In the name of God

S.U.M.S.

Value of Core Needle Biopsy as the First Diagnostic Procedure in the Palpable Breast Masses.

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Abstract:
Backgrounds: Breast core needle biopsy (CNB) provides enough tissue for histopathologic diagnosis and is considered a reliable method for establishing preoperative tissue diagnosis. The purpose of this study is to evaluate CNB as the first diagnostic step instead of excisional biopsy in palpable breast masses.
Materials and Methods: In this prospective study, patients with palpable breast mass who underwent CNB were enrolled. Based on pathology report, patients with malignant lesions revealed by CNB were immediately candidate for surgery and those who had benign lesions were followed up to 3 years.
Results: 112 females with palpable breast mass were enrolled in the study. In 103 (91.9%) of cases first attempt CNB provided adequate sample tissue. CNB detected malignant lesion in seventy eight (69.6%) patients. All (100%) malignant CNB reports were confirmed at surgery specimen pathology. In 34 (30.4%) patients CNB revealed benign lesion. At the end of 3 years follow up period, 25 (73%) of these patients underwent open biopsy leading to the detection of 1 (3%) malignant tumor. Overall, according to the gold standard defined as positive surgical biopsy or positive follow-up, sensitivity of CNB was calculated as 98.7% (95% CI, 94.1-100%) and its accuracy was 99.1% (95% CI, 97.4-100%). The specificity of the CNB procedure was 100%.
Conclusion: These findings suggest that the malignancy detection power provided by CNB may be weighed equal to that of open biopsy. Therefore, we propose CNB as the first choice in diagnostic evaluation of palpable breast mass especially for those in accessible sites and in experienced hands.

Introduction:

Excisional biopsy is the gold standard procedure for diagnosis of breast lesions. Core needle biopsy (CNB) has been replaced surgical excision at some institutions during recent years. CNB is a minimally invasive procedure while it facilitates preoperative planning just as efficient as open biopsy. In benign conditions CNB obviates unnecessary breast surgery. Several studies have shown that CNB has accuracy similar to that of excisional biopsy. CNB not only decreases patient morbidity and cost but also shortens the gap between clinical detection, biopsy and treatment which is especially important in malignant cases.[1-3]

CNB has potential limitations, including technical difficulties in deeply located lesions, small or central lesions in large breasts, dense breast tissue resistant to needle traversing, and complications such as hematoma formation. Its accuracy depends on the experience of the surgeons and pathologists.[1-6]

The present study was undertaken to evaluate accuracy of CNB as the first diagnostic step in palpable breast lesions.

Methods:

In this prospective study, female patients with palpable breast mass referred to the surgery clinics of a tertiary referral hospital were included between October 2000 to September 2003. The protocol of the study was approved by the ethics committee of affiliated university. The patients were fully informed about the nature of the procedure and informed consent was obtained. CNB was performed by a Tru-Cut biopsy needle (14 gauge), under local anesthesia in an out-patient setting. A nick was made in the skin with a No.11 blade to permit easy entry of the biopsy needle into the breast tissue and into the lesion. The lesion was held steady in the nondominant hand while the biopsy needle is advanced into the lesion and a core sample obtained. At least two samples that filled the needle gap were taken. If the histopathology report indicated malignant changes, the patient was candidated for surgical treatment with no further diagnostic attempt. In this group, tissue diagnosis made from CNB was compared with the final pathology report of the surgical specimen. Those with benign pathology report were followed by mammography every 6 months for the first year and then annually up to 3 years. The patients were also instructed to do breast self examination and report readily any suspicious finding.

Results:

112 female patients with palpable breast mass underwent CNB.The procedure was repeated in 9 (8.1%) (95% CI, 3-13%) patients because their samples obtained at first attempt were inadequate. Tumor laterality was almost equal in either breast. 46 (41.1%) tumors were located in upper outer quadrant of the breasts and 9 (8%) tumors were central.

In 78 patients (69.6%) (95% CI, 61.1-78.2%) CNB indicated malignancy,

including 49 (43.8%) (95% CI, 34.6-52.9%) cases of invasive ductal and 5 (19.5%) (95% CI, 6.4-82.9%) cases of invasive lobular carcinoma. In this group, 52 patients (67%) had other findings at physical examination and imaging that were also in favor of malignancy. Malignant histopathologic diagnoses made at CNB sample were in concordance with those of surgery specimen in all (100%) of these cases.

Thirty four (30.4%) (95% CI, 21.8-38.9%) CNB reports indicated benign lesions. At 3 years follow up period, 25 of those patients (73.5%) (95% CI, 58.7-88.4%) had open biopsy led to detection of one malignant case (2.9%) (95% CI, 0-8.6%). This patient underwent open biopsy within less than one year after her benign CNB report,

because of enlargement of breast mass and mammography findings suggestive of malignancy. The remaining 9 patients (26.5%) developed no suspicious changes mandating biopsy.

Since CNB missed one malignant case (out of 79), according to the gold standard defined as positive surgical biopsy or positive follow-up, its sensitivity for diagnosis of malignancy was calculated as 98.7% (95% CI, 94.1-100%) and the specificity of the CNB procedure was 100%. For benign lesion, CNB sensitivity was calculated as 100% and its specificity was 98.7% (95% CI, 94.1-100%). Overall CNB accuracy was 99.1% (95% CI, 97.4-100%) (Table 1).

Table 1. The comparison of the CNB with surgical pathology in breast lesions.

		Surgical pathology or positive follow-up					
		Benign		Benign		Total	
CNB pathology	Malignancy	78	(Sen= 98.7%)	0	(FP= 0%)	78	69.6%
	Benign	1	(FN=1.3%)	33	(Spec= 100%)	34	30.4%
	Total	79	70.5%	33	29.5%	112	100%

CNB = Core Needle Biopsy, FP = False Positive, FN = False Negative, Sen = Sensitivity, Spec = Specificity.

Discussion:

Tissue diagnosis of a palpable breast mass may be obtained by means of fine-needle aspiration (FNA) biopsy, CNB, or open surgical biopsy.

Over the past decade, CNB has found its place in the management of breast lesions. CNB offers a reliable and accurate preoperative assessment of breast lesions pathology and hormone receptor status as well.[4] CNB is currently used not only as a

diagnostic modality before definitive breast cancer surgery, but also for sampling any breast lesions in both the screening and diagnostic context. CNB is considered a highly accurate method of diagnosing breast carcinoma with a sensitivity of approximately 95% to 97 %.[5-12] Similar to FNA biopsy, this procedure costs low, is safe, easy to perform, and less invasive than surgical biopsy. As with FNA biopsy, the false positive rate is very low. False negative rate are significantly lower than

for FNA biopsy, but higher with needle smaller than 14 gauge, with freehand rather than image-guided biopsy, and with less experienced operators. Most authors do not recommend definitive treatment based on FNA cytologic examination. The presence of carcinoma cells on FNA does not differentiate between in situ and invasive breast cancer.[13] But CNB provides all the information necessary for decision-making in the management of breast cancer and its accuracy is higher than FNAC.[14] In a study by Ivan et al, there was an excellent correlation between the CNB and excisional biopsy in the diagnosis of benign and malignant breast lesions.[15]

False negative rate (FNR) is one of the most important measures of accuracy for tissue sampling. We reported a FNR of 1.2% which is comparable to previous reports, ranging from 1.2 to 39 %.[1,5,6,10,16,17] In this study, the concordance rate between CNB pathology and final pathology for malignant lesions was 100 % (false positive rates: 0%). As for any test, CNB has some pitfalls. Inadequate sampling is one of its limitations. Inadequacy rate for CNB in this series was 7%, keeping up with the published data (2-10 %).[18-21]

In comparison with studies of image-guided CNB, we report higher sensitivity for CNB in diagnosis of breast cancer (98.7% versus 96.3%).[21] This may be largely attributed to our inclusion criteria (only palpable masses) and may be in part

explained by the experience of the surgeon and pathologist on CNB.

In the present study the accuracy of CNB for malignancy was 99.1% (CI 95%, 97.4-100%), in addition to high sensitivity, excellent specificity and zero false positive rate. The results of current investigation, when combined with findings from previous studies, demonstrate that CNB can be reliably used for preoperative diagnosis of palpable breast lesions as the first diagnostic step with high sensitivity, specificity, and accuracy for both malignant and benign lesions. However, benign lesions, diagnosed this way, must be followed by frequent examinations. Future large scale studies may better substantiate our conclusion.

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