with prostate cancer, the present trial was the largest by about 2-fold. In all 6 trials, there was no improvement in OS, while there was an improvement in biochemical disease-free survival. The rates of grade 2+ GI toxicity were similar in the late phase in 6 trials, but the rate of GU toxicity was slightly higher in the present study.

ICORG 05-03 Results: Lower Dose of Radiation Noninferior in MSCC

Written by Mary Mosley

Malignant spinal cord compression (MSCC) is a common cancer-related complication for which the current standard of care is direct decompressive surgery plus postoperative radiation therapy (RT) [Patchell RA et al. *Lancet*. 2005]. The optimal modality and schedule for RT have not been determined. No significant difference between 3 different schedules of external beam radiation therapy (EBRT) was found in 2 different studies [Maranzano E et al. *J Clin Oncol*. 2005; *Radiother Oncol*. 2009]. The Spinal Cord Compression trial [ICORG 05-03, V6; NCT00968643] therefore tested 2 alternative schedules of RT in patients with MSCC treated with EBRT only. Of the 116 eligible patients, 76 patients (38 per group) were randomized to 20 Gy in 5 fractions (control arm, the commonly used dose in Ireland and the United Kingdom at trial initiation) or 10 Gy in 1 fraction (experimental arm). The trial was conducted from 2006 to 2014 in 5 centers, which showed the difficulty of conducting trials of emergency RT, stated Pierre Thirion, MD, St. Luke's Radiation Oncology Network, Dublin, Ireland. The patients in the treatment arms were similar at baseline. A low median Karnofsky Performance Status (KPS) score was found in the eligible vs evaluable patients.

The primary end point was change in mobility at 5 weeks using the modified 3-point Tomita scale. The overall response was similar in the control and experimental arms (68.4% and 78.9%, respectively). Only 10.5% of each arm had an improvement in mobility, whereas it remained the same in 57.9% of the control arm and 68.4% of the experimental arm. The mean score change was –0.29 and –0.08 in the control and experimental arms. The difference in the mean score change between the 2 arms was –0.21 (95% CI, –0.56 to –0.14), which fulfilled the noninferiority hypothesis. The only independent prognostic factor for the mobility status at 5 weeks was the baseline mobility status, stated Prof Thirion.

The secondary outcome of change in bladder control at 5 weeks, assessed by an in-house 3-point scale, was also similar in both groups, with an overall response of 75.7% and 86.8% in the control and experimental arms. The rates of improvement and stability in bladder control were 10.8% and 2.6% in the control arm and 64.9% and 84.2% in the experimental arms. The mean score change was –0.22 and –0.16 in the control and experimental arms.

Survival free of neurological deterioration was similar in both arms, with a median time to a neurological event of 1.4 months. Overall survival (OS) was also similar, with a median time of only 4 months. The independent prognostic factors for OS were young age, a primary cancer that was not lung cancer, high baseline KPS, and preserved baseline mobility.

Only 1 non-neurological event occurred acutely (in the experimental arm) and 2 occurred in the long term (1 in each arm). The rates of grade 0, 1, 2, and 3 toxicity were 47.6%, 31.1%, 20.3%, and 1% in the acute phase, and the long-term rates were 51%, 23.5%, 21.6%, and 3.9%, respectively.

EBRT alone provided only short-term stabilization of function in patients with MSCC, and their vital and functional prognosis remains poor. Similar outcomes were achieved with the 10-Gy and 20-Gy RT schedule. Prof Thirion stated that a 10-Gy single-fraction schedule represents a reasonable standard in clinical practice. Further clinical research is needed to improve outcomes in these patients.