

Core Needle Biopsy of Palpable Breast Lump: The Influence of Needle Size

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Summary

The diagnostic value of core needle biopsy is increasingly being preferred because of its better characterization of benign and malignant lesions and lower frequency of insufficient samples. The aim of this study was to determine the diagnostic accuracy and complication rates with 2 different gauges of core biopsy needle in the preoperative diagnosis of palpable breast lumps. A total of 150 consecutive core biopsies were included in this prospective non-randomised study of palpable breast lump from May 2000 to May 2001. The tissue diagnosis made from the core biopsy specimen was compared with the final histopathology reports from the excised specimen. However, if the lump is not excised, a presumptive diagnosis of benign lesion was made only after at least 6 months follow up with no change in the breast lump. The data were analysed for sensitivity, specificity, predictive values, diagnostic accuracy and complications. The results from the 2 different sizes of core needle biopsies were compared accordingly and a statistical analysis was performed using Chi-squared test. Ninety-six core specimens were acquired with 14G needle while the other 54 with 16G needle. There was no significant statistical difference between the accuracy of both needle sizes. However, 4 complications occurred with the larger size 14G needle while none with the 16G needle, but this was not statistically significant. In conclusion the size 16G core biopsy needle provided an accurate diagnostic reliability that is comparable to the larger size 14G needle in the preoperative diagnosis of palpable breast lump.

Key Words: Core needle biopsy, Needle size, Palpable breast lump

Abbreviations: Fine-needle aspiration cytology (FNAC), Histopathology examination (HPE)

Introduction

A preoperative diagnosis of a palpable breast lump should be made prior to any surgical intervention to allow appropriate planning with the best therapeutic options. Over the years fine-needle aspiration cytology (FNAC) has been widely accepted as a reliable means of establishing tissue diagnosis¹⁻³. It has a high diagnostic accuracy rate

in the hands of experienced cytopathologists with a sensitivity ranging from 65% to 98%^{4,9}. However, as only smear of cells is available for assessment, FNAC is unable to distinguish invasive carcinoma from intraductal carcinoma and as high as 20% of yield may be inconclusive^{6,9}. Nonetheless, it must be emphasised that the FNAC requires experienced cytopathologists and this expertise is not readily available in most centres in our country.

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The automated Bard® Biopsy gun introduced in the mid 1980's revolutionised the core needle biopsy¹⁰. It overcomes many drawbacks of FNAC and insufficient tissue specimen is rarely a problem. Furthermore, due to its rapidity, it overcame the problem with firm, fibrotic and mobile lump in addition to reducing the patient's discomfort. More importantly, the core specimen is of better quality and integrity^{11,12}. Large-core gun biopsies theoretically decrease false negative results because they obtain larger quantities of tissue per pass. A core biopsy provides histological specimen rather than smear of cells thus providing more details on the tumour architecture. Hence, core biopsy obviates the need for a trained cytopathologist⁹⁻¹¹. The aim of our study was to determine the diagnostic accuracies and complication rates with two different gauges of core biopsy needles in the preoperative diagnosis of palpable breast lumps.

Materials and Methods

A total of 150 consecutive core biopsies were included in this non-randomised prospective study from May 2000 till May 2001. Information was obtained from the database at the Breast and Endocrine Surgical Unit, Hospital Kuala Lumpur. Cases that were excluded from the study are those with impalpable breast lesion, or follow-up of less than 6 months duration. Those patients who had a core biopsy performed were allocated to either size 14G or 16G core biopsy needle (Bard® Magnum® Core Tissue Biopsy Needle, C. R. Bard Inc., Covington, GA 30014, U.S.). Although the diameter of the 16G needle is less than that of the 14G needle by 0.4mm (19%), with their similar length of notch sample of 19mm, the estimated volume of sample notch is reduced by 22.7mm³ (34.5%). This would translate into a 1/3 reduction in the amount of tissue to be taken for HPE. This core biopsy needle is to be attached to an automated spring-loaded biopsy device (Bard® Magnum® Reusable Core Biopsy Instrument, C. R. Bard Inc., Covington, GA 30014, U.S.). The gun is adjusted to long-throw of 22mm excursion and

performed under local anaesthesia with strict asepsis technique. The HPE reports from the core biopsy would then be compared with the final HPE reports from the removal of the breast lesion. For those patients with benign HPE reports from core biopsy and opted not to have any surgical intervention, they would be closely observed for at least 6 months. The diagnosis is presumed to be benign should there be no changes in the lump as described by Simon et al¹⁴. The pain experienced during the procedure was recorded using a visual analogue scoring system on a scale of 1 to 10. The data was analysed for sensitivity, specificity, predictive values, diagnostic accuracy and complications using chi-squared test.

Results

All patients studied had palpable breast lumps; their age ranged from 20 - 80 years. However, the commonest age group at presentation for both the benign and malignant lumps was from 41-50 years of age. Benign lumps are commoner in the younger age groups and as the age advances, the ratio of malignant to benign lump increases. One hundred and fifty core biopsies in 145 patients were accrued in this study with 96 core biopsies using the 14G needle (Group I) and the remaining 54 with 16G needle (Group II). The ethnic distribution of our patients was Malay (58%), Chinese (22%), Indians (18%) and other (2%).

One hundred and five (72.4%) of the total 145 patients in this study had surgery for their breast lesions and thus had a final surgical HPE report, which is accepted as the gold standard. The other 40 (27.6%) patients diagnosed, as benign lesion from the core biopsy did not have any surgery performed for their breast lesions for one reason or another: thirteen patients had mastitis that resolved with antibiotics and 2 had granulomatous mastitis that resolved with steroid therapy, the other 25 patients with no surgery were followed-up for at least 6 months (range from 6 months to 13 months) and did not show any increase in the size of their breast lumps. For all the 40 patients with

no surgical removal of the lesions, they were presumed to have benign lesions.

In Group I, of the 53 core biopsies reported as benign, there were 3 malignant cases. Of the 43 core biopsies reported as malignant, there was 1 benign surgical HPE report (Table I). In Group II, of the 31 core biopsy specimens reported benign, 1 was malignant in nature. Of the 24 core biopsies reported as malignant, 1 was reported as benign after complete removal. This lady was diagnosed to have a T_{4b} breast cancer and had neo-adjuvant cyto-reduction chemotherapy prior to surgery. As such this case was not considered for analysis (Table II).

A comparison of the accuracy of the results obtained from 2 sizes of core biopsy needles use in the diagnosis of breast lumps was made (Table III). There was no significant difference between the two groups (p>0.05). Overall there was no difference in the pain experienced in both groups during the procedure (p>0.05). Nonetheless bleeding and haematoma formation was observed much higher using a larger size 14G needle, but this was statistically not significant (p>0.05). Wound infection occurred in 3 patients in Group I, and none from Group II (p >0.05).

Table I: Core biopsy HPE result with 14G needle compared with the disease status

Core biopsy with 14G needle	Disease status	
	Malignant	Benign
Malignant	42	1
Benign	3	50

Sensitivity (93.33%), Specificity (98.04%), Positive predictive value (97.67%), Negative predictive value (94.34%), False positive (2.33%), False negative (5.66%). Diagnostic accuracy (efficiency of the test) (95.83%)

Table II: Core biopsy HPE result with 16G needle compared with the disease status

Core biopsy with 16G needle	Disease status	
	Malignant	Benign
Malignant	23	0
Benign	1	30

Sensitivity (95.83%), Specificity (100%), Positive predictive value (100%), Negative predictive value (96.77%), False positive (0), False negative (3.23%), Diagnostic accuracy (efficiency of the test) (98.15%)

Table III: Comparing the accuracy in diagnosing breast lump between 14g and 16G needles (p = 0.2474)

Needle size	Disease status		Total
	Core HPE	Surgical HPE	
14G	43 (65.2%)	42 (64.6%)	85 (64.9%)
16G	23 (34.8%)	23 (35.4%)	46 (35.1%)
Total	66 (100%)	65 (100%)	131 (100%)

Discussion

Although breast cancer is the most common cancer found in Malaysian women, benign breast lumps are however, 10 times more common than breast cancer. As such obtaining an accurate pre-operative diagnosis is important for both benign and malignant breast lumps. A definitive diagnosis of a benign breast lump alleviates unnecessary fear and anxiety to the patient, while that of a malignant breast lump allows appropriate preoperative counseling and planning of treatment. Early work with percutaneous breast biopsy primarily involved FNAC per se. However, more recently core biopsy appears to be preferable because of its better characterisation of benign and malignant lesions and lower frequency of insufficient samples¹²⁻¹⁷.

In this study, the majority of patients with breast lumps fall between 31 years to 60 years with the 41-50 years age group comprising almost 42% patients. The younger patients tend to present with benign lump while the older patients with malignant lump. Only 8 out of 75 patients (10.7%) diagnosed with breast cancer were less than 40 years old. This figure is slightly higher than that reported in the Surveillance Epidemiology and End Results database between 1987 and 1989 of only 6.5%^{18,19}. The majority of the patients in our center were Malay, comprising 58%, followed by the Chinese at 22% and then the Indian at 18%. Although these data were only hospital-based and do not reflect the overall population based of breast cancer in our country, it gives an indirect insight into the ethnic distribution of breast cancer in our society.

The core biopsy obtained from the size 14G needle tends to be larger and longer in dimension and not fragmented, whereas with size 16G needle, it is smaller in all dimensions and occasionally fragmented despite the fact that the specimen notch of both the needles is equal in length. Under the naked eye, the core specimen obtained with 14G core biopsy needle appears more satisfactory but after processing and mounting on the slides for routine HPE, the specimen obtained with 16G core biopsy needle gives the similar cellular and architectural information as that of the 14G core biopsy needle.

The preliminary review of our result from the first 150 core biopsies acquired with the 2 different core biopsy needles in this study showed that almost 10% of all benign core biopsy HPE reports of palpable breast lumps were indeed proven malignant. A number of factors could have contributed to this result: first the cost of this disposable single-use core biopsy needle is prohibitory (RM80/each) and hence was recycled and repeatedly being reused. On an average, each core biopsy needle was recycled for reuse. Secondly small deep-seated lesions of 2cm or less should have a core biopsy performed under ultrasound guidance or stereotactic core biopsy to

avoid sampling error^{12,13}. None of our patients in this study had the biopsy done under ultrasound guidance. This is especially true if the lump is very firm to hard in consistency thereby deflecting the core biopsy needle off its trajectory²⁰.

A wide local excision is advocated should a strong clinical suspicion arise although the preoperative histological assessment is negative. There was 1 cases of malignant core biopsy HPE report in this study in which the excised surgical specimen was reported as benign disease. The core biopsy of this particular case was acquired with 16G needle and was clinically a 6cm T₄ malignant tumour with skin changes prior to surgery from neoadjuvant cytreduction chemotherapy. Minkowitz et al²¹, in his study evaluating the success of core needle biopsy achieved a sensitivity and specificity of 89% and 100% respectively and McMahon et al²² reported a sensitivity, specificity and accuracy at 88%, 100% and 94% respectively. The core biopsy result obtained in this study has a diagnostic accuracy of 96.7%. More importantly the size 16G core biopsy needle provided an accurate diagnostic reliability that is comparable to the larger size 14G needle. On the contrary others have argued that large gauge needles may associate with increase complication and related morbidity^{23,24}.

The pain experienced during the core biopsy procedure was recorded using a visual analogue scoring system on a scale of 1 to 10. They showed satisfactory performance and comparable outcomes and pain score in both the needle size. In addition to the fact that the most painful part of the procedure as related by many patients was infiltration of lignocaine. The actual core biopsy proper during which the core specimens were acquired was painless except for the sensation of a 'tug' on the breast during the firing of the automated biopsy device.

Bleeding following core biopsy is a common sequel, which normally ceased after application of pressure for approximately 5 minutes followed by pressure dressing. In one patient (1%) in whom

the 14G needle was used experienced troublesome bleeding from the entry site. None of the patients using the 16G needle had similar complaints. A few patients from both groups developed some skin contusion around the core biopsy site and resolved after an average of 2 weeks. From the Pearson Chi Square Test comparing troublesome bleeding between the two needles, the 'p' value is 0.437 (>0.05). Therefore, there is no statistically significant difference in the complication rate between the two groups. Of interest in one study with larger needle, Simon et al reported excessive bleeding in 5 (7.5%) out of 67 patients, of which 4 patients required only additional compression and 1 patient required suturing¹⁴.

Wound infection following core biopsy occurred in 3 patients in this study and all had core biopsy using 14G needle and none with 16G needle. Two patients had mastitis with breast abscess and the other one had infiltrating ductal carcinoma. It is interesting to note that in over 1000 core biopsies performed with 14G needles at the Breast Diagnostic and Counseling Centre, Englewood, Colorado, no significant haematoma or infection occurred. A similar lack of significant complications has also been reported by Myer et al²⁵. A potential disadvantage of core biopsy is the needle tract seedling with tumour cells. Therefore, it is prudent to place the core biopsy tract in such

a way as to be included in future surgery. In those undergoing mastectomy, it is preferable to excise the tract whereas in those with breast-conservation surgery, this potential seedling is likely to be controlled by radiotherapy¹³.

Tumour cells displacement may occur with any percutaneous breast biopsy procedure, including FNAC and core biopsy²⁶. In the largest study on epithelial displacement after core biopsy of the breast, Diaz et al found displacement of malignant epithelium in 32% cases²⁷. The frequency of tumour displacement was 37% after automated gun biopsy, 38% after palpation-guided biopsy and 23% after vacuum-assisted biopsy. There is an inverse relationship between the amount of tumour displacement observed and time to excision suggesting that tumour cells do not survive displacement.

We conclude that the size 16G core biopsy needle provided an accurate diagnostic reliability that is comparable to the larger size 14G needle in the preoperative diagnosis of palpable breast lumps.

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ORIGINAL ARTICLE

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