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Ultrasound-Guided Breast Biopsy: Do we still need 5 cores?

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Purpose: Prior studies report that 12-14G needles require 4-5 cores for diagnosis, with incidence of non-diagnostic cores up to 25%. The purpose of this study is to determine the number of core biopsy samples necessary for accurate histological diagnosis and tumor grading in ultrasound-guided biopsy of non-palpable breast lesions using a new coaxial biopsy device.

Methods and Materials: From 12/05/02 to 4/10/03, 4 breast centers used a new coaxial device with vacuum assistance and a radiofrequency positioning tip to biopsy non-palpable lesions in consecutive clinically appropriate patients (SenoCor 360, SenoRx, Aliso Viejo, CA). Sequential samples were submitted separately to each center's pathology laboratory and the case reviewed for patient care purposes. Representative step sections (taken at the time of initial examination) of each sample (up to 4 per case) were then collected centrally, uniquely identified, masked to patient identity, history and initial diagnosis, and reviewed in random order by a single independent pathologist. For each sample, the reviewer recorded confidence of diagnosis, diagnostic category (benign, high risk, in situ, invasive), histological diagnosis and tumor grade. Analyses included diagnostic accuracy for each sample and for the number of samples required for definitive diagnosis, defined as agreement with the subsequent surgical excision, or concordance with imaging in non-operated cases.

Results: A total of 213 individual samples (1 - 4 per case) from 73 biopsy cases were submitted from the breast centers for independent review. Definitive diagnosis was obtained in all 73 cases and was achieved with the first 2 sequential samples in 99% of the cases (95% confidence interval, 0.97 to 1.00). Two sequential core specimens were sufficient to determine the tumor grade in 91% of 23 cancer cases.

Conclusions: In 99% of cases, the first 2 samples obtained with a new biopsy device provided the definitive diagnosis. Large samples of consistent diagnostic quality decreased sampling error, improved accuracy of diagnosis and enabled reliable tumor grading.