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Rate of diagnostic underestimation in ultrasound-and mammography guided core needle biopsies of breast lesions

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ABSTRACT

Introduction: Core needle biopsy (CNB) of suspicious breast lesions classified by the *Breast Imaging Reporting and Data System* (BI-RADS®) can be guided by ultrasound (US) or mammography (MMG), and it is important to monitor the rate of diagnostic underestimation when performing these procedures. **Methods:** This is a retrospective study of 524 breast lesions (BI-RADS®≥3) submitted to core needle biopsy (CNB) at a tertiary hospital in Curitiba/PR between 2019 and 2022. Of these, 261 were subsequently submitted to surgical excision. The underestimation frequency was evaluated at two time points: comparing BI-RADS® with CNB histology and with surgical excision; and between CNB histology and the surgical excision report, separately for each guiding method – Ultrasound-Guided Core Needle Biopsy (US-CNB) and Mammography-Guided Core Needle Biopsy (MMG-CNB). **Results:** A total of 83 MMG-CNB and 441 US-CNB were performed. The BI-RADS® 5 malignancy rate in US-CNB was 89.7% in percutaneous biopsy and 92.7% in surgical excision ($p<0.05$). When comparing histology from MMG-CNB and surgical excision, underestimation was significantly higher in MMG-CNB, with 7/29 lesions (24.13%) underestimated versus 9/232 lesions (3.89%) in US-CNB ($p<0.05$). **Conclusions:** There was no underestimation between the BI-RADS® classification and the histology of CNB. In the latter, however, underestimation was observed in comparison with surgical excision, especially in MMG-CNB, indicating the need for a better evaluation of the lesions to avoid diagnostic errors and ensure greater accuracy in clinical treatment.

KEYWORDS: Breast neoplasm; core needle biopsy; breast ultrasound; mammography.

INTRODUCTION

In Brazil, breast cancer is the leading cause of cancer death among women, accounting for 11.71 deaths per 100,000 women, and is most prevalent after the age of 50[1]. Annual bilateral mammography for breast cancer screening is recommended by the Brazilian Society of Mastology for women between 40 and 74 years of age, and may be complemented by other imaging tests[2]. Based on the results of imaging exams, the *Breast Imaging Reporting and Data System* (BI-RADS®) classification system is used to standardize breast lesions, also indicating the subsequent medical conduct. The classification of findings is gradual, being 0 (incomplete and requires further evaluation), 1 (negative for malignancy — 0% malignancy), 2 (benign — 0% malignancy), 3 (probably benign — 0 to 2% malignancy), 4A (low suspicion of malignancy — 2% to 10% malignancy), 4B (moderate suspicion of malignancy — 10% to 50% malignancy), 4C (high suspicion of malignancy — 50% to 95% malignancy), 5 (highly suggestive of malignancy — >95% malignancy), and 6 (malignancy confirmed by biopsy). Lesions classified as BI-RADS® 4 and 5 must be referred for biopsy, while BI-RADS® 3 requires an individualized assessment[3]. Thus, breast changes seen on imaging may suggest the need for a biopsy, and the histological result can determine if the lesion is benign, pre-malignant, or malignant.

In Brazil, between 2019 and 2022, approximately 12 million bilateral screening mammograms were performed, of which 167,416 were referred for breast biopsies[4]. Given the importance of this procedure, Core Needle Biopsy (CNB) stands out as a minimally invasive method of choice for evaluating suspected lesions, emerging as an alternative to surgical biopsy[5]. This new approach can be guided by different equipment, with ultrasound (US) and mammography (MMG) being the main resources available. Ultrasound-guided core needle biopsy (US-CNB) is commonly

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used because it is more comfortable for the patient, faster, and easier to perform compared to mammography-guided core needle biopsy (MMG-CNB)[6]. If the lesion is diagnosed solely by mammography, then CNB is guided by this examination. However, it is important to note that CNB, when analyzing a sample of the lesion, may lead to an underestimation of the diagnosis when compared to the BI-RADS® classification and/or the histological result after excisional surgery.

This study aimed to verify the presence of underestimation between the BI-RADS® classification and the histological result of US- or MMG-guided CNB separately, as well as to verify if there is also underestimation in the histological result of percutaneous biopsy compared with the surgical excision report. Therefore, accurately knowing the underestimation rates in various contexts is essential for improving diagnostic and surgical protocols, promoting safer and more appropriate clinical management for the patient.

METHODS

This was a retrospective observational study conducted at a tertiary care hospital in Curitiba, Paraná, Brazil. The analyzed data refer to patients referred from the public healthcare network to the mastology outpatient clinic of the Hospital de Clínicas Complex of the Federal University of Paraná (CHC-UFPR), where the medical evaluation was defined. This work includes the results of procedures performed by a multidisciplinary team represented by the Diagnostic Imaging Unit, the Pathology Unit, and the Gynecology Unit of CHC-UFPR between January 2019 and December 2022.

Data from 524 breast lesions in women over 18 years of age, all classified with BI-RADS® 3 or higher, who underwent ultrasound-guided or mammography-guided core needle biopsy at CHC-UFPR, were analyzed. Of this sample, 261 lesions were subsequently surgically excised, according to the medical decision of the hospital's mastology team. Exclusion criteria were breast cysts, biopsies performed on lymph nodes, axillary nodules, absence of reports/data in the system, and patients who needed surgery but did not undergo it by December 2023. The project was approved by the Ethics Committee of CHC-UFPR under the Certificate of Presentation of Ethical Appraisal number 66631223.6.0000.00.

Biopsy

CNB is a minimally invasive procedure performed by trained professionals at the Breast Unit of CHC-UFPR. For the examination, the patient is instructed to lie in the supine position when ultrasound is the preferred guiding method, or in a position that facilitates access to the lesion when mammography is chosen. Antisepsis of the area to be biopsied is also performed, followed by local anesthesia with 2% lidocaine without vasoconstrictor, and then an incision of approximately 1 cm in the breast area.

In the case of ultrasound-guided CNB, the *General Electric Healthcare® Logiq5-7* device with a 5 MHz linear transducer is used. Mammography-guided CNB is performed using the *Hologic® Selenia Dimensions* mammography system. Both are performed with a 14G needle adapted to the *Hologic®* Affirm™ *breast biopsy guidance system*. This device has a propulsion system capable of quickly and efficiently grasping the targeted tissue. Samples collected for analysis are stored in a vial with 10% formalin and sent to the hospital's pathology department, which is responsible for issuing histopathological reports.

Medical record analysis

The purpose of consulting the electronic medical records was to gather general patient information, such as age at the time of CNB, and to obtain access to procedure reports and histopathological analysis after excisional surgery, when available.

Regarding the CNB report, data concerning the quadrant, laterality, BI-RADS® classification, and major axis of the lesion were included, in addition to the number of samples collected during the biopsy and the histological result. This, in turn, was subdivided into benign, pre-malignant, and malignant lesions.

Among the benign lesions, fibroadenoma, stromal fibrosis, usual ductal hyperplasia, and simple adenosis were identified. Premalignant lesions included intraductal papilloma, atypical papilloma, atypical ductal hyperplasia, and carcinoma *in situ*. Malignant lesions include invasive ductal carcinoma, invasive lobular carcinoma, and mixed invasive carcinoma, excluding malignant *phyllodes* tumors and lymphoid neoplasia.

Regarding the lesions submitted to US-CNB, the lesion description included classification by echogenicity (hypoechoic, hyperechoic, isoechoic, and anechoic), orientation (parallel and perpendicular), and margin (circumscribed, indistinct, spiculated, microlobulated, macrolobulated, and lobulated), considering non-nodular lesions separately.

Regarding the lesions submitted to MMG-CNB, information concerning architectural distortions and microcalcifications was also included. These were subclassified into linear, clustered, and segmental.

The data obtained from the surgical excision reports include the largest axis of the lesion, the time elapsed between the CNB and the surgery, as well as the histopathological result.

Statistical analysis

The data were collected and tabulated in Microsoft Excel® spreadsheets and analyzed using the *Statistical Package for the Social Sciences* (IBM® SPSS® Statistics v. 25.0, SPSS Inc, Chicago, USA). The results were expressed as means, medians, minimum values, maximum values, and standard deviations (quantitative variables); or as frequencies and percentages (qualitative variables). Pearson's χ^2 test was used for inferential analyses. P-values <0.05 were considered significant.

Including all collected samples, the BI-RADS® classification was correlated with the histological result of the CNB. Underestimation was analyzed separately for each guideline method by comparing these two factors. Lesions where there was a discrepancy between the CNB report and the cancer risk standardized by the BI-RADS® classification, according to the *American College of Radiology*, were considered underestimated. In cases where the diagnosis corresponds to the expected classification, concordance was considered. Selecting both surgical excisions and lesions submitted to surgery, in both categories the age of the patients included in the study was subdivided into two groups, one with an age range under 50 years and the other 50 years or older. According to the BI-RADS® classification and the histology of the percutaneous biopsy, these data were correlated with the histological result of the surgical excision.

Regarding lesions submitted to surgery, those in which the histological result of CNB was discordant with the histopathological analysis of the surgical excision were considered underestimated, with a separate analysis performed for each guiding method. Thus, pre-malignant lesions reported as benign and malignant lesions reported as benign or pre-malignant in the CNB were considered underestimated. When the histopathological results coincided, the lesions were considered concordant.

Data not found in electronic medical records or reports were considered missing and were not incorporated into the statistical analysis of this study.

RESULTS

A total of 524 lesions corresponding to patients who underwent CNB with a median age of 51 years (±14.162; 18–86) were analyzed. The median number of samples collected was 4 for US-CNB and 5 for MMG-CNB, with a maximum of 10 for both guide methods. The Upper Lateral Quadrant (ULQ) was the most affected, corresponding to 35.1% of cases.

Of the total lesions, 83 underwent MMG-CNB, including 5 architectural distortions and 78 microcalcifications. The latter were subdivided according to their arrangement and comprised 59 clustered (75.64%), 3 segmental (3.85%), 5 linear (6.41%), and 11 with unspecified arrangement (14.1%). Surgical intervention was performed in 29/83 lesions, encompassing 26 cases of microcalcifications and 3 of architectural distortions.

Among the 441 lesions evaluated by US-CNB, 428 correspond to nodules and 13 to non-nodular lesions. Regarding the echogenicity of the nodules, the analysis shows 216 hypoechoic lesions (50.47%), 4 isoechoic (0.93%), 2 hyperechoic (0.47%), 1 anechoic (0.23%), and 205 missing (47.9%). As for orientation, 111 parallel (25.93%), 51 perpendicular (11.92%), and 266 missing (62.15%) lesions were identified. Regarding margins, 125 were circumscribed (29.2%); 271 were irregular (63.32%); and 32 were missing (7.48%). 232 out of 441 lesions were referred for surgical excision, of which 7 were non-nodular and 225 were nodular.

The correlation between percutaneous biopsy histology and surgical excision histology with the BI-RADS® classification is described in Tables 1 (US-CNB) and 2 (MMG-CNB).

Of the 232 lesions submitted for surgical excision, 19 presented pre-malignant lesions on US-CNB (3 columnar cell changes, 4 ductal carcinoma *in situ* (DCIS), 4 intraductal papillomas, 2 atypical cell proliferations, 1 atypical papillary lesion, and 5 atypical ductal hyperplasias). Regarding surgical excision, 9 biopsied lesions (3.89%), shown in Table 3, were underestimated; 3 corresponded to DCIS and progressed to invasive ductal carcinoma, 1 progressed from atypical cell proliferation to invasive lobular carcinoma, while the other 5 lesions considered benign in the biopsy histology progressed to pre-malignant lesions, including 1 ductal carcinoma in situ, 1 atypical ductal hyperplasia, 2 intraductal papillomas, and 1 residual Paget's disease. Of those previously considered benign, two had a major lesion axis greater than 2 cm. It was not possible

Table 1. Histological findings in different BI-RADS® classifications using ultrasound as a guide method.

US-CNB		BI-RADS® Classification					p-value
		3	4A	4B	4C	5	
		n (%)	n (%)	n (%)	n (%)	n (%)	
Histology Biopsy Percutaneous	Benign	85 (95.5)	87 (91.6)	30 (68.2)	9 (23.1)	12 (6.9)	<0.05
	Pre-malign	3 (3.4)	4 (4.2)	4 (9.1)	3 (7.7)	6 (3.4)	
	Malign	1 (1.1)	4 (4.2)	10 (22.7)	27 (69.2)	156 (89.7)	
Total		89	95	44	39	174	
Excision Surgical	Benign	11 (91.7)	26 (81.3)	10 (43.5)	1 (3.6)	4 (2.9)	<0.05
	Pre-malign	1 (8.3)	3 (9.4)	4 (17.4)	4 (14.3)	6 (4.4)	
	Malign	0	3 (9.4)	9 (39.1)	23 (82.2)	127 (92.7)	
Total		12	32	23	28	137	

Source: the authors (2024).
US-CNB: Ultrasound-guided core needle biopsy; BI-RADS®: *Breast Imaging Reporting and Data System.*

to analyze the lesion characteristics due to a lack of available data in the system. The number of samples collected from these lesions varied between 3, 4, and 5.

When analyzed by MMG-CNB, of the 29 surgical excisions, 10 lesions were considered pre-malignant, including 1 columnar cell alteration, 4 atypical ductal hyperplasias, 4 ductal carcinomas *in situ*, and 1 lobular carcinoma in situ. Furthermore, 7 biopsied lesions (24.13%) that underwent surgical excision, shown in Table 4, were underestimated. This demonstrates that 3 lesions considered DCIS in the CNB were evaluated as invasive ductal carcinoma at surgical excision, while four others were benign and were reported as pre-malignant post-surgery, including two ductal carcinomas *in situ*, two atypical ductal hyperplasias, and one intraductal papilloma. The number of samples collected from these lesions ranged from 5, 6 and 10.

The lesions considered underestimated according to the analysis comparing histology from percutaneous biopsy and surgical excision are listed in Table 5.

Table 2. Histological findings in different BI-RADS® classifications using mammography as a guiding method.

MMG-CNB		BI-RADS® Classification					p-value
		3	4A	4B	4C	5	
		n (%)	n (%)	n (%)	n (%)	n (%)	
Histology Biopsy Percutaneous	Benign	10 (90.9)	32 (97.0)	25 (92.6)	4 (33.3)	0	<0.05
	Pre-malign	1 (9.1)	1 (3.0)	2 (7.4)	6 (50.0)	0	
	Malign	0	0	0	2 (16.7)	0	
Total		11	33	27	12	0	
Excision Surgical	Benign	1 (50.0)	6 (85.7)	3 (30.0)	3 (30.0)	0	0.087
	Pre-malign	1 (50.0)	1 (14.3)	6 (60.0)	3 (30.0)	0	
	Malign	0	0	1 (10.0)	4 (40.0)	0	
Total		2	7	10	10	0	

Source: The authors (2024).
MMG-CNB: Mammography-guided core needle biopsy; BI-RADS®: *Breast Imaging Reporting and Data System*.

Table 3. Histological findings from surgical excision and percutaneous biopsy associated with malignancy using ultrasound-guided methods.

US-CNB		SURGICAL EXCISION			p-value
		Benign	Pre-malign	Malign	
		n (%)	n (%)	n (%)	
Age	<50	42 (40.8)	6 (5.8)	55 (53.4)	<0.05
	≥50	10 (7.8)	12 (9.3)	107 (82.9)	
Histology biopsy percutaneous	Benign	46 (90.2)	5 (9.8)	0	<0.05
	Pre-malign	6 (31.6)	9 (47.4)	4 (21.4)	
	Malign	0	4 (2.9)	158 (97.1)	

Source: the authors (2024).
US-CNB: Ultrasound-guided core needle biopsy; BI-RADS®: *Breast Imaging Reporting and Data System*.

Table 4. Histological findings from surgical excision and percutaneous biopsy associated with malignancy using a mammography-guided method.

MMG-CNB		SURGICAL EXCISION			p-value
		Benign	Pre-malign	Malign	
		n (%)	n (%)	n (%)	
Age	<50	3 (37.5)	3 (37.5)	2 (25.0)	0.772
	≥50	10 (47.6)	8 (38.1)	3 (14.3)	
Histology biopsy percutaneous	Benign	12 (70.6)	4 (23.5)	1 (5.9)	<0.05
	Pre-malign	1 (10.0)	7 (70.0)	2 (20.0)	
	Malign	0	0	2 (100)	

Source: the authors (2024).
MMG-CNB: mammography-guided core needle biopsy.

Table 5. Analysis of lesions underestimated in relation to discrepancies between histopathological results.

	Classification BI-RADS®	Histology biopsy percutaneous	Excision surgical	Largest axis of lesion on biopsy percutaneous (cm)
US-CNB (n=9)	3	benign	pre-malign	1
	4A	benign	pre-malign	0.89
	4B	benign	pre-malign	1.5
	4C	benign	pre-malign	2.41
	4C	pre-malign	malign	0.9
	5	pre-malign	malign	2.2
	5	pre-malign	malign	2.1
	5	pre-malign	malign	1
	5	benign	pre-malign	2.7
MMG-CNB (n=7)	4B	benign	pre-malign	0.5
	4B	benign	pre-malign	-
	4B	benign	pre-malign	1
	4B	benign	pre-malign	-
	4B	pre-malign	malign	-
	4B	pre-malign	malign	-
	4C	pre-malign	malign	5

Source: the authors (2024).
US-CNB: Ultrasound-guided core needle biopsy; MMG-CNB: mammography-guided core needle biopsy; BI-RADS®: *Breast Imaging Reporting and Data System.*

DISCUSSION

The selection of cases for percutaneous biopsy is based on the BI-RADS® classification. In this study, BI-RADS® was category 3 in 19.1%, category 4 in 47.7%, and category 5 in 33.2%, considering the two imaging methods included in the study. The recommendation for BI-RADS® 3 is to repeat the examination at 6, 12 and 24 months. If the lesion progresses during follow-up, a biopsy is indicated. In this study, only one lesion (1%), identified through US-CNB, showed malignancy upon surgical excision. Therefore, the assessment of the probability of malignancy according to BI-RADS® 3, in relation to the two guide methods, agrees with the literature, being between 0% and 2%, in relation to the histology of both the CNB and the surgical excision[3], justifying its histological investigation. The high number of biopsies in BI-RADS® 3 nodules is justified by the number of examiners and imaging laboratories that examine the same person, often without comparison to the previous examination.

The BI-RADS® 4 is intended for lesions that do not qualify as malignant, but have suspicious characteristics to be evaluated by biopsy[7], encompassing a group with a high probability of malignancy (2% to 95%). As expected, in this study there is a predominance of this category. Regarding BI-RADS® 4A, the chance of being malignant is between 2% and 10%, which corresponds to the results found in the study, of 3.1% in CNB and 9.4% in surgical excision in this category. BI-RADS® 4B indicates a moderate suspicion of malignancy with a 10% to 50% probability of malignancy, which also agrees with the statistics evidenced in the research, being 14.1% and 39.1% referring to CNB and surgical excision, respectively. Regarding the BI-RADS® 4C classification, the probability of malignancy is between 50% and 95%, accounting for 56.9% in CNB and 82.2% in surgical excision[3]. Only lesions submitted to US-CNB were considered for surgical excision analysis due to the non-significant analysis in relation to MMG-CNB (p=0.087), probably due to the reduced number of lesions submitted to surgery.

The BI-RADS® 5 classification, corresponding to a high probability of malignancy (value equal to or greater than 95%), is described only in US-CNB[3]. Contrary to the literature, the present study did not reach the described percentage, corresponding to 89.7% in percutaneous biopsy histology and 92.7% in surgical excision. Therefore, this data suggests the occurrence of overestimation of benign and pre-malignant lesions totaling 10.3% in the analysis. This finding suggests that evaluators, possibly with less experience, may have overestimated images that were classified as BI-RADS® 5. The absence of BI-RADS® 5 classification related to MMG-CNB was evidenced as a characteristic of the service analyzed.

All biopsy guns used in the procedures were 14G caliber, standardizing the samples. Regarding the number of fragments, lesions submitted to US-CNB had a median of four samples from the biopsied lesions, agreeing with the author. In the case of microcalcifications, the authors recommend a minimum of ten samples for those submitted to MMG-CNB. Considering this, there was disagreement, since, in this study, only 3/89 analyses

followed this recommendation[8]. Given these data, the higher rate of underestimation in MMG-CNB may be associated with lesions with calcifications, which are more frequently detected by mammography. In these cases, vacuum-assisted biopsy, for example, could provide more representative samples and, consequently, reduce diagnostic underestimation. The results of this study suggest that vacuum-assisted biopsy could, in addition to reducing the underestimation rate, spare patients from unnecessary procedures.

In this study, performing CNB allowed 50.2% (263/524) of the lesions to avoid unnecessary surgery. Of these, 49.8% (261/524) underwent surgical excision. The underestimation rate of CNB compared to the histological result after surgical excision, based on the total number of lesions analyzed, was 6.1% (16/261). Ahkeel Allen et al.[9] Surgical excision of pre-malignant lesions diagnosed by biopsy, such as carcinoma in situ, is recommended. Visualization of DCIS in biopsy histology has a 33.8% underestimation rate for invasive ductal carcinoma, making it important to identify tumor characteristics in the lesions[10,11]. Corroborating the previous data, it is noted that, in this study, regardless of the guiding method in the biopsy, DCIS showed a greater tendency to underestimation, representing 37.5% (6/16) of the lesions considered underestimated. However, the histological characteristics of DCIS were not evaluated in the present study.

Lesions identified as benign on US-CNB with a diameter greater than 2 cm have a 2.1% risk of becoming malignant and a 6.3% risk of evolving into pre-malignant lesions. Therefore, surgical excision of these lesions should be considered[12]. In this study, among the underestimated lesions, 56.3% (9/16) were benign, with 5 of them having previously undergone US-CNB. Of these, 2 were larger than 2 cm and were considered pre-malignant after surgical excision. This result raises a warning about underestimating CNB in larger lesions. The small size of the fragment is sometimes insufficient for definitive diagnoses.

In agreement with previous studies[1,2], the median age of the patients included in the research was 51 years. Also, regarding the diagnosis of cancer in patients undergoing US-CNB, there was a prevalence in those aged 50 years or older. As confirmed by guidelines on breast cancer, the most affected area by lesions is the upper lateral quadrant, justified by having a greater amount of glandular tissue[13]. The higher number of lesions evaluated by US-CNB (441) compared to MMG-CNB (83) is based on the ease, speed and comfort that US provides during the procedure, being chosen when the lesion is visible by this method[5,6,14]. Despite this, US-CNB visualization is limited in terms of microcalcifications, only being able to identify those associated with other findings. Other positive points are that it does not use radiation and the lesion can be evaluated in real time[14]. On the other hand, MMG-CNB is the method of choice when microcalcifications and other findings visualized exclusively on MMG are present.

The limitations of this study include: the absence of data in medical records and other online systems of CHC-UFPR, the surgery not having been performed by the time of data collection, as well as the surgery being performed in external services. Also, patient follow-up was hampered by the cancellation and postponement of procedures due to the COVID-19 pandemic. Furthermore, the reduced number of MMG-CNB procedures performed contributed to the lack of statistically significant relevance for the analysis of lesions guided by this imaging method. This research was conducted in a single center with a specific sample of patients with breast lesions. Moreover, it is pertinent to include the characteristics of the underestimated lesions in a future study in order to discern which imaging characteristic aided in the accuracy of the diagnosis.

CONCLUSION

It was concluded that there was no underestimation between the BI-RADS® classification and the histological result of the US- and MMG-guided CNB. However, underestimation was found in relation to the histological result of the percutaneous biopsy compared to the surgical excision report. Finally, the data demonstrate the importance of a better evaluation of the lesions to avoid underestimation in order to obtain greater accuracy in the clinical treatment of patients. The service analyzed is in consensus with previous studies.

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