Abstract Code: IUC26567-91

A Novel, Cost-Reducing Hyaluronic Acid and Lipiodol Composite for Perirectal Tissue Spacing in Prostate Cancer: Safety and efficacy

S. Elgarhy [1], A.G. El-Gowily [2], M.M. Elshafei [3], E. Elalfy [4], Y. Elsaid [3], A. Eldrieny [5], D. Salama [6], R. Elsaka [7], A.A. Elsaid [7]

(1) cancer management and research, Medical research institute , Alexandria - Egypt, (2) clinical oncology department ,faculty of medicine, Alexandria - Egypt, (3) Radiology department, Faculty of medicine, Alexandria - Egypt, (4) cancer management and research department , medical research institute , Alexandria - Egypt, (5) Faculty Applied Health Sciences Technology,Pharos University,Alexandria - Egypt, (6) Specialized universal network of oncology, Alexandria - Egypt, (7) Clinical oncology department ,faculty of medicine ,Alexandria - Egypt

Abstract:

Introduction: Perirectal spacers still hold a place in preserving rectal toxicity in PCA radiotherapy even with modern radiation techniques.

Methods: We conducted a prospective phase II trial enrolling patients with localized or locally advanced PCa undergoing definitive, conventionally fractionated radiotherapy (78 Gy in 39 fractions) intensity-modulated radiation therapy (IMRT) or volumetric-modulated arc therapy (VMAT). Patients were allocated to receive or not receive a transrectal spacer injection into the perirectal space. The spacer consisted of a high-molecular-weight hyaluronic acid mixed with lipiodol to ensure CT radiopacity for precise delineation, measurement setup, and treatment stability. The primary objectives were to evaluate the safety, stability, and dosimetric efficacy of the spacer. Acute and late toxicities were assessed using the Radiation Therapy Oncology Group (RTOG) scale. The study was approved and conducted at Alexandria oncology Centers, Egypt.

Results: Fifty patients were enrolled (25 spacer, 25 control). The median age was 71 years in the spacer arm and 68 years in the control arm ($p > 0.38$). Baseline clinical N1 disease was present in 28% of overall patient population, and 38% had high or very

high-risk disease. The median anteroposterior spacer thickness was 1.50 cm (IQR: 1.14–2.0) at CT simulation and decreased to 0.96 cm (IQR: 0.70–1.0) at the end of treatment ($p < 0.001$). Spacer injection significantly reduced rectal dosimetry: median V50 was 24.90% (IQR: 21.0–32.0) vs. 31.70% (IQR: 26.5–41.6) in the control arm ($p = 0.008$), and median V70 was 5.30% (IQR: 1.70–8.99) vs. 11.30% (IQR: 9.0–16.0) ($p < 0.001$). Other organs-at-risk showed no dosimetric differences. The spacer arm experienced significantly less acute gastrointestinal (GI) toxicity during and at completion of radiotherapy (Grade 2: 12% vs. 24% in controls, $p = 0.014$; no Grade 3 toxicity reported). No significant differences in GI toxicity were observed at 3 months or 2 years post-radiotherapy. Complications included one perirectal abscess and one case of epididymo-orchitis following spacer injection.

Conclusion: The novel high-molecular-weight hyaluronic acid and lipiodol composite serves as a stable, radiopaque, and clinically effective rectal spacer.