

Cancer patients with malignant spinal cord compression have preserved mobility

September 16 2014

Mobility is equally preserved in cancer patients suffering from malignant spinal cord compression (MSCC) who receive a single dose of 10 Gy of radiation therapy (RT), compared to patients who receive five daily doses of 4 Gy of RT each, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 56th Annual Meeting.

Malignant spinal cord compression (MSCC) is a complication of metastatic cancer mostly with bone involvement that occurs when a tumor's secondary deposit presses on the spinal cord and nerves. This pressure exposes patients to neurological damage that can result in pain, loss of muscle strength and function of one or more of the senses. In some cases, the neurological damage can lead to paralysis of the entire body below the neck or paralysis of one or more limbs.

Although the standard of care for patients with MSCC is a combination of direct decompressive surgery and [radiation therapy](#), sometimes surgery is not an option and patients receive only therapeutic radiation therapy. Currently, there is not a defined, optimal radiation therapy technique, or dose and schedule for patients with MSCC who do not undergo surgery.

This ICORG (All Ireland Co-operative Oncology Research Group) prospective, randomized, non-inferiority, Phase III trial compared two radiation therapy fractionation schedules in patients with MSCC who had not undergone surgery. From 2006 to 2014, five centers in Ireland

and the United Kingdom accrued 116 patients with pathologically proven [metastatic cancer](#). The study included 42 women and 74 men, with a median age of 69. The patients' median Karnofsky performance status (KPS) score was 60 out of a possible 100. (KPS is a standard scale used to assess patients' ability to perform ordinary tasks).

The patients' main primary tumor sites (initial locations of the patients' cancer) were 24 percent prostate cancer (28 patients); 20 percent breast cancer (23 patients); and 19 percent lung cancer (22 patients).

The patients' MSCC sites included 4.3 percent cervical (five patients); 67 percent thoracic (78 patients); 23.5 percent lumbar (27 patients); 2.6 percent sacral (three patients) and 2.6 percent two synchronous occurring in more than one area at the same time (three patients).

Patients were randomized into two groups, with baseline characteristics balanced between both groups. Group One (the control group) received 20 Gy of EBRT, delivered over five treatment days. Group Two received an experimental high-dose of 10 Gy of EBRT, delivered in one single treatment.

The study measured the change in the patients' mobility at five weeks based on a modified Tomita scoring system. The modified Tomita score evaluated patient mobility using a three-class scale, with class I indicating the patient was mobile and unaided; class II indicating the patient was mobile with a walking aid; and Class III indicating the patient was bed-bound (which corresponds to the original Tomita scale class III and IV).

The study also evaluated patients' changes in bladder function at five weeks, using an in-house scoring scale, acute and long-term side effects (based on the Radiation Therapy Oncology Group, or RTOG scale) and overall survival (OS).

At five weeks post-treatment, 76 patients—38 patients in Group One and 38 patients in Group Two were evaluable. Analysis of the evaluable patients showed no statistically significant difference in overall mobility score change at five weeks post-treatment, with an overall response (improvement/stability) rate of 68.4 percent (10.5 improvement/57.9 percent stability) for Group One; and 78.9 percent (10.5 percent improvement/68.4 percent stability) for Group Two. Additionally, there wasn't a significant difference in mean mobility score changes, with a difference of -0.29 for Group One and a difference of -0.08 for Group Two (difference = -0.21, 95%CI: -0.56 to 0.14, +0.4 non-inferiority margin outside 95%CI), confirming the non-inferiority statistical hypothesis.

No significant differences were also detected in patients' bladder function score changes at five weeks post-treatment, with an overall response (improvement/stability) rate of 75.7 percent (10.8 percent improvement/ 64.9 stability) for Group One; and 86.8 percent (2.6 percent improvement/84 percent) for Group Two. The groups' mean sphincter score changes were -0.22 for Group One and -0.16 for Group Two (difference = -0.06, 95%CI: -0.44 to 0.32).

The neurological deterioration-free survival and overall survival median durations were similar in both groups, with a median neurological deterioration free survival time of 1.4 months and a median overall survival time of four months

Additionally, the reported overall toxicity (side effect rate) for the entire group of patients was low; there was one, Grade 3 acute side effect reported and two Grade 3 long-term side effects reported.

"Our study shows that while radiotherapy alone provides only short-term neurological stabilization, the single treatment, high-dose experimental treatment was as effective as the current standard of care," said lead

author Pierre Thirion, MD, consultant radiation oncologist a at St. Luke's Radiation Oncology Network in Dublin, Ireland. "Sometimes less treatment is as effective, and our research can help reduce the burden of treatment and frequency of hospital visits for this patient population, while maintaining the same clinical outcome and quality of care, as well as the treatment cost. The study also highlights the poor overall outcome for MSCC patients, both in terms of daily living and overall survival, since less than half of these [patients](#) survived four months. These findings confirm the importance of further clinical research to improve patient outcome and the essential role of cooperative clinical research group, such as ICORG, to lead it."

More information: The abstract, "ICORG 05-03: Prospective Randomised Non-Inferiority Phase 3 Trial Comparing Two Radiation Schedules in Malignant Spinal Cord Compression not Proceeding with Surgical Decompression," will be presented in detail during the plenary session at ASTRO's 56th Annual Meeting at 2:15 p.m., Pacific time on Monday, September 15, 2014.

Provided by American Society for Radiation Oncology

Citation: Cancer patients with malignant spinal cord compression have preserved mobility (2014, September 16) retrieved 26 April 2024 from <https://medicalxpress.com/news/2014-09-cancer-patients-malignant-spinal-cord.html>

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