

Concordance of Core Needle Biopsy and Post-operative Histopathological Grading in Breast Carcinoma

Maysam Muaamar Hameed¹, Zainab Waleed Aziz ^{*2}

¹ Al-Jumhuri Teaching Hospital, Ninevah Health Directorate, Mosul, Iraq.

² Department of Pathology, College of Medicine, Ninevah University, Mosul, Iraq.

* Corresponding author: zainab.aziz@uoninevah.edu.iq

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ABSTRACT

Background A core biopsy is commonly conducted as the first step in assessing the pathological grade of breast cancer. Discrepancies in histological grading can sometimes arise between core biopsy and surgical specimens. This holds significance in breast cancer cases because the histological grade plays a crucial role in identifying high-risk patients and strongly influences the choice of treatment plan.

Objectives: To evaluate the concordance of histopathological grade between core needle biopsies and subsequent surgical excision specimens in patients with invasive breast carcinoma, and to determine factors that might affect the accuracy of grade classification.

Methods: a retrospective case-series agreement study was conducted at Al-Jamhuri Teaching Hospital, Mosul, Iraq. Eighty-eight consecutive breast core biopsies with invasive carcinoma were evaluated and compared with corresponding excision specimens. Comprehensive clinical, radiological, and pathological data were analyzed. Histological grading and agreement were statistically analyzed. The study was approved by the institutional ethics committee.

Results: The histological grade concordance rate between core biopsy and corresponding excision specimen was 69.3% (61/88 cases). Discord occurred in 30.7% (27/88) of cases. Underestimation of the grade of the tumor was due primarily to misgrading the mitotic index in grade 1 and 2 tumors and to overestimation of the grade more in grade 3 tumors due to higher nuclear pleomorphism scores. Number of core biopsies taken ($p = 0.041$), total length of core biopsies ($p = 0.001$) and non-ultrasound-guided biopsy technique ($p = 0.022$) were all factors that significantly affected the accuracy of the grade.

Conclusion: Post-operative and core needle based histological grading in breast cancer agree poorly, but are clinically useful. The discrepancy might be related to underestimated mitotic index and intra-tumor heterogeneity. Clinicians should be cautious when deciding for treatment, especially neoadjuvant treatment, purely based on the grade obtained during core biopsy, due to this significant discrepancy. The results highlight the clinical significance of adopting a standardized approach in core biopsy techniques and cautioning for intra- and inter-observer grade variation in the multidisciplinary treatment plan. Further validation studies might be needed before using protocol changes in clinical practice.

Introduction

Breast cancer is the most frequent health problem in women around the world and diagnosis and staging are crucial in making the best decision for women's therapy [1]. Histopathological grading is the basis for a large part of the understanding of the biological behaviour and the potential evolution of breast carcinomas. Core needle biopsy (CNB) is commonly used in clinical practice as a first-line, minimally invasive procedure for diagnosis and characterization of breast lesions, before surgery. This involves taking a small sample of

tissue with a needle and looking at it under the microscope to check for the presence of cancer and to determine its type, grade, hormone receptor status and other characteristics [4].

Pathologists and clinicians need an accurate correlation of the results of pre-operative core needle biopsy and post-operative pathological grading. Obtaining a diagnosis from core needle biopsies provides initial clues to the nature of the tumour, but there is a concern for the correct representation of the architectural and cellular features of the overall tumour [3]. Once the diagnosis of a breast carcinoma is made by a core biopsy, the next step is typically surgical removal of the tumor. Several factors should be assessed and documented on the histopathology report such as tumor size, histologic type, tumor grade, hormone receptor status, HER2/neu status and lymphovascular invasion [4].

In breast carcinoma, there is a significant correlation between core biopsy and excision, which must be taken into account in diagnosis and treatment. This is done to make sure the results from the minimally invasive core biopsy are consistent and accurate with the results of the subsequent excisional biopsy to diagnose and characterize breast cancer. High concordance between CNB and excision should be desirable to increase the confidence in initial diagnosis and to aid in treatment planning, as well as prognostic assessments [5]

The aim of this study was to determine the degree of agreement between core needle biopsy (CNB) and open surgical specimens' histopathological grading to better understand the diagnostic accuracy of CNB as a test assessment and open surgical specimens as the gold standard in assessment of breast carcinoma.

Methods

Materials and Methods:

This retrospective case series agreement study was conducted at Al-Jamhuri Teaching Hospital, Mosul city, Iraq between January 2022 and July 2023, and involved 88 patients. Ethical approval was obtained from the Medical Research Ethics Committee, University of Ninevah, College of Medicine (Reference number: UON/COM/MREC/2022(158)).

Study Population

Inclusion Criteria: All patients with a suspicious breast mass, identified on clinical examination and/or imaging study, who underwent core needle biopsy (CNB) followed by surgical excision and histopathologically confirmed an invasive breast carcinoma.

Exclusion Criteria: All patients with in situ or micro-invasive breast cancer, multifocal tumors, metastatic disease, individuals who received neoadjuvant chemotherapy, and patients with non-neoplastic breast lesions.

Data Collection

The following data were collected for all patients: demographic information (age and gender), clinical findings (tumor location and size), radiological findings (BIRADS category), the number and length of core biopsy, and the histopathological characteristics of both core and surgical samples.

Sampling Technique

Core needle biopsy Procedure: All CNBs were performed under ultrasound guidance, as possible, using a 14-gauge needle biopsy. A minimum of four core tissue specimens were obtained from different lesion areas to ensure adequate sampling and minimize bias due to heterogeneity of the tumor. The samples were immediately fixed in 10% formalin and processed according to standard protocols.

Surgical excision procedure: All patients subsequently underwent a modified radical mastectomy, and sent for histopathological examination.

Histopathological Assessment

In the histopathology department, processing and evaluation were done on both specimens, following standard protocols. Hematoxylin and eosin stained tissue sections were studied with the light microscope. Mammary carcinoma grading was done based on the modified Bloom-Richardson-Elston scoring system involving three parameters: the degree of tubule formation, nuclear pleomorphism, and the count of mitoses. Each parameter was marked with a score of 1-3 and the overall grade was determined as follows: Grade I (well differentiated) – 3-5 points, Grade II (moderately differentiated) – 6-7 points, Grade III (poorly differentiated) – 8-9 points. To reduce observer bias, all slides were assessed blindly by two independent pathologists. When there was an inter-observer discrepancy, it was resolved by consulting with a third pathologist.

Statistical Analysis Data were analyzed using SPSS software version 20.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all variables, with categorical variables presented as frequencies and percentages, and continuous variables as means $\pm$ standard deviation or medians with interquartile ranges as appropriate.

The primary outcome measure was the concordance rate between core needle biopsy and surgical specimen grading, calculated as the percentage of cases with identical histological grades. Inter-observer agreement was assessed using Cohen's kappa (κ) coefficient, with interpretation as follows: $\kappa < 0.20$ (poor agreement), $\kappa = 0.21-0.40$ (fair agreement), $\kappa = 0.41-0.60$ (moderate agreement), $\kappa = 0.61-0.80$ (good agreement), $\kappa = 0.81-0.99$ (very good agreement), and $\kappa = 1.0$ (perfect agreement).

Categorical variables were compared using Fisher's exact test or Pearson's chi-square test as appropriate. Statistical significance was defined as $p \leq 0.05$. All tests were two-tailed, and 95% confidence intervals were calculated where appropriate.

Results

A total of 88 consecutive core needle biopsies were evaluated and compared with mastectomy specimens obtained from patients with invasive breast carcinoma.

The ages of patients ranged from 32-78 years with a mean age $\pm$ SD (55.034 ± 12.21), with the most common age group identified was between 61- 70 years.

All patients were females, with 49 (55.7%) of them presented with left sided breast lesion.

The concordance rate was assessed between the core needle biopsy (CNB) and excision specimen for various pathological parameters, as depicted in **Table 1**. In summary, according to the Nottingham grading system, nine cases (10.2%) were initially diagnosed as Grade 1 in the CNB samples, **Figure (1)**. However, in the excision specimens, only one case retained its Grade 1 status, while eight cases were reclassified as Grade 2.

For Grade 2 cases, thirty-five (39.8%) were identified as Grade 2 in the CNB samples **Figure (2)**. Among these, 26 cases maintained their Grade 2 status in the excision specimens, while nine cases were upgraded to Grade 3. Furthermore, in the case of CNB, forty-four (50.0%) instances were classified as Grade 3, **Figure (3)**. However, in the excision specimens, only 24(37.5%) cases remained classified as Grade 3, with the remaining cases being downgraded to Grade 2. Overall, the agreement in histopathological grade between the core needle biopsy (CNB) and excision specimen was found to be satisfactory, at 69.3%, demonstrating a significant level of concordance (Kappa index 0.618).

In terms of tubule formation, nuclear pleomorphism, and the mitotic activity index, the agreement rates were 79% (with a Kappa value of 0.68), 71.5% (Kappa 0.45), and 68% (Kappa 0.34), respectively. Overestimation of grade 3 was primarily attributed to the higher rating of nuclear pleomorphism, accounting for 22 cases (or 54.5% of all cases). Conversely, the low estimation of grade was primarily due to underrating the mitotic index, with 8 cases

(representing 88% of all cases) for grade 1 and 9 cases (constituting 25.7% of all cases) for grade 2.

Histological diagnosis was most commonly found to be invasive ductal carcinoma (88%) in the CNB samples, with 6.8% of samples being lobular invasive carcinoma, and the remaining 4.5% samples being other carcinomas. However, a notable discrepancy was identified in two cases of initially diagnosed invasive ductal carcinoma, which were subsequently reclassified as invasive lobular carcinoma upon examination of the excision specimens. Overall, the agreement in the histopathological type of carcinoma between the core needle biopsy (CNB) and excision specimen was remarkably high, at 97.7%, indicating a significant level of concordance (Kappa index 0.863). Regarding the pathological findings, the agreement rate between CNB and excision biopsy for vascular invasion, perineural invasion, and presence of carcinoma in situ were 76.1%, 81.82%, and 70.45%, respectively.

Table 1: The concordance rate for different pathological variables between core needle biopsy and excision specimen from patients with invasive breast carcinoma.

Characteristics	Specimen type		Kappa index	Concordance rate	P-value
	CNB (n=88) No. (%)	Excision (n=88) No. (%)			
Nottingham histological grade					
Grade 1	9 (10.2%)	1 (1.1%)	0.618	69.3%	0.0242*
Grade 2	35 (39.8%)	54 (61.4%)			
Grade 3	44 (50.0%)	33 (37.5%)			
Histopathological type					
Invasive Ductal carcinoma	78 (88.6%)	77 (87.5%)	0.863	97.7%	0.963
Invasive Lobular carcinoma	6 (6.8%)	7 (8.0%)			
Others	4 (4.5%)	4 (4.5%)			
Vascular invasion					
Present	22 (25.0%)	51 (58.0%)	0.475	67.1%	0.001*
Absent	66 (75.0%)	37 (42.0%)			
Perineural invasion					
Present	4 (4.5%)	16 (18.2%)	0.659	81.82%	0.006*
Absent	84 (95.5%)	72 (81.8%)			
Carcinoma in situ					
Present	14 (15.9%)	39 (44.3%)	0.5841	70.45%	0.001*
Absent	74 (84.1%)	49 (55.7%)			

Kappa values: <0.20 poor agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, 0.81-1.00 almost perfect agreement. *P-value <0.05 was considered statistically significant. CNB: Core needle biopsy.

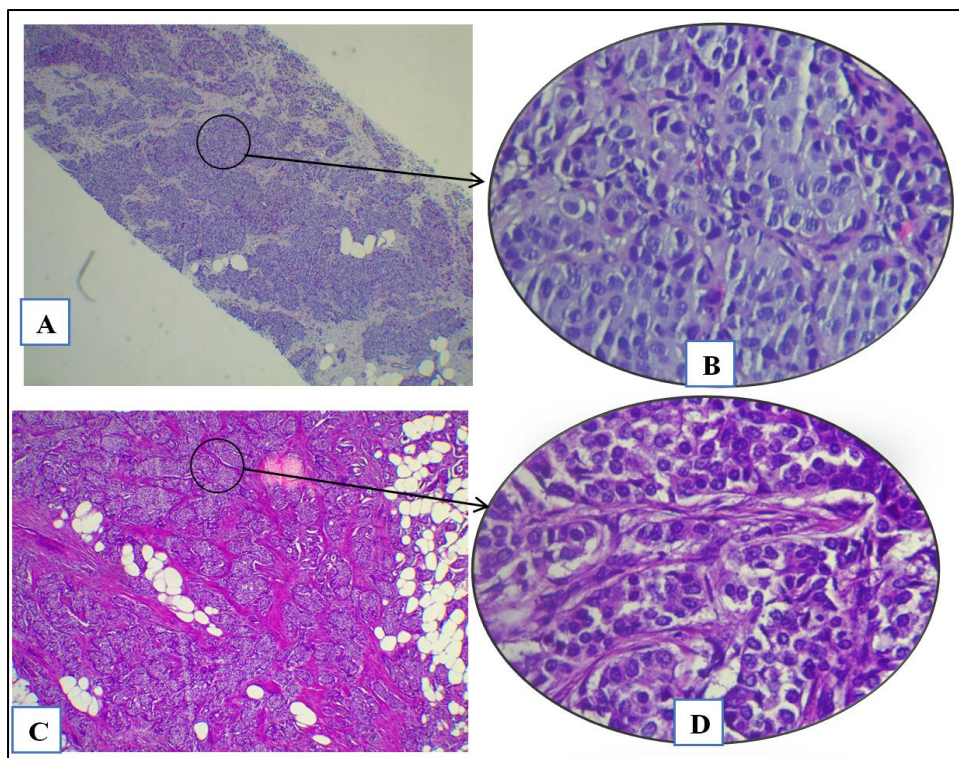


Figure (1): Grade 1 invasive ductal carcinoma. A&B; core needle biopsy (HE, x100 and x400). C & D; subsequent excisional biopsy (HE, x100 and x400).

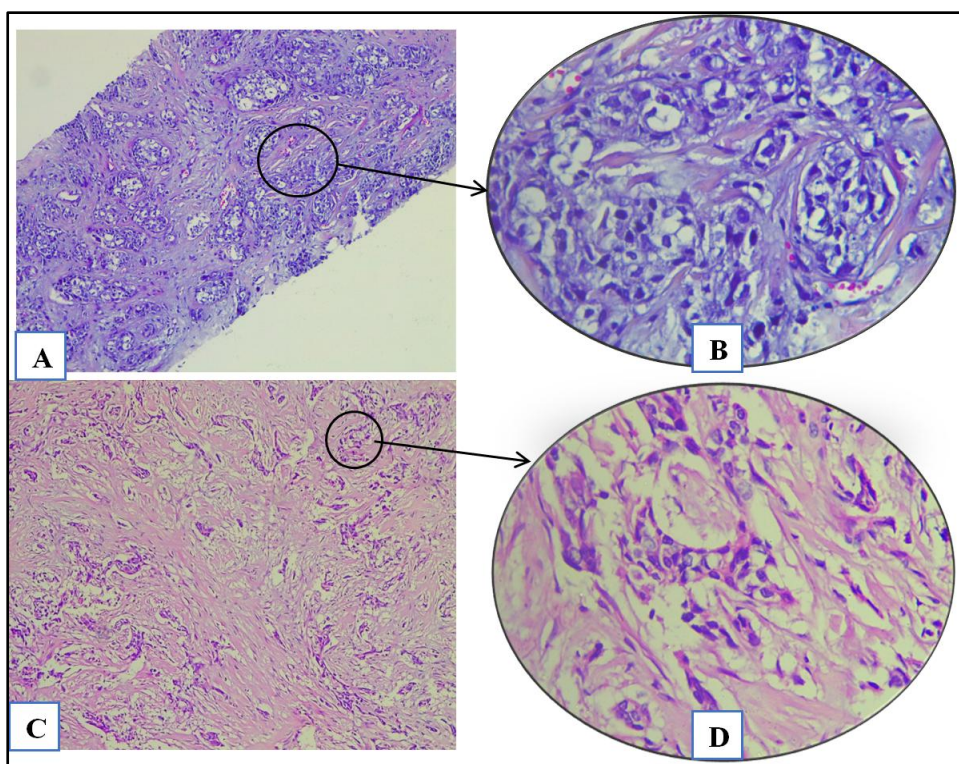


Figure (2): Grade 2 invasive ductal carcinoma. A; core needle biopsy (HE, x100). B; High mitotic activity (black arrows), (HE, x400). C & D; subsequent excisional biopsy (HE, x100 and x400).

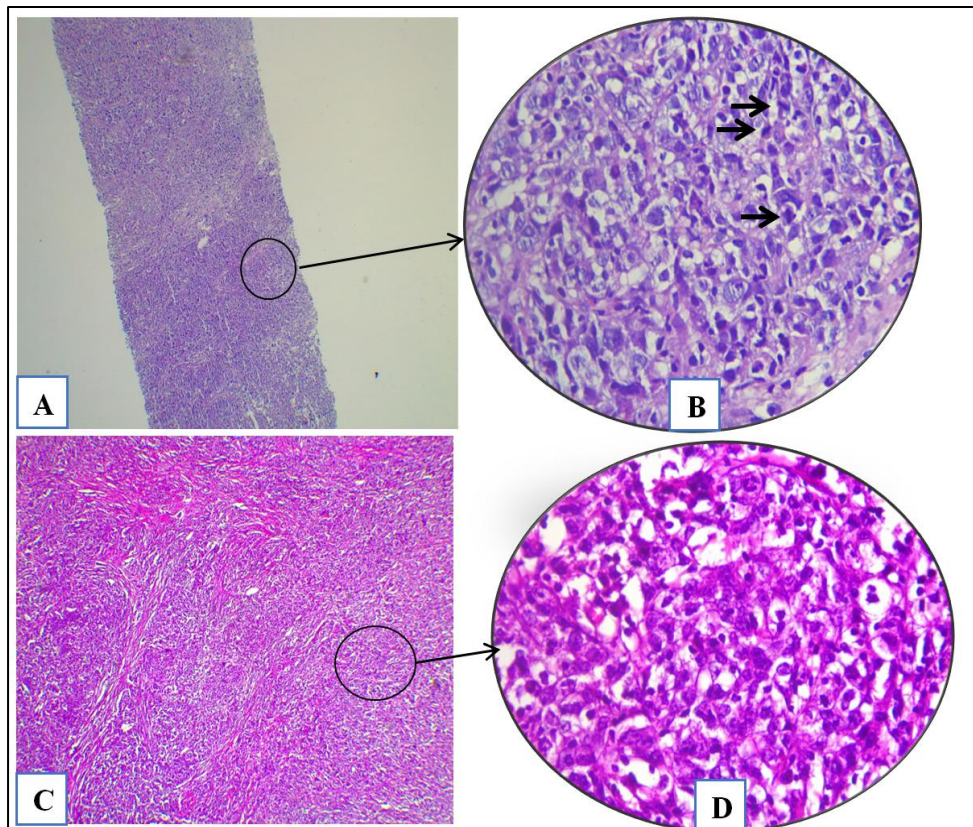


Figure (3): Grade 3 invasive ductal carcinoma. A; core needle biopsy (HE, x100). B; High mitotic activity (black arrows), (HE, x400). C & D; subsequent excisional biopsy (HE, x100 and x400).

Conversely, we have identified certain factors that influence the precision of grade classification in CNB, as depicted in **Table 2**. To summarize, the BI-RAD categories exhibited a concordance rate of 51.14%, indicating agreement in over 50% of the cases. The low p-value of 0.001 indicates the notable significance. Likewise, the number and length of core biopsies had a highly significant p-value of 0.001, highlighting the important role of core numbers and length in maintaining classification consistency.

Table 2: Factors that affected of the accuracy of grade classification on (CNB).

Characteristics	No. of cases (%)	Kappa index	Concordance rate	p-value
BI-RAD category				
3	5 (5.7%)	0.288	70.14%	0.061
4c	32 (36.4%)			
5	51(58.0%)			
Location of tumor				
UOQ	23 (26.1%)	0.1787	30.45%	0.121
LOQ	31 (25.2%)			
UIQ	17 (19.3%)			
LIQ	4 (4.5%)			
Retro-areolar	13 (14.8%)			
Number of cores				
>3	64 (72.7%)	0.6307	73%	0.041*
≤3	24 (27.3%)			
Length of cores				
>1cm	70 (79.5%)	0.5538	83.87%	0.001*
≤1cm	18 (20.5%)			
Ultrasound guided biopsy				
Yes	73 (83.0%)	0.6307	70.5%	0.022*
No	15 (17.0%)			
T size on Ultrasound				
>1cm	65 (73.9%)	0.322	57.5%	0.000*
≤1cm	23 (26.1%)			

BI-RAD: Breast Imaging-Reporting and Data System; UOQ: Upper Outer Quadrant; LOQ: Lower Outer Quadrant; UIQ: Upper Inner Quadrant; LIQ: Lower Inner Quadrant; Kappa values: <0.20 poor agreement, 0.21-0.40 fair agreement, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, 0.81-1.00 almost perfect agreement. *P-value <0.05 was considered statistically significant. T size: Tumor size.

Discussion

As time has passed, the treatment of breast cancer has become more complex, with the number of systemic therapies and surgical approaches available growing [6]. So, the need for accurate diagnosis from core biopsy specimens has greatly increased because many of the treatment decisions depend on the core biopsy result [6]. Core biopsy is a reliable source of information for the clinician that will enable him or her to identify those patients with favourable prognosis tumours and those most likely to benefit from subsequent systemic therapy.

One of the most important factors in deciding treatment for patients with breast cancer is the grade of the tumor. It is one of the most important discriminators, and is used to differentiate between low-grade and high-grade tumors with low and high proliferation rates and good and poor prognosis. [7]

Our results showed that CNB was as good as surgical excision in around 69.3% of the breast cancer patients when it came to tumor grade. This degree of agreement indicates a moderate level of consistency, which is not likely to happen by chance. Notably, not only was underestimation observed more often than overestimation, but also this was observed more often than in the research by Knuttel FM et al., [8] and Harris GC et al., [9] respectively. Multiple studies have analysed the concordance between core biopsies and surgical specimens, usually with large discrepant results, as illustrated in **Table (3)**. It's worth noting that the agreement was at its lowest for grade 1 tumors. On the other hand, grade 2 tumors were most

likely to be confirmed on surgical excisions when CNB assessed the tumors as grade 2. Grasps the concept of surgical excisions with less frequency were aligned with grades 1 and 3.

The lowest level of agreement with the surgical excision was the number of mitoses and the highest was tubule formation among the three components used to determine the grade. This was confirmed by Daveau C et al [7] who also report an underestimate of the mitotic index, which is why there is a discrepancy between the low grade defined by core biopsy and high grade defined by excision specimen. We believe the observed inferior fixation of CNB compared to surgical excision is due to sub-optimal fixation with CNB [8]. In addition, there may be crush artifacts with core needle samples that can lead to a false negative result. Furthermore, CNB might not accurately represent the grade of the tumor because of sampling errors that can occur as a result of the heterogeneous distribution of the tumor. This observation is supported by the findings of Asogan AB et al [10]. Moreover, Morris EA et al., [11] made an important observation regarding histological heterogeneity within tumors. They reported that in 29% of cases with large specimens, there was variation in the histological characteristics between the central and peripheral regions of the tumor. As a result, they concluded that it is essential to examine multiple foci of the same cancer in order to obtain a reliable estimate of tumor grade. The notable discordance rate of 30.7% between core biopsy and excision specimen grading emphasize that while core needle biopsy grading provides valuable prognostic information, treatment decisions should ideally incorporate additional clinical and imaging parameters to optimize patient outcomes in breast cancer management.

Table (3): The concordance rate of tumor grade among different studies comparing CNB and excision specimens in breast cancer patients.

	Researches	Country	year	Number of cases	Concordance rate
1	Current study	Iraq	2025	88	69.3%
2	Mohammed H.J and Faraj F.H [12]	Iraq	2022	116	73.3%
3	Shanmugalingam A et al [13]	Australia	2022	504	72.6%
4	Motamedolshariati M et al [14]	Iran	2014	30	66.6%
5	Tamaki K et al [15]	Japan	2010	353	76.8%
6	Ozdemir A et al [16]	Turkey	2007	61	68.85
7	O'Leary R et al [17]	UK	2004	113	61.65%
8	Andrade VP and Gobbi H [18]	Brazil	2004	120	59%

In the current research, the age of the patients included a range from 32 to 78 years, with a calculated mean age of 55.03 years, which closely mirrors the average age group reported in a study conducted in China (mean age 55.5, range 29-73) [19], and close to those observed in a study conducted in Iran, where the mean age was reported as 51. [14]

In our study, the most frequently encountered histological diagnosis was invasive ductal carcinoma, followed closely by lobular invasive carcinoma. This finding is in line with previous research conducted in Iran [14], which reported a similar pattern. Furthermore, this study demonstrated a substantial level of agreement between the two biopsy methods when it came to determining the histological type of breast cancer. For instance, in a study conducted in Turkey by Aysegül Ozdemir et al., the concordance rate between core and surgical excision specimens for histologic tumor type was found to be 85.2% [16]. Likewise, in a study

conducted in Iraq, the concordance rate for histological type was even higher at 93.1%.[12]. Conversely, a study conducted in Brazil reported a histological type concordance rate of 66.6% [18]. In this work, the variability in these results could potentially be attributed to factors such as varying sample sizes in each study and potential bias in the evaluation by pathologists.

Regarding other pathological findings, our study revealed agreement rates as follows: 76.1% for vascular invasion, 81.82% for perineural invasion, and 70.45% for the presence of carcinoma in situ. Similar results were reported by others. For example, Rakha EA and Ellis IO found a concordance rate of 69% for the detection of vascular invasion.[6]. In a study conducted in China, the concordance rate for perineural invasion was 71.42%. while for carcinoma in situ was notably higher at 87.17%. Conversely, in a study from Japan, the concordance rate for carcinoma in situ was comparatively lower, standing at 58.6% [15]. The variability in concordance rates across different studies for vascular invasion, perineural invasion, and carcinoma in situ likely reflects the interplay of multiple methodological, biological, and institutional factors.

We observed that larger tumor sizes exhibited a higher level of agreement, whereas smaller tumor sizes displayed greater variability and a higher likelihood of non-representative samples. Several factors were associated with this discordance, including the length of the core biopsy, the type of guidance used during the core biopsy procedure, and the size of the core biopsy.

It's noteworthy that in our study, we did not observe any significant differences in concordance rates based on factors such as the BI-RAD category status, tumor location. In contrast, Taghipour zahir and his colleagues, Iran, conducted a study where they correlated CNB findings with ultrasound BI-RADS subtyping and found statistical significance (P value: 0.001). In their research, BI-RADS class 4A emerged as the most common category, while in our study, BI-RAD 4C was the prevailing category [21].

In contrast to our findings, O'Leary et al [17] concluded in their study that the number of core biopsies didn't significantly affect the agreement between preoperative and postoperative histopathology reports. This contradicts our results, where we identified a significant correlation with the number of core biopsies performed, particularly when three or more cores were obtained. Our results align with those of McIlhenny et al., [22] who reported that a single core biopsy had a relatively low accuracy rate of 32% in predicting tumor grade, and this accuracy rate significantly improved to 74% when four core biopsies were performed.

Initially, in pioneering stereotactic studies that used needles of different calibres and excursion, it was recommended that three or four cores were the most appropriate or optimum number of specimens. Furthermore, another study demonstrated a relatively high correlation of histological parameters between CNB and surgical specimens, even when only two cores were obtained [15].

Several studies have demonstrated that CNB diagnostic accuracy improves by increasing tissue samples. Sun et al [23]. found that grade concordance was significantly higher with three or more cores versus fewer than three. Similarly, Ciatto et al [24] reported that CNB sensitivity improved with operator experience and number of cases. These findings suggest that standardizing CNB protocols, including minimum core numbers and adequate sampling of viable tumor tissue, may improve diagnostic reliability.

Several limitations of this study should be noted. These include the small sample sizes, constraints associated with its retrospective nature, such as reliance on existing data, potential gaps in data, and the potential for recall bias. Furthermore, the study was exclusively conducted within a single medical institution, raising concerns about the applicability of its findings to broader populations or different healthcare settings. To overcome these drawbacks, future studies are suggested to be prospective multicentred research with sufficient numbers of cases for more statistical power and generalizability of the results of the study.

Conclusions

There is poor concordance of core needle based histological grade and post-operative grade in breast cancer. This difference could be related to underestimation of the number of mitoses and intra-tumor heterogeneity. As there is this significant disagreement, clinicians should use caution when deciding on treatment based on grading from a core biopsy, especially if neoadjuvant therapy is being considered. The results highlight the clinical significance of the need to standardise core biopsy protocols and be aware of the possible grade variation when planning for multidisciplinary treatment. Further validation studies could be necessary before changes in the protocol can be applied in the routine clinical setting.

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Conflict of Interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript.

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Ethical concern

The medical research ethics committee, College of Medicine, University of Ninevah gave ethical approval to this study (Reference number: UON/COM/MREC/2022(158))

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