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Feasibility and Preliminary Rectal Toxicity Data of Transperineal Polyethylene Glycol Gel Spacer Implantation Prior to Hypofractionated VMAT in Prostate Cancer

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Abstract : **Purpose/Objective(s): To assess the feasibility and safety of Polyethylene Glycol (PEG) gel spacer implant procedure. To measure the ensuing dosimetric advantages on the rectum and assess their impact on rectal radiation-induced morbidity in prostate cancer patients treated with radical volumetric modulated arc therapy (VMAT).**
Materials/Methods: PEG gel can provide a consistent and durable displacement of the anterior rectal wall from the PTV. The kit consists of a dual syringe delivery system and Y-connector with in-line static mixer for combining the two-part polymer gel. The procedure is performed under local anesthesia in lithotomy position with ultrasound guidance. Following transperineal saline injection to achieve separation between the prostate and rectum, the gel is introduced into the peri-rectal space. Typically, 10 mm of separation can be obtained. The displacement is temporary with the gel completely absorbed within approximately 4 months. Since June 2011, 12 patients with biopsy-proven organ-confined prostate cancer (iPSA <20ng/ml, GS ≤ 8 pts,) underwent the procedure. Mean age was 71 years. CT-simulation was performed 5 days after the implant (empty rectum, full bladder). MRI (T2 without contrast agent) was also obtained for optimal gel visualization. Treatment-planning was carried out on fused image sets. Prescription dose was 70 Gy in 28 fractions of 2.5 Gy. A single 358° arc rotation was used in all cases. IGRT verification (KV-Cone-Beam-CT) was daily for the first three sessions and, subsequently, every 5 sessions. Weekly toxicity evaluations were performed.
Results: overall, the procedure was well tolerated. One patient developed a complication (G2) two weeks following the procedure, with the onset of acute rectal pain and bleeding due to a rectal ulcer confirmed by endoscopy. Resolution of the symptoms occurred in about one month and healing of the ulcer was confirmed endoscopically after two months. At CT-simulation complete disappearance of the gel was observed. Dosimetric analisys for the remainder 11 cases showed a mean separation of 1.22 cm (range 0.97-1.7 cm) between the anterior rectal wall and the prostate, resulting in significantly improved rectum DVH's, particularly at high dose. All 11 evaluable patients started radiotherapy within 2 weeks following implantation. Acute toxicity was as follows: one case of acute G1 proctitis; 2 cases of G1 and 3 cases of G2 cystitis.
Conclusions: PEG gel spacer implants are relatively easy to perform and entail a short learning curve. Patients' compliance and tolerance are very good. Due to reduced exposure of the rectum to the high dose region, lower acute and late rectal toxicities are to be expected.
Further assessment of the benefit of this approach using more extreme hypofractionation schedules is currently ongoing.