MP46-19: Multicenter phase II trial of perirectal hydrogel spacer application in men scheduled for dose escalation prostate radiotherapy

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Abstract: MP46-19

Introduction and Objectives

Perirectal spacers are proposed to reduce incidental rectal radiation in men undergoing prostate radiotherapy. This prospective study was designed to evaluate the safety and performance of hydrogel spacer injection in men undergoing intensity modulated radiotherapy (IMRT, 78Gy, 39 Frac) for treatment of prostate cancer.

Methods

Transperineal hydrogel spacer injection (SpaceOAR, Augmenix) was performed using a 18 G needle under transrectal ultrasound (TRUS) guidance. First saline was injected to expand the perirectal space followed by injection of hydrogel precursors that solidify within 10 seconds. The resulting spacer is designed to persist during radiation and absorb in about 6 months. Time for spacer placement, achieved perirectal space and device or procedural related events were monitored. CT was performed before and after spacer injection for treatment planning. Reduction in rectal radiation (V70) was calculated. Patients were monitored during IMRT and at 6, 9 and 15mo following gel injection for procedure related, GU and GI toxicity. Proctoscopy was done at 15 months and scored using the Vienna Rectoscopy Scoring (VRS) method.

Results

52 men with stage T1-T2 prostate cancer, mean prostate volume 57cc, mean PSA 6.9ng/mL, Gleason Score ≤ 6 (n=27) or Gleason Score 7a (n=25) were included in this study. Time for spacer placement (needle in-to-out time) was 7+5 min. On average 18+10ml saline was instilled prior to 10ml (median) hydrogel injections. A perirectal space > 7.5mm was obtained in 96% of patients (mean 10+6 mm). In initial patients the use of end-fire TRUS probes, no steppers and higher gel volumes (up to 30ml) were associated with inadvertent injection into the rectal wall, bladder and urinary retention (events resolved without further sequelae). Following implementation of side-fire TRUS probes, steppers and 10ml injection limits no patient experienced device or procedural related events. Spacer injection resulted in a transient sensation of fullness that dissipated within days. Grade 1, 2 and 3 GU toxicities were 42%, 35% and 2% (acute), and 17%, 2% and 0% (late), respectively. Created space reduced rectal V70 by > 25% in 96% of the patients, resulting in Grade 1 and 2 GI toxicities of 40% and 13% (acute), and 4% and 0% (late), respectively. Proctoscopy resulted in a VRS score of 0 in 71% of patients, with no evidence of ulceration, stricture or necrosis.

Conclusions

Using proper equipment perirectal hydrogel spacer injection is a safe and repeatable procedure, resulting in reduced rectal radiation and low toxicity rates.

Date & Time: May 19, 2014 8:00 AM-10:00 AM
Session Title: Prostate Cancer: Localized IV
Sources of Funding: Study was funded by Augmenix