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Research Article

Ultrasound Guided Core Needle Biopsy in The Diagnosis of Suspicious Breast Lesions: Radiologist's perspectives

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ABSTRACT

Background: Ultrasound guided core needle biopsy is becoming a gold standard in the work up of suspicious breast lesion. In Iraq, radiologists are not taking the lead in core needle biopsy performance.

Objectives: To evaluate the radiologist performance of core needle biopsy highlighting the precession and accuracy of the procedure, the concordance of ultrasound and histopathology, and identifying challenges facing the radiologist during the procedure.

Subjects and Methods: A prospective study involving a total of 50 patients with ultrasound (US) BIRADS IV or V. Ultrasound guided core needle biopsy was performed for each patient. Surgical pathology diagnosis was available for 40 patients. core needle biopsy results were correlated with Breast Imaging-Reporting and Data System (BI-RADS) categories and validity of the test was evaluated.

Results: Malignancy was confirmed by histopathology in 76% of the cores. Concordance between BI-RADS(US) and histopathology for benignity and malignancy was achieved in all cores. Borderline lesions constituted 10% of total cores taken. Surgical resection of these lesions upgraded 3/5 (60%): two atypical ductal hyperplasia and an intraductal papillary lesions diagnosed by core needle biopsy found to be invasive ductal carcinoma after surgical resection. Sensitivity of core needle biopsy in this study was 91.4% with 100% specificity. Positive and negative predictive values were 100% and 62.5% respectively. The underestimation rate in high-risk group was 3/5 (60%). No significant complication was reported.

Conclusion: Ultrasound guided core needle biopsy is a safe, efficient and relatively inexpensive method in diagnosing suspicious breast lesions. Radiologists can produce high sensitivity and specificity results. Radio pathological correlation is of paramount in achieving accurate results.

Introduction

Breast cancer is the most prevalent cancer among women worldwide and the fifth leading cause of death among cancers in both sexes globally (1). In Iraq, newer data from the Iraqi Cancer Registry revealed a rise in the breast cancer rates since 2009 (26.6 per 100000 in 2000 to 31.5 per 100000 in 2009) compared to the relatively stable incidence from 2000 to 2009. Women aged ≥ 50 years making the major contribution to the increase (2, 3). Although the 90% of palpable breast lumps are benign, a new palpable breast mass is a common presenting sign of breast cancer (4). In general, cancers detected symptomatically tend to be more aggressive than screen-detected cancers and to have a poorer prognosis (5). The gold standard in breast mass workup is multidisciplinary or interprofessional approach (6) involving clinician, a radiologist and a pathologist. Core needle biopsy (CNB) is a well-established step in the assessment of palpable and nonpalpable breast lesion diagnosis. CNB is recommended for Breast Imaging-Reporting and Data System (BI-RADS) IV and V lesions (7). For BI-RADS III lesions, CNB is indicated in certain situations including patients genetic or family risk, medical or social difficulties for follow-up, or pregnancy. In addition, alleviating extreme patient anxiety may also prompt tissue sampling (7, 8). Percutaneous biopsy techniques achieve two advantages over FNA: first, maximum degree of accuracy and second, more information about the tumor type, grade, invasion, hormonal receptors. etc. To reach these objectives, the percutaneous biopsy devices have evolved, from FNA cytology towards CNB and later vacuum-assisted biopsy (Liberman, 2000). Ultrasound is the standard guide for breast lesion localization to perform CNB because of patient comfort, efficiency, economy, absence of ionizing radiation, in addition to sampling accuracy due to real-time visualization of the needle within the lesion (9, 10).

Worldwide, well trained interventional radiologists are responsible for performing breast CNB. Although, surgeons and pathologist are sometime involved in the procedure, extensive training and basic knowledge of mammography and breast ultrasound is an essential prerequisite. In Iraq, radiologists are not taking the lead in breast CNB performance. Several factors contribute to this defect; most are related to limited availability of the core needles in most of the hospitals and centers and more importantly patient overcrowding in ultrasound unit of breast clinics reducing the time available for radiologist to take their usual role in biopsy intervention.

The aim of this study was to evaluate the precession and accuracy of the ultrasound (US) guided core needle biopsy and study the concordance of US and histopathology. Additionally, to identifying challenges facing the radiologist during the procedure.

Subjects and methods

This is a prospective interventional study conducted in The Referral and Training Center of Early Detection of Breast Disease, Oncology Teaching Hospital, Bagdad Medical City, Iraq, during the period between April 2020 to December 2020. The study was approved by Medical City Directorate and Oncology Teaching Hospital ethical committees. Informed verbal consents were given by all participants. A total of 50 patients were recruited. Inclusion criteria were; females with palpable BI-RADS IV or V breast mass or non-palpable BI-RADS IV or V lesion referred form ultrasound and screening or diagnostic mammography. Mastectomy bed and male breast lesions were excluded. Patients' data including demographics, characteristics and contacts were collected in an information sheets form patients' card.

Biopsies collected by the procedure were sent in a labeled tube to the pathology lab of the same hospital. Histopathology results were collected after the report was issued and the histo-radiological concordance was discussed for each case.

All patients were followed up after a month by phone contact, 40 patients underwent surgical removal of the mass, the results of surgical histopathology for those patients were sent electronically by the phone, 6 patients were referred to oncology outpatients and scheduled for primary or neoadjuvant chemotherapy, the oncology cards of these patients were reviewed. Patients who were referred for follow up were contacted after 3 months and a follow up US was done to re-evaluate the lesion.

Patient preparation

The procedure and its importance were first explained to the patient. After taking a verbal consent, the patient was asked to lay on the couch in a supine position or semiprone according to the lesion site in order to get the best approach. The biopsy tray was organized as Figure1 shows.

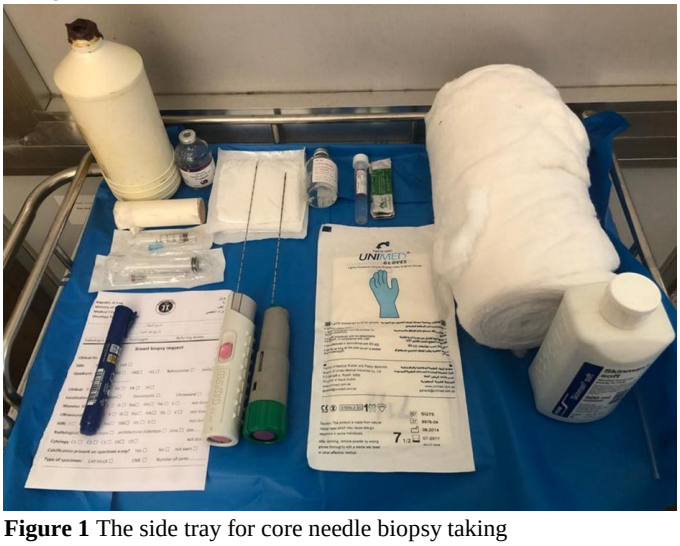

Figure 1 The side tray for core needle biopsy taking

When the patient had taken the right position, the plane through which the lesion could be best approached was localized via a quick scan. The site of the procedure and the transducer were then sterilized with iodide. With the transducer placed vertically on the lesion and the full view of the lesion was displayed, 3cc 2% lidocaine was infused around the lesion subdermally using the in-plain view and following the planned track for the actual biopsy. While awaiting the anesthesia to work, a 10ml tube of formalin was labeled with patient ID and placed on trolly at a close proximity to the radiologist with histopathology request which was filled with necessary information.

Ultrasound guided core needle biopsy technique

The transducer was held fixed over the lesion in the nondominant hand and the biopsy device in the other. The needle was introduced though skin, 1–2 cm from the edge of the transducer by a slight push to ensure a needle path that is parallel with long axis of the transducer.

Once in optimum position in or at the edge of the mass, a prefire image is obtained for documentation. Several variables interfere with the needle tip position, First penetration depth of the needle. BARD fully automated needle (BARD biopsy system, Spain, cat No 441816) used in this study was G18 has a 22mm penetration depth with a sample notch of 17mm and 5 mm dead space. Second is the lesion size. For large lesions the needle tip position was within the lesion as show in Figure 2, with one core included the lesion margin. In smaller lesions, the needle tip usually placed slightly before the mass to ensure the mass lies within the sample notch postfire. The postfire needle position estimation was usually considered before shooting to ensure safe track and avoid chest wall.

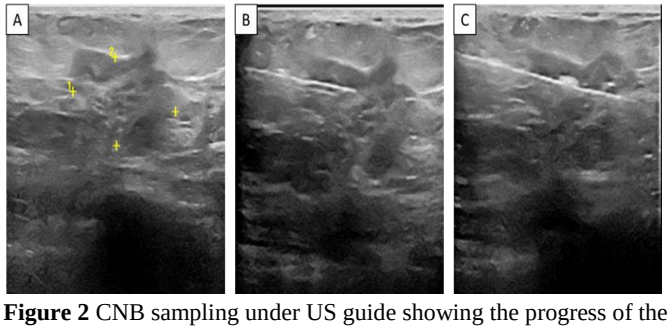

Figure 2 CNB sampling under US guide showing the progress of the needle after shooting

After taking a sample the needle was withdrawn and manual compression was applied to the site with the help of an assistant to prevent bleeding and subsequent bruising. The needle was swished in a small test tube of normal saline to remove the specimen and subsequently transferred to the labeled formalin tube. An average of 3 cores with good quality were taken from each lesion from the same track. The quality of the cores was assessed visually, when the cores are complete, white and sank in the tube. After completing the procedure, dressing gauze was applied on the site of the procedure.

Statistical analyses

All statistical analyses were carried out using Statistical Package for Social Sciences software version 25 (IBM Corp., Armonk, N.Y., USA). Continuous variables were expressed as mean+ range. Chi square and Fisher exact test were used to compare groups when needed. Sensitivity was measured as the proportion of positive tests from all malignant cases. Specificity was measured as the proportion of negative tests from all benign cases. The positive predictive value (PPV) measured as the proportion of true positive from total positive tests. Negative predictive value (NPV) was measured as the proportion of true negative from total negative tests. The overall test accuracy was measured as the proportion of all results that were true. The underestimation rate of CNB-diagnosed high -risk lesions was defined as the proportion of lesions diagnosed as high -risk by CNB that were upgraded to invasive cancer after surgical excision (Barr et al., 2015). A P value <0.05 was considered significant.

Results

The total number of patients is 50 and the mean age of the patients in our cohort was 48 years ranged from 14-72 years. BI-RADS V patients were significantly older (P=0.026). Family history of cancer was reported in 16 (32%) of the cases, 10 (62%) were breast cancer. 41 (82%) of the patients had a palpable breast mass while the rest were referred form follow up or screening mammography. All patients' characteristics are summarized in (Table 1).

Multiple breast lesions identified in only 2(4%) of the patients one was in the same breast and the other was bilateral, all the rest had solitary lesion. 60% of the lesions were in the UOQ, the vast majority (86%) were mass lesions, approximately half of the lesions were BI-RADS V with 60% having suspicious lymph nodes, detailed description showed in Table 1.

Radio-histopathology concordance and dis-concordance

Malignancy was confirmed by histopathology in 38 (76%) of the cores, 35/38 (92%) were invasive ductal carcinoma as shown in Table 2.

Malignant lesions were significantly more in women older than 40 years (P=0.011) and menopausal women 22 (57.7%), P=0.003. Although 26.3% of women with malignant lesions had family history of breast cancer or related cancer, that was statically not significant as 5 (41.7%) of patient with benign lesion also had positive family history. The majority of benign lesions (66.7 %) were in BI-RADS 4a and b subcategories compared to 26 (68.4%) of malignant lesions which were categorized as BI-RADS 5, Table 3.

Surgical removal of the lesion whether excisional, breast conservative or mastectomy was performed for 40 cases(10 cases excluded as surgical biopsy not obtained) .None of the malignant lesions were in BI-RADS IVa category, by contrast all lesions in BI-RADS V were malignant (Table 4).

Thus, concordance between BI-RADS and histopathology for benignity and malignancy was achieved in all cores. Borderline lesions constituted 5 (10%) of total cores taken. These lesions had high risk histopathological changes such as intraductal papillary lesion(IDPL) and atypical ductal hyperplasia(ADH) (Table 5). Surgical resection of these lesions upgraded 3/5 (60%): two atypical ductal hyperplasia and the intraductal papillary lesions diagnosed by CNB upgraded to invasive ductal carcinoma after surgical biopsy.

As guidelines recommended, all these 5 lesions were sent for excisional biopsy. Three out of five turned to be positive for malignancy.

The validity of core needle biopsy

Surgical resection was available for 40 cases. When histopathology of the cores was correlated to that of the surgical resection which is the gold standard, ultrasound guided CNB was able to correctly diagnose 32 malignant lesions out of a total 35 malignant cases diagnosed by surgical excision, however, it missed 3 (8.6%) cases all of which were high risk lesions. Thus, the sensitivity of CNB in this study was approximately 91.4%. On the other hand, none of the cases reported as nonmalignant by CNB were positive for malignancy after surgical resection giving the CNB

test a 100% specificity. CNB positive predictive value was 100% as all the malignant cores were truly malignant (Table 6).

Negative predictive value was 62.5% because positive malignant lesion was identified in 3/12 negative cores. Although the underestimation rate in high-risk group was 3/5 (60%), all lesions were with in BI-RADS IVb-c categories and excisional biopsy was recommended.

Table 1: Patients' characteristics and ultrasound lesions features

Variable	No	%
Age groups		
≤40	11	22
41-59	30	60
≥60	9	18
Family history of cancer		
negative	34	68
breast	10	20
ovary	1	2
bowel	1	2
others	4	8
Menstrual status		
menstruating	27	54
menopause	23	46
Type of referral		
Follow up	9	18
Diagnostic	41	82
Laterality		
Left	23	46
Right	26	26
Bilateral	1	2
Quadrant		
UOQ	30	60
UIQ	7	14
LOQ	6	12
LIQ	3	6
RA	4	8
Number of lesions		
1	48	96
2	2	4
Type of the lesion		
Mass	43	86
Area	7	14
Lesion size		
5-10 mm	4	8
11-20 mm	16	32
21-50 mm	29	53
> 50 mm	1	2
US BI-RADS		
4a	2	4
4b	9	18
4c	13	26
5	26	52
Suspicious LN		
present	17	34
absent	33	66

Table 2: Core needle biopsy characteristics

Variable	No	%
Number of core biopsy		
3	26	52
4	23	23
5	1	2
Complications		
not present	35	70
mild pain	11	22
mild bleeding	4	8
Type of lesion		
malignant	38	76
non malignant	12	24
Type of malignancy		
Invasive ductal ca	36	95
Ductal ca in situ	1	2.5
lymphoproliferative	1	2.5
Management		
Excisional biopsy	6	12
Breast conservative Sx	2	4
Mastectomy	30	62
Chemotherapy	5	10
Neoadjuvant	1	2
Follow up	3	6
Excisional/Mastectomy	3	6

Abbreviations: Ca, cancer; Sx, surgery

Table 3: Clinical and radiological features of malignant and benign lesion diagnosed by core needle biopsy

Variable	No	Malignant	Benign	P value
Age groups	-	-	-	0.011
≤40	11	5 (13.2%)	6 (50%)	
41-59	30	24 (63.2%)	6 (50%)	
≥60	9	9 (23.7%)	0	
Family history of cancer	-	-	-	0.297
negative	34	28 (73.7)	6 (50)	
breast	10	5 (13.2)	5 (41.7)	
ovary	1	1 (2.6)	0	
bowel	1	1 (2.6)	0	
others	4	3 (7.9)	1 (8.3)	
Menstrual status		-	-	0.003
menstruating	27	16 (42.1)	11 (91.7)	
menopause	23	22 (57.9)	1 (8.3)	
Type of referral		-	-	0.299
Screening	9	8 (21.1)	1 (8.3)	
Diagnostic	41	30 (78.9)	11 (91.7)	
Type of the lesion	-	-	-	0.208
Mass	43	34 (89.5)	9 (75)	
Area	7	4 (10.5)	3 (25)	
US BI-RADS	-	-	-	<0.0001
4a	2	0	2 (16.7)	
4b	9	3 (7.9)	6 (50)	
4c	13	9 (23.7)	4 (33.3)	
5	26	26 (68.4)	0	
Suspicious LN	-	-	-	0.004
present	17	17 (44.7)	12 (100)	
absent	33	21 (55.3)	0	

Table 4: Cross tabulation of Core and surgical histology diagnosis in relation to BI-RADS categories:

Histological diagnosis	core biopsy			Total	Surgical biopsy		Total
BI-RADS	+	HRL	-		+	-	
4a	0	0	2 (100%)	2 (100%)	0	2 (100%)	2 (100%)
4b	3 (33.3%)	2 (22.2%)	4 (44.4%)	9 (100%)	4 (66.7%)	2 (33.3%)	6 (100%)
4c	9 (96.2%)	3 (23.1%)	1 (7.7%)	13 (100%)	10 (90.9%)	1 (9.1%)	11 (100%)
5	26 (100%)		0	26 (100%)	21 (100%)	0	21 (100%)
Total	38	5	12	50	35	5	40

Abbreviation, HRL high risk lesion

Table 5: Agreement between initial CNB diagnosis and final pathological diagnosis

Histological diagnosis		core biopsy No (%)	Surgical biopsy No (%)
Malignant		38 (76%)	35 (87.5%)
High risk lesions	**ADH**	4 (8%)	2 (5%)
	IDPL	1 (2%)	-
Low risk lesion (Benign)	**FCUH**	1 (2%)	1 (2.5%)
	INF	2 (4%)	-
	FA	4 (8%)	2 (5%)
Total		50 (100%)	40 (100%)

Abbreviation,, FCUH fibrocystic disease with usual ductal hyperplasia ,,INF inflammation,, FA fibroadenoma

Table 6: The validity of core needle biopsy test

Core needle biopsy	Surgical biopsy	
	Positive for malignancy	Negative for malignancy
Positive for malignancy	32 (91.4%)	0
Negative for malignancy	3 (8.6%)	5 (100%)
Total	35 (100%)	5 (100%)
Sensitivity	91.4%	
Specificity	100%	
PPV	100%	
NPP	62.5%	
Accuracy	92.5%	

The consequences of core biopsy results

Performing the ultrasound guided core biopsy reduced the need for excisional biopsy for 32 cases where 30 patients were sent directly for mastectomy and other 2 underwent breast conservative surgery. More importantly, core needle biopsy provided the diagnosis and immunophenotype for a locally advanced breast cancer who had received neoadjuvant chemotherapy before surgical removal. Similarly, stage IV cases with distant bone metastases were characterized and immunotyped performed on CNB then directed for palliative chemotherapy. On the other hand, all patient with benign low risk lesions were assured and referred for follow up, however, three of them preferred surgical removal.

Complications and management

No significant complications such as pneumothorax were recorded. Hematoma developed in only one patient with no previous history of blood discresia or anticoagulative drug consumption. The lesion was vascular causing hematoma at the time of taking the third core. The hematoma was controlled by local pressure for 5 minutes. When the reexamined by US, the hematoma size was stable and did not obscure the mass, so a fourth core was obtained. Apart of this case, mild bleeding was seen in 6% of the cases and managed by gentle compression. Mild pain was reported by 22% of the patient who were rather afraid form the procedure particularly, the sound of automated core needle shoot. They were all well anesthetized and all they needed assurance.

Difficulties and approaches

As the procedure was performed by the radiologist, both hands were busy holding the probe in one hand and the needle in the other hands. There was difficulty in handling large breast particularly when the mass was retroareolar. This was overcome by assistant who fixed the position of the breast during the procedure.

The second difficulty was in reaching the lesion when surrounded with heavy desmoplastic reaction. There was difficulty in advancing through to reach the target lesion and occasionally the needle bended. This was overcome by approaching the target lesion as close as possible and when the resistance increased preventing further advance the needle was fired to open a track to the lesion then via the same track several cores were taken.

Discussion

In this study, we found a high concordance between the BI-RADS classification and CNB diagnosis. lesions diagnosed as positive for malignancy in initial CNB diagnosis were distributed in 100% of BI-RADS V, 96% of BI-RADS IVc and 33% of BI-RADS IVb. According to the ACR BI-RADS US lexicon, the probability of malignancy in IVa category is 3-10%, category IVb 11–50%, category IVc 51–94%. and in V is >95% (11). We have achieved

excellent US- histo concordance using CNB particularly in BIRADS IVa and V categories. Several other local Iraqi studies reported high BIRADS IV and V US-histo concordance however, they lack subcategorization of BIRAD IV and used inconsistent methods of histological confirmation varied between FNA, CNB and excisional biopsies (12-14).

Reducing the rate of surgical sampling benign lesions is the target of current radiological studies particularly in BI-RADS IV lesions which hold a broad range of malignant risk of 3–94% (15). In our study, High risk lesions (borderline lesions) (this term was not mentioned in the results of the study) were identified in BI-RADS IV b and c which constituted 44% of all cases. High risk lesions are non-cancerous breast lesions that are associated with high risk of concurrent or subsequent cancer development (16). It has been reported that approximately 9.2% of image guided biopsies would reveal high risk lesions (17, 18). This usually raise concerns about under-sampling of the lesion (19, 20) therefore the recommended algorithm for such lesions is excisional biopsy (21, 22). Recently, many advanced technologies are suggested and applied to better characterized BIRADS IV lesion and identify the high-risk lesions that requires further work up and biopsy such as shear wave elastography and contrast enhanced ultrasound (13, 15).

The results of this study also confirm the reliability of US guided CNB in diagnosing breast cancer. We have shown a 100% positive predictive value and specificity of the test. The sensitivity of the test in detecting malignant lesion was 91.4% which is acceptable compared with previously published rates of 88.1-98.1% (23-26). The relatively low negative predictive value seen in our results 62% compared to previously reported values 90-98.9% (23-26) resulted from the 8.4% false negative rate and underestimation of high-risk lesions. Several factors can contribute to this low NPV: 1) The nature of the lesion: histological underestimation occurs when the CNB samples high risk areas with atypical ductal hyperplasia or intraductal lesion while the rest of the lesion contains invasive carcinoma (9, 27, 28). ADH is a risk factor for cancer and can also be found alongside invasive cancer (27-29). Underestimation of ADH is one of the major issues in US guided CNB which could range from 0- 100% (30). All the false negative cases reported in our study were diagnosed as high risk lesions by CNB and the underestimation rate was 60% (3 out of 5) although relatively high, this rate remains with the published range 0-100%. 2) CNB size and number: G14 CNB needles are the recommended size for breast lesions sampling, although recent studies showed no significant difference in the accuracy of CNB results of G16/18 vs G14 in lesions > 10mm (31). 3-6 cores are the standard number of cores recommended to be obtained from a breast lesion (32). Recent studies are less stringent about the number of the cores, once the intralesional position is documented by US. The average number of cores we considered in this study is 4 with CNB G18 which might contribute to the lower sensitivity we had. 3) Selection bias: NPV is affected by the number of true negative rate. As inclusion criteria our recruitment was limited to BI-RASD IV and V lesions and we have had only 2 cases with BI-RADS IVa. Thus, the number of benign lesions was too small resulting low NPV.

Although CNB of the breast is frequently used as gold standard in many Iraqi studies when evaluating various radiological or pathological parameters or advances (33, 34), the sensitivity and specificity of CNB is not frequently reported by radiologists or others specialties. In 2013, Hassan et al (14). compared the validity of FNAC and CNB using excisional biopsy as a gold standard. They concluded that both FNAC and CNB had 100% specificity but CNB was more sensitive (95% vs 80%), yet the results of this study should be interpreted with caution. First, because the procedure in this study was done blindly on palpable masses without correlation to radiological characteristics, and second, because the tests validity was restricted to 20 surgically confirmed malignant cases excluding 100 case surgically confirmed benign lesions. Ahmed et al. also have studies the validity of US guided CNB in 2015 (12). They reported 98.2% sensitivity, 100% specificity, 100% PPV, 90%NPV with overall diagnostic accuracy of 98.4%. Although they have selected their 65 patients based on mammographical and US findings, different inclusion and exclusion criteria may explain the differences in the results. Additionally, both these Iraqi studies did not include high risk lesions which are considered as Aristotle dilemma as described by Javitt, 2012 who cited Aristotle quoit “Virtue for the prudent man lies in moderation between excess and deficiency” to describe the difficulty in managing high risk lesions (35).

It is worth noting that we have not considered repeating the CNB procedures for the high-risk lesions particularly since they were all categorized in BIRADS IVb and c in which cancer risk has wide range from11-95% (36). Although inadequate sampling is a plausible cause for false negative results associated with this type of lesions, surgical excision is the recommendation of American society of breast surgeons and NCCN guidelines for high risk lesions rather than repeating the CNB (21, 22): 1) To avoid underestimation of the CNB and prevent delay in the diagnosis of malignancy for false negative cases, and 2) To reduce the risk of cancer development associated with high risk lesions in true negative cases.

For the rest of our cases (90%), unnecessary surgery for cancer diagnosis was avoided and patient were directed for curative surgery, neoadjuvant therapy, primary chemotherapy or follow up. Thus, ultrasound guided CNB in have achieved the aim of 1) Reducing the cost over open diagnostic surgery when surgery is not curative, 2) Decreasing the number of surgical procedures needed to achieve clear margins as the surgeon has been informed in advance about the malignant nature of the lesion he is going to deal with.

The CNB is a safe procedure. Consistent with many other studies (32, 37), we have not recorded any serious complication by adhering to the standard technical instructions while manipulating lesions. Mild pain or slight bleeding was reported in 22%, 6% respectively and were readily controlled with assurance and manual compression.

The main limitation in this study was the difficulty in recruiting cases because of the prolonged lockdown as a result of COVID-19 pandemic.

Conclusion

CNB is a safe, efficient and relatively inexpensive method in diagnosing suspicious breast lesions. Radio- pathological correlation is of paramount in achieving accurate results. High risk breast lesions are important and challenging group of lesions and associate with high rate of underestimation.

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Conflict of Interest
No conflict of interest

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