Continued Benefit to Rectal Separation for Prostate RT: Final Results of a Phase III Trial


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Purpose/Objective(s): SpaceOAR, an FDA approved hydrogel (Hy) to create rectal-prostate space was evaluated in a single blind Phase III trial of image guided intensity modulated prostate RT (IG-IMRT, Mariados et al, IJROBP 2015). Men (n=222) were randomized 2:1 to hydrogel (markers + Hy) or control (Ct, markers only) receiving 79.2/1.8 Gy to prostate ± SV with the primary end-point reported at 15 months. We now report final results with last follow-up (FU) 4/7/16.

Materials/Methods: Late (>90 days) CTCAE v 4.0 toxicity was evaluated by chi-squared test. For quality of life (QOL) the Expanded Prostate Cancer Index Composite (EPIC) was collected at baseline and serially. Mean changes from baseline in EPIC domains were tested by repeated measures models with contrasts to compare treatments at each time. Proportions of men with minimally detectable changes (MDC) in each domain were tested using repeated measures logistic models with pre-specified thresholds.

Results: There was no difference in FU (median Ct 37.0 mo (range 26-46) vs Hy 37.1 (32-47) p>0.1) or response to EPIC at last FU (Ct 60% vs Hy 65%, p>0.1). The incidence of grade 1+ (Ct 9.2% vs Hy 2.0% p=0.028) or 2+ (Ct 5.7% vs Hy 0% p=0.012) rectal toxicity continued to favor Hy. Grade 1+ urinary incontinence also favored the Hy group (Ct 19.6% vs Hy 4.3% p=0.003); with no difference in grade 2+ urinary toxicity (p=0.7). At last FU the decline in EPIC bowel summary was greater in Ct (-5.3) vs Hy (+0.48, p<0.05). The 5.5 point difference in bowel QOL between arms met threshold for a clinically detectable change (4-6 pts). Moreover from 6 months onward bowel QOL consistently favored Hy (p=0.002); with largest differences in stool frequency and urgency. At last FU Ct men had a greater decline in urinary QOL (-3.3) vs Hy (+0.6, p<0.05), but a difference was not observed at other time points (p=0.13). No difference in sexual or vitality/hormonal QOL was noted between arms (p>0.5).

Conclusion: The benefit of SpaceOAR in reducing rectal dose, toxicity, and QOL changes following IG-IMRT for prostate cancer were maintained or increased with longer follow-up.
providing strong evidence for the benefit of hydrogel spacer in this setting. Analysis of bladder dosimetry is on-going and will be presented.