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Audit of performance of needle core biopsy diagnoses of screen detected breast lesions

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ABSTRACT

Breast needle core biopsy (NCB) is now a standard diagnostic procedure in the triple assessment of screen detected breast lesions. Therefore, it is important to provide robust and up-to-date data on the performance of NCB in the screening setting. However, previous studies of NCB have suffered from either limitation in the number of assessed cases or included a mix of symptomatic and screen detected breast lesions. In this study, we have evaluated the performance of a large series of uniformly assessed NCBs of screen detected lesions (20001 cases) over a period of 10 years (1997–2007). Our results showed a gradual increase in the number of NCBs and an improvement of their performance over the period of the study; absolute sensitivity increased from 84.9% to 96.4% and complete sensitivity increased from 90.9% to 99.7%. There was also a gradual reduction in the number of surgical interventions after benign (B2) and negative (B1) NCB diagnoses. Our study provides data showing variance from the suggested thresholds for the measures of performance of NCB in the United Kingdom which could be used to provide updated evidence-based thresholds for assessment of performance of NCB diagnosis use in the assessment of breast cancer screen detected lesions in the UK and elsewhere.

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1. Introduction

Breast cancer accounts for the largest number of cancer-related deaths of women in Europe. Systematic screening of the female population based on mammography offers the prospect of saving many lives whilst reducing the negative side-effects of treatment by detecting cancer at earlier stages, when it is more responsive to less aggressive treatment. The introduction of the National Breast Screening Programme (e.g., National Health Service Breast Screening Programme in the UK (NHSBSP)) has promoted the importance of pre-

operative diagnosis in the assessment of breast lesions. The role of pre-operative diagnosis is to attempt to provide a definitive diagnosis of malignancy that allows rapid referral for treatment, ideally in one operative procedure. Definitive non-operative diagnosis of benign conditions is also useful, leading to discharge from the clinic and return to routine recall. This pre-operative diagnosis in breast cancer screening is achieved, using triple assessment involving multidisciplinary cooperation between radiologists, surgeons and pathologists. Triple assessment comprises combined evaluation of the independent contributions of clinical examination, a

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radiological assessment (mammography or ultrasound) and a pathological assessment (cytology or core biopsy). Pre-operative pathological diagnosis is largely made using needle core biopsy (NCB), which is now considered as the method of choice for the triple assessment.¹ The published data suggest that the use of core biopsy has increased the pre-operative diagnosis rate in screen detected breast cancers.^{2,3} Needle core biopsy, as compared to fine needle aspiration cytology (FNAC), can reliably distinguish between benign and malignant tumours, between *in situ* and invasive cancers and evaluation of histological, prognostic and predictive factors in breast cancer to assist decision making on subsequent therapy.⁴ In addition, it has been reported that the introduction of NCBs has reduced the number of surgical procedures for invasive breast cancer such as diagnostic wire-guided open biopsies.^{5,6}

Since the introduction of triple assessment of screen detected breast lesions, systems have been developed to allow continuous monitoring of the performance of the clinical (radiological and pathological) modalities involved in the screening process. In the UK, the NHSBSP⁷ has drawn up guidelines and published suggested thresholds for the different measures of performance to enable screening units to audit their performance with the aim of achieving optimum performance. These guidelines have been adopted with minor modifications by the European Union and form the basis of the European guidelines^{8,9} and are endorsed by the European Commission working group on breast screening pathology. In the UK, performance of FNAC in breast screening assessment has been previously audited.^{10,11} However, data on the measures of performance of NCB are either lacking or are based on earlier studies, which included either a limited number of cases or a mix of screen are detected and symptomatic breast lesions.^{12–14}

In this study, we have examined a large series of NCBs of screen detected breast lesions from eight screening units over a period of 10 years to assess the actual performance of NCB of screen detected lesions, changes of performance overtime and variation between screening units. We also aimed to provide robust data on the quality of performance of NCB that can be used to draw up evidence-based revised thresholds for NCB measures of quality.

2. Methods

This is a retrospective study of all women, who attended following invitation for breast screening at the eight screening units in the East Midlands region, UK between 1st April 1996 and 31st March 2007. Of all screened subjects, 20001 women underwent assessment with needle core biopsy (NCB) diagnoses and they are the subject of this study. Criteria for performing NCB were nearly always mammographic findings which were not definitively benign following further imaging (extra views and ultrasound). A small proportion of NCBs (<1%) were performed as a consequence of the patient reporting a physical finding or a radiographer detecting a physical abnormality during mammography. NCB results were categorised according to UK guidelines.⁷ Categories included B1 = normal, B2 = benign, B3 = lesions of uncertain malignant potential,

B4 = suspicious of malignancy and B5 = malignant (*in situ* cancer and invasive cancer). All patients with a NCB diagnosis as part of triple assessment were discussed at a multidisciplinary meeting with a breast radiologist, histopathologist and surgeon present, and a decision for further action was made. During the period of this study, digital stereotaxis was introduced and it began to replace film screen stereotaxis. All units used digital stereotaxis commencing between 1997 and 2004. In addition, vacuum assisted larger volume biopsy was also introduced in some but not in all units (used by six units, commencing between 2000 and 2006). Cases subjected to vacuum assisted biopsy were recorded for the purposes of this study as undergoing a needle core biopsy procedure.

For the purpose of this study, outcomes were determined as follows: 1. Cases with subsequent surgical excision histology (9895, 49.5% of cases) including malignant (*in situ* and invasive) and benign lesions. 2. Cases without surgical excision. Analysis of the results was done in accordance with the standards specified in the National Health Service Breast Screening Programme (NHSBSP) Publication Number 50.¹⁵ Table 1 shows the definitions of the different measures of quality assurance assessed in this study.^{7,8} Quality assurance measures were assessed over the period of the study and amongst the different screening units. Correlations between different variables were evaluated using the Chi-square test and t-test. A *p*-value <0.05 was considered significant.

3. Results

Of all screened examinations (1,243,663) undertaken over the last 10 years, 58,488 women (4.7%) were assessed. Of these, 20,001 women underwent triple assessment with needle core biopsy (NCB) diagnosis (1.6% of all screened women and 34% of the assessed women) (Table 2). There was a gradual increase in the number of NCBs over the period of the study from 1214 cases in 1997/1998 to 2589 NCBs in 2006/2007. Table 2 and Fig. 1 show the proportion of the different NCB categories reported over the 10-year period and their subsequent outcome. Of this study population, 8713 lesions have been prove to be malignant on excision histology (0.7% of screened subjects, 14.9% of the assessed and 44% of those who had NCB diagnoses).

3.1. Quality assurance measures

Table 3 shows the changes in the measures of performance over the 10-year period of this study. These illustrate two important observations. Firstly, there is a clear improvement in performance over-time. Secondly, some of these measures consistently exceed the minimum and preferred thresholds of performance suggested by NHSBSP guidelines¹⁶ including the following performance standards:

- (A) Absolute sensitivity, which has increased from 84.9% to 96.4%.
- (B) Complete sensitivity, which has increased steadily from 90.9% to 99.7%.
- (C) Core biopsy miss rate, which has steadily decreased from 9.1% to 0.3%.

Table 1 – Definition of quality assurance standards^{7,8}

Measure	Definition
Absolute sensitivity	The number of carcinomas diagnosed as such (B5) expressed as % of the total number of carcinomas sampled
Complete sensitivity	The number of carcinomas that were not definitely negative or inadequate on NCB expressed as % of the total number of carcinomas
Specificity (full)	The number of correctly identified benign lesions (the number of B2 results minus the number of false negatives) expressed as % of the total number of benign lesions
Positive predictive value (PPV) for B5	The number of correctly identified cancers (number of B5 results minus the number of false positive value of B5 results) expressed as % of the total number of positive results (B5)
PPV for B4 and B3	The number of cancers identified as suspicious (number of B4 and B3 results minus the number of false value of a B4/B3 suspicious results) expressed as a percentage of the total number of suspicious results (B4 and B3)
False negative rate (FNR)	The number of false negative results expressed as a percentage of the total number of carcinomas sampled
False positive rate (FPR)	The number of false positive results expressed as % of the total number of carcinomas sampled
Inadequate rate	The number of B1 expressed as % of the total number of NCB sampled
Suspicious rate	The total number of B3 and B4 expressed as % of the total number of NCB sampled
Core biopsy miss rate	FNR plus inadequate rate 2
Accuracy	Ability of NCB to detect breast cancer with accuracy as determined by the number of B5 and B4 (that have subsequent histology) expressed as % of total number of malignant cases on the subsequent histology
Underestimation of DCIS rate	Number of cases diagnosed as DCIS on NCB (B5a) that turned out to be invasive malignancy on the final excision histology divided by the total number of B5a diagnoses
Overall proportion of malignancy	Number of definite malignant lesions (on NCB or surgery) divided by total number of NCBs

- (D) Specificity, which has decreased over this period. However, this can be explained by the decreasing occurrence of B2 NCBs followed by surgical excision and hence coded as benign (2/1057 in 06/07 compared to 59/558 in 97/98) combined with an increase in the number of B3 diagnoses followed by excision and reported as benign (81/157 in 06/07 compared to 10/21 in 97/98).
- (E) Accuracy increased from 90.5% to 99.3% over the period of the study.
- (F) The underestimation of DCIS rate has improved from 28.5% in the first 3 years of this study period (1996–2000) to 20.9% over the last 3 years (2004–2007).

These observations also provide an evidence base for the observed positive predictive values for B3 and B4 diagnoses,

Table 2 – Outcomes of NCB diagnoses over the 10-year period (1997–2007)

Histology	B5	B4	B3	B2	B1	Total
Total Malignant	8051	241	191	123	106	8713
Invasive	6439	82	72	65	55	6713
Non-invasive	1612	160	119	58	51	2000
Total benign	41	84	560	325	172	1182
No histology	276	11	249	8697	873	10106
Total NCB	8368	337	1000	9145	1151	20001
Results (%)	(41.9)	(1.7)	(5)	(45.7)	(5.7)	(100)

negative predictive values and inadequate rates. We believe these could be used to address revision of the standards for these measures of performance, should this be considered appropriate.

3.2. Other observations on NCB performance

No associations were found between the workload of the different screening units (number of NCBs per unit) and any of the measures of performance included in this study ($p > 0.05$). No association was found between positive predictive values (PPVs) of B3, B4 or B5 and total number of NCBs assessed.

As we noticed some variation in the PPV of B3 and B4 in the different units, we assumed that this may be due to variation in the proportion of cases coded as B3 or B4. However, no association was found between PPV of B3 and PPV of B4 amongst the different screening units. Also, when we excluded the cases that had no final histological diagnosis, we found that the PPV for B3 increased to 25.4%. Of the B5 (8092) and B4 (326) NCBs that had been followed by surgical excision biopsy, 41 (0.49%) and 84 (25.8%) of cases were diagnosed (coded) as benign (false positive cases). Of the invasive cancer cases on final histology, 95.9% were diagnosed as B5 on NCBs compared to 80.6% of in situ carcinoma cases diagnosed as B5 (Fig. 2).

We also noted a decrease in the surgical excision biopsies of the cases diagnosed as B1 and B2 over the period of the study. In 1997–1998, 21% (141/666) had B1/B2 NCB outcomes with 53 cases subsequently reported malignant compared to 0.8% (10/1242) in 2006–2007 of which four were reported malignant following surgical histology. This can be explained by the improved triple assessment and multidisciplinary discussion of these screen detected cases over the period of this study.

4. Discussion

Since its introduction in the 1980s,¹⁷ Needle core biopsy (NCB) has become a widely used technique for evaluating palpable and non-palpable/radiologically detected breast abnormalities. This technique revolutionised the practice of pre-operative diagnoses of breast lesions in both symptomatic and screen detected practice,⁴ and is now accepted as a reliable alternative to surgical biopsy for histopathologic diagnosis of breast lesions. An improvement in the radiological evaluation of breast lesions, in the sampling technique, in publishing of guidelines for assessing breast lesions and in the reporting of NCB is expected to result in further improvement in the performance of NCB. However, a study of the

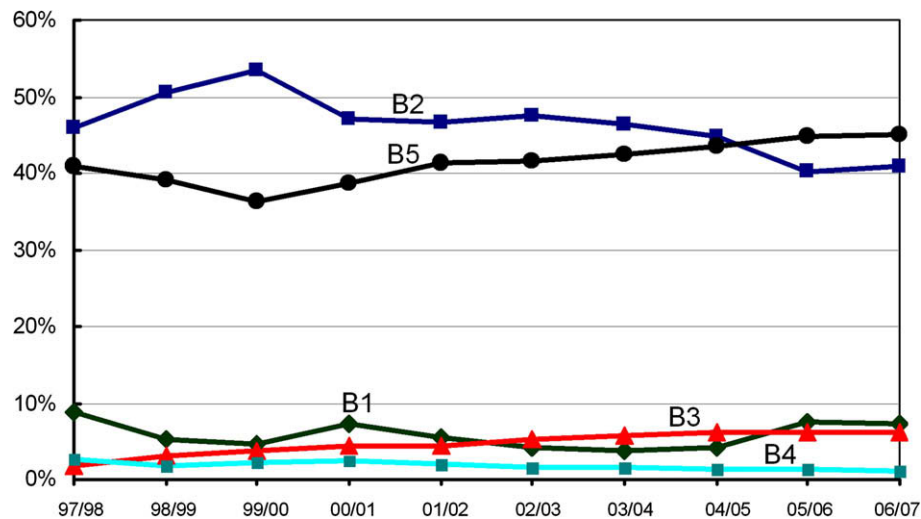


Fig. 1 – Changes in the percentages of the different NCB categories over the 10-year period of this study (number of each NCB category divided by the total number of NCB performed during the same year).

performance of NCB of screen detected breast lesions that provides comprehensive and up-to-date values is lacking.

To our knowledge, this study is the largest to date to report on the performance of NCB of screen detected breast lesions. We have included a consecutive series of NCB cases over a period of 10 years of all subjects who attended eight screening units. All these units followed the same standardised protocols for the reporting of NCB, providing uniform data on NCB performance in the screening setting. Our results showed that there is a gradual increase in the number of NCBs performed over the period of the study. Contributory factors include: (i) Increased radiological detection of subtle breast lesions as a result of increased sensitivity and accuracy of radiological performance during the period of the study. This was largely due to the introduction of Vacuum assisted core biopsies and digital stereotaxis to replace film screen stereotaxis.¹⁸ Digital stereotaxis has been reported to be responsible for improving the performance of biopsy of the calcifications and non-operative diagnosis of DCIS in particular.^{18,19} (ii) Reduction in the use of fine needle aspiration cytology. In fact, NCB has probably not only replaced cytology, but surgical wire-guided diagnostic breast biopsies as well. Previous studies have demonstrated that pre-operative NCB also reduced the number of surgical procedures for invasive cancer,^{5,6} which contributed to the shift from open biopsy to NCB.

There was an improvement in all measures of performance of NCB diagnoses during the period of the study. In the current study, no significant difference was found in the performance of the different screening units, regardless of their workload (data not shown). In general, the improvement in the performance of NCB noted in this study is likely to be due to a learning curve from introduction to familiarisation with its use in addition to the introduction of more advanced radiological techniques which increased the accuracy of detection and sampling of breast lesions during the period of the study. NCB appears to be an inherently successful technique unlike FNAC in general usage as the improvement occurred rapidly and quality assurance targets were soon

surpassed, unlike FNAC, which consistently failed with regard to the achievement of performance targets.

An earlier study has shown that the accuracy of NCB is 87%.²⁰ Subsequent reports have shown that absolute sensitivity ranged from 75% to 89.3% and complete sensitivity ranged from 76.6% to 93.2%.^{15,21,22} In this study, the overall accuracy, absolute sensitivity and complete sensitivity were 97%, 92.6% and 97.7%, respectively. Importantly, during the period of this study, the absolute sensitivity increased from 84.9% to 96.4% and complete sensitivity increased from 90.9% to 99.7%. The accuracy of NCB to detect breast cancer increased from 90% to 99%. Although the preferred values suggested by NHSBSP⁷ and by the European Union⁹ are >80% and >90% for absolute sensitivity and complete sensitivity respectively, our results show that the values for absolute sensitivity and complete sensitivity were above 90% and 95%, respectively, over the last 6 years and it may be prudent to revise the current performance standards. This study also showed a significant reduction in the NCB miss rate with values of less than 1% over the last 4 years (compared to the preferred values of <10%.⁷)

In addition, this study provides values for additional measures of performance that have no recommended thresholds in the published NHSBSP or in the European guidelines.⁹ The overall false negative rate was 1.4%, but was <0.5% over the last 4 years. The positive predictive value (PPV) for B3 was 19.1% (range from 13.3% to 30%) and for B4 it was 74.2% (range from 62.5% to 90.6%). The relatively high number of recorded false positive cases noted in this study (0.5%) can be explained by the fact that in some cases, the malignant tissue is totally sampled and removed in the NCB and, therefore, the excision specimens are tumour free, resulting in benign coding using the current data recording system. All such cases are subject to audit and review by the local multidisciplinary team and by the Regional Quality Assurance Reference Centre. However, due to the importance of this issue in breast cancer screening, all false positive cases will be the subject of a future detailed study.

Consistent with the previous studies that reported an improvement in the underestimation rate of DCIS on

Table 3 – Measures of performance of NCB in the eight screening units from 1997/1998 to 2006/2007 (in percentages)

Measure of performance	Minimum%	Preferred%	97/98	98/99	99/00	00/01	01/02	02/03	03/04	04/05	05/06	06/07	Total
Number of NCB			1214	1583	1641	1787	1703	2045	2311	2395	2733	2589	20001
Absolute sensitivity	>70	>80	84.9	88.7	88.1	89.1	91.2	93.9	94.7	95.6	95.2	96.4	92.6
Complete sensitivity	>80	>90	90.9	94.0	94.5	95.6	96.9	98.0	99.2	99.5	99.7	99.7	97.5
Specificity	n/a	n/a	57.3	51.9	45.0	34.9	28.8	27.4	14.4	11.0	6.9	1.9	27.5
Specificity (Full)	>75	>85	82.8	87.4	89.0	81.3	84.2	84.2	83.7	81.9	75.6	75.8	82.0
PPV of B5 ^a	>99	>99.5	99.6	100.0	100.0	99.6	99.7	99.9	99.3	99.3	99.3	99.1	99.5
PPV of B4	n/a	n/a	90.6	75.9	80.0	75.6	75.8	72.4	67.6	62.5	66.7	75.0	74.2
PPV of B3	n/a	n/a	28.6	30.0	25.0	20.5	25.3	14.5	18.7	15.9	20.6	13.4	19.1
NPV	n/a	n/a	93.9	96.5	98.1	97.9	98.7	99.1	99.8	99.9	99.9	99.7	98.7
False negative rate	n/a	n/a	5.9	4.0	2.5	2.3	1.3	1.0	0.2	0.1	0.1	0.3	1.4
False positive rate ^a	<0.5	<0.5	0.3	0.0	0.0	0.4	0.3	0.1	0.7	0.6	0.6	0.9	0.5
Inadequate rate	n/a	n/a	8.9	5.2	4.5	7.2	5.6	4.2	3.8	4.2	7.4	7.1	5.8
Inadequate rate 2 ^b	n/a	n/a	3.3	2.0	3.0	2.1	1.8	1.0	0.6	0.4	0.2	0.1	1.2
Suspicious rate	<10	<5	4.4	5.0	5.9	6.9	6.4	6.8	7.4	7.4	7.5	7.1	6.7
Core biopsy miss rate	<15	<10	9.1	6.0	5.5	4.4	3.1	2.0	0.8	0.5	0.3	0.3	2.5
NCB accuracy	n/a	n/a	90	93	93	95	96	97	99	99	98	99	97
Underestimation rate ^c	–	–	27	29	28	17	23	16	21	19	22	22	22
OP of malignancy ^d	–	–	0.48	0.44	0.41	0.43	0.45	0.44	0.45	0.45	0.47	0.46	0.45

PPV = Positive predictive value.

NPV = Negative predictive value.

a Some cases may be due to removal of the lesion by the core biopsy.

b Inadequate rate 2 = the number of B1 which turned out to be malignant on final histology expressed as% of the total number of malignant cases.

c Underestimation rate of DCIS.

d Overall proportion of malignancy.

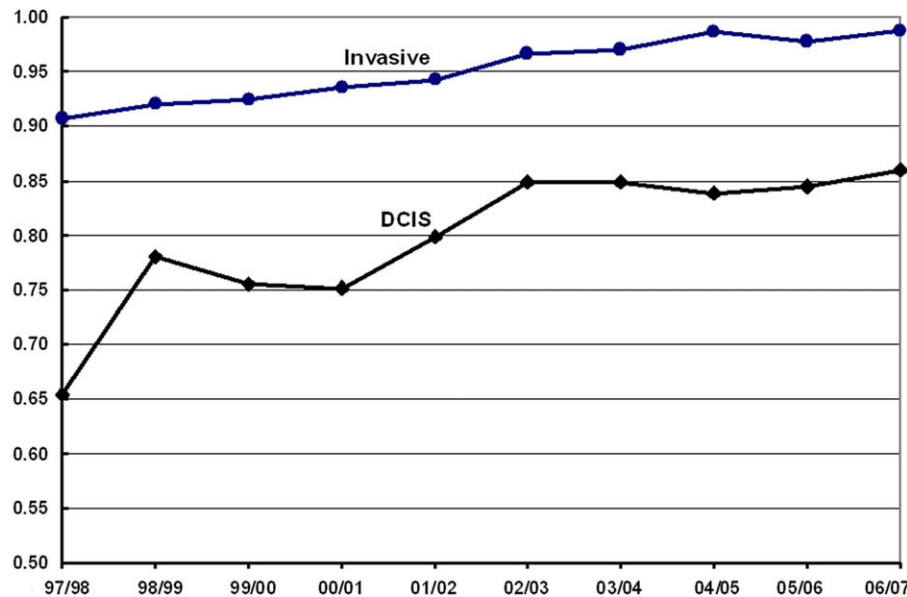


Fig. 2 – This figure shows the improvement in the percentages of invasive and in situ carcinoma cases (based on final excision histology) diagnosed as B5 (malignant) on NCB over the period of the study.

NCB,^{23,24} our results showed a decline in the invasive rate after a preoperative diagnosis of DCIS on NCB from 29% to 21%. Another observation in this study, which may be of relevance to the pathologists and other professionals in the breast screening programme, is the gradual increase in the rate of borderline NCB diagnoses which is accompanied by a decrease in their PPV. For example, the proportion of cases diagnosed as B3 increased from 1.7% in the year 1997–1998 to 6.1% in the year 2006–2007 whilst their PPV decreased from 28.6% to 13.4%, respectively. Therefore, we recommend that the different lesions which result in the diagnosis of these borderline diagnoses be subjected to further investigation in order to reassess the lesion specific PPV and criteria for inclusion of the different lesions under these borderline categories.

In conclusion, our results demonstrate an improvement in the performance of NCB diagnoses of screen detected breast lesions. Although these results are from a UK-based study, the improved performance demonstrated in this study is unlikely to be unique to the UK as the contributing factors for this improvement have been replicated elsewhere. Therefore, this study may provide evidence that can be used to update quality assurance targets currently used by the NHSBSP to assess NCB performance, as well as in other European national breast cancer screening programmes and indeed elsewhere where needle core biopsy is used as part of the breast screening assessment.

Conflict of interest statement

None declared.

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