st April 2005 to 31st March 2008) were collected. These included screening rounds, radiological appearances, radiological opinion, ultrasound opinion, clinical opinion, mammographic and clinical lesions size, type of non-operative and operative procedures, number of NCB attempts and the final histological diagnoses.

In addition, data on breast cancers that developed within 36 months following negative screening results (interval cancers) were collected from the East Midlands region over a period of 3 years (from 1st April 1999 to 31st March 2002). These included breast cancers developing after B1/B2 NCB diagnoses (total 2305 cases) and those developing after negative mammographic screening results (total 321,778 women who did not undergo any further assessment) as a control group.

## 3. Results

From 1999 to 2007, 8,289,216 women were screened. Of those, 395,837 were referred for assessment (4.77%). Of the referred cases, 121,742 women were assessed using needle core biopsy (NCB) (1.47% of screened and 30.75% of referred women). This resulted in the diagnosis of 55,757 breast cancers based on surgical histological examination (0.7% of screened women; 45.8% of women assessed with NCB) including 43,023 invasive and 12,734 *in situ* carcinomas while 57,743 women were discharged without further surgical procedures. During the period of this study, 50,691 (41.6%) were diagnosed as benign (B2) and 9599 (7.9%) were reported as normal (B1) (Table 1).

In this study, 779 of B2 (1.54%, 95% confidence interval (CI) = 1.43–1.65%) and 919 of B1 (9.57%, 95% CI = 9.00–10.18%) were malignant on the subsequent surgical excision histology ($p < 0.001$). These resulted in a false-negative rate of 1.40% (95% CI = 1.30–1.50%) and B1 miss rate from cancers of 1.65% (95% CI = 1.54–1.76%) (Table 1). However when we analysed these cases taking year of diagnosis into consideration, we

**Table 1 – Outcome of benign (B2) and normal (B1) core biopsy diagnoses during the period of the study (1999–2007) and during the first and last 2 years.**

| Diagnosis | 1999–2007 | | | 1999–2001 | | | 2005–2007 | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total No | B1 | B2 | Total No | B1 | B2 | Total No | B1 | B2 |
| Total malignant | 55,757 | 919 | 779 | 10,352 | 419 | 288 | 12,434 | 58 | 57 |
| Invasive | 43,023 | 529 | 435 | 7886 | 233 | 156 | 9672 | 39 | 29 |
| Non-invasive | 12,659 | 389 | 344 | 2778 | 186 | 132 | 2749 | 19 | 28 |
| Total benign | 8242 | 1307 | 2164 | 2327 | 457 | 720 | 1317 | 83 | 205 |
| No histology | 57,743 | 7373 | 47,748 | 9444 | 1570 | 8501 | 11,204 | 1352 | 10,466 |
| Total B results | 121,742 | 9599 | 50,691 | 22,123 | 2446 | 9509 | 24,955 | 1624 | 10,728 |

found that during the first 2 years of this study (1999–2001), the false negative rate was 2.78% and B1 rate was 4.04%. This showed marked improvement over time to reach a figure of 0.45% and 0.46% for false-negative rate and B1 rate respectively during the last 2 years (2005–2007) (Table 1). Interestingly, we also noted firstly that, the benign open biopsy rate decreased from 7.57% to 1.91% after B2 NCB (number of benign open biopsies after B2 NCB diagnoses/total number of B2) ($p < 0.001$) and from 18.68% to 5.11% after B1 diagnoses ($p < 0.001$). Secondly, the proportion of cases diagnosed as B1 decreased from 11.05% to 6.50% while no changes were noted in the proportion of B2 cases during the same time periods.

These data were collected from the computer database with the possibility of incorrect input for inclusion as false-negative NCB, sampling of different lesions, lesions removed by mammotome excision or lesions diagnosed by fine need cytology before surgical intervention. Therefore, we reviewed all cases diagnosed as false-negative or B1 core biopsy rate from cancers that were reported in the East Midlands region during the last 3 years (2005–2008).

**Table 2 – Characteristics of false-negative and B1 rate needle core biopsies (NCB) (14 cases) diagnosed in the East Midland region (2005–2007).**

| | Preoperative imaging | Lesion | FNA | NCB | Comments | Final outcome |
|---|---|---|---|---|---|---|
| 1 | R5, U5 | Mass | C5 | B1 | Normal breast tissue | DCIS and NST (38 mm) |
| 2 | R4, U5 | Mass | C5 | B1 | Normal breast tissue | DCIS and NST (17 mm) |
| 3 | R5 | Mass | C5 | B1 | Normal breast tissue | DCIS and NST (31 mm) |
| 4 | R1, U2 | Mass | C3/4 | B1 | Tiny fragment | DCIS (50 mm) plus 2 mm NST |
| 5 | R5, U5 | Mass/deformity | C2 | B2 | Columnar cell change. There was radiological–pathological discrepancy discovered at MDT and NCB was repeated and the later was reported as B1 | Invasive lobular carcinoma (18 mm) plus DCIS and LCIS |
| 6 | R4, U5 | – | C5 | B2 | Mentioned in report that it is not representative of the lesion | DCIS and NST (10 mm) |
| 7 | R3/4 | – | ? | B2 | No description | DCIS (low grade) and 9 mm tubular carcinoma |
| 8 | R3, U3 | Cystic lesion with solid component | C5 | B2 | No description | DCIS (12 mm) and NST (2 mm) |
| 9 | R2, U2 | Circumscribed lesion (?LN) | – | B2 | Reported as papillary lesion coded as B2 but excision was recommended in the report | Encysted papillary carcinoma |
| 10 | R5, U5 | Speculate mass | – | B2 | Coded as B2 but it was mentioned in the report that discrepancy exists between imaging and histology | DCIS (20 mm) and NST (1 mm) |
| 11 | R4, U4 | Calcification and deformity | – | B2 | Benign calcification was seen so, it was coded as B2 (if this is a representative sample) | Benign lesions plus DCIS (10 mm) |
| 12 | R2, U3 | Well-defined cystic lesion with solid component. ?intracystic papilloma. | – | B1 | NCB showed cyst lined by apocrine epithelium. It was coded as benign but excision is recommended if suspicion persists. During MDT, radiological diagnosis was upgraded to R3 and further levels of NCB indicated papillary lesion and NCB was re-reported as B3. | Encysted papillary carcinoma |
| 13 | R2 | Microcalcification | – | B1 | Crushed cores | DCIS (30 mm) |
| 14 | R5 | Mass | – | B1 | Normal breast tissue | DCIS (3 mm) and NST (5 mm) |

R, mammography; U, ultrasound; C, fine needle aspiration cytology when performed; DCIS, ductal carcinoma *in situ*; NST, invasive carcinoma of no special type; ?, details not available; –, not performed; MDT, multidisciplinary team meeting.

Our results showed that out of 8021 NCB, 7 lesions with a diagnosis of B2 and 7 with B1 were later diagnosed as malignant on open histology (10 invasive and 4 *in situ*); giving a false-negative rate of 0.19% and B1 miss rate of 0.19%. Details of these cases are shown in Table 2. Interestingly, eight cases (Table 2 cases 1–8) were diagnosed in a single unit and both fine needle cytology and NCB were carried out simultaneously. Six cases were diagnosed as malignant or suspicious on the accompanying cytological material.

Of the seven cases reported as benign (B2), it was mentioned in the report that NCB is not representative of the lesion or discrepancy between histology and radiology exists (four cases), the diagnosis was changed to B1 at the multidisciplinary meeting (one case) and one case of papillary lesion was reported as B2 but excision was advised. In the last case, no data was available but it was discussed at the multidisciplinary meeting and a decision for surgical procedure was carried out. Therefore, in this series of 8021 NCB diagnosed in the last 3 years, no impact on patient management resulted from a false-negative diagnosis. The diagnosis was not delayed in any of these cases because they were at least, 'suspicious' for malignancy on radiological studies (R5/US5 in seven cases, R4/US4 in two and R3/US3 in two cases), discrepancy between radiological and histological features was apparent, NCB were unsatisfactory and all these cases were discussed at the multidisciplinary meetings.

In this study, we assessed the number of women with B1/B2 diagnoses who developed breast cancers within the subsequent 3 years (true false negatives) and compared them to women with negative screening mammography (returned to routine recall without further assessment) who developed cancers during the same time period and diagnosed in the same screening region. Our results showed that out of 2305 women diagnosed with B1/B2 NCB, 47 developed cancers (2.04%) compared to 2540 cancers developed in 321,778 women with previous negative mammographic results (0.79%). This difference (1.25%, 95% CI = 0.65–1.85) was statistically significant ($p < 0.001$, Hazard ratio = 2.5, 95% CI = 1.6–4.1) (Table 3). However, in this study, 13 of the 47 cancers were detected on the subsequent screening rounds and therefore, the total number of interval cancers after B1/B2 NCB diagnoses could be considered as 34 tumours giving a percentage of 1.47% of all B1/B2 diagnoses that was not followed by subsequent excision histology.

## 4. Discussion

The performance of FNA in breast screening has been previously assessed and frequency, pitfalls and conditions resulting in a false-negative or inadequate cytology diagnosis have been thoroughly evaluated.[6,8–10] FNA false-negative results have shown variable rates from around 20% particularly in old reports[11,12] to around 5% in recent studies.[13–15] However, data on the frequency, causes and impact of false-negative NCB diagnosis or inadequate/normal diagnosis of malignant lesions are limited.

Therefore, in this study, we have included a consecutive series of NCB cases over a 8-year period of all subjects who attended any of the screening units in the United Kingdom following invitation from the NHSBSP. All these units follow the same protocols for reporting of NCB in a standardised fashion, providing uniform data on NCB performance in the screening setting and follow the United Kingdom published guidelines for reporting and coding NCB results.[6] To our knowledge, this study is the first to report on the false-negative NCB of screen detected breast lesions. Our results showed that 1.54% and 9.57% of NCB diagnosed as benign (B2) or normal (B1) were malignant on subsequent surgical specimens respectively and the difference was significant. The false-negative (FN) rate was 1.4% and B1 miss rate from cancer was 1.6%; giving a total miss rate (B1 + B2 from cancer) of 3.0%.

However when year of diagnosis was taking into consideration, our results showed improvement in the performance with a significant reduction of FN rate and B1 core biopsy rate from cancer when comparing the first 2 years to the last 2 years of this national study., The miss rate (B1 + B2 from cancer) in the last 2 years was 0.9%. This improvement in NCB performance over the most recent years could be related to improved experience of both radiologists and pathologists, using wider core needles and more interaction between radi-

**Table 3 – Interval cancers detected in women screened between 1999 and 2002 with a benign/normal needle core biopsy diagnoses (B1/B2) as the most significant result compared to interval cancers developed in women screened during the same period without assessment (routine recall (RR)) during a period of less than 37 months following screening.**

| Units | Total screened | Women screened without assessment (RR) | | | | Women screened with B1/B2 diagnoses as the most significant results | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Total IC | Total SD | Total cancers | Rate/1000 | B1/B2 | Total IC | Total SD | Total cancers | Rate/1000 |
| 1 | 22,173 | 85 | 107 | 192 | 8.7 | 195 | 4 | 0 | 4 | 20.5 |
| 2 | 47,279 | 218 | 87 | 305 | 6.5 | 406 | 8 | 1 | 9 | 22.2 |
| 3 | 28,837 | 124 | 103 | 227 | 7.9 | 364 | 3 | 2 | 5 | 13.7 |
| 4 | 48,463 | 169 | 254 | 423 | 8.7 | 263 | 8 | 2 | 10 | 38.0 |
| 5 | 24,572 | 101 | 127 | 228 | 9.3 | 227 | 1 | 2 | 3 | 13.2 |
| 6 | 71,253 | 286 | 313 | 599 | 8.4 | 188 | 4 | 2 | 6 | 31.9 |
| 7 | 18,397 | 70 | 67 | 137 | 7.4 | 209 | 2 | 1 | 3 | 14.4 |
| 8 | 60,804 | 270 | 159 | 429 | 7.1 | 453 | 4 | 3 | 7 | 15.5 |
| Total | 321,778 | 1323 | 1217 | 2540 | 7.9 | 2305 | 34 | 13 | 47 | 20.4 |

Total IC, women presented symptomatically within 36 months of their previous screen (interval cancers). Total SD, cancers detected during subsequent screening (<37 months of their previous screen).

ologist, pathologist and clinicians during multidisciplinary meetings and therefore, more accurate patient management decisions.

To eliminate the possible effects of incorrect data entry and to investigate the cause and impact of false negative diagnosis on patient management, we reviewed the cases reported in a single screening region in the United Kingdom diagnosed during the last 3 years of this study. Our results showed that 0.4% of all patients with malignant pathology at surgery were reported as B2 (FN rate 0.19%) and B1 (B1 core biopsy rate from cancer 0.2%). Although for the purpose of data entry and recording, the NCB for these cases was considered as false-negative or normal, from the multidisciplinary perspective, these patients were managed as positive or non-representative of the lesion. Therefore, our results indicate that the rate of false-negative or normal/unsatisfactory NCB diagnoses after multidisciplinary meeting discussion is rare with little or no impact on patient management.

The results of this study provide robust and updated information on core biopsy miss rate from cancers and indicate that performance is much better than recommended in the NHSBSP United Kingdom national guidelines[6] and the European guidelines[10] which considered a miss rate of <15% as a minimum and <10% miss rate as preferred. It is also superior to those figures reported in the literature from both symptomatic and screening patients including solid breast lesion (11%),[16] vacuum-assisted biopsy (7.4% for US guided) and 26% for MRI guided biopsies.[17] Although some previous studies have reported high figures of false negative NCB (4%[18] and up to 9%[19]), consistent with our results, recent studies have demonstrated that false negatives are around 1.5%. Schueller et al.[20] have reported false-negative NCB, which was defined as the proportion of all breast cancers with a diagnosis of benign disease at US-guided 14-gauge NCB, in 0.8% (11/1352 cases) giving a false-negative rate of 1.6%. Importantly, in their study, all false-negative findings were associated with imaging-histological discordance and follow-up of another 291 cases with benign NCB diagnoses showed no malignancy during clinical and imaging follow-up for at least 2 years. Youk et al.[21] have found false-negative NCB in 1.4% (50/3724) of cancers giving a false-negative rate of 2.5%. Of these 50 false negative NCB, discordance between imaging results and NCB histologic findings were present in 28 cases. Our results were also in agreement with the study by Jackman et al.[22] who reported a false-negative rate of 0.9% (5 B2 out of 508 malignant lesions) and found that these five false-negative NCB were related to gauge of the biopsy probe and specimen radiographic findings regarding calcifications.

The results above describe the subset of patients with B1/B2 NCB who, for some reason, underwent subsequent surgery, but this may not represent all false negatives and misses. Some women diagnosed with B1/B2 NCB without subsequent excision histology may develop cancer at a later time (interval breast cancer). We found that 2% of women with a B1/B2 diagnosis developed breast cancers within the subsequent 3 years, compared with 0.8% of women with previous negative screening mammography. This 1.2% difference may be due to failure of initial assessment as a result of inadequate sampling, missing or inability to diagnose the initial target lesion. Although the difference is significant, there are a number of points which need to be considered. Firstly, in this study we do not have data on the site of the interval cancer and whether it correlates with the site of lesion previously assessed. In a previous study of interval cancers, Warren et al.,[23] found that 54.5% of interval cancers (232/426) developed in the contra-lateral breast or in the same breast, but at a different site to that which had been previously assessed. Crystal et al.,[24] have reported that follow-up of 373 benign lesions diagnosed on NCB (follow-up period varied from 27 to 60 months), malignancy was diagnosed at the site of NCB in only three cases. Secondly, this study of interval cancers is derived from cases diagnosed between 1999 and 2002 and there is evidence to show a significant improvement in the screening performance in recent years particularly after the development of digital stereotactic technique and the use of vacuum-assisted biopsy as well as increased operator experience/expertise[4,5] and it is likely that the current proportion of false negative cases is lower. Further studies are needed to address these questions in more detail, in particular the site of subsequent cancers compared with the site of previous B1/B2 core biopsy.

In conclusion, our results showed that the core biopsy miss rate from cancers is low. Under-management of screen detected breast lesions as the result of false-negative or non-representative NCB may be considered almost nil. Our results provide further evidence for the public and health care professionals about the improved performance of breast screening. We would like to emphasise the importance of multidisciplinary meeting discussion for optimal patient management.

## Conflict of interest statement

None declared.

## Acknowledgements

We would like to thank the administrative staff and pathologists involved in provision of the NHS breast screening service in the United Kingdom for their help and support in conducting this study.

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