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**Original Article**

**Comparative Accuracy and Complications of Palpation-Guided Versus Ultrasound-Guided Core Needle Biopsy of Palpable Breast Lumps in Ahmadu Bello University Teaching Hospital, Zaria**



**Abstract**

**Background:** Breast lumps are a common complaint by women. Palpable breast lumps are accessible to core needle biopsy (CNB) with the aim of obtaining tissue for histologic diagnosis. CNB is achievable either by palpation guidance or image guidance. The superiority of either technique in returning an accurate diagnosis has not been demonstrated in our centre. **Aim:** This study aimed to compare the diagnostic accuracy and complications of palpation-guided versus ultrasound-guided CNB techniques in palpable breast lumps. **Materials and Methods:** This was a randomised, controlled, comparative study. Consenting patients were randomised into either a palpation-guided or an ultrasound-guided group. All patients subsequently had open surgical biopsy, which represented the control group. Data analysis was done using SPSS, version 21. **Results:** Each CNB group had 40 patients. In the palpation-guided group, 24 (54.55%) lumps were benign and 13 (29.55%) were malignant, whilst seven (15.90%) were inconclusive. In the ultrasound-guided group, 31 (65.96%) lumps were benign and 15 (31.91%) were malignant, whilst one (2.13%) was inconclusive. The sensitivity and specificity for palpation-guided CNB were 92.9% and 100%, respectively. The sensitivity and specificity for ultrasound-guided CNB were 100% each. There was no statistically significant difference in sensitivity between the two groups (*P* value of 0.4828). One patient (2.5%) in the ultrasound-guided CNB group had a hematoma. **Conclusions:** This study has shown that CNB has high diagnostic accuracy and low complications in the management of breast lumps, either by palpation-guided or ultrasound-guided techniques. There was no significant difference in accuracy or complications of CNB using either technique.

**Keywords:** *Core needle biopsy, palpable breast lump, palpation-guided CNB, ultrasound-guided CNB*

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**Introduction**

Palpable breast lesions are common in women presenting to the breast clinic.[1] A symptomatic breast lump is of great concern to the patient and may have psychological impact on the patient and her family.[2] The presence of a lump in the breast challenges the diagnostic acumen of the surgeon. The primary concern is whether such a lesion is benign or malignant. Malignant breast disease is the dreaded of the two. This is justifiably so, as breast cancer is the most common cancer plaguing women worldwide.[1,3] A lump in the breast burdens the patient with phobia for cancer. Its mere presence poses a threat to the woman’s sense of body image and sexuality,[2] because of either the course of the underlying pathology or its treatment.

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Core needle biopsy (CNB) has been used in breast diagnosis for several decades and shown to be accurate with relatively no significant complications. Although palpation-guided percutaneous CNB continues to be used in the clinic setting in preoperative diagnosis of palpable breast lesions, image-guided CNB is largely employed by breast centres around the world.[4-6]

The overwhelming concern of every woman presenting with a palpable breast lump is to know if it is cancerous or not. CNB is only useful when it has correctly sampled the target lesion and in so doing exposed the patient to the least distress. CNB is minimally invasive, cheaper, associated with fewer complications, and cosmetically more acceptable in comparison to open surgical biopsy.[6-8]

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The majority of CNB performed in our outpatient clinic is palpation-guided. Ultrasound-guided CNB is by default reserved for repeat-biopsy procedures when previous palpation-guided CNB is nonrepresentative; in lumps clinically obscure; or lumps difficult to access. This obviously poses the pitfall of selection bias, as no meaningful evidence-based deductions can be made regarding the superiority of either technique. This study will prospectively seek to verify if either technique is superior to the other and will determine the complications associated with either technique. It further seeks to validate the best practice in obtaining tissue diagnosis in our breast clinic. This potentially offers an evidence-based platform for prompt and accurate diagnosis in effective patient management. It is hoped that this study will contribute to the literature in this field of clinical practice.

The aim of the study was to compare palpation-guided and ultrasound-guided CNB of palpable breast lumps in women.

**Materials and Methods Study design**

This was a randomised, controlled, comparative study. **Study duration**

This study was conducted over a 12-month period from July 2018 to June 2019.

**Study population**

The study included all adult female patients who presented to the General Surgery Unit of the hospital with palpable breast lump(s). This included all patients seen at the surgical outpatient department (SOPD) and patients on admission requiring surgical consultation for suspicious or incidental breast lumps.

**Inclusion criteria**

All consenting adult (18 years and older) female patients with palpable breast lump(s) were included in this study.

**Exclusion criteria**

Following are the exclusion criteria:

1. Patients with fungating breast tumours and locally advanced skin involvement

2. Patients with breast abscesses 3. Patients with breast cysts

4. Patients with uncorrected bleeding disorders

5. Patients with breast lumps less than 2cm in the widest diameter.

**Sample size**

The minimum sample size for this study was calculated using the Yamane formula[9]:

n= 1+N(e)2 

N

 

This gave a minimum of 37 patients in each group.

Thus, the minimum number of patients recruited for this study would be 37×2 = 74.

**Study protocol**

All female patients who presented with a palpable breast lump(s) and who met the inclusion criteria were recruited for this study. Clinical breast examination was carried on all consenting patients after adequate counselling and in the presence of a chaperone at the SOPD. Each patient subsequently had breast ultrasound scan of both breasts and axillae in the breast radiology unit. The same ultrasonography machine was used during this study, including the ultrasound-guided biopsies using the Mindray Ultrasound machine, fitted with a 7.5–13 MHz transducer (DC-8 series, 2013. China). All core needle breast biopsies were carried out using the 14G Geotek semi-automatic CNB device (reference number GSNA1420, Turkey). Patients were randomised into two groups using SPSS-generated random numbers such that each group had half the total patients required for this study: group A being the palpation-guided CNB group and group B being the ultrasound-guided CNB group. Patients in group A had their CNB procedures in the SOPD, whereas those in group B had the procedures done in the radiology department under real-time breast ultrasound interrogation. All patients (groups A and B) had surgical biopsy following CNB results. Patients who had complete clinical-radiologic-pathologic concordant malignant findings, with modified triple test score in keeping with a malignant diagnosis, were however considered true positives. This group of patients was exempt from surgical biopsy to allow for immediate commencement of oncologic multimodal therapy that included mastectomy as indicated. Their definitive mastectomy histology reports were used in place of surgical biopsy results. Patients with a malignant diagnosis also had additional routine imaging using mammography or magnetic resonance imaging, as indicated, as a part of their work-up for definitive management.

Following the CNB procedure for both groups A and B, patients were instructed on the importance of follow-up visits, during which the biopsy site was assessed, the histology report discussed, and subsequent management was planned. The wounds were inspected on the third and seventh day after the procedure. Details of the procedure including any complications (bleeding, hematoma, wound infection, and others) and histology results were entered into the structured *pro forma* for each patient.

**Ethical considerations**

The approval for this study was obtained from the Health Research Ethics Committee (HREC) of the hospital. The nature of this study was carefully explained to the recruited patients and their caregivers in a language they understood,

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and written informed consent was obtained. The patient selection was unbiased, and all patient examination and biopsy procedures were carried out in the presence of a chaperone. Patients reserved the right to withdraw consent at any point during this study. No additional cost was borne by the patient in the course of this study. All data obtained in the course of this study were treated with confidentiality and patient privacy respected.

**Data analysis**

Data obtained were entered into a structured *pro forma* for each patient and analysed using the Statistical Program for the Social Sciences, version 21 (SPSS, Chicago, IL, USA). The chi-square test was used to analyse categorical variables. Confidence interval of 95% was employed, and *P* < 0.05 was considered significant.

**Results**

A total of 80 patients had their data analysed. Forty of these belonged to the palpation-guided CNB group, whereas the other 40 patients belonged to the ultrasound-guided CNB group.

The baseline characteristics of the study population are shown in Table 1.



**Sociodemographic characteristics**

The age distribution of the patients is shown in Table 2.

Twenty-five patients (51.0%) with benign lumps fell within the 20–29 years age group, whilst 13 patients (41.0%) with malignant lumps fell in the 40–49 years age group. Figure 1 shows the age distribution of benign and malignant tumours amongst the study participants.

Figure 2 illustrates the site distribution of breast lumps in this study.

Tables 3 and 4 give the summary of lump dimensions as measured clinically and by breast sonography, respectively.

A total number of 91 breast lumps were biopsied in the 80 patients. Tables 5 and 6 show the histologic outcomes of both CNB procedures.

The proportion of inconclusive CNB results for each method is illustrated in Figures 3 and 4, respectively.

Amongst the conclusive biopsy results returned by palpation-guided CNB, one of the 24 returned as benign was found to be malignant on surgical biopsy. The seven inconclusive CNBs were all confirmed benign following surgical biopsy. Figure 5 illustrates these findings.

**Table 1: Baseline characteristics of the study population**

**Palpation-guided CNB**

**CNB group**

**Ultrasound-guided** **Total CNB**

Age (years)\* Occupation

Marital status

Civil servant

Self-employed Unemployed Student Single Married Divorcee Widow

**N % N** 34 (12) 33 7 (17.5) 8

7 (17.5) 6 11 (27.5) 11 15 (37.5) 15 13 (32.5) 14 23 (57.5) 24 3 (7.5) 0 1 (2.5) 2

**%** **N** **%** (13) 33 (12)

(20.0) 15 (18.8)

(15.0) 13 (16.3) (27.5) 22 (27.5) (37.5) 30 (37.5) (35.0) 27 (33.8) (60.0) 47 (58.8) (0.0) 3 (3.8) (5.0) 3 (3.8)

Values in parentheses are percentages unless indicated otherwise \*Values are mean (standard deviation)

**Table 2: Age distribution of the study population**

**Age group (years)**

<20 20–29 30–39 40–49 50–59 60–69

70 and older Total

**Palpation-guided group, number of patients (%)** 1 (2.5) 17 (42.5) 10 (25.0) 9 (22.5) 2 (5.0) 0 (0.0) 1 (2.5) 40 (100)

**Ultrasound-guided group, number of patients (%)** 7 (17.5) 12 (30.0) 8 (20.0) 9 (22.5) 2 (5.0) 2 (5.0) 0 (0.0) 40 (100)

**Total**

8 (10.0) 29 (36.3) 18 (22.5) 18 (22.5) 4 (3.8) 2 (2.5) 1 (1.3) 80 (100)

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30

Number of Paents

25

25

20

15

10

8 5

0 4 0

<20 20-29

13

9 9

5

2 2

30-39 40-49 50-59

Age Group

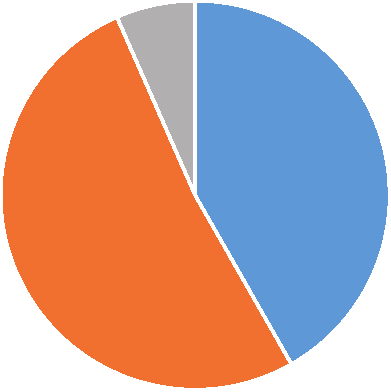
0 2 0 1

60-69 >=70

Benign Malignant

**Figure 1: Age distribution of tumours in the study population**

Lump Site



6.6%

51.6%

Right breast Le breast

**Figure 2: Site distribution of breast lumps**

41.8%

Both breasts

difference in the sensitivity of both methods.Table 8 depicts the accuracy measures for both CNB techniques.

**Complications of CNB**

No patient in the palpation-guided CNB group had any complications following the procedure. One patient (2.5%) in the ultrasound-guided CNB group had a hematoma; no other complication noted in this group.

Fifty-four patients had surgical biopsy following CNB out of the 80 patients in this study. The other 26 patients had modified radical mastectomy following a malignant histology report from CNB. These 26 patients were thus excluded from the analysis for complications of surgical biopsy. Thus, three patients (5.6%) had bleeding, one patient had hematoma, and four patients (7.4%) had wound infection complicating their procedures. No other complication was noted following surgical biopsy. Table 9 shows the complications noted in this study.

The only one inconclusive return from the ultrasound-guided CNB group was confirmed malignant following surgical biopsy. Figure 6 illustrates these findings.

Exact and asymptotic 95% confidence interval for the ability of either CNB technique to adequately sample a lesion returned a *P* value of 0.0270, which was statistically significant.

The measures of diagnostic accuracy were derived using a 2 x 2 cross-tabulation [Table 7 ]. Two-sample test for binomial proportions (Fisher’s exact test) was used to check if there is statistically significant difference in sensitivity between palpation-guided CNB and ultrasound-guided CNB. A *P* value of 0.4828 shows that there is no statistically significant

Figure 7 shows a round hypoechoic mass with microlobulations [Figure 7], whereas Figure 7 shows an echogenic biopsy needle (N) traversing the mass (M) as representative tissue cores were obtained.

**Discussion**

The peak age group with palpable breast lumps in this study was the 20–29 years group, with 36.3% patients. This is similar to the findings by Yusufu *et al.*[10] in a retrospective study on breast masses in Zaria spanning a 14-year period. Benign breast lumps were also found to be commonest in the 20–29 years age group (51.0%). The most common benign histologic diagnosis was fibroadenoma. Similar findings have been documented amongst female patients in their third decade of life in several studies.[11-13]

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**Table 3: Breast lump size by clinical measurement**

**CNB procedure** Palpation-guided CNB Ultrasound-guided CNB Total

**Mean (cm)** 5 5 5

**Standard deviation (cm)** 3 3 3

**Minimum (cm)** 2 2 2

**Maximum (cm)** 14 12 14

**Total lumps** 44 47 91

**Table 4: Breast lump size by sonographic measurement**

**CNB procedure** Palpation-guided CNB Ultrasound-guided CNB Total

**Mean (cm)** 3.34 3.30 3.32

**Standard deviation (cm)** 2.09 2.25 2.16

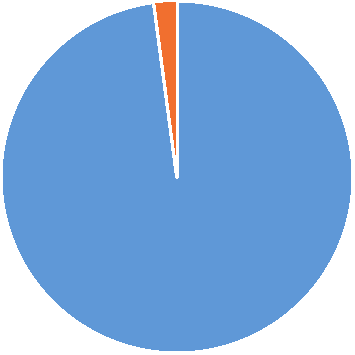
**Minimum (cm)** 0.80 1.05 0.80

**Maximum (cm)** 12.52 10.69 12.52

**Total lumps** 44 47 91

**Table 5: Outcome of histology amongst breast lumps biopsied**

Palpaon guided CNB



**Histology outcome** Malignant Benign Inconclusive Total

**Palpation-guided CNB** 13 24 7 44

**Ultrasound-** **Total guided CNB**

15 28 31 55 1 8 47 91

15.90%

**Table 6: Spectrum of pathologic lesions amongst patients**

**Lesion** Fibroadenoma Lactating adenoma Intraductal papilloma Lipoma

Phyllodes tumour Invasive ductal carcinoma

**Number of patients (%)** 39 (48.75) 2 (2.50) 4 (5.00) 1 (1.25) 3 (3.75)

28 (35.00)

84.10%

Conclusive Inconclusive

Medullary carcinoma Colloid carcinoma Hodgkin lymphoma Total

1 (1.25) 1 (1.25) 1 (1.25)

80 (100)

**Figure 3: Inconclusive biopsies in palpation-guided group**

Ultrasound guided CNB

Malignant breast lumps were found to peak in the 40– 49 years age group in this study (41.9%). Afolayan *et al.*[14] in Ilorin, Nigeria, reported a similar finding for breast cancer amongst Nigerian women. Larsen *et al.*[15] in Oslo, Norway, reported a higher peak incidence in the 50–69 years age group. In the United States, estimated new female breast cancer cases for 2017 showed the peak incidence within the 60–69 years group.[16]

The average clinical size of breast lumps in this study was 5cm in both the palpation-guided and ultrasound-guided CNB groups. The ultrasound-measured breast lump size average was however lower, 3.34cm in the palpation-guided group and 3.30cm in the ultrasound-guided CNB group. Shoma *et al.*[17] demonstrated that ultrasound assessment of breast cancer size is more accurate than both clinical and mammographic assessments of same lesions. Clinical measurement of lump size by palpation may be prone to the overestimation of lump size as it is influenced by factors such as skin thickness, perilesional oedema, and obesity. Allen *et al.*[18] also found that both ultrasound and

2.10%

97.90%

Conclusive Inconclusive

**Figure 4: Inconclusive biopsies in ultrasound-guided group**

mammography were more reliable than palpation in the preoperative estimation of breast cancer size but noted that whilst palpation did tend to overestimate tumour size, ultrasound underestimated size to a lesser degree when compared with the histologic size.

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**Palpaon guided CNB**

**Histology Report of Surgical Biopsy**

25

23 20

15

13 10

5

0 1 0

Malignant Benign **Histology Report of Palpaon guided CNB**

True Benign True Malignant

**Figure 5: Comparison of palpation-guided biopsy to definitive surgical biopsy histology**

**Ultrasound guided CNB** 35



**Histogy Report of Surgical Biopsy**

30 31

25

20

15

15

10

5

0 0 0

Malignant Benign **Histology Report of Ultrasound guided CNB**

True Benign True Malignant

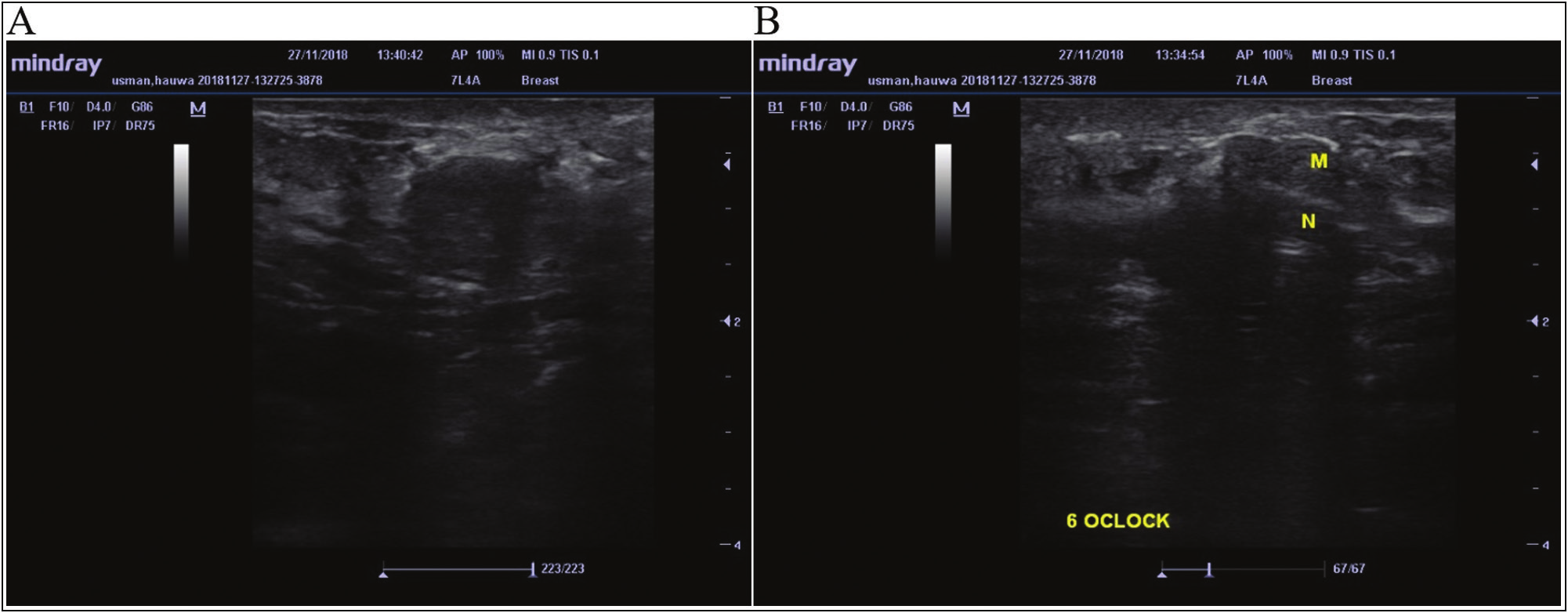
**Figure 6: Comparison of ultrasound-guided biopsy to definitive surgical biopsy histology**

The histology results were inconclusive (inadequate or nonrepresentative tissue cores) in eight out of the 91 breast lumps sampled in the 80 patients in this study. Seven (15.9%) of these inconclusive CNB results were from the palpation-guided group (four nonrepresentative and three inadequate). Only one CNB (2.1%) in the ultrasound-guided group was inconclusive (suspicious, likely malignant). Surgical biopsy returned this lesion as malignant. The difference in returning inconclusive CNB results was statistically significant in favour of ultrasound-guided CNB (*P* value of 0.0270). Six of the eight inconclusive CNB lumps (75%) had

an ultrasound lump dimension 1.60cm or less, suggesting that sampling error may be higher in breast masses less than 2cm in size. All of these lumps measured 2cm or greater by clinical size estimation, indicating their actual size may have been overestimated. Five of these small lesions (83.3%) were biopsied by palpation-guided method and the last one by ultrasound-guided method. Ward *et al.*[19] also found a statistically significant association between a missed breast CNB and the ultrasound-determined size of the lump.

The sensitivity (92.9%) and specificity (100%) of palpation-guided CNB in this study were slightly higher than the

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**Table 7: The measures of accuracy were derived using a 2×2 crosstabulation**

**Disease present** **Disease absent** **Total** Test positive a b a + b Test negative c d c + d Total a + c b + d N

The positive predictive value (PPV) = a/(a + b) The negative predictive value (NPV) = d/(c + d) Sensitivity = a/(a + c)

Specificity = d/(b + d)

Likelihood ratio (LR) = Sensitivity/1−specificity False negative rate (FNR) = 1−sensitivity

False positive rate (FPR) = 1−specificity

findings by Gukas *et al.*[20] in Jos, Nigeria, who reported a sensitivity of 88.9% and a specificity of 96.8%. The sensitivity (100%) and specificity (100%) of ultrasound-guided CNB in this study were similar to those reported by Parker *et al.*[21] Liberman[7] reported a sensitivity of 97%. Bruening *et al.*[8] concluded in a systematic review that it seemed reasonable to substitute certain CNB procedures (including ultrasound-guided CNB) for open surgical breast biopsy, given the similar sensitivity and lower complication rates for some of the percutaneous procedures.

The false negative rate (FNR) (4.2%) in the palpation-guided group was lower than the 7.6% reported by Gukas *et al.*[20] There were no false negatives in the ultrasound-guided CNB

**Table 8: Measures of accuracy of CNB techniques**

**Measures of accuracy** **Palpation-guided CNB** **Ultrasound-guided CNB**

Sensitivity Specificity *P* = 0.483 PPV

NPV

*P* = 0.463 FPR FNR



*P* = 0.463 LR

**% N % N** 92.9 14 100 15 100 23 100 31

100 13 100 15 95.7 23 100 31

0 13 0 15 4.2 24 0 31

40.9 58.1

FPR = false positive rate, FNR = false negative rate, LR = likelihood ratio, NPV = negative predictive value, PPV = positive predictive value

**Table 9: Complications of biopsy techniques**

**Complication (%)** Bleeding (%) Hematoma (%) Wound infection (%) Others (%)

**Palpation-guided CNB** 0 0 0 0

**Ultrasound-guided CNB** 0 2.5 0 0

**Open surgical biopsy** 5.6 1.9 7.4 0

**Figure 7: Breast ultrasound scan: longitudinal view (a) and ultrasound-guided CNB (b)**

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group. This suggests that a standard follow-up protocol must be utilised after palpation-guided CNB to identify patients with malignant tumours early so that definitive management can be instituted. Radhakrishna *et al.*[22] reported an FNR of 8.5%; the study population, however, included screen-detected breast lesions. Varsha *et al.*[23] found that false negative diagnosis of breast carcinoma was more common in CNB performed by palpation-guidance but occurred to a lesser degree in image-guided biopsies.

Only one patient in the ultrasound-guided CNB group had a hematoma complicating her biopsy procedure. This may have resulted from repeated attempts to position the needle under real-time ultrasound visualisation. It was successfully managed by a single episode of ultrasound-guided aspiration of 4.2mL of blood 9 days following the procedure. No complications were reported in the palpation-guided group. Surgical biopsy was complicated by bleeding (5.6%), hematoma (1.9%), and wound infection (7.4%). Dahabreh *et al.*[6] in a systematic review of publications with 2%–10% of surgical biopsies complicated by hematoma formation and 3.8%–6.3% complicated by infection. A10.2% of wire-localised open biopsy procedures were complicated by vasovagal reactions.[8] In the Dahabreh *et al.*[6] review, the incidence of severe complications with CNB was less than 1%.

**Limitations**

1. The study design did not accommodate repeat CNBs. Considering the high accuracy of palpation-guided and ultrasound-guided CNB, the yield of repeat needle biopsies may be worth evaluating.

2. The cost-effectiveness of either technique was not evaluated. It may be an important determinant of acceptance of either technique by patients in our environment.

3. The logistic challenges with routine hormone receptor assay and immunohistochemistry precluded standardised comparison between these parameters in specimen obtained via CNB with those obtained by open surgical biopsy.

**Conclusions**

This study has shown that CNB, using either palpation-guided or ultrasound-guided techniques, has high diagnostic accuracy in the management of breast lumps in female patients. The difference in accuracy is in favour of ultrasound-guided CNB, but this was not statistically significant to recommend the routine use of one technique over the other. The difference in returning inconclusive CNB results was however statistically significant in favour of ultrasound-guided CNB (*P* value of 0.0270).

Both palpation-guided and ultrasound-guided CNBs have been shown in this study to be safe and approaching the accuracy of open surgical biopsy in obtaining the correct diagnosis.

**Recommendations**

1. The evaluation of breast lumps in the breast clinic should include the routine use of CNB for lesions suspected to be malignant as the procedure has been shown to have high diagnostic accuracy and is generally safe with low complication rates compared to open surgical biopsy.

2. Breast lumps 2cm or less in the widest clinical diameter should preferably be sampled by ultrasound-guided CNB to reduce the chances of delayed diagnosis from inconclusive histology results and false negative returns.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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