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

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Introduction

Perirectal spacers continue to play a valuable role in reducing rectal toxicity during prostate cancer (PCa) radiotherapy, even with modern radiation delivery techniques.

Methods

A prospective phase II trial enrolled patients with localized or locally advanced PCa undergoing definitive, conventionally fractionated radiotherapy (78 Gy/39 fractions) via IMRT or VMAT. Patients were allocated to receive, or not receive, a transrectal spacer injection into the perirectal space.

The spacer — a high-molecular-weight hyaluronic acid mixed with lipiodol for CT radiopacity — enabled precise delineation, measurement, and treatment stability. Primary objectives were to assess its safety, stability, and dosimetric efficacy. Acute and late toxicities were graded using the RTOG scale. The study was approved and conducted at Alexandria Oncology Centers, Egypt.

Results

Fifty patients were enrolled (25 spacer, 25 control); median age 71 vs. 68 years ($p > 0.38$). At baseline, 28% had clinical N1 disease and 38% had high/very-high-risk disease.

1.50 → 0.96 cm

Spacer AP thickness: CT-sim to RT end ($p < 0.001$)

24.9% vs 31.7%

Rectal V50: spacer vs control ($p = 0.008$)

5.3% vs 11.3%

Rectal V70: spacer vs control ($p < 0.001$)

12% vs 24%

Acute GI toxicity ≥Grade 2 ($p = 0.014$); no Grade 3

No dosimetric differences were seen in other organs-at-risk, and GI toxicity did not differ significantly at 3 months or 2 years. Complications: one perirectal abscess and one epididymo-orchitis (spacer arm).

Imaging

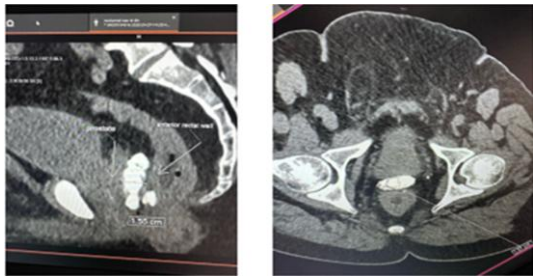

Fig 1. Sagittal & axial CT — spacer separating prostate from rectal wall

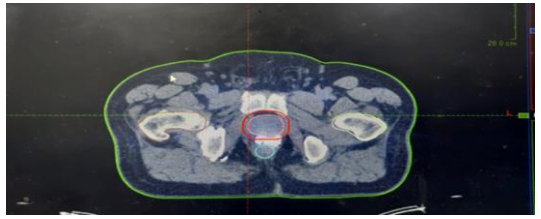

Fig 2. Axial planning CT with rectal and target contours

Conclusion

This novel high-molecular-weight hyaluronic acid–lipiodol composite is a stable, radiopaque, and clinically effective rectal spacer that significantly reduces rectal dose and acute GI toxicity in prostate cancer radiotherapy.