

**Original report title:****SEXUAL QUALITY OF LIFE FOLLOWING PROSTATE INTENSITY MODULATED RADIATION THERAPY (IMRT) WITH A RECTAL/PROSTATE SPACER: SECONDARY ANALYSIS OF A PHASE 3 TRIAL****Authors**

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**Background**

We previously reported the results of a phase 3 trial evaluating a prostate/rectal hydrogel spacer during prostate intensity modulated radiation therapy, which resulted in decreased rectal dose and toxicity and less decline in bowel quality of life (QOL). A secondary analysis was performed to correlate penile bulb dose and sexual QOL.

**Materials and methods**

Sexual QOL was measured with the Expanded Prostate Cancer Index Composite (EPIC) by mean scores, the proportion of patients with a minimal clinically important difference (MID), and analyses of the different items composing the sexual domain.

## Results

A total of 222 men enrolled with median follow-up of 37 months. Hydrogel reduced penile bulb mean dose, maximum dose, and percentage of penile bulb receiving 10 to 30 Gy (all  $P < .05$ ) with mean dose indirectly correlated with erections sufficient for intercourse at 15 months ( $P = .03$ ). Baseline EPIC was low (53 [standard deviation  $\pm 24$ ]) with no difference between arms ( $P > .1$ ). A total of 41% (88/222) of men had adequate baseline sexual QOL (EPIC  $>60$  (mean, 77 [ $\pm 8.3$ ])). This subgroup at 3 years had better sexual function ( $P = .03$ ) with a spacer with a smaller difference in sexual bother ( $P = .1$ ), which resulted in a higher EPIC summary on the spacer arm (58 [ $\pm 24.1$ ] vs control 45 [ $\pm 24.4$ ]) meeting threshold for MID without statistical significance ( $P = .07$ ). There were statistically nonsignificant differences favoring spacer for the proportion of men with MID and 2 $\times$  MID declines in sexual QOL with 53% vs 75% having an 11-point decline ( $P = .064$ ) and 41% vs 60% with a 22-point decline ( $P = .11$ ). At 3 years, more men potent at baseline and treated with spacer had "erections sufficient for intercourse" (control 37.5% vs spacer 66.7%,  $P = .046$ ) as well as statistically higher scores on 7 of 13 items in the sexual domain (all  $P < .05$ ).

## Conclusion

The use of a hydrogel spacer decreased dose to the penile bulb, which was associated with improved erectile function compared with the control group based on patient-reported sexual QOL.



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