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Core biopsy versus FNAC for palpable breast cancers. is image guidance necessary?

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Abstract

The aim of this study was to assess the efficacy of free-hand percutaneous core biopsy (FHCB) and to determine the role of fine needle aspiration cytology (FNAC) as diagnostic tools for palpable radiologically-suspicious breast lumps. This retrospective study was based on reviewing the clinical records of all patients diagnosed as having breast cancer between January 1999 and December 2000 and patients who had benign lesions, but suspicious breast imaging at triple assessment. Absolute sensitivity of FHCB for diagnosing cancer in palpable lesions was 98.7% compared with 51.3% for FNAC. The difference in the sensitivity of FHCB and FNAC was statistically significant ($P < 0.005$, Wilcoxon matched pair test). Since 94.8% of radiologically-suspicious lumps were shown to be cancers, we advocate FHCB for all patients presenting with radiologically suspicious palpable lumps to our breast clinic. We also conclude that the sensitivity of FHCB for the diagnosis of malignancy in palpable radiologically-suspicious breast lesions is so high that image-guidance is unnecessary.

Keywords: Breast malignancy; FNAC; Percutaneous core biopsy; Image-guidance; Retrospective analysis

1. Introduction

Percutaneous image-guided core biopsy is being increasingly used to diagnose palpable and impalpable breast lesions. Not only is the method faster, less expensive and less invasive, it results in minimal scarring or deformity of the breast when compared with open surgical biopsies [1–5]. Fine needle aspiration cytology (FNAC) is used together with clinical examination and imaging (ultrasound with or without mammography) for the initial assessment of symptomatic breast lumps. Percutaneous core biopsy is considered to be less sensitive than FNAC [6] due to sampling errors, but for those lesions that subsequently prove to be cancers, has the advantage of providing a large amount of tissue for a definitive histological diagnosis, information on the receptor status and oncoprotein expression and is generally used as an additional diagnostic test before embarking on a definitive surgical procedure [7,8]. In addition, core biopsy can distinguish between invasive and in situ carcinoma, thus allowing more appropriate management of the axilla. There is an increasing and generally universal tendency to use image-guidance to increase the diagnostic yield of the core biopsy technique. Though necessary for impalpable lesions, the need for image-guidance is not well documented for the diagnosis of palpable breast lesions.

The aim of this study was to ascertain whether free-hand percutaneous core biopsy (FHCB) is justified as the first procedure to obtain tissue diagnosis in patients presenting with a palpable radiologically-suspicious breast lump.

2. Patients and methods

Between January 1999 and December 2000, approximately 4500 patients were investigated in the breast clinic at St. Mary's Hospital, London, UK, and 192 new breast cancers were diagnosed. All but 5 patients that

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were subsequently diagnosed to have breast cancer underwent core biopsy. If the cancer was palpable, core biopsy was performed free-hand without image-guidance by one of the authors.

After infiltrating the skin at a distance of 1–2 cm from the lesion with 2% lignocaine, a small stab incision was made to facilitate the entry of the biopsy needle. A Magnum Bard® gun with a 14G automated needle was used for the procedure. The needle was introduced obliquely and fired tangentially to the chest wall to avoid entering the thorax. A total of 2–4 cores were taken from each lesion depending on the macroscopic appearance of the cores. If the cores appeared solid and rigid when they were taken off the needle then only 2 cores were taken.

All the palpable breast cancers over this period were reviewed retrospectively and all those patients who had a percutaneous core biopsy performed prior to presenting to the clinic were excluded from this study. Also excluded were those patients who had image-guided or free-hand core biopsies performed by other operators due to unavailability of the main clinician.

Patients who presented with radiologically-suspicious palpable breast lumps that subsequently proved not to be cancers also had their records reviewed. There were 8 such patients that presented during the same period of time.

The sensitivity of FHCB was calculated and compared with the sensitivity of FNAC using the Wilcoxon paired test (R software package). Sensitivity was calculated in two ways according to the guidelines of the National Health Service (NHS) breast screening programme in the UK for FNAC and a similar formula was used for FHCB; absolute sensitivity only includes C5 and B5 samples whereas complete sensitivity includes all samples with atypia (C3 and B3), suspicion of malignancy (C4 and B4) as well as malignant samples (C5 and B5) [9].

Absolute sensitivity for FNAC was calculated as: true positive C5/number of cancers that underwent FNAC.

Complete sensitivity for FNAC was calculated as: cancers with C3 or C4 or C5/number of cancers that underwent FNAC.

Absolute sensitivity for FHCB was calculated as: true positive B5/number of cancers that underwent FHCB.

Complete sensitivity for FHCB was calculated as: cancers with B3 or B4 or B5/number of cancers that underwent FHCB.

3. Results

In the designated period of retrospective analysis, 192 patients presenting to the breast clinic were diagnosed as having breast cancer. Four of these patients had bilateral cancers. Of these 196 lesions, 164 were clinically palpable. FHCB was performed on 151 of these lesions. Five patients with palpable cancers had a core biopsy performed elsewhere (image-guided or free-hand) prior to presenting to us. One of these patients had an equivocal histology result, which was highly suspicious of malignancy. A FHCB was performed on her to confirm the diagnosis and this case was included in this analysis. The other 4 patients were excluded from the analysis. Seven further patients with palpable cancers were excluded as their biopsies were performed under image-guidance due to the unavailability of the surgeon on site. One patient had a surgical biopsy following C3 cytology and benign imaging and another patient was started on hormone therapy based on her FNAC diagnosis due to her age and general condition.

The 149 patients with breast cancer finally included in this study with 151 lesions had a mean age of 60.2 years. All patients were female. The size of the tumours ranged from 5 mm to 10 cm (mean 2.5 cm), as reported on ultrasonography, and their details are depicted in Table 1. One hundred and forty-six of these 151 (96.7%) lesions were reported as highly suspicious on ultrasound and/or mammography.

FNAC was performed on 119 of these patients and was conclusive (C5) in 61 patients on the first attempt. For 47 patients, FNAC was reported as C4 and for 11 patients (9.2%) FNAC was inadequate for reliable assessment due to inadequate sampling (C1). Therefore, the absolute sensitivity of FNAC for confirming cancer was 51.3% and complete sensitivity 90.8%. However, there were no cancers with C2 cytology in this series.

A definite histological diagnosis of *in situ* (B5a) or invasive cancer (B5b) was possible in 149 out of the 151 FHCB. In 2 patients, FHCB was reported as B4. These 2 patients underwent repeat core biopsy, one of which was performed free-hand and the other under image-guidance. One of these patients had a 2.5 cm lump and had C1 FNAC. The first FHCB was B4 and a repeat FHCB was again reported as B4. Wide local excision with frozen section was performed and confirmed the presence of invasive ductal carcinoma. The other patient had C4 cytology on FNAC and FHCB showing atypical ductal hyperplasia (ADH) and was suspicious of carcinoma (B4). A repeat core biopsy this time under ultrasound guidance revealed the presence of ADH with foci of carcinoma (B5). The final histology of all patients who had FHCB is depicted in Table 2.

Table 1
Distribution of various lesions according to size ($n = 151$)

Size of lesions (mm)	Number of patients
5–20	79
20–50	60
>50	12

Table 2
Distribution of patients according to final histological diagnosis ($n=151$)

Histological diagnosis	Number of patients
Infiltrating ductal carcinoma	116
Infiltrating mammary carcinoma	14
Infiltrating lobular carcinoma	6
Mucinous carcinoma	2
Papillary carcinoma	3
Atypical ductal hyperplasia	1
Multiple myeloma	1
DCIS	8

DCIS, ductal carcinoma *in situ*.

The absolute sensitivity of FHCB was 98.7% and complete sensitivity was 100%. For lesions under 2 cm in diameter, absolute sensitivity was 100%.

The comparison in absolute sensitivity between the FNAC and FHCB in diagnosing breast cancers was evaluated using the Wilcoxon matched pair test and this was found to be statistically significant ($P<0.005$).

There were a further 8 patients presenting with palpable, radiologically suspicious breast lumps during the same period of time. They all had FHCB reported as B2. Six of these 8 patients underwent excision of the lump and in all but one case the histological diagnosis of the whole lesion correlated with that of the FHCB. In one patient, FHCB showed benign breast change whereas excision biopsy revealed a benign papillary lesion. In the remaining 2 cases, FHCB resulted in a definitive histological diagnosis and excision was not considered necessary.

One hundred and forty-six of 154 (94.8%) palpable, radiologically-suspicious lumps in this series were subsequently proven to be cancers.

4. Discussion

In the 1980s and the early 1990s, surgical excision biopsy of palpable breast lumps was considered the gold standard for the diagnosis of breast lumps [8]. FNAC has been used as a diagnostic modality and is currently used as one of the modalities of triple assessment for breast lesions. However, FNAC has it's own limitations. These include insufficient sampling as demonstrated in the RDOG Multicenter trial, which showed an insufficiency rate of 26.6% [7]. Other studies have demonstrated insufficiency rates between 0 and 28%, false-negative rates between 0 and 35% and false positive rates between 0 and 2% for palpation-guided FNAC [10–14]. Moreover, the need for an expert cytopathologist on site is a limiting factor at various District level hospitals [8].

Percutaneous core biopsy was initially introduced in 1982 by Lindgren for ultrasound guided renal biopsy [15]. Its use was later extended for biopsy of abdominal masses [16] and prostatic biopsy [17]. In 1991, Barreto and colleagues reported a sensitivity of 65% using 18G needle for core biopsies in 107 patients with suspected early breast cancer [18]. Parker and colleagues demonstrated that the use of a 14G needle yielded superior tissue sample in 102 patients and a reported sensitivity of 96% [19,20]. These biopsies were performed under image-guidance. The same authors in another trial reported a 100% concordance between the results of core biopsy and surgery in 49 lesions, with no false negatives and a follow-up period of 12–36 months [21].

With the advent of image-guidance for diagnostic procedures, there has been an increased tendency to perform percutaneous core biopsies under ultrasound or stereotactic guidance even for palpable breast lesions rather than as a free-hand procedure. The reasons cited in the literature for this include a high false-negative rate, high insufficiency rate, occasional false-positive rate [10], difficulty in fixing the deep seated or small lesions [22] and difficulty in positioning the needle in the lesions while performing it as a free-hand procedure [23]. Image-guided percutaneous core biopsy yielded sensitivity rates of 80–100%, specificity of 80–100%, insufficiency rates of 0–17% in various studies [21,22,24–26]. However, no studies have been reported in the literature, which have proved that image-guided biopsy has superior results over FHCB for palpable lesions.

Previous reports on FHCB have shown a sensitivity rate of 42–90% [27–41] false-negative rates 0–36% and insufficiency rates 2–10% [42–45] for FHCB. In our hands, absolute sensitivity of FHCB was 98.7% and insufficiency rate was 0%. There were 2 suspicious specimens and no false-positives. These figures are comparable with the best published figures of image-guided percutaneous core biopsy when considering the fact that 53% of all tumours were less than 2 cm in diameter when assessed by ultrasound, some of them being deep seated, vaguely palpable and mobile.

The argument of performing an image-guided core biopsy due to high insufficiency rates, high false-negative rates and occasional false-positive rates for all palpable breast cancers thus seems to be unjustified as shown by the high sensitivity of FHCB in our series. According to our data, there seems to be no potential advantage in performing core biopsies under image-guidance for palpable breast cancers. Not only is image-guidance more time consuming for the radiologist and expensive, FHCB can easily be done as an outpatient procedure by the surgeon. Although a cost-analysis study was not performed in this retrospective analysis, there are reports suggesting that FHCB is more economical than image-guided percutaneous core biopsy. [10]. In addition, a positive FHCB confirms to the surgeon that the lesion that he/she feels is indeed the cancer.

In this series, FHCB was clearly superior to FNAC particularly in terms of absolute sensitivity. Core biopsy also has the additional advantage of providing tissue for histological typing of tumour, evaluation of hormone receptor status, expression of oncoproteins such as HER 2/neu status and confirmation of invasive disease. FNAC on the other hand is less invasive and has the potential advantage of immediate reporting.

Our results show that if a breast lump is malignant then an appropriately experienced clinician has a 98.7% chance of confirming the diagnosis with FHCB. Therefore FHCB is the procedure of choice in clinics like ours, where it is more practical for the procedure to be performed by the surgeon after breast imaging has been done. Since 94.8% of all palpable, radiologically-suspicious lumps subsequently proved to be cancers, we now advocate FHCB as the initial diagnostic modality for these lesions. It is our standard practice to eventually excise these lesions for diagnostic purposes if a pre-operative cancer diagnosis cannot be made. FNAC should be performed if immediate reporting is considered essential. Image-guidance may be reserved for repeat biopsy or for those patients with multiple lumps where the radiologically-suspicious lesion needs to be biopsied.

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