Cancer Research

Reply to Counterpoint

The Need for Axillary Lymph Node Dissection in T1/T2 Breast Cancer Surgery

See Counterpoint by Sabel, p. 7156

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Dr. M.S. Sabel states that the low accrual and low event rate of the ACOSOG Z011 study are reasons as to why the results may not be ready to be adopted. This is not consistent with his belief that completion of axillary lymph node dissection (ALND) may be omitted in patients with micrometastatic disease based on a study (IBCSG 23-01) that had a target accrual of 1,960 patients with analysis planned after 558 events, closed after randomization of 934, and was analyzed after 100 events rather than the planned 558. What these studies illustrate is not selection bias, as suggested, but rather improvements in breast cancer therapy during the time these trials were planned and patients were recruited. Dr. Sabel's argument about the knowledge of the number of involved lymph nodes being important for selection of adjuvant systemic therapy is unconvincing. As evidence, he cites a single institution study of 132 patients where therapy was not delivered according to any stated guidelines. In contrast, neither the National Comprehensive Cancer Network guidelines nor the St. Gallen Consensus panel in 2011 or 2013 specify the selection of adjuvant systemic therapy based on the number of involved axillary nodes.

His comments about axillary radiotherapy are worthy of further examination, because this is the most commonly raised concern about ACOSOG Z0011. It is true that standard breast tangents treat a significant portion of the axilla, and this undoubtedly contributed to the high rate of local control seen in the study. However, the radiation in ACOSOG Z0011 and AMAROS was not comparable, because AMAROS specified radiation of both the axillary and the supraclavicular fields. Evidence suggests alternate explanations for the high rate of local control seen in ACOSOG Z0011 than the hypothesis (unproven) that radiation oncologists were treating the axilla. In the NSABP B32 trial of patients with negative sentinel nodes, 10% of the patients randomized to ALND had additional positive nodes, and axillary failure was seen in only 0.7% of patients not undergoing ALND, yet axillary irradiation has not been a concern in this study. We readily accept in sentinel node-negative patients that only a small proportion of residual axillary disease becomes clinically evident recurrence with multimodality therapy, so why invoke the specter of protocol violations in the node-positive setting? Finally, what about the apparently contradictory findings of the MA-20 trial? This study is not yet published, but the 2.3% recurrence rate in the ALND (control) arm at 5 years is almost 5 times higher than that seen after ALND in ACOSOG Z011 (0.5%) or AMAROS (0.54%), and equal to what was seen in NSABP B04 (2.5%) in the absence of systemic therapy, and raises questions about the contribution of the poor outcome in the control arm to the benefit of radiotherapy. A single study, which stands in contrast with multiple trials showing that ALND is not necessary for local control or survival benefit, is not an adequate justification for the routine use of ALND.

Disclosure of Potential Conflicts of Interest

No potential conflicts of interest were disclosed.

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