TPS628 Poster Session

Radiation omission in patients with clinically node-negative breast cancer undergoing lumpectomy (ROSALIE).

Elena Parvez, Mark Basik, Sameer Parpia, Mark Norman Levine, Timothy Joseph Whelan, Thierry Muanza; McMaster University, Hamilton, ON, Canada; Segal Cancer Center, Montreal, QC, Canada; Ontario Clinical Oncology Group, Hamilton, ON, Canada; Jewish General Hospital, McGill University, Montreal, QC, Canada

Background: Currently, the standard of care for patients undergoing neoadjuvant chemotherapy (NAC) and breast conserving surgery (BCS) is adjuvant radiation (RT). However, high rates of pathologic complete response (pCR) after NAC have raised questions regarding the necessity of WBRT in these cases. A meta-analysis of 9 German NAC trials demonstrated a 5-year locoregional recurrence (LRR) of only 4% in patients with pCR who underwent BCS with radiation therapy. Data from two large National Surgical Adjuvant Breast and Bowel Project (NSABP) neoadjuvant trials (B.18 and B.27) demonstrated a local recurrence risk of 5.1% at 10 years (2.5% at 5 years) in patients >50 years with node negative breast cancer who had a pCR and were treated with BCS and RT. With such low rates of recurrence, we postulated that the absolute benefit that RT can offer is limited. Radiation therapy is not without side effects, which include both short-term and long-term toxicity. As such, a trial of de-escalation of RT is warranted. **Methods:** This study is a prospective, multi-center, single arm cohort study of omission of WBRT following BCS in patients with a pCR following NAC. Eligible and consenting female patients with newly diagnosed T1-3 node negative breast cancer age >50 years with no clinical evidence of distant metastatic disease, who have been treated with NAC, BCS and axillary staging surgery with final pathology demonstrating a pCR (ypT0N0) will be enrolled to the study and followed. Negative lymph node involvement at initial presentation must be documented by imaging (US or MRI), fine needle aspiration (FNA) or core needle biopsy. Marker clip must have been placed in the tumour bed prior to or during neoadjuvant chemotherapy when the tumour can still be identified. Study participants will not receive adjuvant RT, the current standard of care. Study participants will be followed and assessed for local recurrence, regional recurrence, distant recurrence, DFS and OS. Any additional breast cancer treatments received by the participant for the first recurrence event including repeat BCS, mastectomy, additional systemic therapy and radiation therapy (RT) will be documented. The primary outcome is ipsilateral breast tumour recurrence (IBTR) at median 5-year follow-up. A local recurrence of 5% without RT was felt to be acceptable. Based on a postulated 5-year IBTR risk of 3.0%, 4 years of accrual plus an additional 3 years of follow-up, a 90% two-sided CI for a postulated LR rate of 3.0% at 5 years would have an upper bound of <5% with 300 patients. To account for a 5% potential loss to follow-up and 10% receiving RT contrary to protocol, a sample size of 352 patients will be required. The trial opened in March 2024. Clinical trial information: NCT05866458. Research Sponsor: Canadian Institutes of Health Research (CIHR).