Original paper

Breast carcinoma grading on core needle biopsy – to grade or not to grade?

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Core needle biopsy (CNB) is well established as an important diagnostic tool in diagnosing breast cancer and it is now considered the initial method of choice for diagnosing breast disease and the basis for the treatment planning. The concordance rate between CNB and surgical excision specimen in determination of histological grade (HG) varies widely across literature, ranging from 59-91%. The aim of our study was to investigate the level of concordance between CNB and surgical excision specimen for the determination of HG for breast cancer patients. The study population included 157 women with a breast tumor who underwent a core needle biopsy for breast carcinoma and a subsequent surgical excision of the tumor. The concordance level between core needle biopsy and surgical resection specimen for overall histologic grading was 73%: for tubule formation – 71%, for nuclear pleomorphism – 91%, for the mitotic index – 59%. Our study shows that our institution's histologic grading of CNBs and surgical excisions shows a fairly good correlation and is useful for the planning of treatment.

Key words: breast cancer, grading, core needle biopsy.

Introduction

Breast cancer is the most common cancer affecting women worldwide [1, 2]. It is also the leading cause of cancer deaths among women [3]. Although the incidence of breast cancer has been increasing since the implementation of mass mammography screening and continues to grow due to the aging population, mortality has decreased over the past years [4]. This decrease in mortality rate is in part due to the earlier detection of cancer with mammography screening, as well as the development of more effective treatments [5, 6].

Presently non-operative diagnosis of breast lesions comprises „triple assessment" based on physical examination, imaging (mammography and/or ultrasound), and pathology [7]. Since 2015, the European Society of Medical Oncology guidelines for the clinical practice of breast cancer require that patients suspicious for malignancy have a pathological diagnosis performed by core-needle biopsy (CNB) before starting any treatment [8]. This allows for the personalization of the approach to the oncological patient and the determination of the basic prognostic and predictive factors necessary to make the right therapeutic decision and start surgical treatment or systemic therapy.

In contrast to fine needle aspiration (FNA), CNB provides architectural information allowing for the evaluation of prognostic and predictive factors for breast cancer, including histological grade (HG) – one of three prognostic factors used to calculate the Nottingham Prognostic Index [9-13]. The advantages of CNB over FNA include also a more definitive histological diagnosis, differentiation between in situ and invasive tumors, and the possibility of molecular profiling and assessment of biomarkers [14].

In comparison to an excisional biopsy (EB), a core needle biopsy is a simple, cost effective, and less invasive procedure with a low complication rate that has been proven to have a high accuracy, sensitivity, and specificity in diagnosing breast cancer [15]. Previous studies have shown CNB to be almost as accurate as open excisional biopsy in diagnosing breast disease [16], and to have an excellent agreement between diagnosis made by examination of CNB and surgical specimens [17, 18]. This concordance is also observed in the context of histopathological biomarkers such as ER, PR and HER2, indicating that retesting for surgical excision may not be necessary [19, 20]. All this means that CNB is well established as an important diagnostic tool in diagnosing breast cancer and it is now considered the initial method of choice for diagnosing breast disease [15, 16, 18, 21-24]. In many cases, CNB may be the only cancer sample for patients showing complete pathological response to neoadjuvant therapy, which is increasingly used to down-stage primary tumors prior to breast-conserving therapy, and to reduce the risk of metastasis [25].

One of the powerful independent prognostic and predictive factor assessed in the breast cancer tissue is the histological grade. Several studies have previously described the concordance rate between CNB and EB specimen in determination of HG [26-29]. Many studies has also been conducted to find out the cytological grading system that correlates well with histological grading. However, the concordance rate previously ascribed to overall grade is controversial and varies widely across literature, ranging from 59-91% [26, 30-33]. This may potentially exclude some patients that would benefit from neoadjuvant therapy. This fact makes the determination of the actual concordance of HG in the core biopsy sample and the excisional biopsy specimen an important clinical problem.

To the best of our knowledge, no study investigating the level of agreement between CNB and surgical excision specimen for the determination of HG for breast cancer patients has been performed in Poland. The aim of our study was to evaluate the relevant data recorded at our institution and compare our results to those described in previous literature.

Material and methods

The study population included 157 women with a breast cancer who underwent a core needle biopsy and a subsequent surgical excision of the tumor. Samples were routinely processed and embedded in paraffin wax (FFPE). All specimens were assessed in 2 μm HE-stained FFPE sections as part of the routine reporting, by experienced breast pathologists. HG was assessed only in core needle biopsies containing at least 10 well preserved HPF ($\times$400, field diameter 0.55 mm) with invasive tumor. The total score of HG consisted of the evaluation of individual histological features: tubule formation, nuclear pleomorphism, and mitotic count. *Evaluation of tubule formation* was based on the percentage of cells in the *tumor* that have tube-shaped structures with clear central lumina: score 1 – over 75% of the cancer was composed of tubular structures, score 2-10-75% of the tumor had a tubular pattern and score 3-less than 10% of the tumor contained tubules. The assessment of nuclear pleomorphism in areas with the greatest atypia was based on a qualitative analysis of the nuclear morphology of the tumor, assessed microscopically on a scale of 1 to 3, reflecting increasing differences in appearance compared to normal epithelium:

- nuclear pleomorphism score 1 – nuclei similar in size to nuclei of normal epithelial cells ($<$ 1.5 $\times$ the size of normal epithelial cell nuclei), minimal nuclear variation in size and shape, small regular uniform cells, invisible or very small nucleoli,
- nuclear pleomorphism score 2 – nuclei larger (1,5-2 $\times$ the size of normal epithelial cell nuclei), moderate nuclear variation in size and shape, visible but small nucleoli,
- nuclear pleomorphism score 3 – nuclei larger ($>$ 2 $\times$ the size of normal epithelial cell nuclei), marked nuclear variation in size and shape, large nucleoli.

The mitotic counts were divided into three mitotic scores: mitotic score 1 for 0-8 mitoses/10 HPF, mitotic score 2 for 9-17 mitoses/10 HPF and mitotic score 3 for ≥18 mitoses/10 HPF (field diameter 0,55 mm).

Both materials were evaluated for the determination of histological grade depending on the sum of the points obtained: G1 (3-5 points), G2 (6-7 points) and G3 (8-9 points).

Samples from patients before and after neoadjuvant chemo- or hormone therapy were excluded from the study.

The illustrations were done from the whole slide images using Medlan scan viewer.

The degree of concordance between CNB and surgical excision specimen for the determination of tumor grade was assessed by Cohen's κ coefficient. The κ coefficient used was $\kappa = 0.703$, 95%

Table I. General criteria for assessing the degree of concordance based on κ-value

κ -value	Interpretation
κ min = –1.00	No concordance
0 < κ < 0.40	Very poor concordance
0.40 ≤ κ ≤ 0.75	Good concordance
κ > 0.75	Very good concordance
κ max = 1.00	100% concordance

Table II. Concordance between CNB and surgical excision for histological grade

	Surgical excision			
	G1	G2	G3	Total
CNB				
G1	21	12	1	34
G2	5	52	20	77
G3	1	3	40	44
Total	27	67	61	155

CI: 0.5728-0.8332. Table I describes the general criteria used to assess the degree of concordance based on κ-value [34-36]. A weighted coefficient was applied in the analysis in order to assign a particular weight for each stage. The higher the stage, the higher the weight (ordinal scale: the higher the level, the worse condition) (Table I).

Results

Retrospective comparison of medical records and pathological reports revealed that CNB correctly predicted the histological grade in 113 of 155 cases (73%). The level of agreement between core needle biopsy and surgical resection specimen for overall histologic grading was 73% (113 of 155 cases). CNB correctly predicted the grade of the surgical excision specimen in 21 cases for grade 1 tumors (**κ = 0.525**, 95% CI: 0.36340-0.6818 F, 52 cases for grade 2 tumors (κ = 0.5652, 95% CI: 0.458-0.667), and 40 cases for grade 3 tumors (κ = 0.6154, 95% CI: 0.4862-0.7309). The highest level of agreement was observed in grade 3 malignancies (Table II).

The concordance rate for tubule formation was 71% (126 out of 155 cases) with a κ of 0.7489, 95% CI: 0.5868-0.911. Analyzing tubule formation scores separately, the concordance rates were 100% (8 of 8 cases) for grade 1 tumors, 72.4% (42 of 58) for grade 2 tumors, and 85.4% (76 of 89) for grade 3 tumors. The highest concordance rate for tubule formation as an individual parameter of HG was observed amongst tumors assigned a score of 1 (Table III).

Table III. Concordance between CNB and surgical excision for tubule formation

	Surgical excision			
	G1	G2	G3	Total
CNB				
G1	8	0	0	8
G2	3	42	13	58
G3	0	13	76	89
Total	11	55	89	155

Table IV. Concordance between CNB and surgical excision for nuclear pleomorphism

	Surgical excision			
	G1	G2	G3	Total
CNB				
G1	1	1	0	2
G2	0	100	12	112
G3	0	1	40	41
Total	1	102	52	155

Table V. Concordance between CNB and surgical excision for mitotic index

	Surgical excision			
	G1	G2	G3	Total
CNB				
G1	30	24	15	69
G2	7	30	13	50
G3	0	4	32	36
Total	37	58	60	155

Table VI. Comparison of tumor grade between CNB and surgical excision

	Grade (%) (n = 155)
CNB = surgical excision	113 (73%)
Surgical excision > CNB	33 (21%)
CNB > surgical excision	9 (6%)

The score for nuclear pleomorphism was concordant in 91% of all cases (141 of 155, **κ = 0.801**, 95% CI: 0.5556-1). The concordance rates for the individual grades were 50% (1 of 2 cases) for grade 1, 89.3% (100 of 112) for grade 2, and 97.6% (40 of 41)

Table VII. Concordance rate (%) between core biopsies and subsequent surgical excisions in the literature [46]

Authors	No.	Grade (%)	Tubule formation (%)	Nuclear pleomorphism (%)	Mitoses (%)
Daveau *et al*. (2014)	350	78 grade 1 68 grade 2 95 grade 3 75 combined grade	75	66.5	75
Lorgis *et al*. (2011)	175	75.4			
Ough *et al*. (2011)	209	63			61
Park *et al*. (2009)	104	80.8			
Ozdemir *et al*. (2007)	201	77.8 grade 1 69.2 grade 2 61.5 grade 3 68.8 combined grade			
Usami *et al*. (2007)	111	75		61	
Cahill *et al*. (2006)	95	77			
Burge *et al*. (2006)	87	81 grade 1 83 grade 2 65 grade 3 77 combined grade			
Badoual *et al*. (2005)	110	73.1	78.5	79.6	60.2
Usami *et al*. (2005)	22	80		54	
Monticciolo (2005)	288	74.3		76.6	
Deshpande *et al*. (2005)	105	100 grade 1 71 grade 2 50 grade 3 75 combined grade			
O'Leary *et al*. (2004)	113	61.6	55.6	57.4	59.4
Andrade and Gobbi (2004)	120	59	54.7	58.9	62.1
Harris *et al*. (2003)	500	60 grade 1 60 grade 2 84 grade 3 67 combined grade	82	73	58
Connor *et al*. (2002)	44	64			
McIntosh *et al*. (2002)	133	91			
Shannon *et al*. (2001)	734	75 grade 1 70 grade 2 86 grade 3			
Sharifi *et al*. (1999)	79	75			

for grade 3. The highest level of agreement for nuclear pleomorphism was observed in tumors assigned a score of 3 (Table IV).

The mitotic index was concordant in 59% of all cases (92 of 155, $\kappa = 0.4901$, 95% CI: 0.363-0.6172). Only 30 of 69 cases were correctly determined to be grade 1 for mitotic index in both core biopsy and surgical excision specimens (concordance rate 43.5%). The concordance levels for grade 2 and grade 3 mitotic indexes were 60% (30 of 50 cases) and 88.9% (32 of 36 cases), respectively. The greatest rate of concordance for mitotic index was in tumors

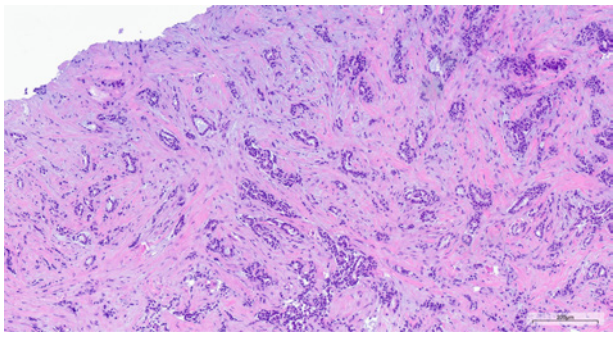

Fig. 1. HG 1 on CNB and HG 1 on ES in the same patient (HE stain, magnification 100×)

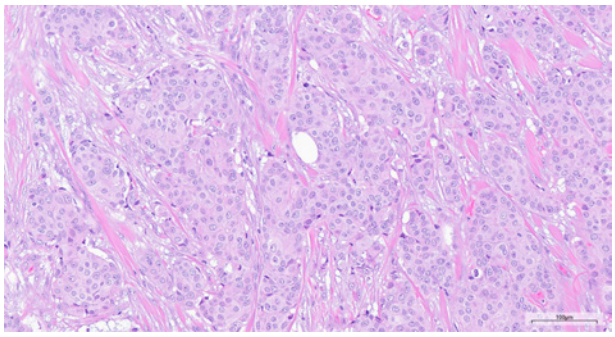

Fig. 2. HG 2 on CNB and HG 1 on ES in the same patient (HE stain, magnification 200×)

assigned a score of 3 (Table V). Comparison of HG based on core needle biopsy and excisional biopsy is shown in Table VI, VII. Figures 1-3 demonstrate comparison of tumor HG on CNB and EB.

Discussion

Accurate evaluation of breast cancer on biopsy samples is of crucial importance to guide therapeutic decisions. This fact justifies a thorough assessment of the concordance between the prognostic and predictive factors routinely determined in the biopsy material and in the excised tumor. One of the factors considered in this assessment is histological grade.

HG in breast carcinoma is the combination of three histological features: tubule formation, nuclear pleomorphism, and mitotic count. Since 1991, histological grade as part of the Nottingham (Elston Ellis) modification of the Scarff-Bloom-Richardson grading system, also known as the Nottingham Grading System (NGS), has continuously proven to be a powerful prognostic factor in guiding the management of breast cancer patients [26, 36-40]. In comparison to novel prognostic molecular tests, histological tumor grade remains an easily accessible and highly accurate alternative method for assessing tumor morphology and biological characteristics, as well as patient prognosis.

In breast cancer, histological evaluation performed on tumor samples after breast-conserving surgery or mastectomy is the standard of care [41, 42]. However, HG in excision specimens may change or become difficult if not impossible to assess following neoadjuvant chemotherapy. In the case of a complete pathological response, as in metastatic patients who are not amenable to surgical resection, core needle biopsy specimen is the only available sample of primary tumor. In such circumstances, it becomes essential to know the HG initial result to determine the prognosis of the patient. Similarly, it may be necessary to know the grade of breast

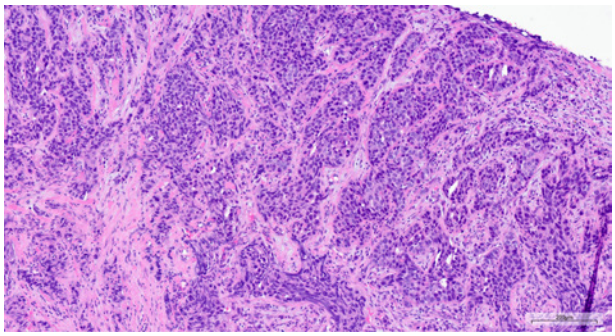

Fig. 3. HG 3 on CNB and HG 3 on ES in the same patient (HE stain, magnification 100×)

carcinoma before tumor excision, to decide about neoadjuvant treatment [43]. Optimally, the result obtained from the CNB should be consistent with the surgical sample. HG evaluated in core needle specimens, although widely used, has shown a variable concordance with the final histological grade in previous studies [31-33, 44, 45].

In presented study we evaluated the concordance rate of breast carcinoma histological grade and individual parameters of HG on CNB and subsequent surgical specimen. Our results showed that histological grade of CNB accurately predicted that of surgical specimen in 113 of 155 cases (73%) with a κ-value of 0.703. Earlier studies have obtained similar results ranging from 51–91% [31-33, 44, 45], with pooled agreement 71.1% calculated in meta-analysis [46]. Among 33 of 42 (79%) discordant cases, the grade was higher in the surgical excision than in the CNB. This accounted for 21% of the full 27% of discordant cases in our study. In 9 of 42 (21%) discordant cases, the grade was higher in the CNB than in the surgical excision. This composed 6% of the overall discordance. These results corresponds to the noted in the literature, showing that underestimation occurs more frequently than overestimation [46]. There are various explanations for discordance between CNB and HG profiles in breast cancer, including tumor heterogeneity and pre-analytic variation [20].

Analysis of the separate histological grades revealed concordance rates of 62% (21 of 34) in grade 1, 68% (52 of 77) in grade 2, and 91% (40 of 44) in grade 3 tumors. These results are similar to those reported by Daveau *et al.*, Harris *et al.*, Shannon *et al.,* and Focke *et al.* whose values for grade 1, grade 2 and grade 3 tumors vary from 60-78%, 60-70%, to 84-99%, respectively [30, 41, 47, 48]. The higher concordance rates we observed in high grade tumors (grade 3; 91%) in our study is consistent with previous reports. However, the opposite results have been found in other studies, notably Desphpande *et al.*, Burge *et al.*, and Ozdemir *et al*. For those studies, the concordance rates for grade 1, grade 2, and grade 3 tumors were 77.8-100%, 69.2-83, and 50-65%, respectively [33, 49, 50].

We also assessed three morphological features that constitute the grade for an individual tumor. Regarding tubule formation, nuclear pleomorphism, and mitotic index, the concordance rate was 71% (κ = 0.7489), 91% (κ = 0.801), and 59% (κ = 0.4901), respectively. Previous studies have shown similar concordance rates ranging from 54.7-82%, 54-79.6%, and 58-75% for tubule formation, nuclear pleomorphism, & mitotic indices, respectively [26, 30-33, 51]. The greatest discrepancy between concordance rates for individual parameters of HG in our study was observed in the mitotic index. A possible reason for this could be the inevitability of sampling error. In comparison to a surgical excision specimen, a CNB offers much less tissue for histological evaluation and may not guarantee an adequate specimen from the periphery of the tumor where the active growth would likely contain the most mitotic activity [37].

The majority of obtained results fall within the ranges of concordance rates reported in earlier studies, and in a similar fashion demonstrate that the under grading of breast carcinoma on CNB is largely due to the underestimation of mitotic counts and the overestimation of nuclear pleomorphism [37, 52, 53]. The reported in presented study and in the literature discordance in tumor grading between CNB and resection specimens from breast cancer affects the indication for adjuvant therapy in only a small minority of patients with invasive carcinoma [54].

In this study, we performed a retrospective analysis of HG concordance between CNB and breast cancer EB specimens, comparable to others reported in the literature. Our study focused on clinically relevant end points based on discordance, incluour data was collected from an academic and tertiary referral center. However, the study also has inherent limitations given its retrospective design and relatively small sample size. Improvements in concordance scores can only be expected from increasing the size and representativeness of biopsy specimens (e.g. using vacuum-assisted biopsy) and gaining more experience of the breast pathologist.

Conclusions

Presented study shows that our institution's histologic grading of CNBs and surgical excisions shows a fairly good correlation and is consistent with findings in previous reports. Despite the inevitable limitations of CNB, it is an effective method for diagnosing breast cancer and managing treatment options. Assessment of tumor grade by CNB is useful for the planning of treatment, so in authors opinion it is worthy to implement it in daily practice.

Institutional Review Board Statement: Ethical review and approval were waived for this study due to analysis based on archival data only [55].

The authors declare no conflict of interest.

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