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Use of BioProtect balloon in patients with low- or intermediate-risk prostate cancer receiving dose-escalated EBRT: A retrospective, single institution study reporting rectal spacing and dosimetry

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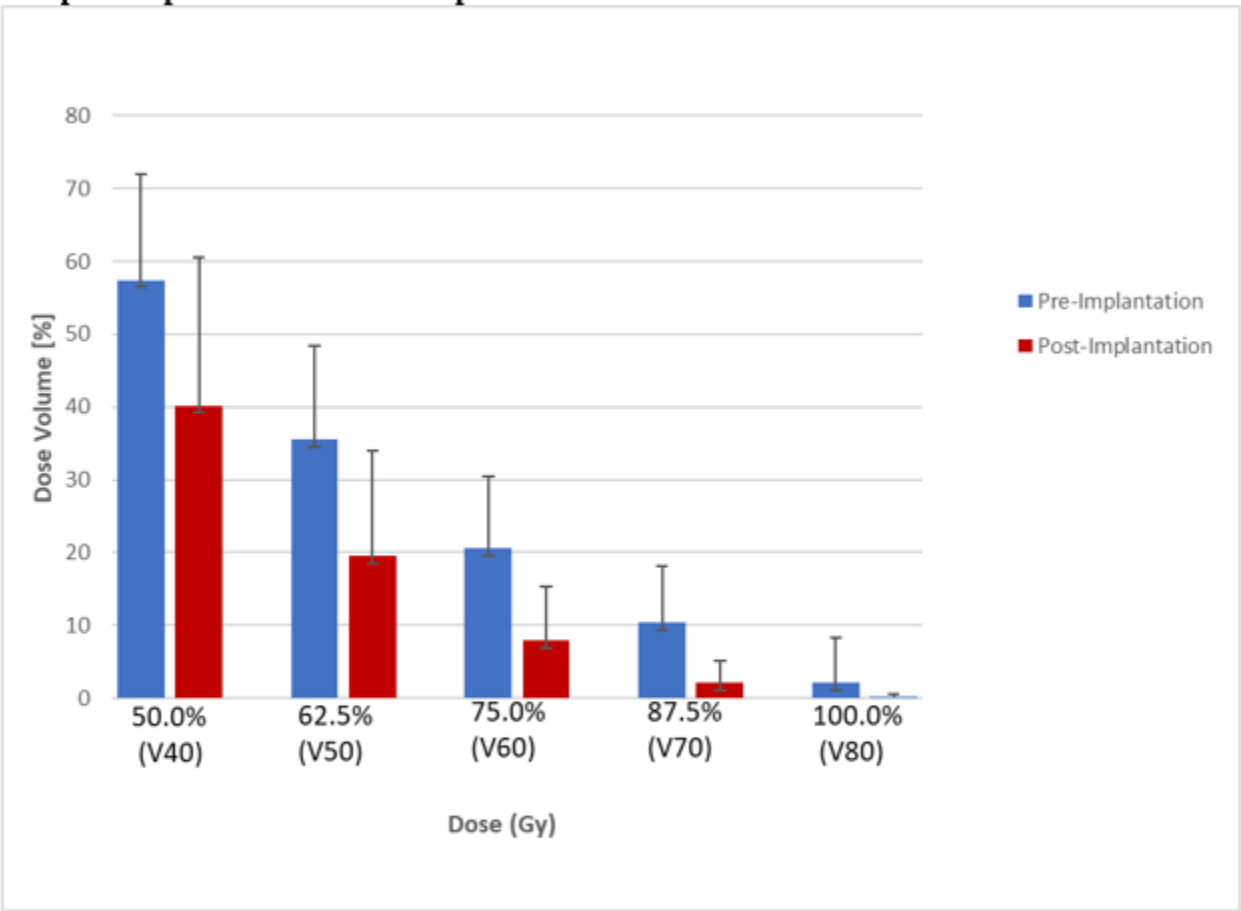
Introduction & Objectives: Radiotherapeutic dose increment in prostate cancer (PC) improves locoregional control but has the potential to increase toxicity to organs at risk. Perirectal spacers, which increase prostate-rectum separation, are an innovative option designed to protect the anterior rectal wall. This study aims to evaluate radiation dose to the rectum in PC patients undergoing EBRT with the BioProtect Balloon Implant System (BioProtect, Israel).

Materials & Methods: A Single-center retrospective analysis included 75 PC patients with a clinical stage of T1-T3a who were treated with BioProtect balloon followed by EBRT. Computerized tomography (CT) scans were taken pre-and post- balloon implantation. All patients were treated with conventional and moderate hypofractionation RT with a biologically equivalent prescription dose of 78-81 Gy in 1.8-2 Gy fractions. DVH for the rectum and bladder were compared from pre and post-implantation treatment planning. Wilcoxon signed rank test was. Mean prostate-rectum separation was also measured.

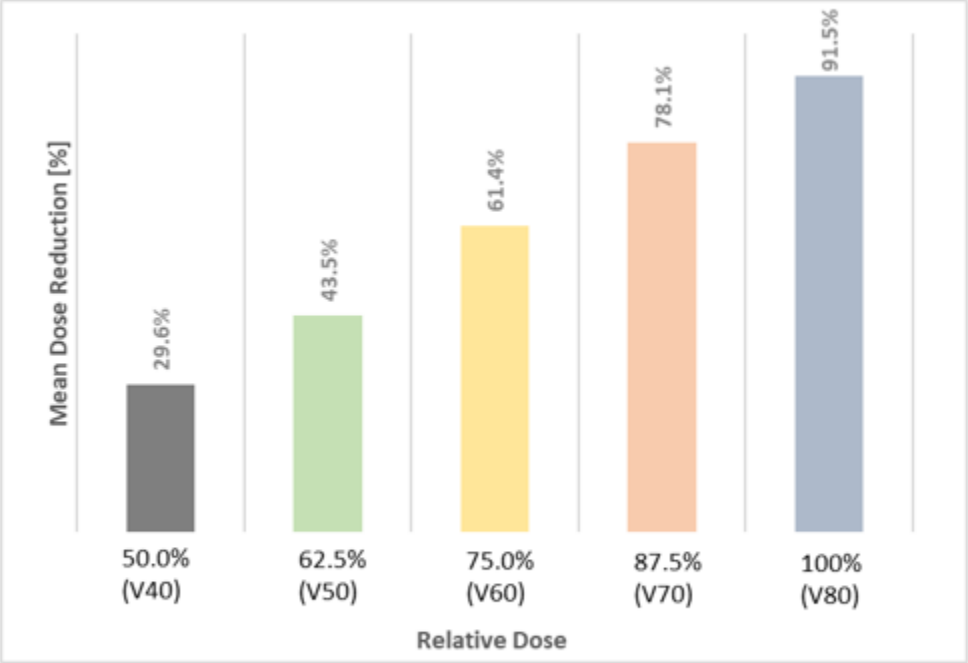
Results: Mean Prostate-rectum separation resulted in 18 mm post Balloon implantation. Mean dose reduction >25% was achieved in 68/75 patients (91%), with a significant relative mean reduction of 78.1% at rV70. Insertion of BioProtect balloon was uniformly successful, with 3 minor procedure-related adverse events (AEs) noted over a mean follow-up period of 29.4 months (range, 3-65 months).

Figure 1: Dose-volume graphic showing mean rectal doses± SD for 75 patients on pre- and post-implantation treatment plans



Difference in sparing of the rectum with radiation treatment of V40, V50, V60, V70 and V80, representing 50.0%, 62.5%, 75.0%, 87.5% and 100.0% of the prescribed dose.Values are represented as mean percentage ± standard deviation (represented in error bars).

Figure 2: Mean relative rectal doses reduction



Mean relative dose reductions in rectal V40, V50, V60, V70 and V80 (representing 50.0%, 62.5%, 75.0%, 87.5% and 100.0% of the prescribed dose) are depicted.

Conclusions: BioProtect balloon implantation was safe with the establishment of adequate prostate-rectum separation that resulted in reduced rectal irradiation volumes. Controlled studies will be needed in order to determine if this spacer is an effective tool that can enable RT dose escalation and limit GI and GU toxicity.