PUBLISHED BY

INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY • BIOLOGY • PHYSICS

APRIL 1, 2017, VOLUME 97, ISSUE 5, PAGES 976–985

Clinical investigation title:

CONTINUED BENEFIT TO RECTAL SEPARATION FOR PROSTATE RADIATION THERAPY: FINAL RESULTS OF A PHASE III TRIAL

Authors

Daniel A. Hamstra, MD, PhD, Texas Oncology, Texas Center for Proton Therapy, Irving, Texas; **Neil Mariados, MD,** Associated Medical Professionals of NY, PLLC, Syracuse, New York; **John Sylvester, MD,** 21st Century Oncology, Inc, Lakewood Ranch, East Bradenton, Florida; **Dhiren Shah, MD,** Western New York Urology Associates, LLC, Doing Business as Cancer Care of WNY, Cheektowaga, New York; **Lawrence Karsh, MD,** The Urology Center of Colorado, Denver, Colorado; **Richard Hudes, MD,** Chesapeake Urology Associates, Doing Business as Chesapeake Urology Research Associates (The Prostate Center), Owings Mills, Maryland; **David Beyer, MD,** Arizona Oncology Services Foundation, Phoenix, Arizona; **Steven Kurtzman, MD,** Urological Surgeons of Northern California Inc, Campbell, California; **Jeffrey Bogart, MD,** The Research Foundation of State University of New York/State University of New York Upstate Medical University, Syracuse, New York; **R. Alex Hsi, MD,** Peninsula Cancer Center, Poulsbo, Washington; **Michael Kos, MD,** Urology Nevada, Reno, Nevada; **Rodney Ellis, MD,** University Hospitals Case Medical Center, Cleveland, Ohio; **Mark Logsdon, MD,** Sutter Health Sacramento Sierra Region, Doing Business as Sutter Institute for Medical Research, Sacramento, California; **Shawn Zimberg, MD,** Advanced Radiation Centers of New York, Lake Success, New York; **Kevin Forsythe, MD,** Oregon Urology Institute, Springfield, Oregon; **Hong Zhang, MD, PhD,** University of Rochester, Rochester, New York; **Edward Soffen, MD,** CentraState Medical Center, Freehold, New Jersey; **Patrick Francke, MD,** Carolina Regional Cancer Center, LLC, 21st Century Oncology, Inc, Myrtle Beach, South Carolina; **Constantine Mantz, MD,** 21st Century Oncology, Inc, Fort Meyers, Florida; **Peter Rossi, MD,** Emory University, Atlanta, Georgia; **Theodore DeWeese, MD,** The Johns Hopkins University, Baltimore, Maryland; **Stephanie Daignault-Newton, MS,** Department of Biostatistics, University of Michigan, Ann Arbor, Michigan; **Benjamin W. Fischer-Valuck, MD,** Washington University School of Medicine, St Louis, Missouri; **Anupama Chundury, MD,** Washington University School of Medicine, St Louis, Missouri; **Hiram Gay, MD,** Washington University School of Medicine, St Louis, Missouri; **Walter Bosch, DSc,** Washington University School of Medicine, St Louis, Missouri; and **Jeff Michalski, MD, MBA,** Washington University School of Medicine, St Louis, Missouri

Summary

A phase III trial was performed using an absorbable hydrogel (SpaceOAR™ System) to provide space between the prostate and rectum for men undergoing dose-escalated prostate radiation therapy. At 3 years, the men in the spacer arm had decreased bowel toxicity and fewer declines in both urinary and bowel quality of life compared with the control group.

Purpose

SpaceOAR™ Hydrogel, intended to create a rectal-prostate space, was evaluated in a single-blind phase III trial of image guided intensity modulated radiation therapy. A total of 222 men were randomized 2:1 to the spacer or control group and received 79.2 Gy in 1.8-Gy fractions to the prostate with or without the seminal vesicles. The present study reports the final results with a median follow-up period of 3 years.

Materials and methods

Cumulative (Common Terminology Criteria for Adverse Events, version 4.0) toxicity was evaluated using the log-rank test. Quality of life (QOL) was examined using the Expanded Prostate Cancer Index Composite (EPIC), and the mean changes from baseline in the EPIC domains were tested using repeated measures models. The proportions of men with minimally important differences (MIDs) in each domain were tested using repeated measures logistic models with pre-specified thresholds.

Results

The 3-year incidence of grade ≥ 1 (9.2% vs 2.0%; P=.028) and grade ≥ 2 (5.7% vs 0%; P=.012) rectal toxicity favored the spacer arm (Figures 2A and 2B). Grade ≥ 1 urinary incontinence was also lower in the spacer arm (15% vs 4%; P=.046), with no difference in grade ≥ 2 urinary toxicity (7% vs 7%; P=0.7) (Figures 2C and 2D).

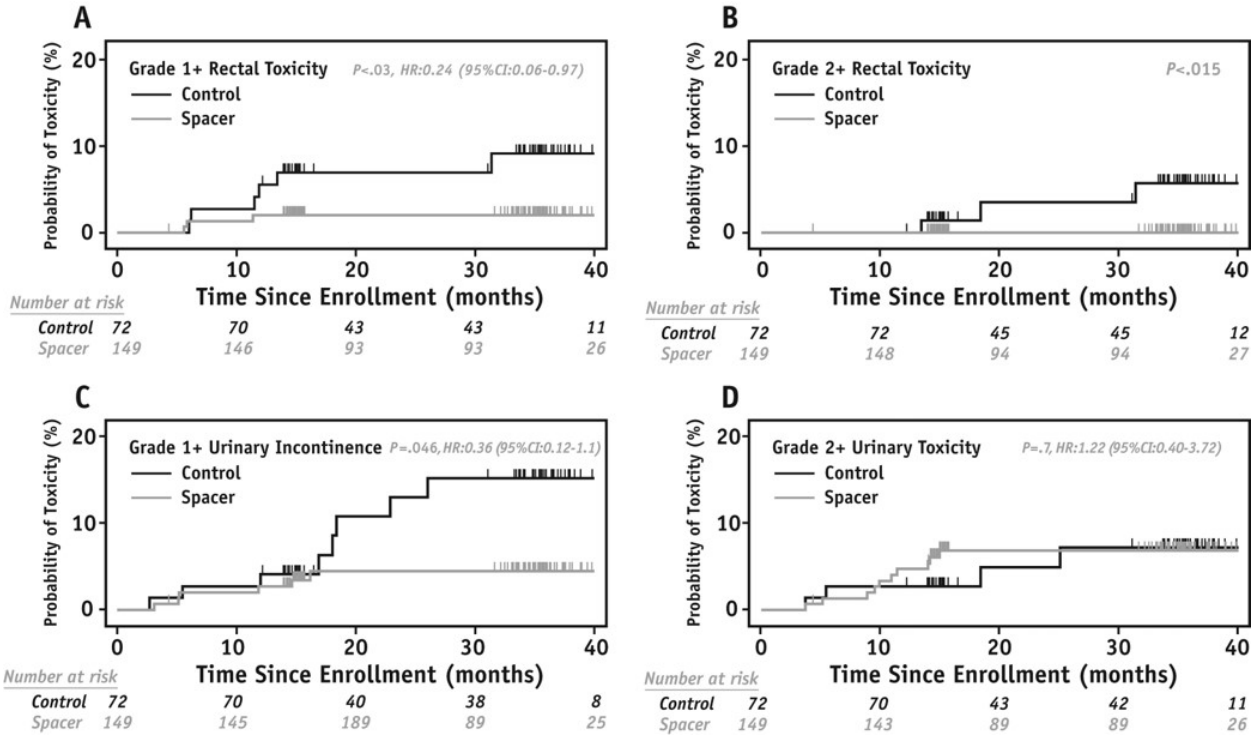

Figure 2. The cumulative incidence of grade ≥1 (A) and ≥2 (B) bowel toxicity and grade ≥1 urinary incontinence (C) and grade ≥2 urinary toxicity (D). Abbreviations: CI = confidence interval; HR = hazard ratio.

From 6 months onward, bowel QOL consistently favored the spacer group (P=.002), with the difference at 3 years (5.8 points; P<.05) meeting the threshold for a MID. The control group had a 3.9-point greater decline in urinary QOL compared with the spacer group at 3 years (P<.05), but the difference did not meet the MID threshold. At 3 years, more men in the control group than in the spacer group had experienced a MID decline in bowel QOL (41% vs 14%; P=.002) and urinary QOL (30% vs 17%; P=.04). Furthermore, the control group were also more likely to have experienced large declines (twice the MID) in bowel QOL (21% vs 5%; P=.02) and urinary QOL (23% vs 8%; P=.02) (Figures 3 and 4).

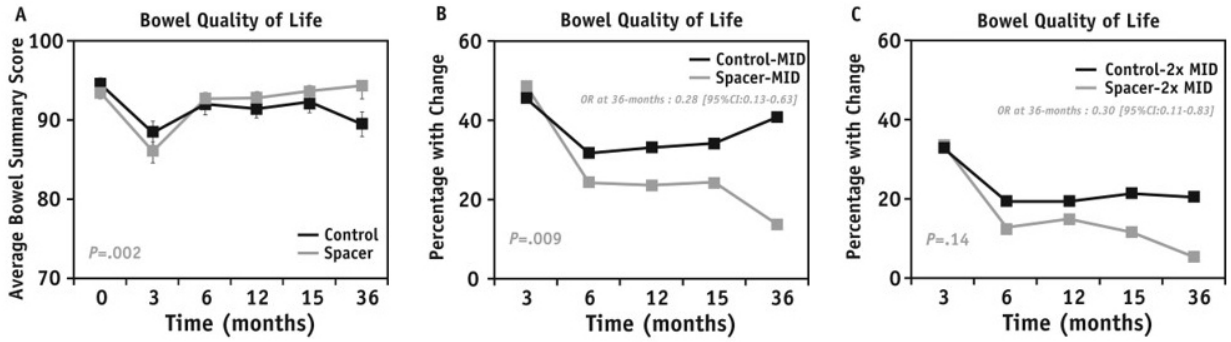

Figure 3. Mean changes in bowel quality of life summary score (A) as a function of treatment arm. Data presented as mean ± standard error of the mean. The proportion of patients with detectable changes in bowel quality of life at the 5-point (B) or 10-point (C) threshold. Abbreviations: CI = confidence interval; MID = minimally important difference; OR= odds ratio.

Results cont.

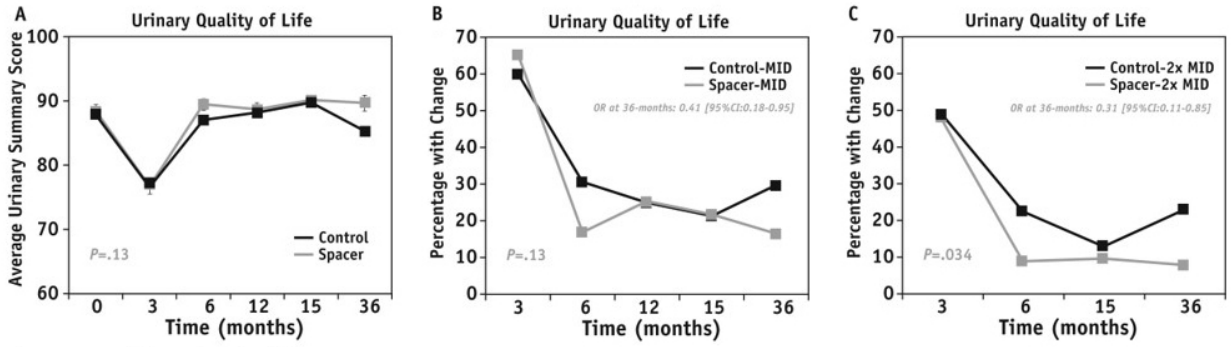

Figure 4. Mean changes in urinary quality of life summary score (A) as a function of treatment arm. Data presented as mean ± standard error of the mean. The proportion of patients with detectable changes in bowel quality of life at the 6-point (B) or 12-point (C) threshold. Abbreviations: CI = confidence interval; MID = minimally important difference; OR = odds ratio.

Conclusion

The benefit of a hydrogel spacer in reducing the rectal dose, toxicity, and QOL declines after image guided intensity modulated radiation therapy for prostate cancer was maintained or increased with a longer follow-up period, providing stronger evidence for the benefit of hydrogel spacer use in prostate radiation therapy.

Link to full article
https://www.redjournal.org/article/S0360-3016(16)33598-2/fulltext

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.BostonScientific.com

URO-728605-AA NOV 2019