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Original article

Evaluation of the Diagnostic Accuracy of Ultrasound-Guided Biopsy versus Surgical Biopsy for Breast Cancer, Using Histopathology as the Gold Standard

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Abstract
Breast cancer is the most common cancer among women worldwide and a leading cause of cancer death. Ultrasound-guided core needle biopsy (US-CNB) is a minimally invasive method for evaluating suspicious breast masses. This study aimed to evaluate the diagnostic accuracy of US-CNB compared with surgical biopsy, using histopathology as the gold standard. In this retrospective cross-sectional study at the National Cancer Institute, Misurata, Libya, the records of 137 women biopsied between January 2024 and May 2025 were reviewed, and 65 cases with complete data for both 14-gauge US-CNB and surgical biopsy were included (mean age 49.8 ± 11.1 years; range 26–85). Diagnostic performance was assessed using the chi-square test, sensitivity, specificity, predictive values, accuracy, and the Kappa coefficient. For malignancy detection, US-CNB achieved a sensitivity and positive predictive value of 100%, with an overall accuracy of 98.5% (Kappa = 1.00). For histological tumor typing, sensitivity and positive predictive value were 95.4% (Kappa = 0.94). For sample adequacy, sensitivity was 100%, specificity 80%, and efficiency 98.3% (Kappa = 0.88). For tumor grading, accuracy ranged from 90.3% to 93.5%, with moderate overall agreement (Kappa = 0.56). No statistically significant difference was found between the two methods in malignancy detection ($p = 1.000$) or identification of the affected side, whereas tumor grading differed significantly ($p < 0.001$), with surgical biopsy remaining more accurate. US-CNB is an accurate and reliable alternative to surgical biopsy and is recommended as the first-line option for diagnosing breast masses, although tumor grade should be interpreted with caution.
Keywords. Breast Cancer, Core Needle Biopsy, Ultrasound-guided Biopsy, Surgical Biopsy, Diagnostic Accuracy.

Introduction

Breast cancer arises when cells in the breast grow abnormally and without control. These malignant cells usually begin in the milk ducts or in the milk-producing lobules and, if left untreated, can spread to other parts of the body. Although it occurs in both sexes, breast cancer is overwhelmingly a disease of women and is the most common cancer among women worldwide [1]. According to the World Health Organization, there were 2.3 million new cases and 670,000 deaths from breast cancer in 2022, and it was the most frequent cancer in women in 157 of 185 countries. Only about 0.5–1% of cases occur in men. Improving outcomes depends above all on early, timely diagnosis followed by comprehensive treatment [1]. The picture in Libya mirrors the global one: the National Cancer Registry recorded 1,547 new breast cancer cases in 2020, accounting for 23.2% of all cancers. Weak early-detection programs and a shortage of mammography equipment in some regions contribute to this burden [2].

Screening and early detection rely on several complementary tools, including clinical examination, ultrasound, mammography, magnetic resonance imaging, and biopsy. Breast self-examination, in which women check their own breasts for changes in shape or texture, remains an important first step towards early detection and lower mortality [3].

Yet a study from Misrata found that awareness of both breast self-examination and mammography was very low among Libyan women [4]. Breast ultrasound plays a central role in this setting. It complements mammography in diagnosis and follow-up, is the first-line imaging method in young women, and reliably distinguishes solid masses from cysts. It is also safe, non-invasive, widely available, and inexpensive, and its real-time imaging allows lesions to be assessed dynamically [5]. Its reported sensitivity is about 95%, with a specificity of 77% [6]. Mammography remains the reference standard for screening because it detects both masses and microcalcifications, although its accuracy falls in women with dense breast tissue. Henderson et al. found that biennial screening mammography in women aged 40 to 74 years reduces breast cancer mortality [7].

A biopsy is the removal of cells or tissue for examination by a pathologist, usually under a microscope, to diagnose diseases such as cancer [8]. Breast lesions can be sampled either by image-guided needle biopsy or by surgical biopsy, and over recent years the less invasive options have steadily expanded. Percutaneous image-guided biopsy is now the standard approach for suspicious breast lesions: it is accurate and carries fewer complications than surgical diagnosis. The main techniques are fine-needle aspiration (FNA), core needle biopsy (CNB), and vacuum-assisted biopsy (VAB), and the choice of imaging guidance depends on how clearly the lesion is seen, where it lies, and how difficult the procedure is expected to be. As a rule, ultrasound is the preferred guidance method because it shows the needle in real time and allows it to be placed precisely in the target while keeping complications to a minimum [9]. It is also the most widely used form of guidance, being readily available, easy to use, and free of ionizing radiation [9]. Surgical biopsy still provides the most complete specimen for histological evaluation, but it is more invasive, more costly, and associated with more complications [10].

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Against this background, the present study compared ultrasound-guided core needle biopsy (US-CNB) with surgical biopsy in women with breast cancer, using histopathology as the gold standard, in order to determine whether US-CNB can be relied upon for preoperative diagnosis in our setting.

Methods

This retrospective study reviewed the medical records of women who underwent both ultrasound-guided core needle biopsy and surgical biopsy for a breast mass at the National Cancer Institute in Misurata, Libya, between January 2024 and May 2025. Of the 137 cases identified, 65 were malignant which met the inclusion criteria. The remaining 72 cases were excluded: 27 involved benign lesions, and in 45 cases, both procedures had not been performed, precluding comparison.
Data were obtained from the Institute's patient-records archive. The final study sample comprised 65 cases with complete data. The mean age was 49.8 ± 11.1 years (range: 26–85 years); age was not recorded for one patient. All core needle biopsies were performed using a 14-gauge needle under ultrasound guidance, with a 5–12 MHz high-frequency linear transducer on a US-manufactured ultrasound system. Histopathological examination served as the gold standard. Diagnostic accuracy was assessed by comparing the initial core biopsy diagnosis with the final histological diagnosis.
Data were summarized using descriptive statistics. Results of US-CNB and surgical biopsy were compared using the chi-square test, and diagnostic performance was expressed as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy. Agreement between the two methods was measured with Cohen's Kappa coefficient. Analyses were performed with SPSS version 21, and a p-value of ≤ 0.05 was considered statistically significant.
Ethical approval was obtained from the administration and the Ethics Committee of the National Cancer Institute, Misurata (NBC: 021.H.25.05). The study was conducted in accordance with the Declaration of Helsinki, and all patient data were anonymized before analysis.

Results

For the detection of malignancy, US-CNB performed excellently, with a sensitivity and positive predictive value of 100% and complete agreement with surgical biopsy (Kappa = 1.00). Specificity and negative predictive value could not be calculated because the sample contained no benign cases. There was no statistically significant difference between the two methods (p = 1.000) (Table 1).

Table 1. Comparison between ultrasound-guided core needle biopsy (Tru-Cut 14G) and surgical biopsy in the diagnosis of breast cancer (chi-square test).

Ultrasound-guided core needle biopsy * Surgical biopsy Crosstabulation	Surgical biopsy				Total	P value
	Modified Radical Mastectomy	Excision	Wide Local Excision + Axillary Clearance	Simple mastectomy		
Ultrasound-guided core needle biopsy Tru-Cut 14G	36	9	19	1	65	1.000
Total	36	9	19	1	65	

The two methods also agreed (100%) in identifying the affected breast. The right breast was involved in 35 cases (53.8%), the left in 29 (44.6%), and both breasts in one case (1.5%). Every case classified as malignant by US-CNB was confirmed as malignant on surgical biopsy, giving a sensitivity of 100% and an overall accuracy of 98.5% (Table 2). Only one case was reported as non-specific on core biopsy.

Table 2. Comparison of benign and malignant tumor results between ultrasound-guided core needle biopsy and surgical biopsy.

Crosstabulation of Tumor Type by Biopsy Method (Ultrasound-Guided Core Needle Biopsy vs. Surgical Biopsy)		Type of Tumor Surgical biopsy Type of Tumor Surgical biopsy	Total
		Malignant Tumor	
Type of Tumor Ultrasound-guided core needle biopsy	Malignant Tumor	64	64
	Not Specified	1	1
Total		65	65

We next assessed how closely US-CNB matched surgical biopsy in identifying the histological type of the tumor: ductal carcinoma in situ (DCIS), invasive ductal carcinoma (IDC), invasive breast cancer (IMC), and invasive lobular carcinoma (ILC). Sensitivity and positive predictive value were both 95.4%, and agreement was almost perfect (Kappa = 0.94) (Table 3). As before, specificity and negative predictive value could not be calculated because there were no negative cases.

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Table 3. Histological tumor type determined by ultrasound-guided core needle biopsy and surgical biopsy.

Tumor type: Histological core needle biopsy (ultrasound-guided)		Histological type tumor surgical biopsy				Total	P value
		DCIS	IDC	IMC	ILC		
Histological type: Tumor for ultrasound-guided core needle biopsy	Not Specified	0	1	0	1	2	0.000
	DCIS	8	0	0	0	8	
	IDC	2	45	0	1	48	
	IMC	0	0	1	0	1	
	ILC	0	0	0	6	6	
Total		10	46	1	8	65	

Obtaining an adequate tissue sample is essential to the success of US-CNB, since it directly determines diagnostic accuracy. When the adequacy of core samples was compared with surgical biopsy, sensitivity was 100%, specificity 80%, and efficiency 98.3%, with excellent agreement (Kappa = 0.88; $p < 0.001$) (Table 4). Almost all samples were classified correctly.

Table 4. Sample adequacy classification (adequate/inadequate) by ultrasound-guided core needle biopsy and surgical biopsy.

Biopsy Classification (Adequate/Inadequate) Ultrasound-guided core needle biopsy		Biopsy Classification Adequate/Inadequate Surgical biopsy		Total	P value
		Not Specified	Adequate		
Biopsy Classification Adequate/Inadequate Ultrasound-guided core needle biopsy	Not Specified	6	0	6	0.000
	Inadequate	0	4	4	
	Adequate	1	54	55	
Total		7	58	65	

(Table 5) shows the distribution of tumor grades obtained by each method, and Table 6 gives the sensitivity, specificity, PPV, NPV, and accuracy for each grade. Here, unlike the other outcomes, the two methods differed significantly ($p < 0.001$).

Table 5. Tumor grade determined by ultrasound-guided core needle biopsy and surgical biopsy.

Tumor Grade Ultrasound-guided core needle biopsy * Tumor Grade Surgical biopsy Crosstabulation		Tumor Grade Surgical biopsy				Total	P value
		Not specified	Low grade	Intermediate grade	High grade		
Tumor Grade Ultrasound-guided core needle biopsy	Not specified	2	2	3	0	7	0.000
	Low grade	0	3	5	1	9	
	Intermediate grade	0	0	28	4	32	
	High grade	3	0	0	14	17	
Total		5	5	36	19	65	

Table 6. Diagnostic performance of ultrasound-guided core needle biopsy in determining tumor grade compared with surgical biopsy.

Grade	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Accuracy	kappa	P value
G1	60%	94.9%	33.3%	97.3%	93.5%	0.56	0.000
G2	77.8%	92.0%	87.5%	86.8%	90.5%		
G3	73.7%	96.4%	87.5%	91.5%	90.3%		

Discussion

This study compared ultrasound-guided core needle biopsy with surgical biopsy, using histopathology as the gold standard, in women with breast cancer. Previous work has shown US-CNB to be a valuable tool for evaluating suspicious breast lesions, with high diagnostic yield and sensitivity for malignancy, histological type, sample adequacy, and tumor grade. Our results support this view. As shown in (Table 1), US-CNB identified the primary tumor with complete accuracy, supporting its use as the first diagnostic step before surgery. Used in this way, it can reduce the need for surgical intervention and lower costs without compromising diagnostic accuracy. Our findings agree with those of Gana et al., who reported 100% sensitivity and specificity for needle biopsy compared with surgical biopsy and concluded that surgery could be avoided in most cases [11]. Mocian et al. likewise reported a sensitivity of 98.6% and a PPV and specificity of 100% [11,12].

Both methods identified the affected breast correctly in every case. In our sample, the right breast was affected more often (53.8%) than the left (44.6%), with one bilateral case (1.5%). This differs from most published series, which report a slight

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left-sided predominance: Amer found left-sided disease in 50.9% of cases and right-sided disease in 46.1% [13], and Zeeneldin et al. reported 53.6% and 46.4%, respectively [14]. The reason for this difference is unclear and may simply reflect our small sample [13,14], but it does not affect our main conclusion that US-CNB is as reliable as surgical biopsy in identifying the affected side.

(Table 2) confirms that US-CNB distinguishes reliably between benign and malignant tumors. All tumors in this study were malignant, and the diagnostic accuracy of 98.5% means that no malignant case was missed, which minimizes the risk of a delayed or incorrect diagnosis. Abd ElRazik et al. reported similar results, with a sensitivity of 94.7%, specificity of 100%, and overall accuracy of 95% [15].

Agreement between the two methods in determining histological type was also high (Table 3), with sensitivity and PPV both above 95%. US-CNB can therefore be relied upon for the initial diagnosis, particularly for the common tumor types such as IDC and DCIS. These results are consistent with those of Wiratkapun et al. in Thailand, who reported a sensitivity of 96% in 674 women, and Jung et al. in South Korea, who reported a sensitivity of 95% in 7,039 women [16,17].

US-CNB also performed well in obtaining adequate samples (Table 4): 64 of the 65 cases matched, with an efficiency of 98.3%. The significant p-value ($p < 0.001$) reflects a small discrepancy between the methods due to unspecified cases, with a false-negative rate of 1.5%. Such cases were few, however, and the overall picture is of a technique that reliably yields enough tissue for diagnosis while keeping complications low. Obajimi et al. in Nigeria reported comparable results, with a sensitivity of 100%, specificity of 80%, diagnostic efficiency of 87.5%, and an inadequate-sample rate of 12.5% [18]. In a multicenter study from the Netherlands, core samples were adequate for histological diagnosis in almost all cases, with a sensitivity of 97%, specificity of 99%, an insufficient-sample rate of 1.5%, and a diagnostic accuracy of 97% [19].

Tumor grade was the one area where the two methods differed significantly (Tables 5 and 6; $p < 0.001$), with surgical biopsy proving more accurate. Grade was misclassified by US-CNB in 40% of G1 tumors, 22% of G2 tumors, and 26.3% of G3 tumors. PPV was high for G2 and G3 but low for G1, while NPV and accuracy were high for all grades. The weaker performance in G1 tumors probably reflects the difficulty of grading a small sample: the core may come from an area with little tumor tissue, or from a less aggressive region whose glands resemble normal breast tissue. Rakha et al. made the same observation [20].

In that UK study, agreement between core biopsy and the excised specimen was good overall, weakest for grade 1, and good to excellent for grades 2 and 3 [20]. Zheng et al. in Canada likewise rated US-CNB as good to excellent for these higher grades [21]. In our study, overall agreement on tumor grade was 72.3% (Kappa = 0.56), indicating moderate agreement. This is close to the 75% agreement and Kappa of 0.59 reported by Daveau et al. in France [20–22].

Surgical implications

From a surgical perspective, these findings have several practical implications. First, the high accuracy of US-CNB in establishing malignancy and histological type provides a definitive preoperative diagnosis, allowing patients to proceed directly to planned definitive surgery rather than undergoing a diagnostic excisional biopsy followed by a second operation [9,10]. In a comparative study, Liberman et al. reported that a single surgical procedure was performed in 84% of patients whose cancer was diagnosed by core biopsy, compared with only 29% of those diagnosed by surgical biopsy [23]. This reduces the number of operations, exposure to general anesthesia, operating-room time, and costs, and avoids the scarring and tissue distortion that may complicate subsequent breast-conserving surgery and imaging follow-up.

In addition to its diagnostic accuracy, US-CNB offers a clear safety advantage. A large systematic review comparing core needle and open surgical biopsy found that severe complications occurred in fewer than 1% of core needle biopsies, compared with 2% to 10% of open surgical biopsies; these complications included bleeding and hematoma requiring treatment, significant pain, and scarring [24]. US-CNB is a brief outpatient procedure performed under local anesthesia, usually allowing same-day discharge and a rapid return to normal activity. In contrast, surgical biopsy often requires general anesthesia and hospital admission, may be complicated by seroma, wound infection, and alteration of breast contour, and is followed by a longer recovery period. The same review also showed that women whose cancer was diagnosed by core needle biopsy were considerably more likely to be treated with a single surgical procedure (odds ratio 13.7) [24].

Second, a preoperative histological diagnosis enables the surgeon to discuss treatment options with the patient in advance, to select the appropriate procedure—breast-conserving surgery or mastectomy, with axillary staging when indicated—and to refer suitable patients for neoadjuvant systemic therapy before any surgical intervention. For these reasons, needle biopsy preceding definitive surgery has been adopted as a quality measure in breast cancer care, and its use has increased steadily in recent years [25].

Third, the moderate agreement for tumor grade (Kappa = 0.56) indicates that the grade obtained from core biopsy should not be relied upon alone when planning the extent of treatment; the final grade must be confirmed on the surgical specimen. Finally, cases with inadequate or non-diagnostic core samples, or with discordance between imaging and pathological findings, should still be referred for surgical excision biopsy. Surgical biopsy therefore remains an essential complementary tool in the diagnostic pathway rather than being entirely replaced by US-CNB.

Limitations

This study has several limitations. The sample was small (65 cases) and drawn from a single center, so the results should be generalized with caution. Because of the retrospective design, some data were incomplete, and a considerable number of records had to be excluded. In addition, all cases in the final sample were malignant, so specificity and negative

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predictive value could not be calculated for malignancy detection or histological type. Larger prospective studies that include benign lesions are needed to confirm these findings.

Conclusion

This study concluded that an ultrasound-guided core needle biopsy is an accurate and safe procedure for evaluating breast tumors and can help avoid unnecessary surgery. Ultrasound diagnostic performance was comparable to that of surgical biopsy: sensitivity was 100% with an overall accuracy of 98.5% for malignancy (Kappa = 1.00), sensitivity was 95.4% for histological type (Kappa = 0.94), and sensitivity was 100% with an efficiency of 98.3% for sample adequacy (Kappa = 0.88). Performance was lower for tumor grade (accuracy 90.3%–93.5%; Kappa = 0.56), where surgical biopsy remained superior. Combined with ultrasound's practical advantages in speed, cost, and complication rate, these results make US-CNB a less invasive, safer, and faster-recovery alternative to surgical biopsy. From a surgical standpoint, it allows definitive treatment to be planned in a single stage and reduces unnecessary diagnostic operations, whereas surgical excision remains necessary for inadequate or discordant samples and for final confirmation of tumor grade.

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Conflicts of Interest

The authors declare no conflicts of interest.

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