Primary outcome results of NSABP B-32, a randomized phase III clinical trial to compare sentinel node resection (SNR) to conventional axillary dissection (AD) in clinically node-negative breast cancer patients.

D. N. Krag; S. J. Anderson; T. B. Julian; A. Brown; S. P. Harlow; J. P. Costantino; T. Ashikaga; D. Weaver; E. P. Mamounas and N. Wolmark

National Surgical Adjuvant Breast and Bowel Project and University of Vermont, Burlington, VT; National Surgical Adjuvant Breast and Bowel Project Biostatistical Center and the University of Pittsburgh, Pittsburgh, PA; National Surgical Adjuvant Breast and Bowel Project and Allegheny General Hospital, Pittsburgh, PA; National Surgical Adjuvant Breast and Bowel Project and Aultman Cancer Center, Canton, OH

LBA505

Background: NSABP B-32 is the largest prospective randomized phase III trial designed to determine in SN negative patients that SNR alone results in the same survival and regional control as SNR + AD while reducing morbidity. It was designed to detect a survival difference of 2% between the 2 groups at 5 years.

Methods: 5,611 women with operable, clinically N0, invasive breast cancer were randomized to SNR + AD (Group 1) or to SNR alone with AD only if SNs were positive (Group 2). 3,989 (71.1%) of the 5,611 patients were SN negative and followed for events. 99.9% of these SN negative patients had follow-up information: 1,975 in Group 1 and 2,011 in Group 2. Median time on study was 95.3 months. Patients were well balanced across clinical strata. Log-rank tests for unadjusted analyses and Cox proportional hazard models adjusting for study stratification variables were used to compare overall survival (OS) and disease-free survival (DFS) between the two groups. Two-sided p-values were used. HR values > 1 indicate a more favorable outcome in Group 1 (SNR + AD).
**Results:** Comparisons of OS (Group 1 vs. Group 2) yielded an unadjusted HR of 1.20 (p = 0.12) and an adjusted HR of 1.19 (p=0.13). Five-year Kaplan-Meier estimates for OS are 96.4% in Group 1 and 95.0% in Group 2 and the 8-year estimates are 91.8% and 90.3%, respectively. Comparisons of DFS (Group 1 vs. Group 2) yielded an unadjusted HR of 1.05 (p=0.54) and an adjusted HR of 1.07 (p=0.57). No substantial differences could be seen across sites for first treatment failure. Five-year Kaplan-Meier estimates for DFS are 89.0% in Group 1, and 88.6% in Group 2 and the 8-year estimates are 82.4% and 81.5%, respectively.

Local and Regional Recurrences: There were 54 local recurrences in Group 1 and 49 in Group 2 (p=0.55). There were 8 regional node recurrences as first events in Group 1 and 14 in Group 2 (p=0.22).

**Conclusions:** No significant differences were observed in OS, DFS, or regional control between the trial groups. Within the limits of this trial, SNR without AD is validated as a safe and effective method for regional node treatment of SN negative breast cancer patients.