

"Frontiers in Breast Care"



Fall, 2007

Vol. 1, No. 2



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When is a Core Biopsy Not Enough?

One of the more delightful aspects of our job as physicians is telling a patient that their biopsy is "negative" or "benign". As the trend in breast biopsy is towards less invasive biopsy procedures, it is more commonplace that a primary care giver orders a biopsy prior to consulting a surgeon. In many health care systems where the ordering physician is contacted with the biopsy result, knowledge of results becomes paramount.

Whenever possible, the breast should be biopsied via a less invasive technique. These techniques employ the use of image guidance to direct a core biopsy needle to an image detected abnormality. Stereotactic core biopsies utilize mammography to direct a core needle to lesions visible by mammogram only, whereas ultrasound guidance is used when lesions are ultrasound visible. By obtaining small samples of tissue, the pathologist renders a diagnosis, and further surgical treatment, if needed, can be planned.

Most core biopsy diagnosis are relatively straight forward, either benign or malignant. Some benign diagnosis, however, are associated with a fairly significant "upstage" risk. Diagnosis such as papilloma, atypical ductal or lobular hyperplasia, and radial scar, have been documented as having about a 5% risk of being associated with invasive or intraductal carcinoma. This is similar to biopsies of colon polyps where the result is adenoma with or without atypia. In these circumstances, complete excision of the polyp, even via colectomy, is indicated.

To be clear, the need for excision typically is following a core or needle biopsy. The need for a "clear margin" following an excisional biopsy is somewhat controversial except in instances where these lesions are transected. It is not uncommon for the pathologist to refer to the need for complete excision within the body of the pathology report. If there is ever a question, a consultation with a surgeon or directly with the pathologist, can be very beneficial.

About Oncotype DX

Oncotype DX™ is a diagnostic assay that quantifies the likelihood of breast cancer recurrence in women with newly diagnosed, early stage breast cancer. In addition to predicting distant disease recurrence, Oncotype DX also assesses the benefit from certain types of chemotherapy. The assay analyzes the expression of a panel of 221 genes and the results are provided as a Recurrence Score™ (0-100).

In early stage of breast cancer, the evaluation of the likelihood of distant recurrence is based on multiple factors, such as nodal status, tumor size, tumor grade, and ER (estrogen receptor), PR (progesterone receptor), and HER2 status. However, there is a significant unmet need: quantitative, clinically validated predictors of disease recurrence risk that provide significant insight into breast cancer treatment decisions. To help address this unmet need, the research team at Genomic Health developed Oncotype DX™ that utilizes gene expression profiling to quantitatively assess the likelihood of breast cancer recurrence more precisely and reliably than markers currently available in clinical practice.

Oncotype DX is clinically validated to assess the likelihood of distant recurrence in women with newly diagnosed, stage I or II, node-negative, estrogen receptor-positive breast cancer who will be treated with tamoxifen. The performance of Oncotype DX exceeds standard measures such as tumor size, tumor grade, and patient age in terms of either predictive power or reproducibility.

In addition to quantifying breast cancer recurrence risk, Oncotype DX also assesses the benefit from certain types of chemotherapy. While adjuvant chemotherapy is an important part of the care of breast cancer patients, a major challenge in oncology has been to better define the risk/benefit ratio for candidates of adjuvant chemotherapy. By characterizing an individual's risk of recurrence and responsiveness to treatment, Oncotype DX can provide physicians with the information they need to develop a treatment plan tailored to the individual patient.

Oncotype DX is validated for use in breast Cancer patients whose disease is:

- Newly diagnosed
- State I or II
- Node-negative
- Estrogen receptor-positive

And who will be treated with tamoxifen



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