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A Multi-institutional Clinical Trial of Carbon-ion Radiotherapy for Localized High-risk Prostate Cancer (J-CROS 1509)

Hiraku Sato*, Hiroshi Tsuj[1], Hidemasa Kawamura[2], Tatsuya Ohno[3], Shingo Toyama[4], Yoshiyuki Shioyama[4], Hiroyuki Katoh[5], Tamiki Hikake[6], Yosuke Inaba[6], Tomohiko Ichikawa[7], Koichiro Akakura[8], Hiroyoshi Suzuki[9], Tomoaki Okimoto[10], Osamu Suzuki[11], Masaru Wakatsuki[1], Hitoshi Ishikawa[1]

* Department of Radiation Oncology, Yamagata University Faculty of Medicine, Japan, [1] QST Hospital, National Institutes for Quantum Science and Technology, Japan, [2] Gunma University Heavy Ion Medical Center, Gunma University, Japan, [3] Department of Radiation Oncology, Gunma University Graduate School of Medicine, Japan, [4] Ion Beam Therapy Center, SAGA-HIMAT Foundation, Japan, [5] Department of Radiation Oncology, Kanagawa Cancer Center, Japan, [6] Chiba University Clinical Research Center, Chiba University Hospital, Japan, [7] Department of Urology, Funabashi Central Hospital, Japan, [8] Department of Urology, Japan Community Health-care Organization Mishima General Hospital, Japan, [9] Department of Urology, Toho University Sakura Medical Center, Japan, [10] Department of Radiology, Hyogo Ion Beam Medical Center, Japan, [11] Department of Radiology, Osaka Heavy Ion Therapy Center, Japan

Objectives

To evaluate the long-term efficacy and safety of carbon-ion radiotherapy (CIRT) in patients with high-risk localized prostate cancer through the J-CROS 1509 prospective multi-institutional clinical trial.

Methods

J-CROS 1509 was a prospective, single-arm clinical trial (UMIN000025921) conducted by the Japan Carbon-ion Radiation Oncology Study Group across four CIRT centers in Japan. Eligible patients had high-risk localized prostate cancer defined by the presence of any one of the following: clinical T3a (UICC 7th), PSA >20 ng/mL, or Gleason score ≥8, with no regional lymph node or distant metastasis (N0M0). Histological diagnosis of prostate adenocarcinoma (excluding ductal carcinoma) was required. All patients received CIRT at a dose of 51.6 Gy (RBE) in 12 fractions over 3 weeks (4 fractions per week). Neoadjuvant hormone therapy (HT) for 3 to 12 months was mandatory; adjuvant HT for up to 12 months was recommended but not mandatory. The primary endpoint was 5-year biochemical relapse-free survival (bRFS), defined by the Phoenix definition. Secondary endpoints included overall survival (OS), disease-specific survival (DSS), and late toxicity (CTCAE v4.0).

Results

Between 2016 and 2018, 156 patients were enrolled; 149 (95.5%) were evaluable for efficacy and safety analysis. The median age was 70 years (range, 49–85), with a median follow-up of 60.0 months (range, 3.7–60.0). The 5-year bRFS was 89.7% (95% CI: 83.6–93.7), exceeding the pre-defined efficacy threshold of 70%. The 5-year OS and DSS were 96.6% (95% CI: 92.0–98.6) and 99.3% (95% CI: 95.9–99.9), respectively. No Grade ≥3 late toxicities were observed. Grade 2 genitourinary toxicity occurred in 6 patients (4.0%), and no Grade 2 or higher gastrointestinal toxicity was reported. A total of 5 deaths occurred, including 1 due to prostate cancer.

Conclusions

CIRT with 12 fractions was effective, well tolerated, and associated with low toxicity in high-risk localized prostate cancer, supporting its use as a promising treatment option.