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Breast Core-Needle Biopsy in a Large Tertiary Oncologic Centre—1-Year Experience after the Introduction of the Method

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Abstract

Ultrasound (US)-guided core-needle biopsy (CNB) is currently the procedure of choice for work-up of suspicious breast lesion. It is mainly used for evaluation of suspicious breast lesions categorized as BI-RADS 4 and 5 (Breast Imaging-Reporting and Data System). The conducted study included 56 female patients with detected suspicious breast leasions, and they underwent US-guided CNB during 1-year period with the aim to investigate the value of US-guided CNB of the breast in a tertiary-level large-volume oncological centre setting with respect of indications, technical adequacy and safety. 2 patients who entered the study were previously diagnosed as BIRADS 2, 3 patients as BIRADS 3, 18 patients as BIRADS 4 and 33 patients as BIRADS 5. In 14 patients with BC (breast cancer), both FNA (fine-needle aspiration) and CNB were performed, and the malignancy was accurately diagnosed by cytology in 9 patients, confirmed by subsequent CNB in all of them. ADH (atypical ductal hyperplasia) was initialy diagnosed by FNA in 5 patients, and in 2 of them, BC was initialy missed by FNA, but deteced by CNB. As it is known, the cytology has lower sensitivity for detection of BC than hystology, with false-negative rate ranging from 2.5% to 17.9%. In our material, 18.7% of carcinomas were initialy left undetected by FNAC, and subsequently confirmed by CNB. All confirmed carcinomas were correctly suspected on imaging, and categorized as BI-RADS 4 or 5, while all BI-RADS 2 and 3 findings were confirmed as benign on hystology. False-positive rate of imaging was 8%. An average number of 4 tissue cores (range: 2 - 7) was taken in our experience if good quality of the first 3 core was achieved, and there was no consistent reason to proceed with sampling.

Keywords

Breast Cancer, US-Guided Core Needle Biopsy (CNB), Suspicious Breast Lesion, Tissue Core

1. Introduction

Breast cancer (BC) is one of the most common malignant tumors and an important cause of cancer-related deaths among women. Mammography (MG) is still considered to be the best screening test for BC, with breast ultrasound (US) as the most appropriate complementary imaging modality [1] [2]. First described by Parker *et al*. in the early 1990s, US (ultrasound)-guided core-needle biopsy (CNB) is currently the most accurate method of tissue-sampling, and is the procedure of choice for work-up of US-detected suspicious breast lesion [3].

CNB is recognized as a reliable alternative to surgical biopsy for obtaining histologic diagnosis, commoly used for evaluation of suspicious breast lesions categorized as BI-RADS 4 and 5 (Breast Imaging-Reporting and Data System) [4] [5], valuable also in cases of undeterminate or probably benign lesions [6] [7] [8]. US-guided CNB has high sensitivity (97.5%) in the detection of BC, and many advantages such as high safety due to real-time needle guidance and lack of radiation, possibility of evaluation of tumor grade and receptors, good patient comfort, wide availability, acceptable time consumption and more than fourfold lower costs than surgical biopsy in Croatia (official health service price-list, Croatian Health Insurance Office, 2015). However, an important limitation includes unability to biopsy lesions not clearly detectable by US such as microcalcifications and architectural distortions. Such lesions should be identified and targeted either stereotactically or by use of MRI, in order to avoid a false negative outcomes [3] [7]-[13].

US-guided CNB is a well-established procedure only in large clinical centres in Croatia, while in many mid-size and smaller county hospitals, the method is yet not accepted, mainly due to the lack of qualified personel. Retrospective study performed in the largest Croatian hospital centre, which included imaging-histological concordance analysis, revealed high accuracy, low percentage of false-negative results and high safety of the procedure [14].

Our study aimed to investigate the value of US-guided CNB of the breast in a tertiary-level large-volume oncological centre setting with respect of indications, technical adequacy and safety.

2. Materials and Methods

The study included 56 female patients with detected suspicious breast leasions, who underwent US-guided CNB during 1-year period (September 2014-October 2015). Breast CNB was performed as part of the *tripple assessment* routinely applied in the institution. In selected cases the fine-needle aspiration (FNA) with cytological analysis was done prior to CNB, particularly in patients with clinical suspicion of neoplasm but without imaging findings suggestive of BC, and patients with probably benign imaging findings (BIRADS 3) and no evidence of increased risk for BC. Informed consent before the procedure was mandatory for every patient.

US-guided CNB of the breast—the procedure: The women were placed in the supine position with ipsilateral upper limb resting behind their heads. After the patients' skin

was prepped and the target area covered with sterile drapes, the radiologist performed the puncture using the "freehand technique", holding the transducter with one hand while identifying the target lesion and manipulating the spring-loaded CNB device with the other hand. Under US-guidance 2-5 mL of lidocaine was injected along the presumed needle pathway. A small skin nick was made at the needle entry site, and the biopsy needle was inserted. Disposable HTC device (HUNTER Automatic guillottine system, Tsunami Medical, Italy) with 10 or 15 cm long 14-G needle with 22-mm throw was used for all procedures. The oblique approaching pathway of the needle, with consequent parallel needle position to the chest wall during firing was preferred in order to provide good visualisation of the needle and to assure the best safety. After the CNB device was fired, the needle tip was identified inside the mass, and image was recorded to document the correct targeting. The adequacy of tissue samples was visually checked for integrity and colour. Each specimen was put into the 10%-buffered formaldehyde solution, checked for floating (predominantly fat tissue) or sinking (presumably glandular and/or fibrous tissue), and sent to pathology for analysis.

The referring diagnoses, distribution of BI-RADS categories, reasons for US-guided CNB, and diagnostic outcome after tissue sampling were shown in percentages and discussed. The length of tissue cores was measured by ruler. The number of cores per procedure was analysed. The quality of tissue cores were visualy analysed for floating in the formaldechyde solution, integrity (fragmentation) and bloodiness. Pathologist's observations upon inadequacy of sampling material were considered.

3. Results and Discussion

Fifty-six patients (58.7 years, range 37 - 80, 48.2% premenopausal) were included in our series. The patients were referred to our hospital by breast surgeons, oncologists or family doctors with the request to get breast CNB performed. No special preparation was proposed, except anticoagulants or aspirin withdrawal 3 days prior to procedure. **Table 1** shows referring diagnoses from request forms for the patients which underwent US-guided CNB. In the vast majority of cases the indication for CNB was based on clinical and/or radiological suspicion of breast malignancy. Relatively high proportion of referring diagnoses reflected disease non-confined to the breast (39/67, 58.2%), while 46.4% (26/56) patients was assigned a simple clinical diagnose *breast neoplasm*, without any other specification. In 22/56 (39.2%) of women lymph node metastases were clinicaly suspicious (18 cases of axillary, and 4 cases of other regional lymphadenopathy). In 1 patient CNB was indicated after cytological detection of atypical ductal hyperplasia (ADH) in fine-needle aspiration (FNA) material [15] [16].

The distribution of BI-RADS categories of patients underwent US-guided CNB was shown in **Table 2**. There was no patients assigned as BI-RADS 0 or 1 in our material, meaning that CNB was not done in patients with incomplete diagnostic work-up or in patient in which imaging was normal, even if clinical finding was suspicious. BIRADS 0 category requires either repeat of MG or further imaging study(ies), hence no CNB is indicated [4]. In our institution the patients without imaging findings suggestive of

Table 1. Referring diagnoses assigned to patients submitted to US-guided CNB.

Referring diagnosis	Number of patients	Comment/remark
Breast cancer (BC) (without other specification)	26	
Bilateral BC	6	
Inoperative/exulcerated BC	7	
Inflammatory BC	1	
BC with enlarged axillary nodes	18	
BC with enlarged neck nodes	2	
BC with enlarged supraclavicular nodes	2	
BC with distant metastases	2	
BC with infiltration of pleura	1	
Fibroadenoma	1	Palpatory suspect, enlarging
Mastopathia	1	Palpatory suspect, atypical ductal hyperplasia detected by cytology
Total number of diagnoses	**67**	Some patients were assigned with more than one referring diagnose

Table 2. BI-RADS categories of patients underwent US-guided CNB: the highest US, MG or MR BI-RADS category was taken into account if more than one imaging modality were done prior to CNB.

Imaging category	Number of patients	Comment/remark
BIRADS 2	2	Palpatory suspect
BIRADS 3	3	
BIRADS 4	18	
BIRADS 5	33	
Total number of patients	**56**	

neoplasm, but with palpatory suspicion of malignancy undergo FNA as only primary sampling method. Two BI-RADS 2 patients with palpatory suspicious breast lump had equivocal FNA findings from other institution, and were biopsied following the request of other doctors, which thought that the findings were of limited accuracy. Very low proportion of BI-RADS 3 patients in our material (3/56, 5.4%) reflects the practice that patients with probably benign breast lesions are commonly submitted to US-guided FNA, and regular US follow-up in 6-months periods [5]. BI-RADS 5 is the most frequent category in our series (33/56, 58.9%) as clinicaly and radiologicaly clearly malignant or advanced breast neoplasms tend to cumulate in our specialized national oncology centre in which a wide spectrum of diagnostic and treatment options are readily available for patients with BC.

Reasons for US-guided CNB were specified in Table 3. Remarkable proportion of patients (28/56, 50%) were candidates for neoadjuvant therapy, and CNB is mandatory

Table 3. Reasons for US-guided CNB.

Reasons for biopsy	Number of patients
Preoperative PHD	24
Neoadjuvant therapy planned	28
Other reasons	4
Total number of patients	**56**

for such patients as it enables proper choice of the best antineoplastic agent [17]. The category *other reasons* include inconclusive FNA findings and lesions suspected by MR detectable also by US.

In the subgroup of 14 patients with BC both FNA and CNB were performed, and the malignancy was accurately diagnosed by cytology in 9 patients, confirmed by subsequent CNB in all of them. ADH was initialy diagnosed by FNA in 5 patients, and in 2 of them BC initialy missed by FNAC was subsequently found at hystology. As it is known, the cytology has lower sensitivity for detection of BC than hystology, with false-negative rate ranging from 2.5% to 17.9%. In our material 18.7% of carcinomas were initialy left undetected by FNAC, and subsequently confirmed by CNB, which is not significantly different from the results in the literature [15] [16] [18].

Table 4 shows histological diagnoses obtained from CNB in comparison to imaging findings. As expected, the majority of tumors were invasive ductal carcinomas, and only 2 tumors of lobular origin were found. All carcinomas confirmed by hystology were correctly suspected on imaging, and categorized as BI-RADS 4 or 5. All BI-RADS 2 and 3 findings were confirmed as benign on hystology; these patients were proceeded to CNB because of palpatory suspicion for malignancy. False-positive rate of imaging was 8%, as a result of 2 false-positive MRI findings and 2 false-positive MG findings.

With each CNB procedure, an average number of 4 tissue cores (range 2 - 7) were taken from different parts of the US-detectable lesion. The central, possibly necrotic areas of the tumor were consistently avoided from targeting. The length of tissue cores in our material ranged 19 - 23 mm.

No cores obtained in our material was considered by pathologist as inadequate for hystological analysis, hence no re-biopsies were requested neither by pathologist nor by clinician. Other authors report up to 10% of re-biopsies in their material [14] [19] [20]. We observed fragmentation in 27% of cores, which did not compromised the value of CNB. First obtained tissue core was of the best quality in 49/56 (87.5%) of cases, while subsequent cores were more or less blood, as the destruction of the breast architecture, and local haemorrhage occurs. The last tissue core was bloody and fragmentated in 33/56 (58.9%) of procedures.

European guidelines are not too dogmatic about the number of cores, realizing that variablity can be accepted between cases and operators [21]. We think that even a single core may be sufficient for the diagnosis of a solid mass, if the radiologist is confident of sampling adequacy. If good quality of the first 3 core was achieved, there was no consistent reason to proceed with sampling in our experience. This may differ from the

Table 4. Pathophysiological diagnoses (PHD) obtained from CNB in comparison to imaging findings.

PHD	Number of patients	BI-RADS 4 or 5	BI-RADS 2 or 3
Invasive ductal carcinoma	44	44	0
Lobular carcinoma in situ	1	1	0
Invasive lobular carcinoma	1	1	0
No tumor	10	4*	6**
Total number of patients	**56**	**50**	**6**

*MR BI-RADS 4 in 2 patients, MG BI-RADS 4 in 2 patients; **palpatory suspicious BI-RADS 2 in 3 patients, BI-RADS 3 in 3 patients.

opinion that larger core number is necessary [6] [22]. The higher the number the cores, the higher representativeness of the material in the sense of accurate targeting the lesion of interest. Hovewer, our patients had relatively large tumors, and no risk of off-target cores existed, hence even limited number of samples seemed to be acceptable. With small lesions, even more than 4 cores might be needed to surpass the risk of non-representative targeting, which can compromise the procedure and cause the recall. Absolute care should be taken that first 2 - 3 cores were sampled from representative place in the breast, as the bleeding, especialy in loose breasts, can obscure precise targeting in the further course of the procedure.

Only 2.3% of tissue cores floated in formaldechyde solution, which meant that they could be predominantly fatty, hence unrepresentative for analysis. The cores from the lesions containing microcalcifications were not radiographed, as the detection of micro-calcifications in the samples would not be critical for further work-up.

All patients tolerated the procedure well, with only one case of psychosomatic reaction (fainting, dizziness) and 2 patients experiencing moderate local breast pain. No significant complications related to the procedure were recorded. In one patient prolonged venous bleeding occured, treated with consistent compresion of the puncture site for 20 minutes. In one patient local anesthesia was not applied, as the patient informed the staff about severe anaphylactoid reaction 3 years ago, related to lidocaine injection prior to small surgical procedure. The patient agreed that CNB would be performed using only lidocaine skin spray, and experienced moderate but tolerable local pain in the breast.

Our study have some limitations: As the method is not yet generaly accepted in the region as a standard, the indication were set inconsistently in some cases, and the method is done less frequently than necessary because of lack of resources. This is a low-volume study intended primarily to describe the initial experience rather than profoundly examine the value of the procedure, which is already well investigated by many authors. The procedure was performed by three operators with different skill in the technique (1 highly, 2 moderately experienced) which may influence the quality of specimens and the safety.

4. Conclusion

In conclusion, US-guided breast CNB is accurate, safe, and a well tollerable tissue sampling procedure which can be performed only with limited resources, and the results are valuable in the work-up of patients with suspicion of breast malignancy. The operator should adhere to basic interventional US safety standards, and take into account advantages and limitation of the method.

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