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COMPARISON BETWEEN ULTRASOUND GUIDED TRU-CUT BIOPSY AND NON-ULTRASOUND GUIDED TRU-CUT BIOPSY IN THE DIAGNOSIS OF BREAST MASS CONFIRMED BY OPEN SURGICAL BIOPSY

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Abstract

Of all breast issues, benign breast illness is by far the most common. Approximately one-third of women will experience some sort of benign breast issue that necessitates treatment. This is particularly true when the symptoms start to negatively impact the woman's mental health. A lump, soreness, or both are the most prevalent signs. Before surgery, the triple evaluation was the gold standard for non-surgical breast lump identification; it also helps determine whether a patient with breast cancer will benefit from conservative or neo-adjuvant therapy options.

In recent years, the revised Triple Assessment has surpassed its predecessor as the gold standard in diagnostics. Not only that, but ultrasound-guided Tru-cut biopsy is less expensive and more effective than surgical biopsy and stereotactic guidance. The good safety profile of this approach makes it preferred for obtaining biopsies from worrisome non-palpable breast lesions revealed by ultrasonography. .Method One hundred women with breast lumps visited the breast clinics at Al-Kindy teaching hospital and Baghdad teaching hospital (oncology center) in Baghdad between June 1, 2018, and October 1, 2020, for this cross-sectional study.

We used a pre-made algorithm to compile all of the patient data, which included age, lump location (right or left), and BIRADS ultrasound results. The first group consists of 50 patients who received Tru-cut needle biopsy without ultrasound guidance, while the second group consists of 50 instances that underwent Tru-cut needle biopsy with ultrasound guidance. According to their histology findings, patients underwent surgical procedures; the most advanced cases received

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treatment first. Result The breast clinic saw one hundred ladies who were dealing with breast lumps. The average age of the 74 individuals with malignant lesions was 47.19 years. Of the 26 cases, 34.9±11.5 years were associated with benign lesions.
Among malignant lesions, ductal carcinoma ranks first with 66 cases, whereas among benign lesions, fibroadenoma ranks first with 17 cases. With a Sen=90.1% and a spec=100, the agreement between the open biopsy and the Tru-cut biopsy in the first group was 0.840, and the p-value was 0.001. In contrast, the second group achieved a Sen=97.6%, spec=100 agreement with a p-value of 0.001. Conclusion Based on these findings, we recommend using ultrasound-guided Tru-cut biopsies to diagnose any abnormality in the breast, whether it is palpable or impalpable (seen only by ultrasound). For the treatment of any breast issue, we must adhere to the guidelines of the modified triple evaluation. Aim of the Study The purpose of this study is to assess the ultrasound-guided Tru-cut biopsy for breast mass detection in terms of its sensitivity, specificity, accuracy, utility, and function.

Keyword Breast cancer, Tru-cut biopsy, Ultrasound.

Introduction

Of all breast issues, benign breast illness is by far the most common.Approximately one-third of women will experience some sort of benign breast issue that necessitates treatment. This is particularly true when women encounter psychological distress or unbearable symptoms. A lump, soreness, or both are the most prevalent signs. The primary objective of treatment is to rule out cancer, followed by alleviating any persistent symptoms. one (1) A thorough history and physical examination are the foundational components of any new patien t condition evaluation, regardless of specialization. This is the first step in the management process. Additionally, many women may arrive with significant apprehension, so it's crucial to reassure, them, in, compassionate manner.

The patient is the best authority on her own body, so listen carefully to her worries.

When we evaluate the woman, we should value and consider her breast self-exams and her findings regarding any changes in them. We will order imaging scans and other interventions based on the patient's history and our own physical assessment. (2) In the past, the gold standard for non-surgical breast lump diagnosis was the triple assessment, which included a physical exam, mam mography imaging, and fine needle aspiration biopsy. This allowed for the evaluation of breast c ancer patients for conservative and neo adjuvant primary treatment prior to surgical intervention. Triple assessment has the potential to be a safe substitute for open biopsy, and it is also a quick and inexpensive way to evaluate the breast lump. Triple assessment of the breast is considered the gold standard in mass screening for breast cancer diagnosis due to its usefulness in detecting breast cancers at an earlier stage, with the majority of cases discovered at stage I or stage II (T1 or T2, N0 or N1, M0). Because the triple assessment is either non-invasive or minimally invasive, the patient did not require hospitalization.

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(4) Triple evaluation modalities have their limitations; for example, mammography is less accura te in symptomatic women under the age of 45 due to thick breasts in this age group.
This suggests that age and breast density are significant factors in determining mammography ac curacy.
For women aged 60 and up, mammography's sensitivity has been steadily rising throughout the y ears.Mammograms are more reliable when women's breasts are fuller and less thick.
Although mammography is the gold standard for detecting breast cancer, ultrasonography may b e a better first imaging choice for younger women and those with thick breasts.
(5) In nations without systematic screening, screening ultrasonography, especially with portable, lowcost ultrasound systems available, could be a good substitute for mammography, according t o different data results.,Women who have dense breasts but do not fulfill the high-
risk criteria for screening MRI or who are unable to tolerate MRI should nevertheless consider ul trasonography as a supplementary test, even in cases when mammography is accessible.
(6) When it came to preoperative evaluation of breast disorders, a Chinese study indicated that ul trasound was superior to mammography.These findings point to the possibility that ultrasound is a more practical method for identifying breast lesions.When using fine needle aspiration, triple assessment has additional limitations. Despite its many benefits, fine needle aspiration cytology has a few drawbacks or restrictions. The results were inconclusive or inadequate for 4–13% of the samples. Differentiating between invasive and in-situ carcinoma is more challenging. Diagnosis may involve a cytopathologist with more experience.If the results are not definitive, a second biopsy, usually with a core needle biopsy or vacuum assistance, is required.
Compared to fine needle aspiration cytology, there are a few benefits to using a true-cut biopsy. One of these benefits is that a true-cut biopsy can provide a histological diagnosis, and its findings consistently align with the final histopathological report. It clarifies the cancer type, grade, lympho-vascular invasion, and receptor status.
The sensitivity, specificity, and accuracy of FNAC in evaluating breast lumps are high, but the hi stological diagnosis and accuracy provided by a tru-cut,biopsy are always greater. Researchers found that modified triple assessments are more effective than original triple assessments for evaluating patients with breast lumps and detecting breast malignancies, for all,the,reasons,mentioned
above. This is accomplished by substituting ultrasonography for mammography and Tru-
cut biopsy for fine needle aspiration cytology, depending on the facility's availability. (10) Tru-cut biopsy does have a few minor drawbacks, among which include the following: ● The biopsy of calcifications. ● The non-palpable breast tumor. 11) Ultrasound has the ability to detect several non-palpable masses that mammography has not yet identified. Compared to stereotactic guidance and surgical biopsy, ultrasound-guided Tru-
cut biopsy has several advantages and is more cost-effective. We prefer this approach for obtaining biopsies from worrisome non-palpable breast lesions revealed by ultrasonography due to its good safety profile. We recommend collecting a minimum of three core biopsies from each lesion for optimal diagnostic results.
(12) When sonographic imaging of a lesion is available, the most reliable biopsy technique is the true-cut biopsy. Under ultrasound guidance, a combination of a tru-cut biopsy and a tiny needle

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aspiration biopsy can accurately diagnose breast abnormalities before surgery, providing crucial information for the appropriate treatment. By identifying discordant results through thorough radiological-histopathological correlation, we can reduce the false-negative rate. If you lack the necessary training to evaluate palpable breast lesions for diagnostic purposes, you can opt for a 16G ultrasound-guided Tru-cut biopsy instead of a surgical biopsy. Members of the interdisciplinary breast care team still needed additional training, even after they achieved their goal of providing timely, accurate diagnoses. To demonstrate competency in this approach, multiple samples were required, and initially, more than one pathologist was required to examine the Tru-cut biopsy specimens. We continue this process until we achieve competence. Even countries with limited resources can implement a team approach to diagnosing breast disorders effectively. (15). Patients report minimal side effects and a high satisfaction rate following a true-cut biopsy procedure. (15) The patient will be able to get treatment for her stressful condition more quickly with the support of more reliable results obtained with a true -cut biopsy. The advent of true-cut biopsy, which is accurate, easily trainable, cost-effective, and more, has eliminated the need for unnecessary open surgery to rule out cancer. Despite its underutilization in underdeveloped nations, a trained team comprising a surgeon, interventional radiologist, and pathologist can execute this approach with greater speed and accuracy, thereby alleviating patient stress. (15)

Study Limitations

We are proud to have conducted one of the few studies that aims to bring attention to the grave is sues surrounding breast cancer and the need for improved methods of detecting tumors in the bre ast.

There aren't enough facilities to increase the number of sample collections due to a lack of equip ment (tru-cut needles) needed to conduct the procedure.

We require an interventional radiologist and/or an interventional pathologist, but there is a severe lack of qualified personnel to fill these roles.

Patients and Method

One hundred women with breast lesions visited the breast clinics at Al-Kindy teaching hospital and Baghdad teaching hospital (oncology center) in Baghdad between J une 1, 2018, and October 1, 2020, for this cross-sectional study.

Every patient underwent a comprehensive physical examination and medical history review. Fifty instances used ultrasound guidance for Tru-cut needle biopsies, while the other fifty cases used non-ultrasound guidance. Histopathology examined all specimens from mastectomy, excisional biopsies, and Tru-cut needle biopsies.

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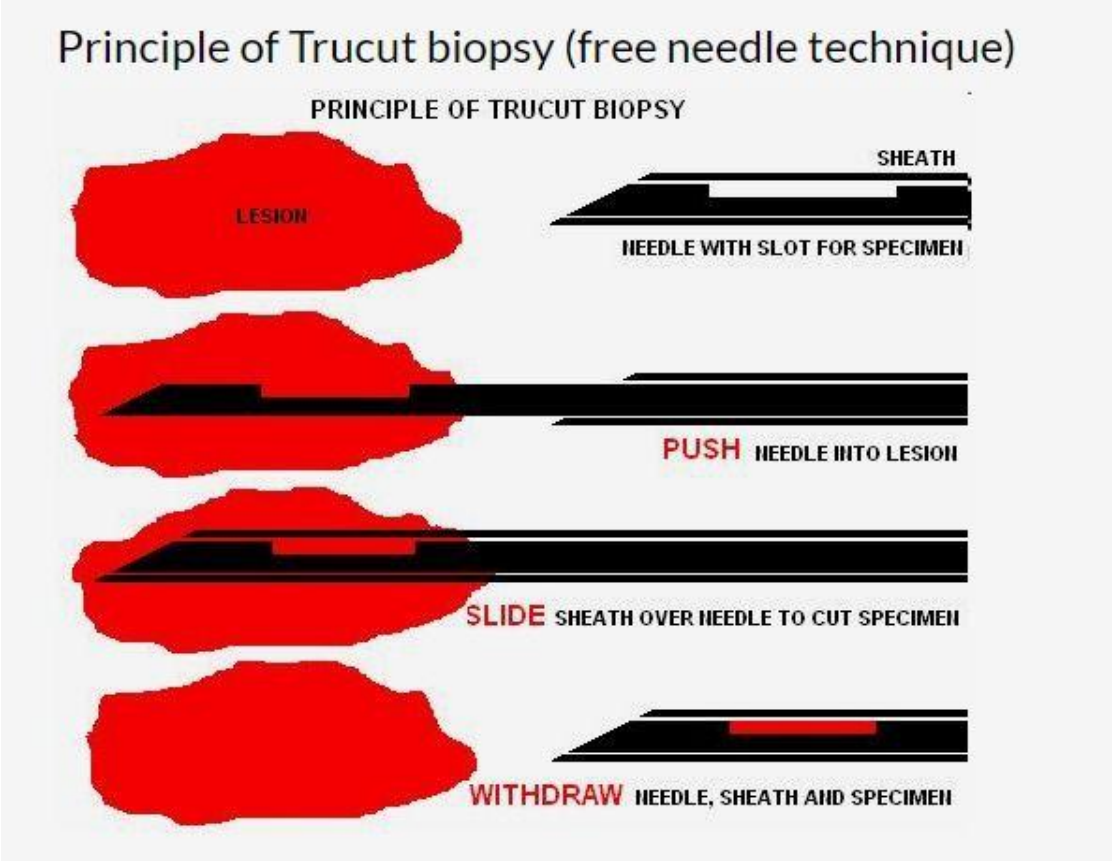

Figure 1: Principle of Tru-cut biopsy

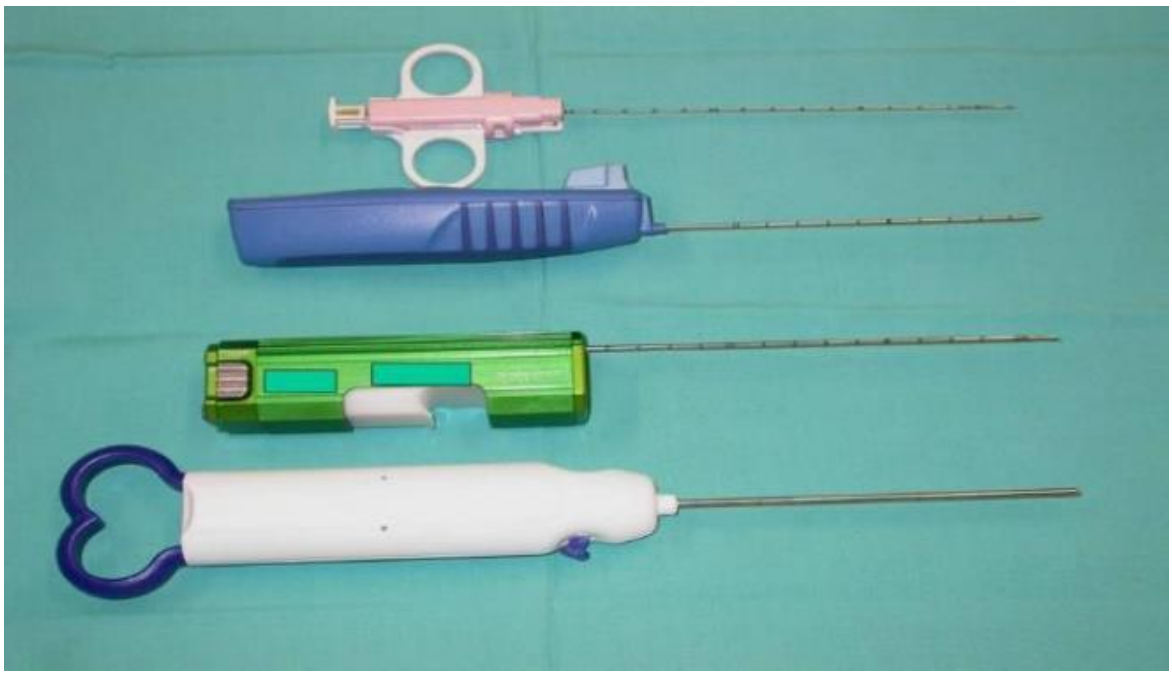

Figure 2: Types of Tru-cut biopsy needles

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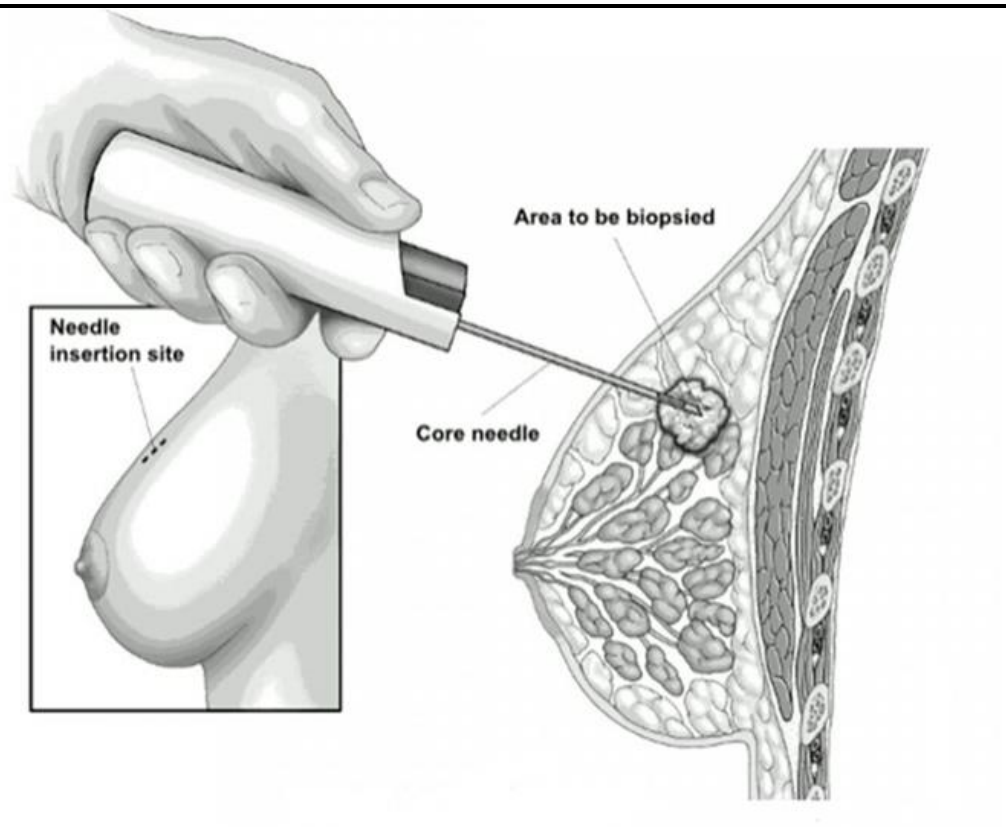

Figure 3: Tru-cut biopsy

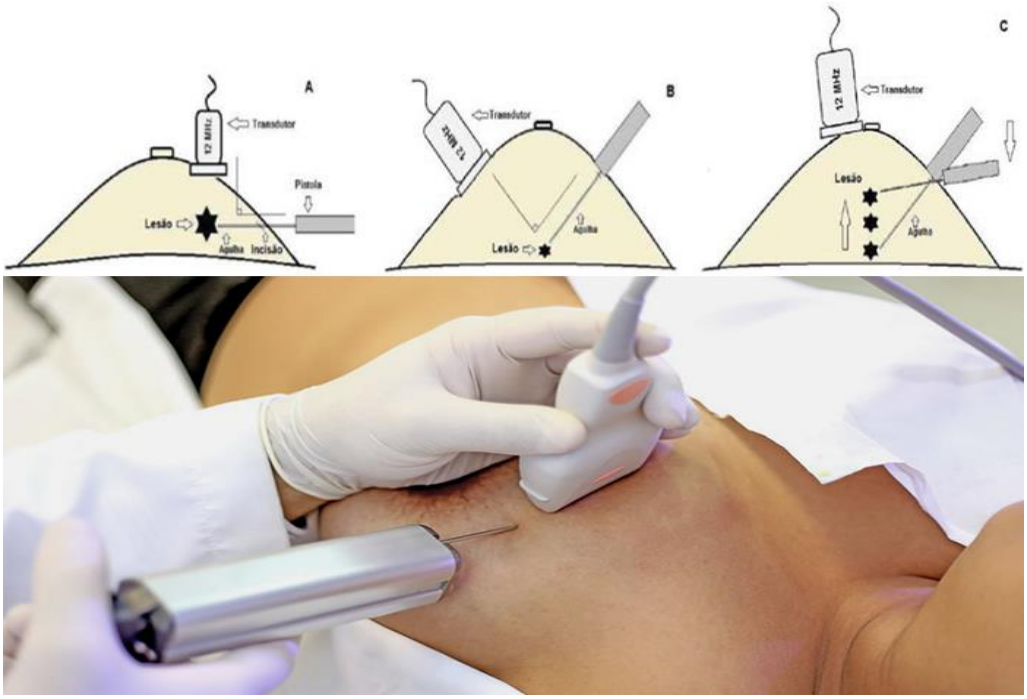

Figure 4: Ultrasound guided Tru-cut biopsy

Statistical analysis

of the collected data was introduced into Microsoft Excel sheet 2016 and loaded into SPSS V26 statistical program.

Descriptive statistics were presented using tables (mean ± standard deviation and frequency and percentage) and graphs.

Kappa agreement was used to find out degree of agreement between two raters that are rating the same thing, corrected for how often that the raters may agree by chance. Here we have Tru-cut biopsy diagnosis and excisional biopsy diagnosis in both groups of the study.

Accuracy of diagnosis using Tru-cut biopsy whether in ultrasound guided or non-guided methods in comparison with excisional biopsy and/or mastectomy as the gold standard method for diagnosis in both groups.

Diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value were also calculated in order to find out which method is better.

P-value less than 0.05 was considered as a discrimination point for significancy.

Results

The results of the 100 cases that were included in this study, which include 50 cases in Al-Kindy teaching hospital where the non-ultrasound guided Tru-cut biopsy was done, and 50 cases in Baghdad teaching hospital (Oncology center) where the ultrasound guided Tru-cut biopsy was done.

The mean age of the total studied sample was 44±11.6 year, as shown in figure 5.

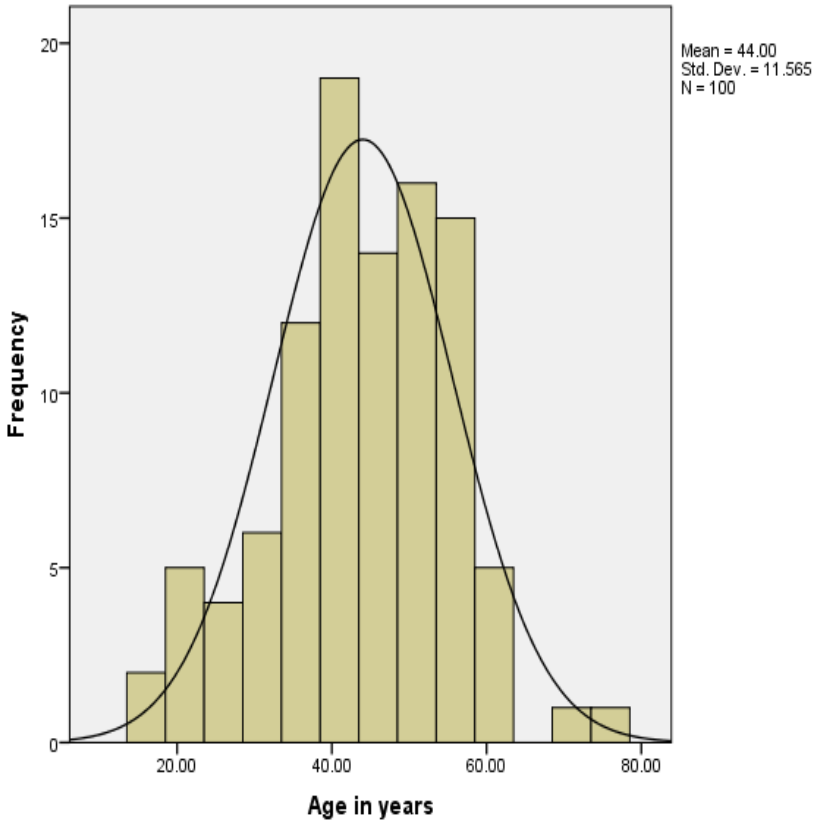

Figure 5: Distribution of studied cases according to age.

Table 1 shows that 74 cases of the studied cases got a malignant lesion with mean age =47.19 years which is significantly higher than the mean age in the 26 case with benign lesions (34.9±11.5 year), p value 0.001.

So, there is a significant relation between the age and the final histopathological result.

Table 1: Difference between mean age of studied cases according to malignancy of lesion.

Group	N	Mean	Std. Deviation	P value
Malignant	74	47.1892	9.81427	0.001
Benign	26	34.9231	11.51668	

Figure 6 shows that the lesion affect left breast in 55 case, right breast in 43 and both breasts in 2 cases.

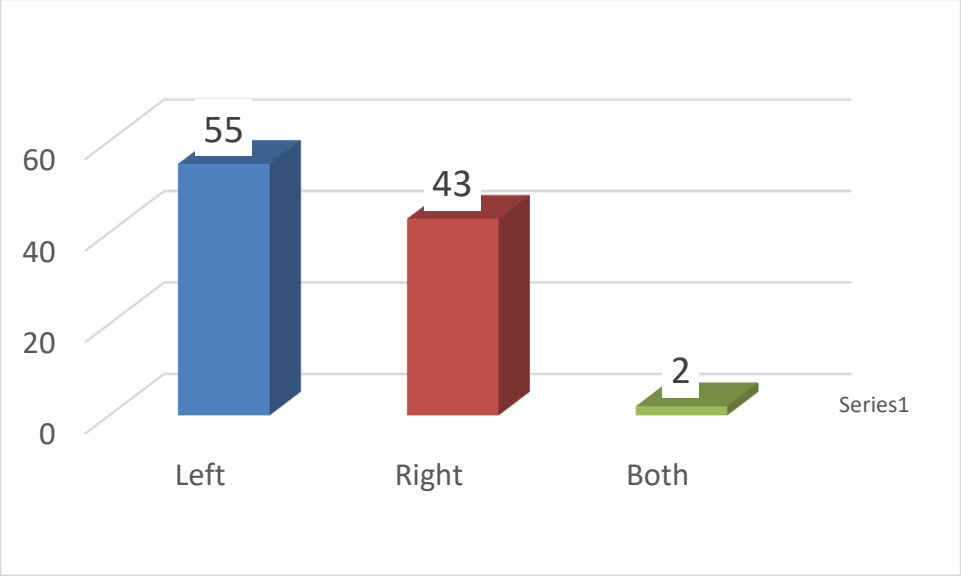

Figure 6: Distribution of studied cases according to laterality.

It was found that 62% of lesions affected right breast were malignant ones, while 83% of left breast lesions were malignant, p value=0.048, which means than the association between left side lesion and malignancy is significant.

Table 2: Association between laterality and malignancy of the lesion.

		Malignant		Benign		
		Count	Row N %	Count	Row N %	P value
Laterality	Right	27	62.8%	16	37.2%	
	Left	46	83.6%	9	16.4%	0.048
	Both	1	50.0%	1	50.0%	

Figure 7 shows that ductal carcinoma sit on the top of malignant lesions (66 cases), while Fibro adenoma came first in the benign lesions list (17 cases).

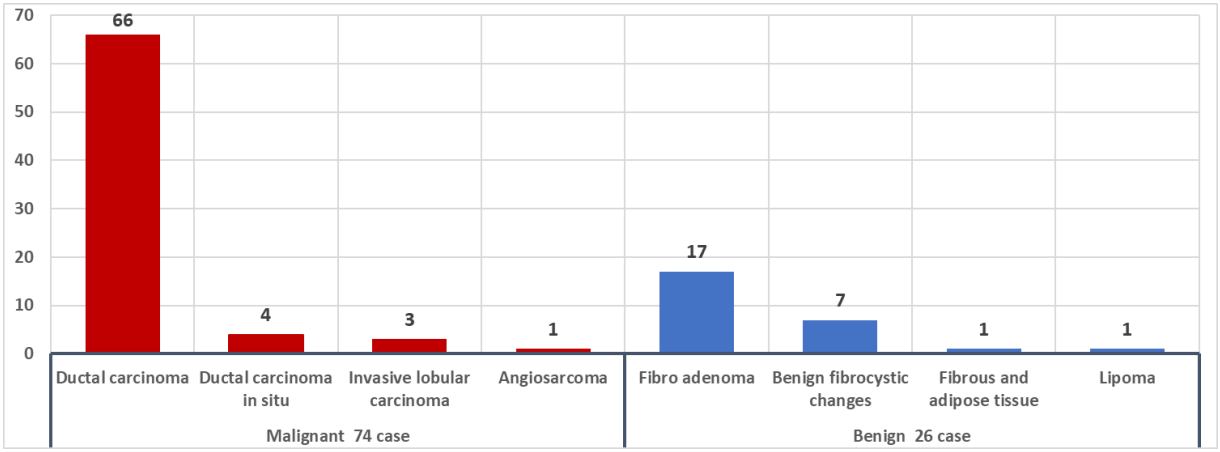

Figure 7: Distribution of total cases by type of lesion according to final excisional biopsy histopathology (gold standard).

Table 3 shows that the Kappa agreement between non-ultrasound guided Tru-cut needle biopsy Histopathology result and final diagnosis according to total excisional biopsy histopathology (Gold standard) was 0.840, p value =0.001.

Table 3: Agreement between non-ultrasound guided Tru-cut biopsy histopathological results and Final diagnosis according to total excisional biopsy histopathology.

		Final diagnosis according to total excisional histopathology (Gold standard)							
		Ductal carcinoma in situ	Ductal carcinoma	fibro adenoma	Invasive lobular carcinoma	Benign fibrocystic changes	Lipoma	Angiosarcoma	Total
Tru-cut Histopathology results of non-ultrasound guided group	Ductal carcinoma in situ	1	0	0	0	0	0	0	1
	Ductal carcinoma	0	27	0	0	0	0	0	27
	Fibro adenoma	0	0	11	0	0	0	0	11
	Invasive lobular carcinoma	0	0	0	1	0	0	0	1
	Benign fibrocystic changes	0	0	0	0	3	0	0	3
	Fibrous and adipose tissue	1	0	0	0	0	0	0	1
	Lipoma	0	0	0	0	0	1	0	1
	Inadequate tissue	0	2	2	0	0	0	0	4
	Angiosarcoma	0	0	0	0	0	0	1	1
Total		2	29	13	1	3	1	1	50
Kappa agreement=0.840. p value=0.001									

Table 4 shows that the sensitivity of non-ultrasound guided Tru-cut needle biopsy in detecting malignant lesion =90.1%, specificity =100, positive predictive value =100%, negative predictive value =85%, and accuracy of the test = 94%.

Table 4: Power of non-ultrasound Tru-cut needle biopsy in differentiation between benign and malignant breast lesion.

		Excisional biopsy		
		Malignant	Benign	Total
		Count	Count	
Tru-cut biopsy	Malignant	30	0	30
	Benign	3	17	20
Total		33	17	50
Sen=90.1%, spec=100, ppv=100%, npn=85%, accuracy= 94%				

Table 5 shows that the Kappa agreement between ultrasound guided Tru-cut needle biopsy histopathological results and the final diagnosis according to total excisional histopathology (Gold standard) was 0.954, p value =0.001.

Table 5: Agreement between Ultrasound guided Tru-cut needle biopsy histopathological results and Final diagnosis according to total excisional histopathology.

		Final diagnosis according to total excisional histopathology (Gold standard)						
		Ductal carcinoma in situ	Ductal carcinoma	Fibro adenoma	Invasive lobular carcinoma	Benign fibrocystic changes	Fibrous and adipose tissue	Total
Tru-cut Histopathology results of guidance group	Ductal carcinoma in situ	1	0	0	0	0	0	1
	Ductal carcinoma	0	37	0	0	0	0	37
	Fibro adenoma	0	0	4	0	0	0	4
	Invasive lobular carcinoma	0	0	0	2	0	0	2
	Benign fibrocystic changes	0	0	0	0	4	0	4
	Fibrous and adipose tissue	0	0	0	0	0	1	1
	Chronic infection	1	0	0	0	0	0	1
Total		2	37	4	2	4	1	50
Kappa agreement=0.954. p value=0.001								

Table 6 shows that the sensitivity of ultrasound guided Tru-cut needle biopsy histopathology in detecting malignant lesion =97.6%, specificity =100, positive predictive value =100%, negative predictive value =90%, and accuracy of the test =98%.

Table 6: Power of ultrasound guided Tru-cut needle biopsy in differentiation between benign and malignant breast lesion.

		Excisional biopsy		
		Malignant	Benign	Total
		Count	Count	
Tru-cut biopsy	Malignant	40	0	40
	Benign	1	9	10
Total		41	9	50
Sen=97.6%, spec=100, ppv=100%, npn=90%, accuracy=98%				

Discussion

This study covered one hundred cases. 74 patients, a relatively high number, received a malignant lesion diagnosis. We sourced these patients from a tertiary care cancer institution that specializes in treating extremely concerning breast tumors, which explains their high diagnosis rate. The average age of all breast lesions in the examined sample ranged from 20 to 76 years. The mean age for malignant lesions was 47.19±9.8 years, and the mean age for benign lesions w as 34.9±11.5 years. This closely aligns with the findings from Rahman MA's 2014 study. He collected data from people aged 12 to 80, with a mean age of 32.87.

For inflammatory lesions, the mean age of presentation was 30.33 years; for benign lesions, it wa s 27.88 years; and for malignant lesions, it was 44.28 years. 16 Ramin Saadaat's 2020 study yielded similar findings.

His study included participants aged 15 to 75, with an average age of 35.38 (SD ± 13.11) years. And malignant lesions had an average age of 43.6 years, whereas benign lesions had an average age of 23.4 years. 17

The laterality was one of the outcomes of our research.

According to the results, 55 cases included the left breast, 43 involved the right breast, and 2 inv olved both breasts.

Lesions affecting the right breast were more likely to be malignant (62% vs. 83% for the left bre ast).

Additionally, the correlation between the left side lesion and cancer is statistically significant (p = 0.048).

Similar to what Faidah Badru stated in her study, "There is an acknowledgement that breast canc er occurs more frequently in the left than the right breast." 18

This finding is in line with that of Ahmed A. Zeeneldin, who found that among Egyptian patients , the left breast had a higher cancer risk than the right.

Although tumors on the right side appeared more aggressive, cancers on the left side typically ha d a worse prognosis in terms of survival. 19

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Our sample includes 66 cases of ductal carcinoma, the most common malignant lesion.
Findings from the study by Fadi M. Alkabban and Troy Ferguson were in agreement with this outcome. Half to three-quarters of all invasive breast cancers are ductal carcinomas, making them the most prevalent type of the disease. This is in line with the findings of the editorial and medical content teams at the American Cancer Society, which found that ductal carcinoma accounts for 70–80% of breast cancers.
21Our research indicated that among benign breast tumors,
fibroadenoma ranked highest (17 instances).
This aligns with the findings of Angrit Stach's study.
Fiberoadenomas are the most prevalent benign tumors of the breast, occurring in 25% of cases. The peak onset age is 15–35 years.
22Having a conclusive nonoperative diagnosis for breast lesions is highly beneficial for planning the course of treatment.
According to I O Ellis's study, "The role of non-
operative diagnosis in the assessment of breast lesions is to provide, whenever possible, a definitive diagnosis, allowing rapid referral for treatment in malignant cases, ideally in one operative procedure." This aligns with the above statement.
It is also helpful to be able to definitively diagnose benign disorders without surgery, which allows for faster reassurance, discharge from the clinic, and recovery to normal recall. 23
For the purpose of histological identification of breast lesions, we employed a less invasive approach known as a tru-cut needle biopsy. We compared the histopathological results of the conventional open biopsy and/or mastectomy specimens with those of the first group that underwent a non-ultrasound-guided Tru-cut biopsy. Since the histological diagnosis in 45 cases was the same in both the Tru-cut needle biopsy and the excisional biopsy, we reached a Kappa agreement of 0.840.
Angiosarcoma, a rare cancer whose cause is unclear, was one of the 45 cases.
Although it accounts for around 8% of breast sarcomas, it only accounts for 0.04% of breast tumors overall. 24 There was one mismatch and four insufficient tissue samples. The tru-cut needle biopsy showed a significant p-value of 0.001. This resulted in a diagnostic accuracy of 94% (no false positives), a sensitivity of 90.1%, a specificity of 100%, a positive predictive value of 100%, and an efficiency of 85%.
Furthermore, TCB displayed a sensitivity of 95.1%, specificity of 100%, PPV of 100%, NPV of 97.2%, and an overall DA of 98.2%, according to Ammar Rikabi's findings.
In addition, it identified the specific kind and grade of tumor in 74 out of 96 (77.1%) cancer cases, which was in agreement with the final histology report. 25
Sagarika Samantaray's outcome is likewise comparable.
In addition to a sensitivity of 97% and a specificity of 100%, his study also did not have any false positive biopsies. 26 Yasemin Altintas and Mehmet Bayrak's study demonstrated the complete accuracy of TCB, with a sensitivity of 95.4%, specificity of 100%, PPV of 100%, NPV of 96.1%, and diagnostic accuracy of 97.8%. True positives did not occur in any of the situations. 27
We also compared the histology of conventional open biopsy and mastectomy specimens with th

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at of our second group that had ultrasound-guided Tru-cut biopsies.

The histological diagnosis was the same in 49 out of 50 instances when we compared Tru-cut needle biopsy with excisional biopsy, leading us to a Kappa agreement of 0.954. The Tru-cut biopsy correctly diagnosed all cases, except for one with ductal carcinoma in situ, as chronic infections. Necrotic tissue may have caused the inaccuracy in the sample. The tru-cut needle biopsy revealed a significant p-value of 0.001. With these parameters, our test has a sensitivity of 97.6%, a specificity of 100%, a ppv of 100%, an npn of 90%, and a diagnostic accuracy of 98%. This case also did not yield a false positive. This outcome was supported by Woodcock, who raised the issue first. His investigation reported a sensitivity level of 97.9% for the identification of substantial pathology. This series achieved a 100% specificity, as it detected no false-positive biopsies. 28

The results are likewise very similar to those of Millicent Olubunmi Obajimi's research.

For the core biopsy,

she discovered a sensitivity of one hundred percent and a specificity of eighty percent. 29 Our findings align with those of Sahar Basim Ahmed. With a sWith a sensitivity of 98.2%, specificity of 100%, positive predictive value of 100%, negative predictive value of 90%, and diagnostic accuracy of 98.4%, Sahar Basim Ahmed found that Tru-Cut biopsy was the best option. treThese prior studies demonstrate the strength of the ultrasound-guided tru-cut biopsy compared to the traditional non-ultrasound-guided tru-cut This is especially true for breast masses that can't be felt. In the same way, Varsha I. Shah found that image-guided biopsies led to fewer false-negative diagnoses of breast carcinoma than CNBx done without it. 31

That is in line with the findings of Smriti Hari's study, which found that image-guided biopsy had better sensitivity, false negative rate, and repeat biopsy rates than palpation-guided biopsy in cases of palpable breast masses. His findings showed that palpation-guided biopsy was an effective method for identifying breast cancer with a sensitivity of 46.7%, specificity of 100 percent, PPV of 100 percent, and NPV of 27.3%. The image-guided biopsy, on the other hand, was completely specific and had a sensitivity of 96.3%.

Using image-guided biopsy, we did not encounter any cases of insufficient samples or imaging-histologic discrepancies. 32 Ward also recommends using ultrasound guidance for core biopsies. It is possible to restrict the use of a freehand method to superficial lesions.

Compared to lesion size and breast volume, depth is a better predictor of a missed biopsy. 33

Conclusion

By utilizing the Tru-cut biopsy, we are able to collect high quality tissue samples from patients with minimal discomfort. One of its benefits is the simplicity of the process.

2. A higher quality specimen that provides us with more accurate cellular morphology. If the lesion is palpable, we can perform a core needle biopsy to obtain tissue samples for histological analysis. Most of the time, they are accurate, and the infrequent instances of a false negative are linked to very small tumors.

In particular, this aids in differentiating between invasive and in situ cancers, which is crucial for a correct histologic diagnosis. We palpate the lump to obtain a core

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biopsy. The use of ultrasound allows for more precise outcomes.
Before firing, ultrasound helps position the needle with
respect to the lesion, and after firing, it helps position the needle within the lesion.
We recommend using ultrasonography-guided Tru-cut biopsies to evaluate all breast abnormalities, whether palpable or impalpable (only visible byultrasound). For the treatment of any breast issue, we must adhere to the guidelines of the mo dified triple evaluation.

Recommendation

If a patient presents with a breast lump, whether palpable or impalpable, we advise them to under go an ultrasound-guided Tru-
cut needle biopsy so that we can determine the best course of treatment.

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Patient Name:
Age:
History of Present Illness:
Site of Mass:
Duration:

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Examination

BIRADS by US:

Tru-cut Biopsy Histopathological Result:

Open Biopsy Histopathological Result:

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