

# Tailoring breast cancer therapy

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A major scientific aim of the American College of Surgeons Oncology Group (ACOSOG) Breast Committee (chaired by Kelly Hunt, MD, FACS) is to identify novel biomarkers that determine risk of recurrence in patients who are potentially cured by primary surgical therapy. This endeavor is seen in the early ACOSOG breast cancer trial Z10 (of which Armando Giuliano, MD, FACS, is the study chair). This trial enrolled 5,500 patients to study immunohistochemistry (IHC) detection of micrometastasis in hematoxylin- and eosin-negative sentinel lymph nodes and to correlate the presence of micrometastases with survival. The hypothesis is that breast cancer patients with IHC micrometastases in sentinel lymph nodes are at higher risk for disease relapse. The trial is actively following patients, and surgeons await the results.

Gene expression profiling of the primary breast cancer is another method that has been developed to identify early stage breast cancer patients who have a higher risk of disease. Risk of recurrence is particularly true for stage I and II breast cancer patients who are node negative and estrogen-receptor positive. Although adjuvant chemotherapy is of benefit in such an average risk population, the majority of patients are treated unnecessarily to benefit a few.

In some cases, 100 patients must be treated in order to benefit only three or four patients. This is commonly referred to as “one size fits all.”

It is clear that a risk stratification system is needed to identify patients who were at different degrees of risk for developing recurrent disease. Stratification of low to high risk would then allow surgeons to tailor the intensity of postoperative adjuvant therapy for their patients. Recent studies have shown that gene expression profiling of the primary breast cancer using microarray methods can reliably identify the varying degrees of risk of recurrent disease in node-negative estrogen-receptor-positive breast cancer patients.

This identification process has set the stage for the development of a prospective clinical trial called TAILORx. This trial takes T1 or T2 positive breast cancer patients who are estrogen receptor positive, progesterone positive, or both, who are also node negative and candidates for postoperative adjuvant chemotherapy plus hormonal therapy. The primary tumor undergoes a gene expression assay called Oncotype DX assay, which is commercially available at [www.genomichealth.com](http://www.genomichealth.com).

In the TAILORx trial, this assay identifies three patient populations. Group I patients

have a low recurrence score (less than 11) and receive postoperative hormonal therapy. Group II is a high-risk patient population with a recurrence score greater than 25, and such patients are treated with postoperative chemotherapy plus hormonal therapy. The primary study group has an intermediate risk of recurrent disease (score 11-25). This group is randomized to either postoperative hormonal therapy or postoperative chemotherapy plus hormonal therapy.

TAILORx is one example of using risk stratification to identify patients who will benefit from postoperative systemic adjuvant chemotherapy. This study is an attempt to identify the patients who will more likely benefit from specific treatment. Because this approach fits within the major scientific aim of the ACOSOG Breast Committee, ACOSOG has endorsed this trial and is urging its surgical membership to refer or enroll patients. More specific information and enrollment procedures are available online by doing a search on TAILORx.

There are very few competing trials for this patient population and it is important for surgeons to explain this trial to their patients and encourage medical oncologists to enroll patients. Surgeons can also enroll patients into this trial. The protocol does not specify the

postoperative chemotherapy regimen or hormonal therapy. The primary objective is disease-free survival.

ACOSOG surgeons are enrolling such patients into the trial and, as of March 1, 16 patients

have been enrolled through ACOSOG. Genomic profiling of primary tumors offers a rational approach to individualizing postoperative adjuvant therapy for these patients based on risk assessment. We ask surgeons

to consider this trial for their node negative T1 or T2 breast cancer patients who are estrogen receptor positive, progesterone positive, or both.

*Dr. Ota and Dr. Nelson are ACOSOG Group Co-Chairs.*

## ACS to cosponsor NIH K08/K23 Awards

The American College of Surgeons has announced a program that will provide supplemental funding to up to five individuals who receive a Mentored Clinical Scientist Development Award (K08/K23) from the National Institutes of Health (NIH). This award is directed at surgeon-scientists working in the early stages of their research careers. The award requires cosponsorship with

an approved surgical society of a three-, four-, or five-year period of supervised research experience that may integrate didactic studies with laboratory or clinical research.

This award program will offer a means to facilitate the career development of individuals pursuing careers in surgical research by enhancing salary support over and above that offered by the K08/K23 mecha-

nism. The application deadline is June 12. Funding begins July 1, 2008. Awardees must be members in good standing of both the College and a cosponsoring surgical society.

For further details, visit the College's scholarships Web page at <http://www.facs.org/memberservices/research.html>, or contact Kate Early, ACS Scholarships Administrator, at [kearly@facs.org](mailto:kearly@facs.org).

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