A series of classic randomized trials, including NSABP-B-04, formed the basis for level I and II axillary-node dissection becoming a standard of care for women with invasive breast cancer. The emergence of sentinel lymph node biopsy (SLNB) as an initial staging procedure led to a new generation of trials evaluating the need for axillary dissection in women with pathologically negative or positive nodes. Recently reported results from NSABP-B-32 and the ALMANAC trial support the use of SLNB for women with clinically node-negative disease. Preliminary data indicate that SLNB has a nine to 10 percent false-negative rate. Sentinel node biopsy provides staging accuracy equivalent to axillary dissection, and the morbidity is clearly less—only the immediate postoperative morbidity but also two years later in measurable differences in pain, lymphedema, arm motion and lymphedema. Additionally, we now know long-term local tumor control is good.

Michael Blumstein, MD

NSABP-B-32 SENTINEL NODE STUDY

The preliminary specificity and sensitivity data from NSABP-B-32 shows a nine to 10 percent false-negative rate for detecting positive nodes with the sentinel node removal. One can say that surgeons with more experience have a lower rate than that if we examine two or three sentinel nodes, we can lose that rate. However, if we examine four to five nodes, we can't really talking about an axillary sentinel node dissection.

When we examined some of the older NSABP data to determine how many nodes were necessary to establish positive nodes in the axilla, the numbers were between six and eight. Any number of nodes below that had a high false-negative rate, while any number above that was superfluous.

I don't believe questioning the accuracy of axillary node dissection is particularly helpful. In this randomized trial with over 2,000 women, the false-negative rate with sentinel node biopsy is nine to 10 percent and that's the inescapable conclusion of this trial.

Harry D Bear, MD, PhD

THE ALMANAC TRIAL

The ALMANAC data show a significant decrease in arm morbidity problems and lymphedema with sentinel node biopsy. However, there is the concern about the morbidity experienced by the sentinel node group because 25 percent of those patients actually underwent axillary sentinel node biopsy or they received axillary radiation. I believe the numbers were skewed against sentinel node biopsy and that the associated morbidity is probably much lower than these data suggest, which are already much lower than the results seen in the axillary node dissection group.

Rory J Dacre, BSc, PhD

I was the primary investigator for the quality of life study in the ALMANAC trial, and it was probably the first time since I've been in this area that we've actually had quality of life as the primary endpoint in a surgical trial. In fact, anxiety was not affected and the quality of life benefits were superior in women who underwent sentinel node biopsy rather than surgical treatment because they experienced less arm morbidity.

Another important aspect of this study is that, although physicians are deeply concerned about their patients, often the focus of attention when reviewing clinical trial data is predominantly on the occurrence of adverse events. For example, one of our endpoints was surgical site — surgery, chemotherapy or hormone manipulation — non-lymphedema, but nevertheless significant side effects can dramatically impair quality of life. Lymphedema usually does not affect quality of life, often with a few patients whose affected limbs are so painful that it definitely affects one’s ability to function adequately in the home and professional world and in care-taking roles. The ALMANAC trial has at least given us clear indications that the sentinel lymph node procedure should become the standard of care.

Lester Falkoff, PhD