

# RADIATION PROCTITIS-WHICH TECHNOLOGY IS SAFEST?



Richard G. Stock, MD.  
Professor of Radiation Oncology  
Mount Sinai School of Medicine  
New York, NY

◆ I have no financial disclosures

# Rectal Dose/Volume Effects on Rectal Bleeding

DEFINING THE RISK OF DEVELOPING GRADE 2 PROCTITIS FOLLOWING  
<sup>125</sup>I PROSTATE BRACHYTHERAPY USING A RECTAL DOSE-VOLUME  
 HISTOGRAM ANALYSIS

KURT M. SNYDER, M.D.,\* RICHARD G. STOCK, M.D.,\* SUZANNE M. HONG, M.A.,\*  
 YEH CHI LO, PH.D.,\* AND NELSON N. STONE, M.D.†

Table 1. Relationship between volume of rectal wall receiving a given dose and 5-year risk of developing Grade 2 radiation proctitis

Dose (Gy)	Rectal volume cutpoint (cc)	5-Year actuarial Grade 2 proctitis rate (%)		<i>p</i> value
		≤Volume cutpoint	>Volume cutpoint	
80	4.0	5	21.0	0.0007
100	3.0	4	20.0	0.0006
120	2.5	5	21.0	0.0002
140	2.0	5	23.6	0.0001
160	1.3	5	18.0	0.0010
180	1.2	5	22.0	0.0002
200	0.8	6	20.0	0.0009
220	0.5	5	18.0	0.0040
240	0.4	5	20.0	0.0009

# Proctitis after prostate brachytherapy ● K. M. SNYDER *et al.*

I. J. Radiation Oncology ● Biology ● Physics

Volume 50, Number 2, 2001

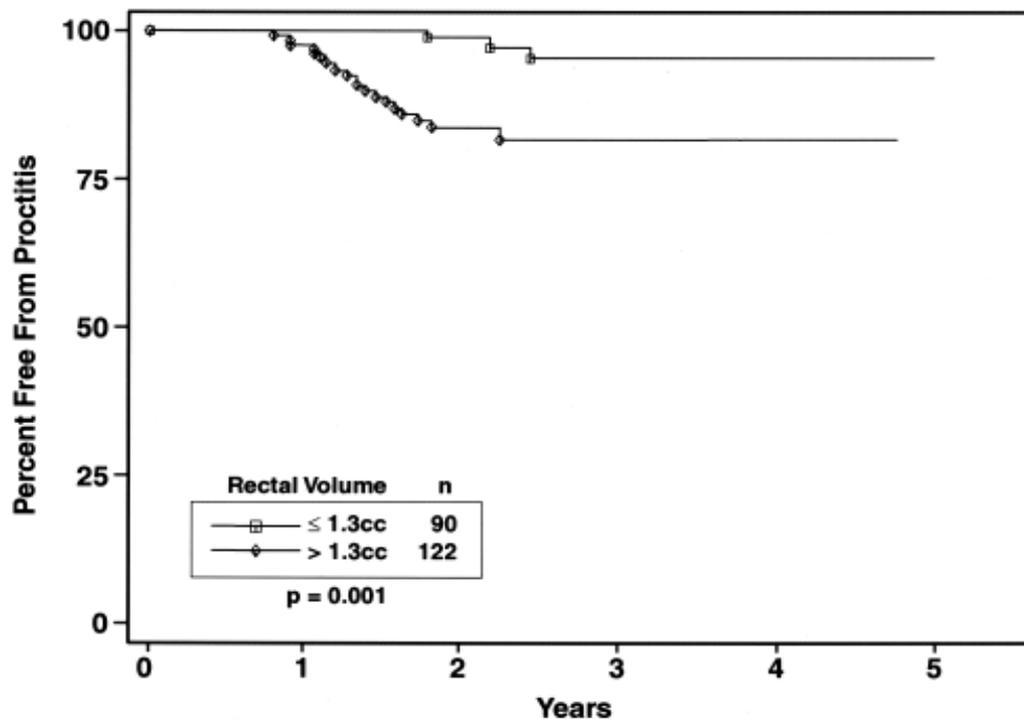


Fig. 2. Effect of rectal volume receiving 160 Gy on Grade 2 proctitis.

CC OF RECTAL VOLUME

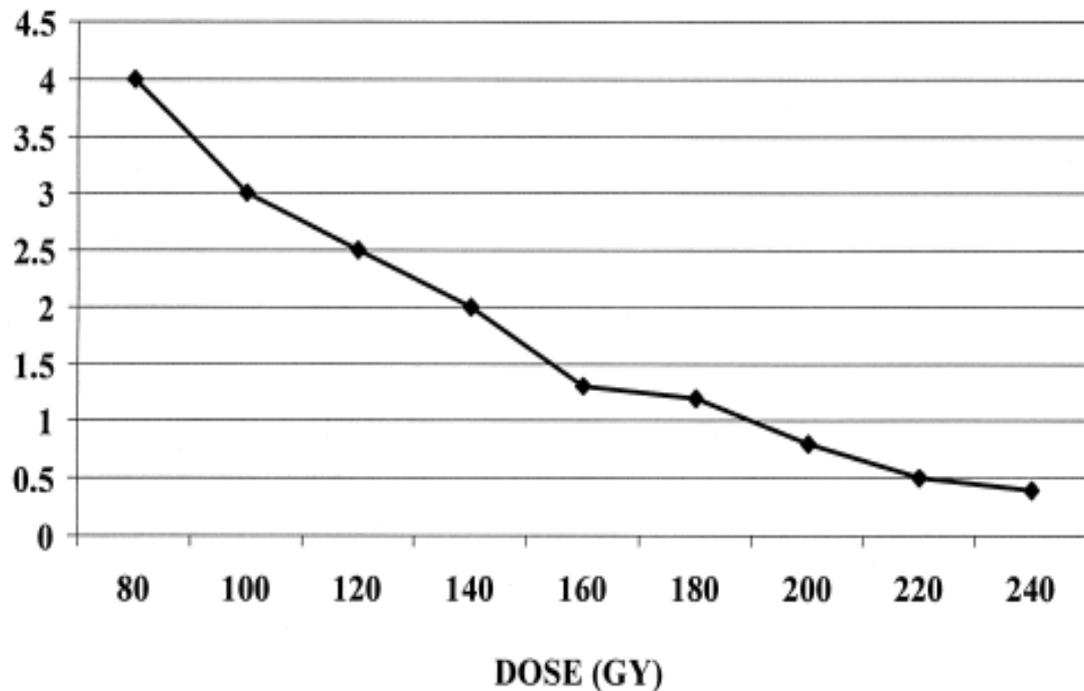
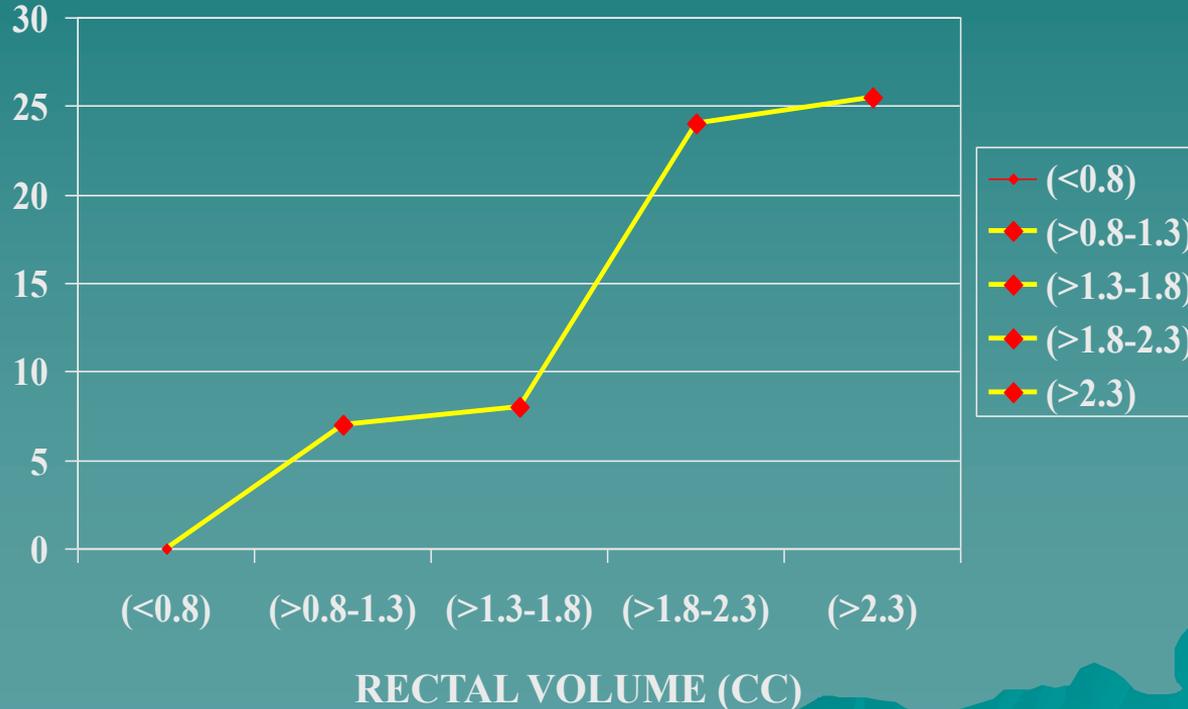


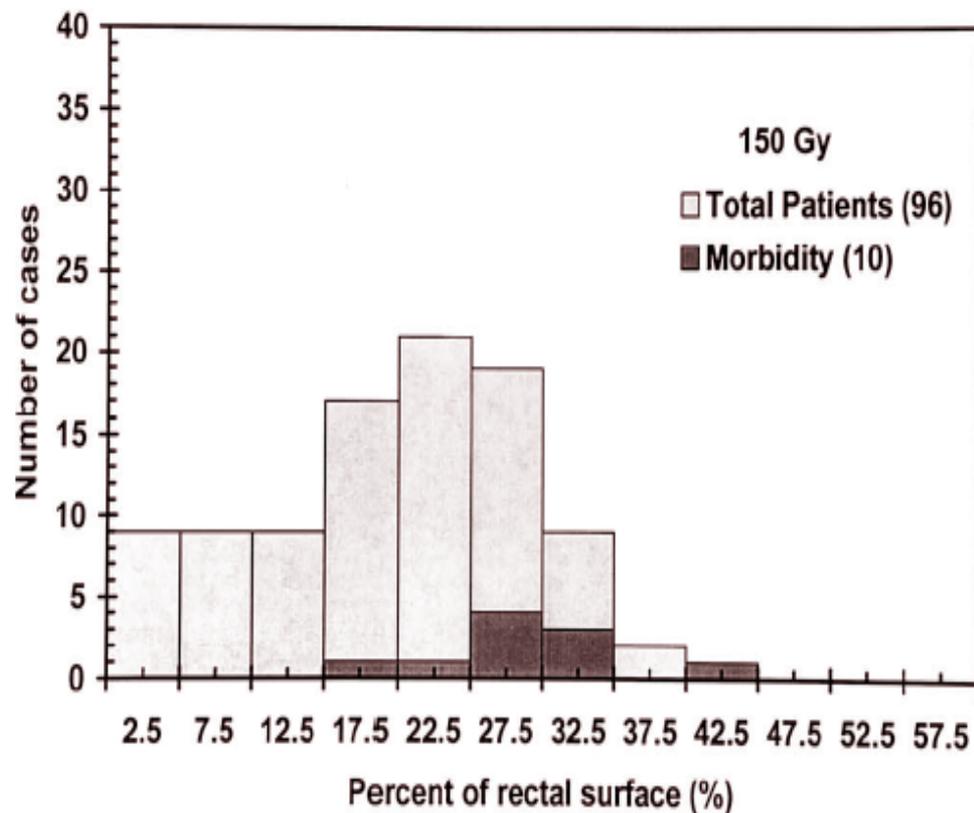
Fig. 4. Rectal volume thresholds associated with  $\leq 5\%$  risk of Grade 2 proctitis at 5 years.

# EFFECT OF RECTAL VOLUME RECEIVING 160 GY

## PERCENT WITH GRADE 2 PROCTITIS



Probability of late rectal morbidity ● F. M. WATERMAN *et al.*



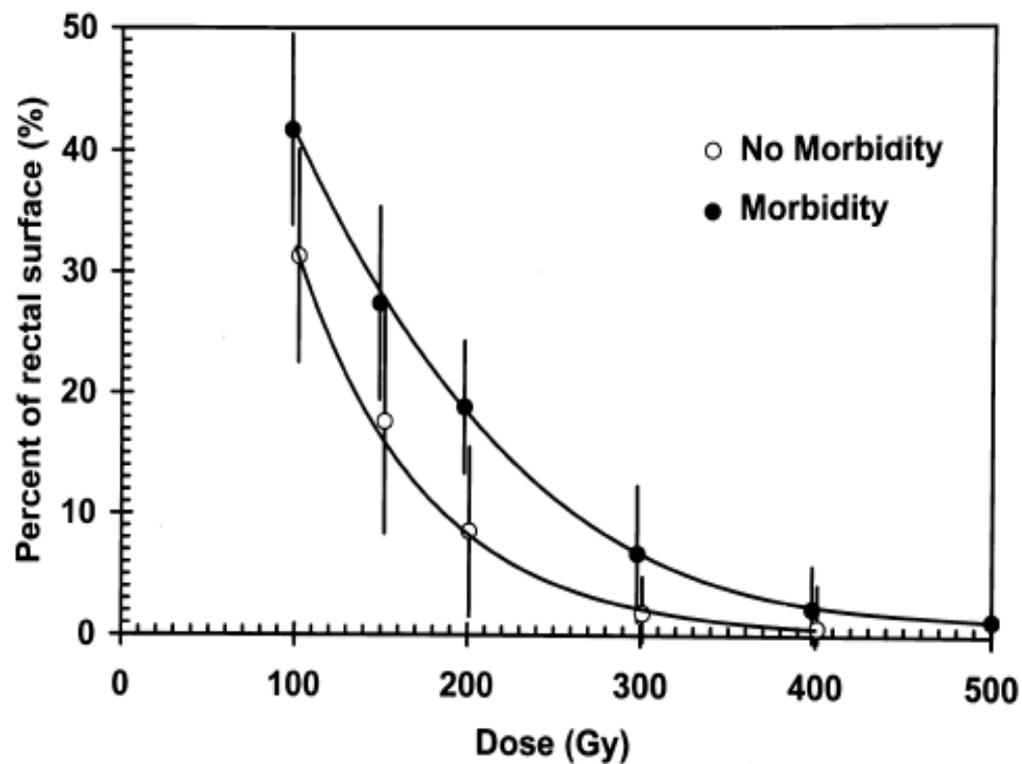


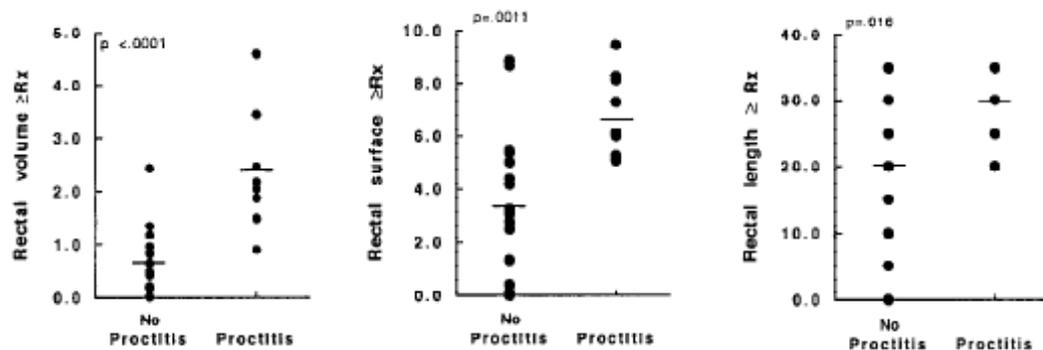
Fig. 2. Mean DSHs of patients who did and did not experience late rectal morbidity. Only the portion of the DSH >100 Gy is shown.

## Dosimetric and Radiographic Correlates to Prostate Brachytherapy-related Rectal Complications

Ben H. Han, M.D.,<sup>1,2</sup> and Kent E. Wallner, M.D.<sup>1,2\*</sup>

<sup>1</sup>*Department of Radiation Oncology, University of Washington, Seattle, Washington*

<sup>2</sup>*Radiation Oncology, Puget Sound Health Care System, Department of Veterans Affairs, Seattle, Washington*



*Han and Wallner: Prostate Brachytherapy-related Rectal Complications*

**Table 1. Rectal Dosimetric Parameters Exceeding the Prescription Dose in Patients with or without Postimplant Bleeding**

	Controls (n = 18)	Proctitis (n = 9)	Significance (two-tailed <i>t</i> -test)
Rectal volume $\geq$ Rx dose <sup>a</sup>	0.6 cc ( $\pm$ 1.3)	2.5 cc ( $\pm$ 0.8)	<i>P</i> = 0.000008
Rectal surface $\geq$ Rx dose	3.1 cm <sup>2</sup> ( $\pm$ 1.4)	6.9 cm <sup>2</sup> ( $\pm$ 1.0)	<i>P</i> = 0.001
Rectal length $\geq$ Rx dose	19 mm ( $\pm$ 3.2)	31 mm ( $\pm$ 3.6)	<i>P</i> = 0.02
Maximum rectal dose	224 Gy ( $\pm$ 101)	798 Gy ( $\pm$ 151)	<i>P</i> = 0.000001

<sup>a</sup>Rx dose = prescription dose.

Original article  
Defining the rectal dose constraint for permanent radioactive seed  
implantation of the prostate

Michele Albert, M.D.<sup>a,\*</sup>, Jun S. Song, Ph.D.<sup>a</sup>, Delray Schultz, Ph.D.<sup>c</sup>,  
Robert A. Cormack, Ph.D.<sup>a</sup>, Clare M. Tempany, M.D.<sup>b</sup>, Steve Haker<sup>b</sup>,  
Phillip M. Devlin, M.D.<sup>a</sup>, Clair Beard, M.D.<sup>a</sup>, Mark D. Hurwitz, M.D.<sup>a</sup>,  
Wonsuk W. Suh, M.D.<sup>a</sup>, Ferenc Jolesz, M.D.<sup>b</sup>, Anthony V. D'Amico, M.D., Ph.D.<sup>a</sup>

<sup>a</sup> Department of Radiation Oncology, Brigham and Women's Hospital and Dana Farber Cancer Institute, Boston, MA 02115, USA

<sup>b</sup> Department of Radiology, Brigham and Women's Hospital and Dana Farber Cancer Institute, Boston, MA 02115, USA

<sup>c</sup> Department of Mathematics, Millersville University, Millersville, PA 17551, USA

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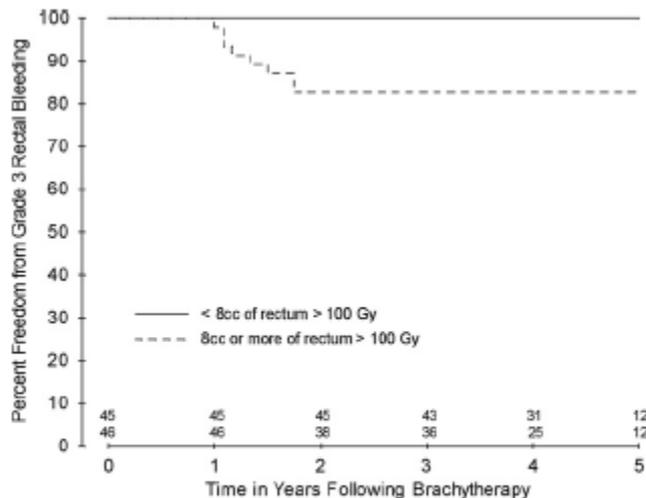


Fig. 1. Estimates of freedom from rectal bleeding requiring argon plasma coagulation stratified by the median volume of rectal contoured exceeding 100 Gy. Log-rank  $P = 0.004$ .

6 week post implant  
dosimetry

# Intraoperative real-time planned conformal prostate brachytherapy: Post-implantation dosimetric outcome and clinical implications

Michael J. Zelefsky<sup>a,\*</sup>, Yoshiya Yamada<sup>a</sup>, Gil'ad N. Cohen<sup>b</sup>, Neha Sharma<sup>a</sup>,  
Alison M. Shippy<sup>a</sup>, David Fridman<sup>a</sup>, Marco Zaider<sup>b</sup>

<sup>a</sup>Department of Radiation Oncology and <sup>b</sup>Department of Medical Physics, Memorial Sloan-Kettering Cancer Center, NY, USA

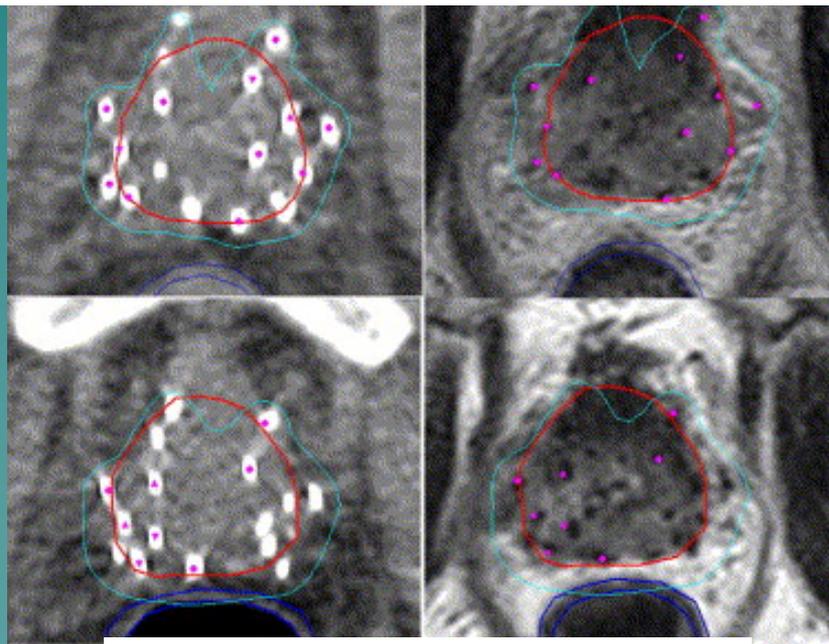
% grade 2 proctitis



## RECTAL-WALL DOSE DEPENDENCE ON POSTPLAN TIMING AFTER PERMANENT-SEED PROSTATE BRACHYTHERAPY

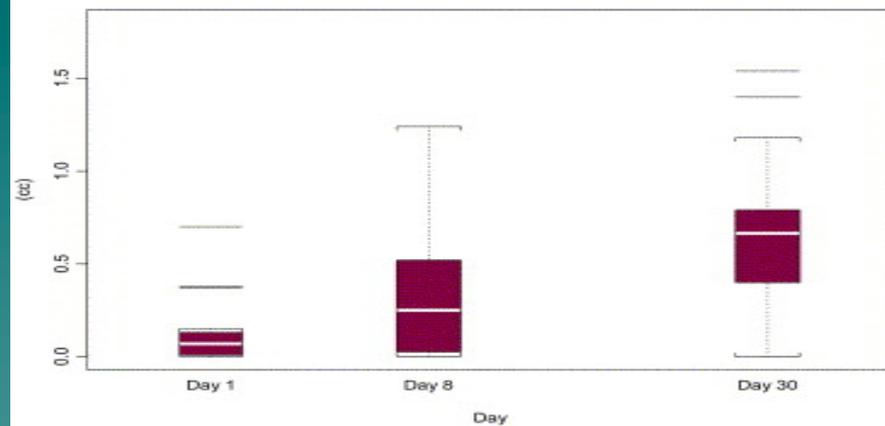
DANIEL TAUSSKY, M.D.,\* IVAN YEUNG, PH.D.,† THERESA WILLIAMS, R.T.T.,‡  
SHANNON PEARSON, R.T.T.,‡ MICHAEL MCLEAN, M.D.,\* GREGORY POND, M.Sc.,§  
AND JUANITA CROOK, M.D.\*

Departments of \*Radiation Oncology, †Radiation Physics, ‡Radiation Medicine, and §Biostatistics, Princess Margaret Hospital,  
Toronto, Canada



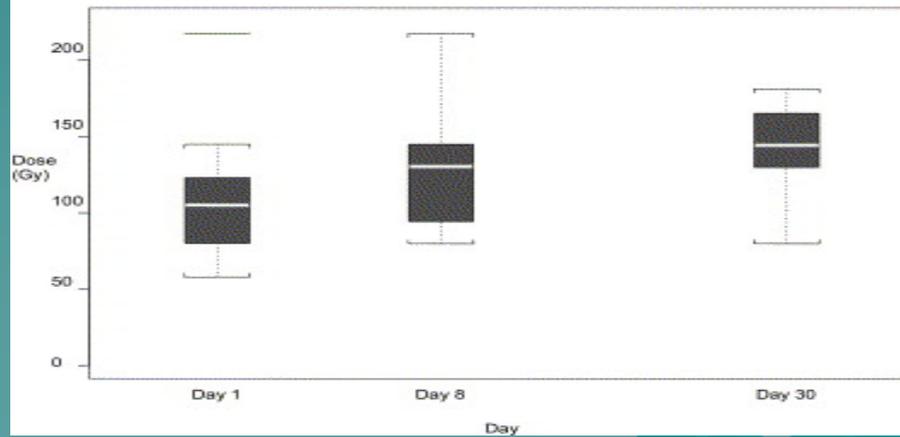
**(a)**

RV100



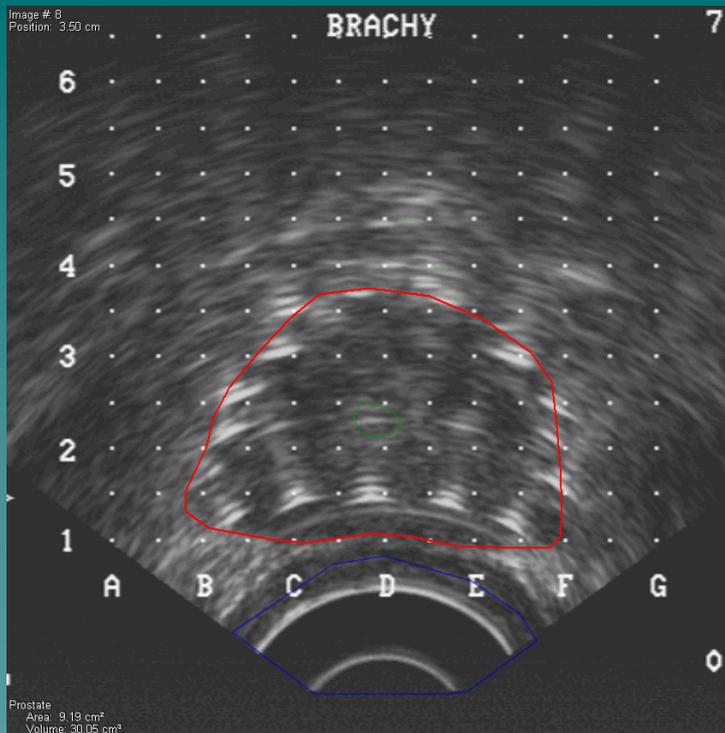
**(b)**

RD (1cc)



# ARE THERE FACTORS THAT WE CAN NOT CONTROL?

- the exact seed distribution within the prostate
- genetics of radiation response



US #8 (real time)

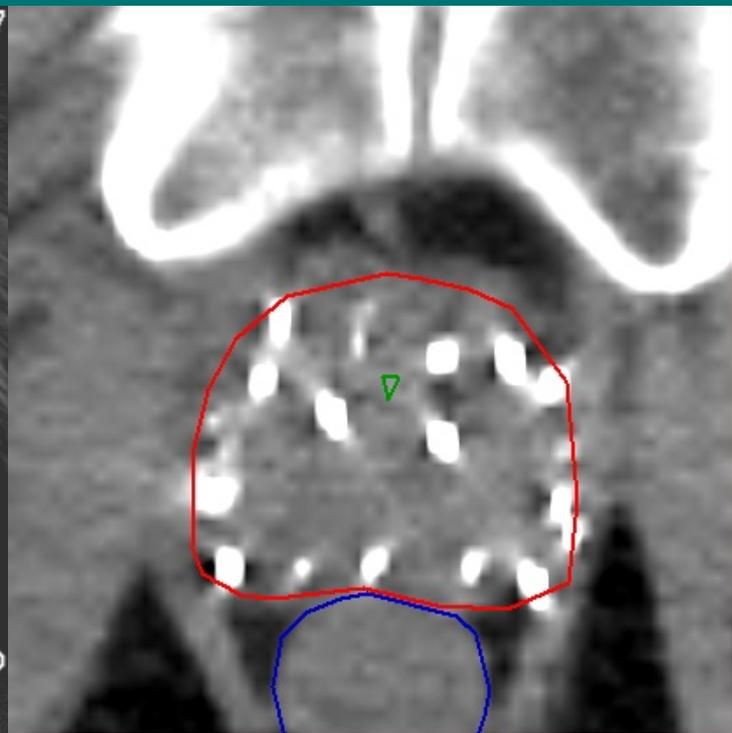
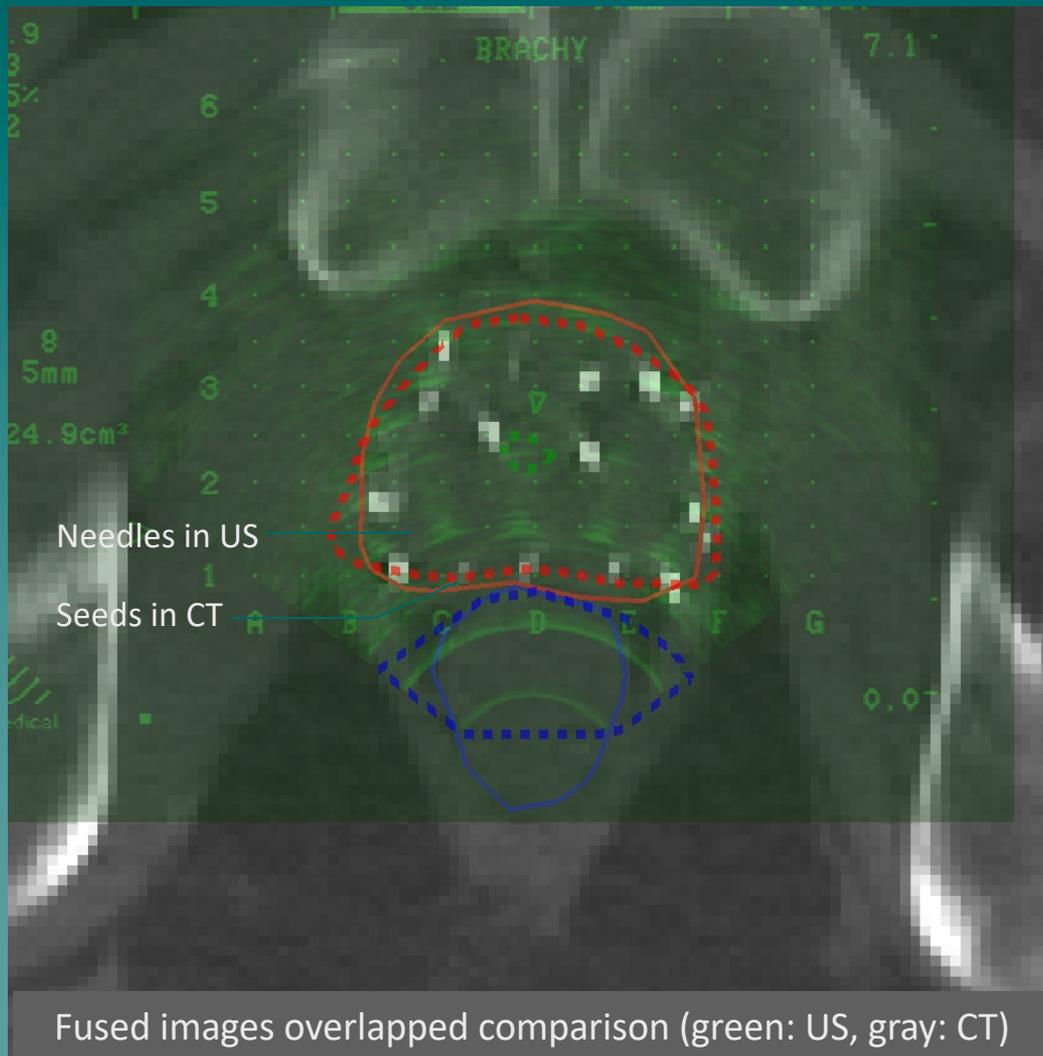
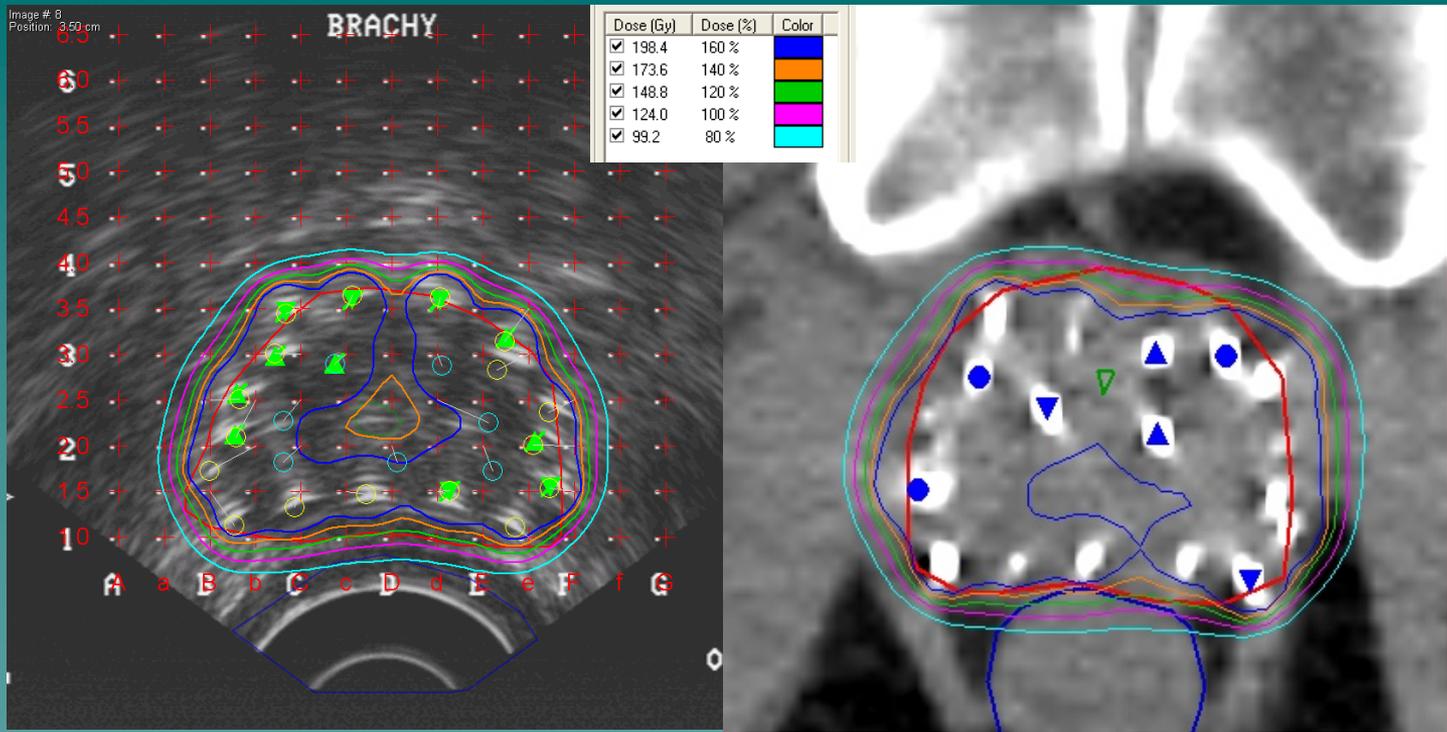


Image #26 (PID)





US #8 (real time)

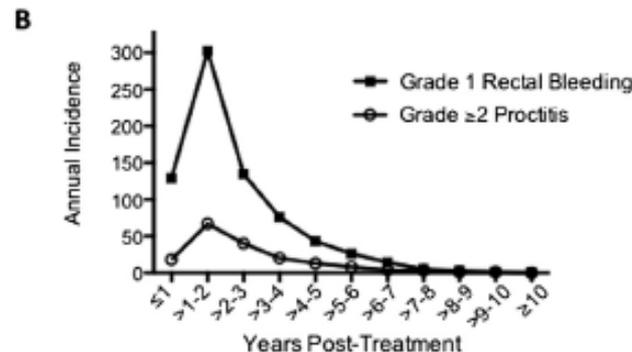
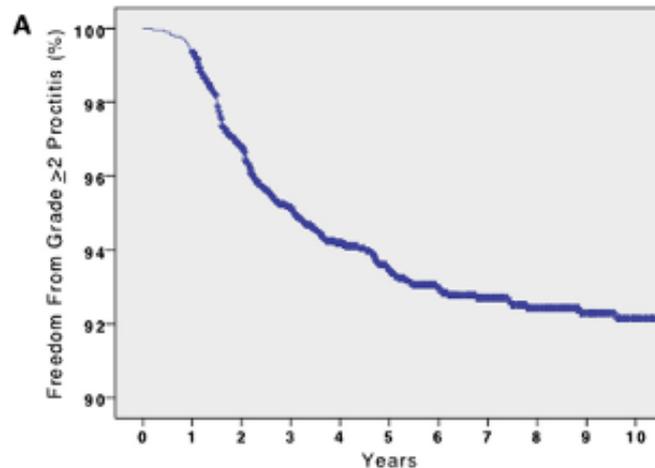
Image #26 (PID)

Clinical Investigation: Genitourinary Cancer

## Predictive Factors and Management of Rectal Bleeding Side Effects Following Prostate Cancer Brachytherapy

Jeremy G. Price, BA,\* Nelson N. Stone, MD,<sup>†</sup> and Richard G. Stock, MD\*

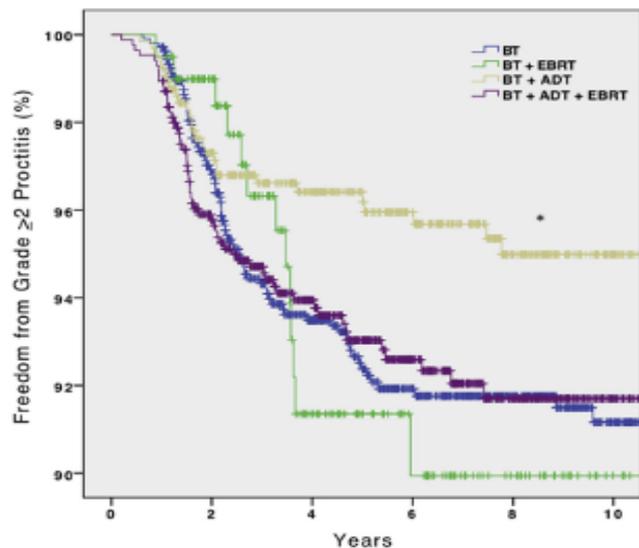
Departments of \*Radiation Oncology and <sup>†</sup>Urology, Icahn School of Medicine at Mount Sinai, New York, New York



2752 patients

**Fig. 1.** (A) Ten-year freedom from grade  $\geq 2$  proctitis (%). (B) Annualized incidence of rectal bleeding toxicities following brachytherapy.

# Predictive Factors and Management of Rectal Bleeding Side Effects Following Prostate Cancer Brachytherapy



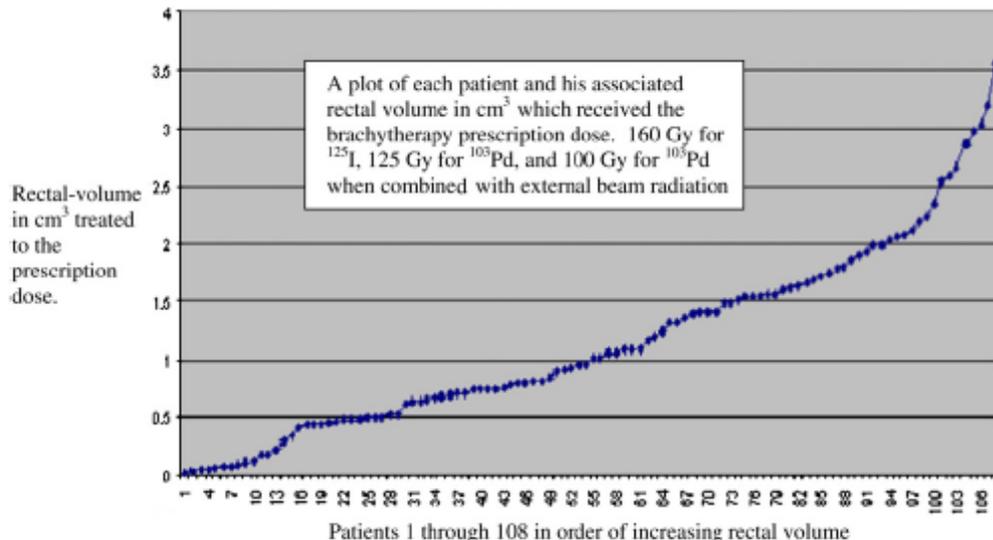
**Fig. 2.** Effect of treatment modality on the 10-year freedom from grade  $\geq 2$  proctitis (%). \* $P < 0.05$ . ADT = androgen depletion therapy; BT = brachytherapy; EBRT = external beam radiation therapy.

**Table 3** Incidence and rates of rectal morbidities and treatments

Morbidity: n (%)	
Grade 1 bleeding	566 (20.57)
Grade $\geq 2$ proctitis	175 (6.36)
Fistula	3 (0.11)
Ulceration	6 (0.22)
Mean duration (follow-up visits)	1.14
Treatment: n (%)	
Formalin	9 (0.33)
Cauterization	18 (0.65)

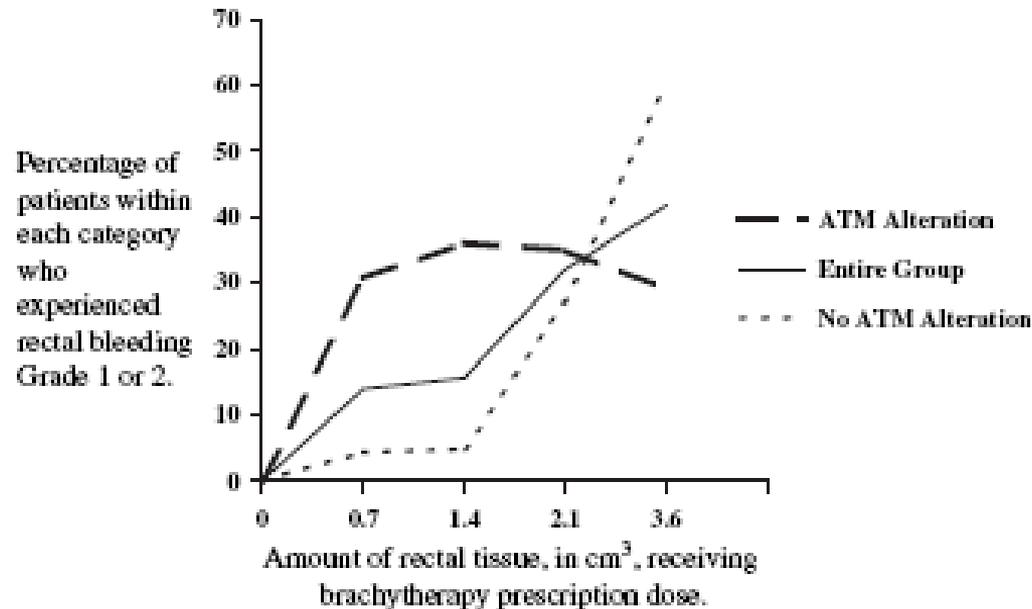
## A GENETICALLY DETERMINED DOSE-VOLUME HISTOGRAM PREDICTS FOR RECTAL BLEEDING AMONG PATIENTS TREATED WITH PROSTATE BRACHYTHERAPY

JAMIE A. CESARETTI, M.D., M.S.,\* RICHARD G. STOCK, M.D.,\* DAVID P. ATENCIO, PH.D.,\*  
SHEILA A. PETERS, B.A.,\* CHRISTOPHER A. PETERS, M.D.,\* RYAN J. BURRI, M.D.,\*  
NELSON N. STONE, M.D.,\* AND BARRY S. ROSENSTEIN, PH.D.\*†‡§



dicine;

Fig. 1. Rectal dose as represented in volume of rectal tissue treated to the prescription dose using brachytherapy. All 108 patients have a completed characterized *ATM* gene in addition to a detailed clinical history, with a median follow-up of 45 months (range, 12–107 months).



Number of	36	32	28	12
ATM Alteration	4 / 13	4 / 11	6 / 17	2 / 7
No ATM	1 / 23	1 / 21	3 / 11	3 / 5
Fisher's Exact	$p=0.05$	$p=0.04$	$p=1$	$p=0.56$

Fig. 2. Incidence of Grade 1 or 2 rectal bleeding (%) in the entire group of 108 patients given brachytherapy for prostate cancer and according to their *ATM* gene status.



GWAS in prostate cancer RT

## Genome-wide association study identifies a region on chromosome 11q14.3 associated with late rectal bleeding following radiation therapy for prostate cancer<sup>☆</sup>

Sarah L. Kerns<sup>a,b</sup>, Richard G. Stock<sup>a</sup>, Nelson N. Stone<sup>a,c</sup>, Seth R. Blanksburg<sup>a</sup>, Lynda Rath<sup>a</sup>, Ana Vega<sup>d</sup>, Laura Fachal<sup>d</sup>, Antonio Gómez-Caamaño<sup>e</sup>, Dirk De Ruyscher<sup>f,g</sup>, Guido Lammering<sup>g</sup>, Matthew Parliament<sup>h</sup>, Michael Blackshaw<sup>h</sup>, Michael Sia<sup>i</sup>, Jamie Cesaretti<sup>j</sup>, Mitchell Terk<sup>j</sup>, Rosetta Hixson<sup>j</sup>, Barry S. Rosenstein<sup>a,k,l,m,n,1</sup>, Harry Ostrer<sup>b,n,1</sup>

### ABSTRACT

**Background and purpose:** Rectal bleeding can occur following radiotherapy for prostate cancer and negatively impacts quality of life for cancer survivors. Treatment and clinical factors do not fully predict rectal bleeding, and genetic factors may be important.

**Materials and methods:** A genome-wide association study (GWAS) was performed to identify SNPs associated with the development of late rectal bleeding following radiotherapy for prostate cancer. Logistic regression was used to test the association between 614,453 SNPs and rectal bleeding in a discovery cohort (79 cases, 289 controls), and top-ranking SNPs were tested in a replication cohort (108 cases, 673 controls) from four independent sites.

**Results:** rs7120482 and rs17630638, which tag a single locus on chromosome 11q14.3, reached genome-wide significance for association with rectal bleeding (combined  $p$ -values  $5.4 \times 10^{-8}$  and  $6.9 \times 10^{-7}$  respectively). Several other SNPs had  $p$ -values trending toward genome-wide significance, and a polygenic risk score including these SNPs shows a strong rank-correlation with rectal bleeding (Sommer's  $d = 5.0 \times 10^{-12}$  in the replication cohort).

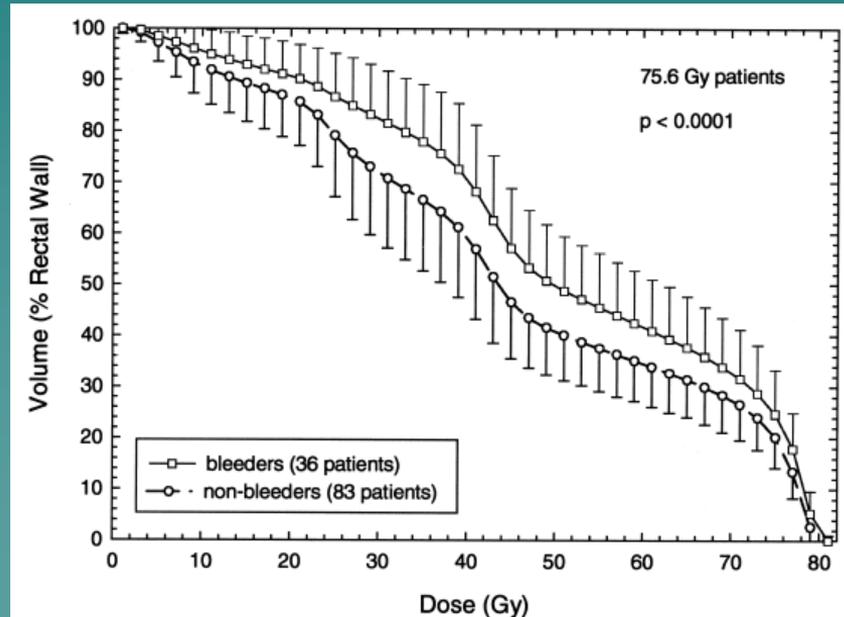
**Conclusions:** This GWAS identified novel genetic markers of rectal bleeding following prostate radiotherapy. These findings could lead to the development of a predictive assay to identify patients at risk for this adverse treatment outcome so that dose or treatment modality could be modified.

## LATE RECTAL BLEEDING AFTER CONFORMAL RADIOTHERAPY OF PROSTATE CANCER (II): VOLUME EFFECTS AND DOSE-VOLUME HISTOGRAMS

ANDREW JACKSON, PH.D.,\* MARK W. SKWARCHUK, PH.D.,\*<sup>1</sup> MICHAEL J. ZELEFSKY, M.D.,<sup>†</sup>  
DIDIER M. COWEN, M.D.,<sup>†‡</sup> ENNAPADAM S. VENKATRAMAN, PH.D.,<sup>§</sup> SABINE LEVEGRUN, PH.D.,\*<sup>||</sup>  
CHANDRA M. BURMAN, PH.D.,\* GERALD J. KUTCHER, PH.D.,\* ZVI FUKS, M.D.,<sup>†</sup>  
STEVEN A. LIEBEL, M.D.,<sup>†</sup> AND C. CLIFTON LING, PH.D.\*

Departments of \*Medical Physics, <sup>†</sup>Radiation Oncology, and <sup>§</sup>Biostatistics, Memorial Sloan-Kettering Cancer Center, New York, NY;  
<sup>‡</sup>Department of Radiation Oncology, Institut Paoli-Calmettes Cancer Center, Marseille, France; <sup>||</sup>Department of Medical Physics,  
Deutsches Krebsforschungszentrum, Heidelberg, Germany

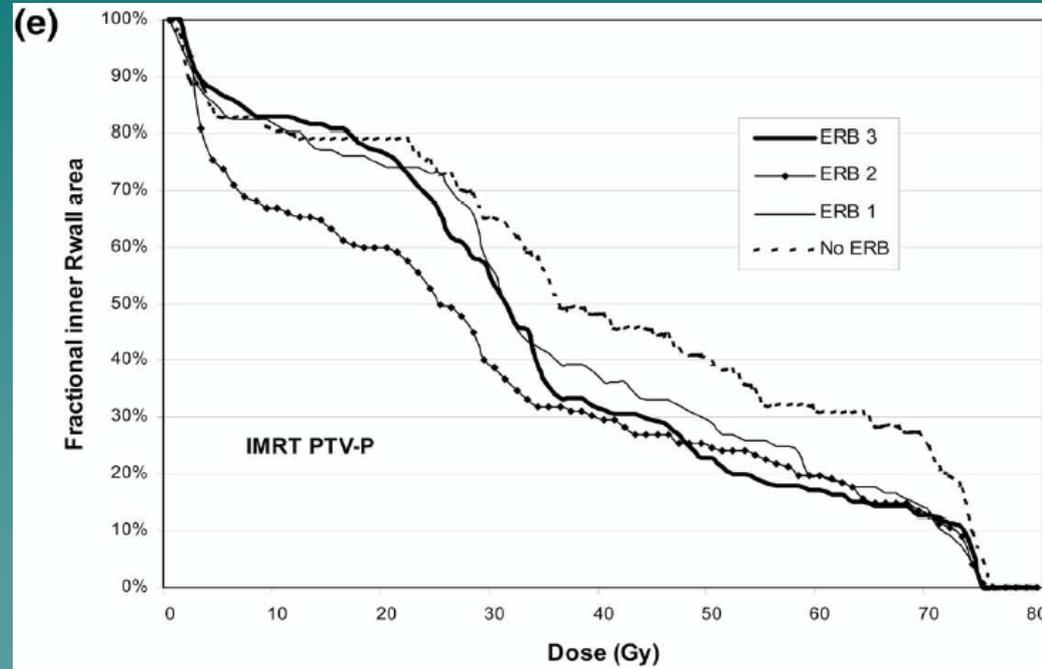
Int. J. Radiation Oncology Biol. Phys., Vol. 49, No. 3, pp. 685-698, 2001  
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0360-3016/01/\$-see front matter



## RECTAL WALL SPARING EFFECT OF THREE DIFFERENT ENDORECTAL BALLOONS IN 3D CONFORMAL AND IMRT PROSTATE RADIOETHERAPY

EMILE N. J. TH. VAN LIN, M.D., ASWIN L. HOFFMANN, M.Sc., PETER VAN KOLLENBURG, B.Sc.,  
JAN WILLEM LEER, M.D., Ph.D. AND ANDRIES G. VISSER, Ph.D.

Department of Radiation Oncology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands



# IMRT Plan

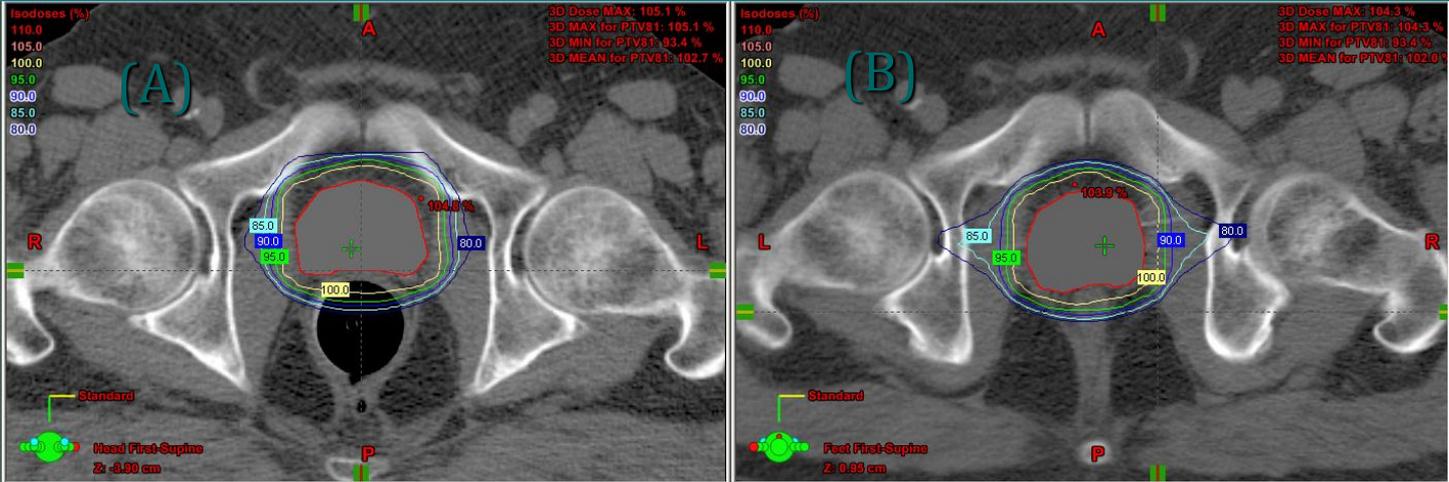
Int. J. Radiation Oncology Biol. Phys., Vol. 63, No. 2, pp. 565-576, 2005

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# Results

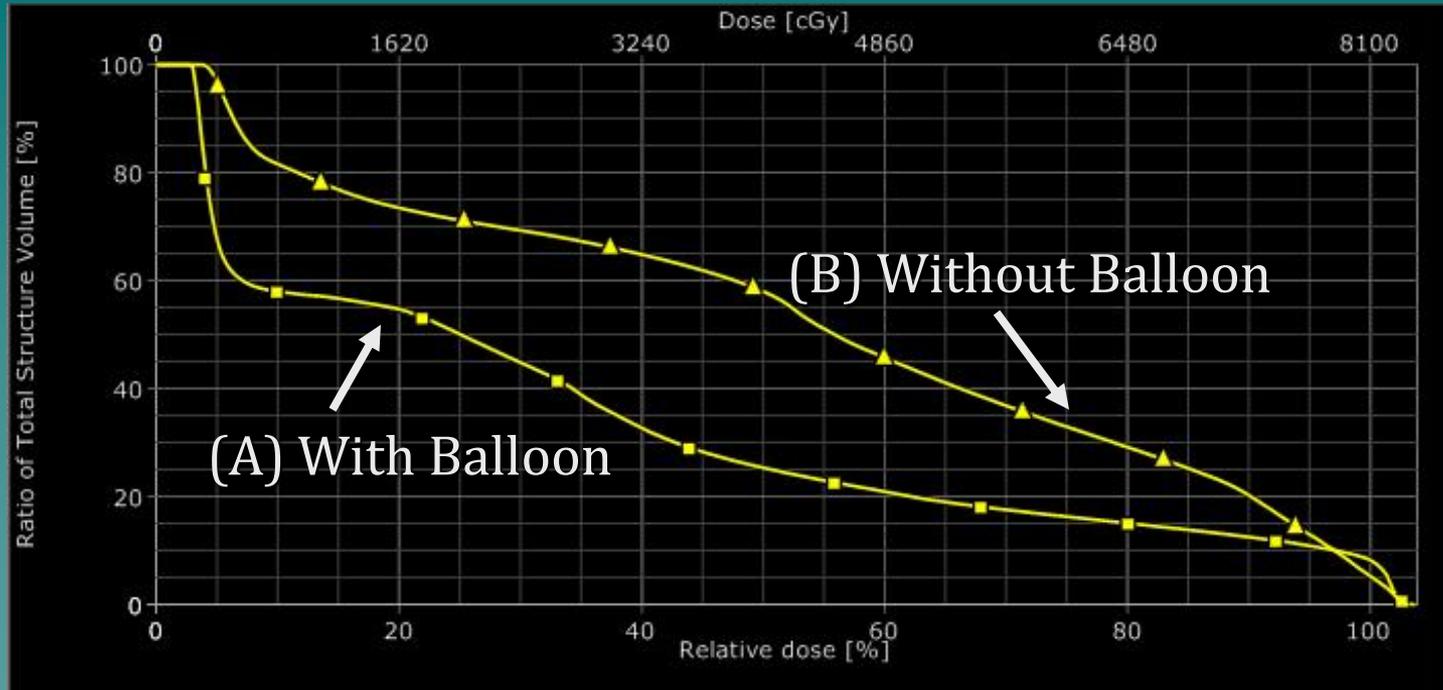


(A) With Balloon

(B) Without Balloon

Sample screen shot showing isodose lines around prostate with (A) and without (B) rectal balloon in place

# Results



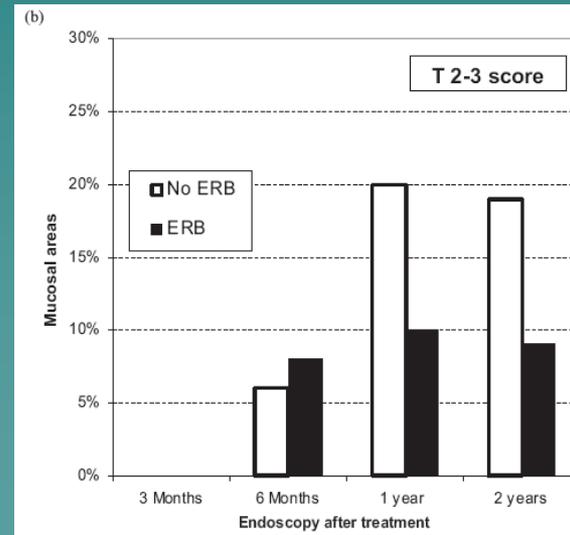
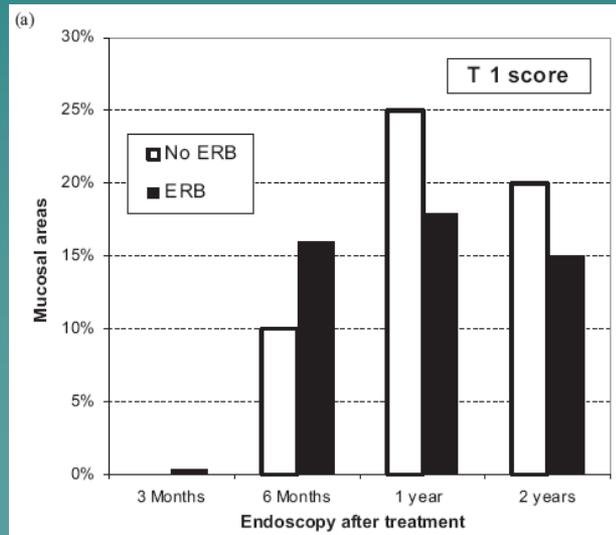
Sample screen shot showing rectal wall DVH (cumulative) with (A) and without (B) rectal balloon in place.

## REDUCED LATE RECTAL MUCOSAL CHANGES AFTER PROSTATE THREE-DIMENSIONAL CONFORMAL RADIOTHERAPY WITH ENDORECTAL BALLOON AS OBSERVED IN REPEATED ENDOSCOPY

EMILE N. J. TH. VAN LIN, M.D.,\* JÓN KRISTINSSON, M.D.,<sup>†</sup> MARIËLLE E. P. PHILIPPENS, M.D.,\*  
DIRK J. DE JONG, M.D., PH.D.,<sup>†</sup> LISETTE P. VAN DER VIGHT, B.Sc.,\*  
JOHANNES H. A. M. KAANDERS, M.D., PH.D.,\* JAN WILLEM LEER, M.D., PH.D.,\*  
AND ANDRIES G. VISSER, PH.D.\*

\*Department of Radiation Oncology, Radboud University Nijmegen Medical Centre, and <sup>†</sup>Department of Gastroenterology and Hepatology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

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0360-3016/07/\$—see front matter

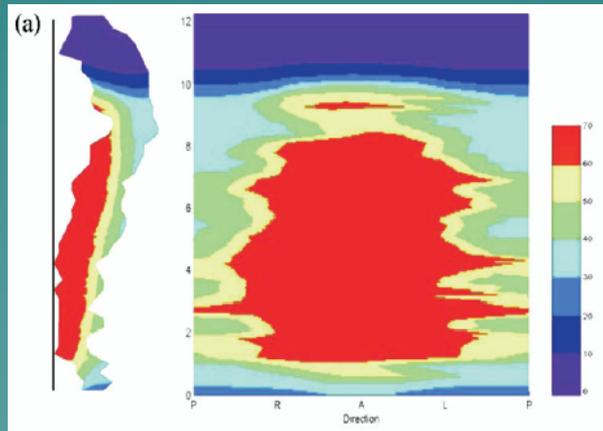


REDUCED LATE RECTAL MUCOSAL CHANGES AFTER PROSTATE  
THREE-DIMENSIONAL CONFORMAL RADIOTHERAPY WITH  
ENDORECTAL BALLOON AS OBSERVED IN REPEATED ENDOSCOPY

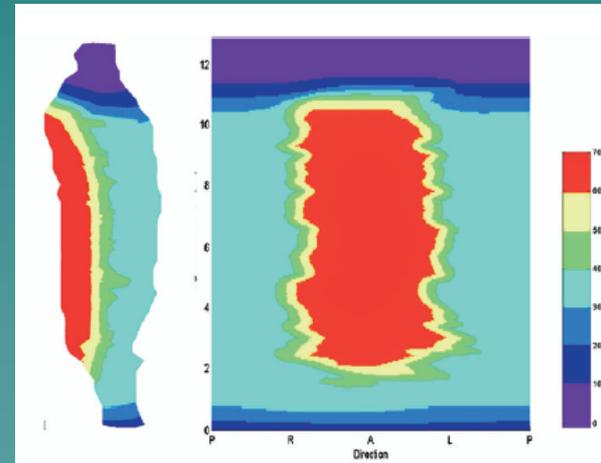
EMILE N. J. TH. VAN LIN, M.D.,\* JÓN KRISTINSSON, M.D.,† MARIELLE E. P. PHILIPPENS, M.D.,\*  
DIRK J. DE JONG, M.D., PH.D.,† LISETTE P. VAN DER VIGHT, B.SC.,\*  
JOHANNES H. A. M. KAANDERS, M.D., PH.D.,\* JAN WILLEM LEER, M.D., PH.D.,\*  
AND ANDRIES G. VISSER, PH.D.\*

\*Department of Radiation Oncology, Radboud University Nijmegen Medical Centre, and †Department of Gastroenterology and Hepatology, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

WITHOUT RECTAL BALLOON



WITH RECTAL BALLOON



Int. J. Radiation Oncology Biol. Phys., Vol. 67, No. 3, pp. 799–811, 2007

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0360-3016/07/\$—see front matter

## PATIENT TOLERANCE OF RECTAL BALLOONS IN CONFORMAL RADIATION TREATMENT OF PROSTATE CANCER

BRIAN B. RONSON, M.D., LES T. YONEMOTO, M.D., CARL J. ROSSI, M.D.,  
JAMES M. SLATER, M.D., F.A.C.R., AND JERRY D. SLATER, M.D.

Department of Radiation Medicine, Loma Linda University Medical Center, Loma Linda, CA

### 3561 men with prostate cancer over 25 years

Table 1. Patient tolerance of rectal balloons

Patient group/s	Patients tolerating balloon throughout treatment	Patients not tolerating balloon throughout treatment	Comment
All patients	3474/3561 (97.6%)	87/3561 (2.4%)	Balloon utilized for 85.5% (mean percent) of treatment days in 87 patients not tolerating balloon throughout treatment $p < 0.001^*$
Prostate vs. prostate/pelvic irradiation	1721/1730 (99.5%) vs. 1753/1831 (95.7%)	9/1730 (0.5%) vs. 78/1831 (4.3%)	
2D vs. 3D planning of pelvic X-ray fields	1372/1433 (95.74%) vs. 381/398 (95.72%)	61/1433 (4.26%) vs. 17/398 (4.28%)	$p = 0.990^*$

\* Chi-square analysis.

Int. J. Radiation Oncology Biol. Phys., Vol. 64, No. 5, pp. 1367–1370, 2006

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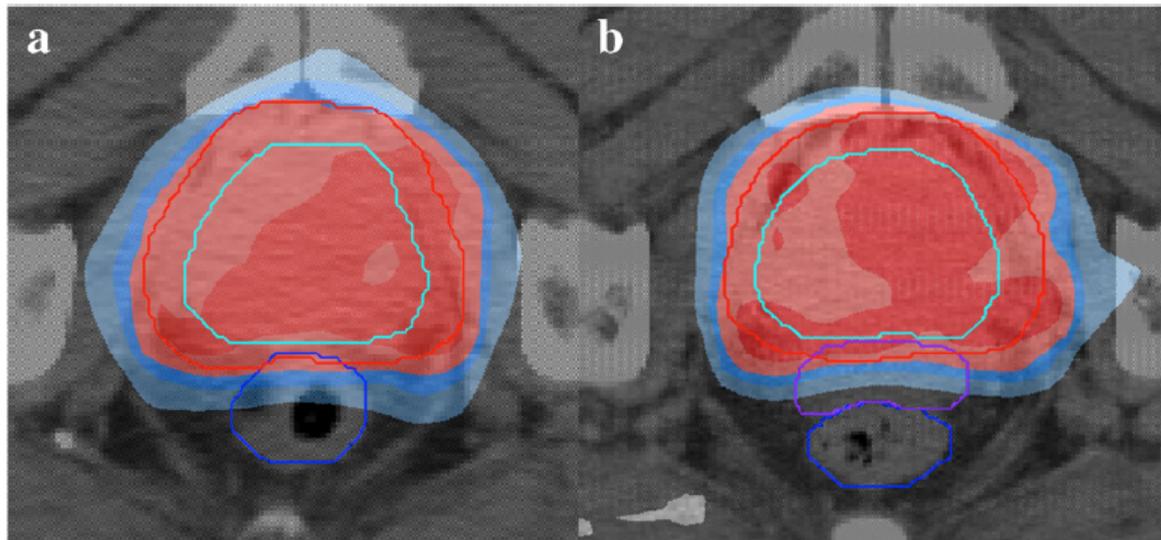
0360-3016/06/\$—see front matter

RESEARCH

Open Access

## Absorbable hydrogel spacer use in men undergoing prostate cancer radiotherapy: 12 month toxicity and proctoscopy results of a prospective multicenter phase II trial

Matthias Uhl<sup>1\*</sup>, Klaus Herfarth<sup>1</sup>, Michael J Eble<sup>2</sup>, Michael Pinkawa<sup>2</sup>, Baukelien van Triest<sup>3</sup>, Robin Kalisvaart<sup>3</sup>, Damien C Weber<sup>4</sup>, Raymond Miralbell<sup>4</sup>, Danny Y Song<sup>5</sup> and Theodore L DeWeese<sup>5</sup>



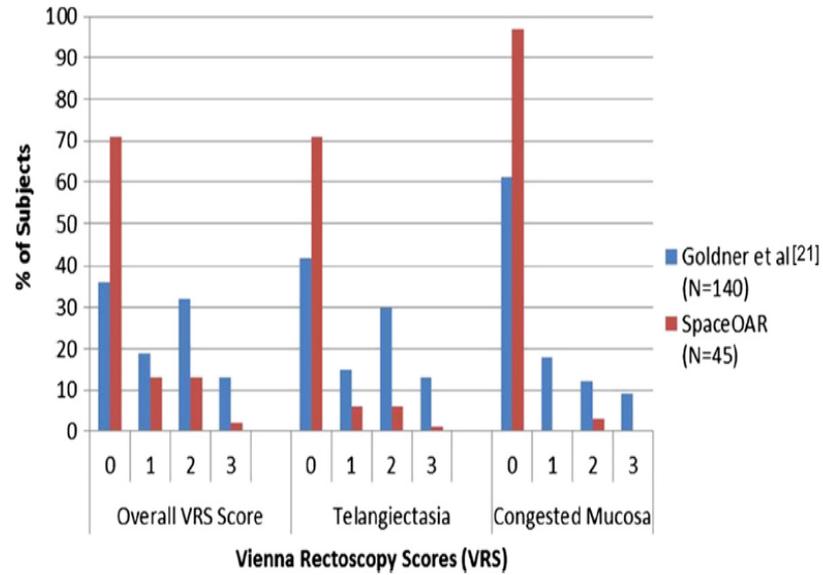


Figure 3 Comparison of Vienna rectoscopy scores at 12 months for men treated with SpaceOAR vs. the literature [21].



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Rectal spacers

## Comparison of two different rectal spacers in prostate cancer external beam radiotherapy in terms of rectal sparing and volume consistency



Frank Wolf<sup>a,1,\*</sup>, Christoph Gaisberger<sup>a,1</sup>, Ingrid Ziegler<sup>a</sup>, Elisabeth Krenn<sup>f</sup>, Philipp Scherer<sup>a</sup>,  
Stephan Hruby<sup>b</sup>, Tobias Schätz<sup>b</sup>, Rosemarie Forstner<sup>c</sup>, Josef Holzinger<sup>e</sup>, Andrea Vaszi<sup>a</sup>,  
Gerhard Kameträger<sup>a</sup>, Philipp Steininger<sup>d</sup>, Heinz Deutschmann<sup>a,d</sup>, Felix Sedlmayer<sup>a,d</sup>

<sup>a</sup> Dpt. of Radiation Oncology; <sup>b</sup> Dpt. of Urology; <sup>c</sup> Dpt. of Radiology; <sup>d</sup> Institute for Research and Development on Advanced Radiation Technologies (radART); <sup>e</sup> Dept. of Surgery; and <sup>f</sup> Salzburg University of Applied Sciences, Paracelsus Medical University of Salzburg, Austria

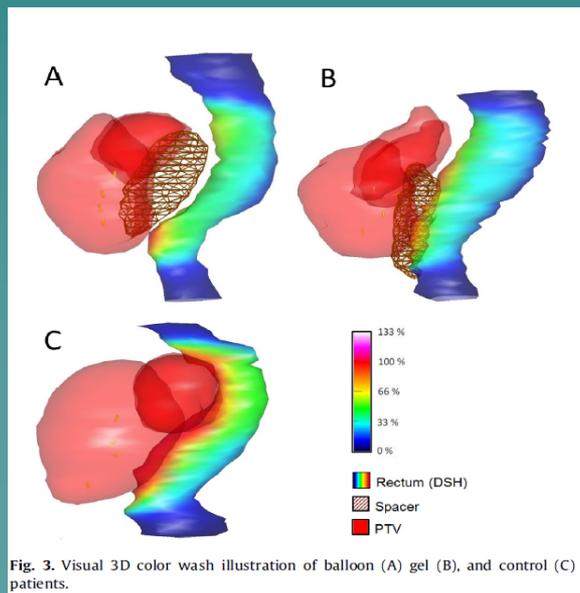


Fig. 3. Visual 3D color wash illustration of balloon (A) gel (B), and control (C) patients.

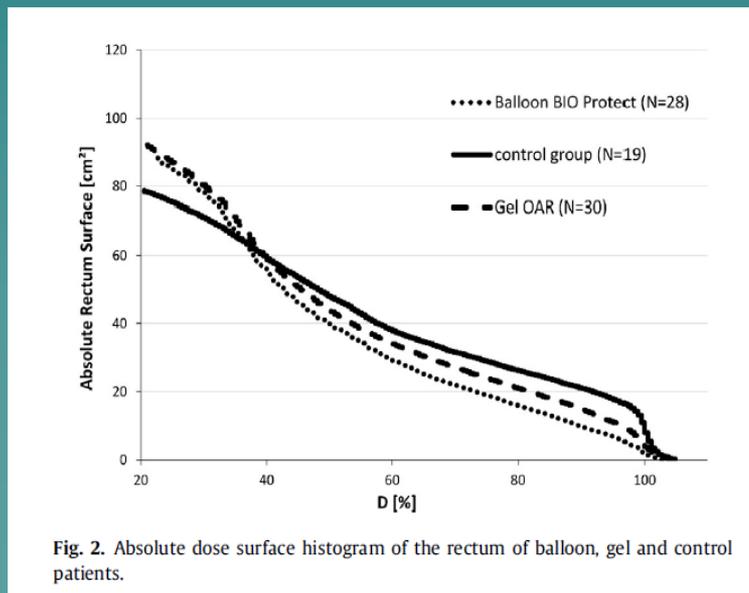


Fig. 2. Absolute dose surface histogram of the rectum of balloon, gel and control patients.

**TRANSPERINEAL INJECTION OF HYALURONIC ACID IN ANTERIOR PERIRECTAL FAT TO DECREASE RECTAL TOXICITY FROM RADIATION DELIVERED WITH INTENSITY MODULATED BRACHYTHERAPY OR EBRT FOR PROSTATE CANCER PATIENTS**

PEDRO J. PRADA, M.D.,\* JOSÉ FERNÁNDEZ, M.D., PH.D.,\* ALVARO A. MARTINEZ, M.D.,†  
ÁNGELES DE LA RÚA, M.D.,\* JOSE M. GONZALEZ, M.D.,\* JOSE M. FERNANDEZ, M.D.,‡ AND  
GERMAN JUAN, M.D.\*

Departments of \*Radiation Oncology and †Radiology, Hospital Central de Asturias, Oviedo, Spain; ‡Department of Radiation Oncology, William Beaumont Hospital, Royal Oak, MI.

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Volume 69, Number 1, 2007

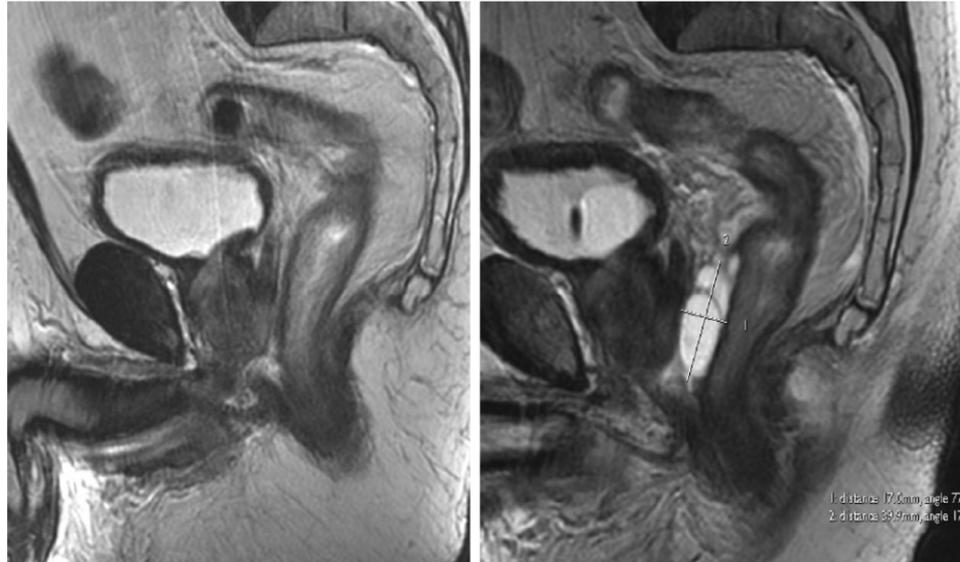
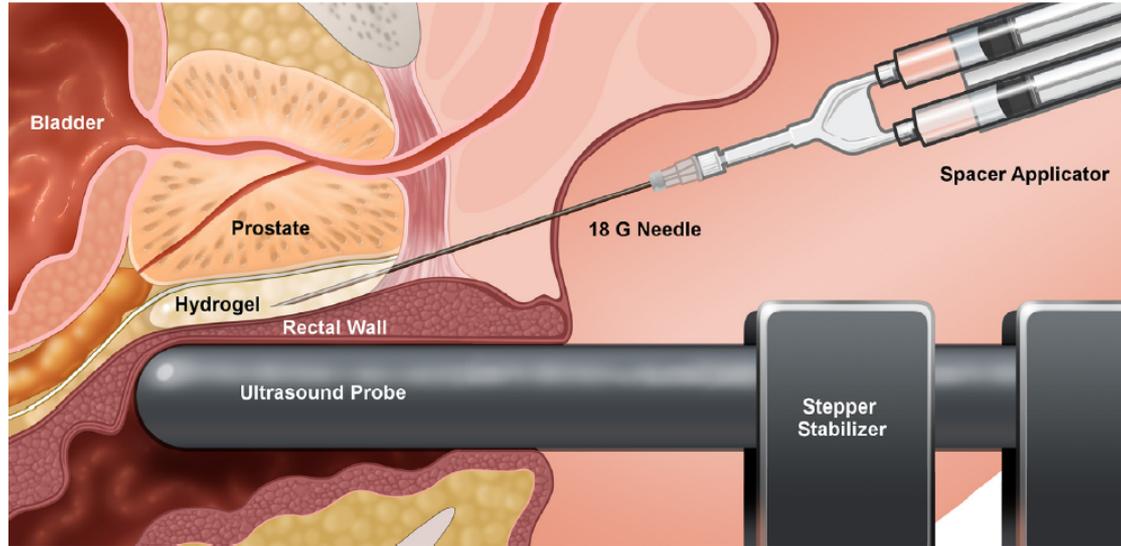


Fig. 4. Magnetic resonance image demonstrating the additional perirectal space created by the hyaluronic acid injection.



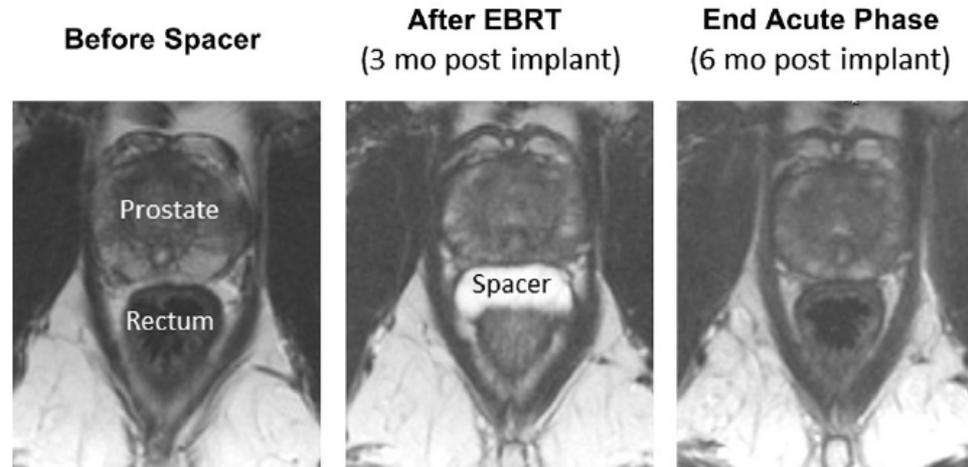
**Figure 2.** Illustration of transperineal polyethylene glycol hydrogel spacer injection. The needle is placed at the mid-prostate level between Denonvilliers fascia and rectal wall, hydrodissection is performed to confirm proper positioning, and the hydrogel is injected.

# A Multi-institutional Clinical Trial of Rectal Dose Reduction via Injected Polyethylene-Glycol Hydrogel During Intensity Modulated Radiation Therapy for Prostate Cancer: Analysis of Dosimetric Outcomes

Vol. 87, No. 1, pp. 81–87, 2013

Danny Y. Song, MD,\* Klaus K. Herfarth, MD,† Matthias Uhl, MD,† Michael J. Eble, MD,‡  
Michael Pinkawa, MD,‡ Baukelien van Triest, MD, PhD,§ Robin Kalisvaart, MSc,§  
Damien C. Weber, MD,|| Raymond Miralbell, MD,|| Theodore L. DeWeese, MD,\*  
and Eric C. Ford, PhD¶

International Journal of Radiation Oncology • Biology • Physics



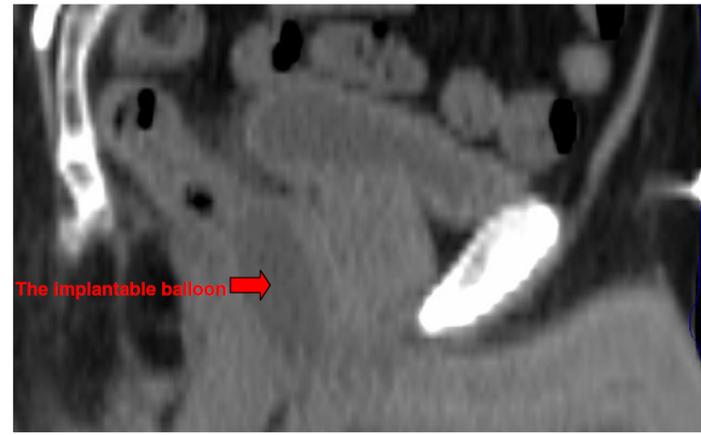
**Fig. 1.** Axial T2 magnetic resonance images of a patient before hydrogel injection (left), after radiation therapy (middle), and 6 months after injection (right).

RESEARCH

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## Application of an interstitial and biodegradable balloon system for prostate-rectum separation during prostate cancer radiotherapy: a prospective multi-center study

Eliahu Gez<sup>†</sup>, Shmuel Cytron, Rahamin Ben Yosef, Daniel London, Benjamin W Corn, Shlomi Alani, Giovanni Scarzello, Fabrizio Dal Moro, Guido Sotti, Filiberto Zattoni, Ike Koziol, Taryn Torre, Matthew Bassignani, Shalom Kalnicki, Reza Ghavamian, Dukagjin Blakaj, Mitchell Anscher, Martin Sommerauer, Dieter Jocham, Corinna Melchert, Stefan Huttenlocher, Gyoergy Kovacs<sup>‡</sup> and Madhur Garg



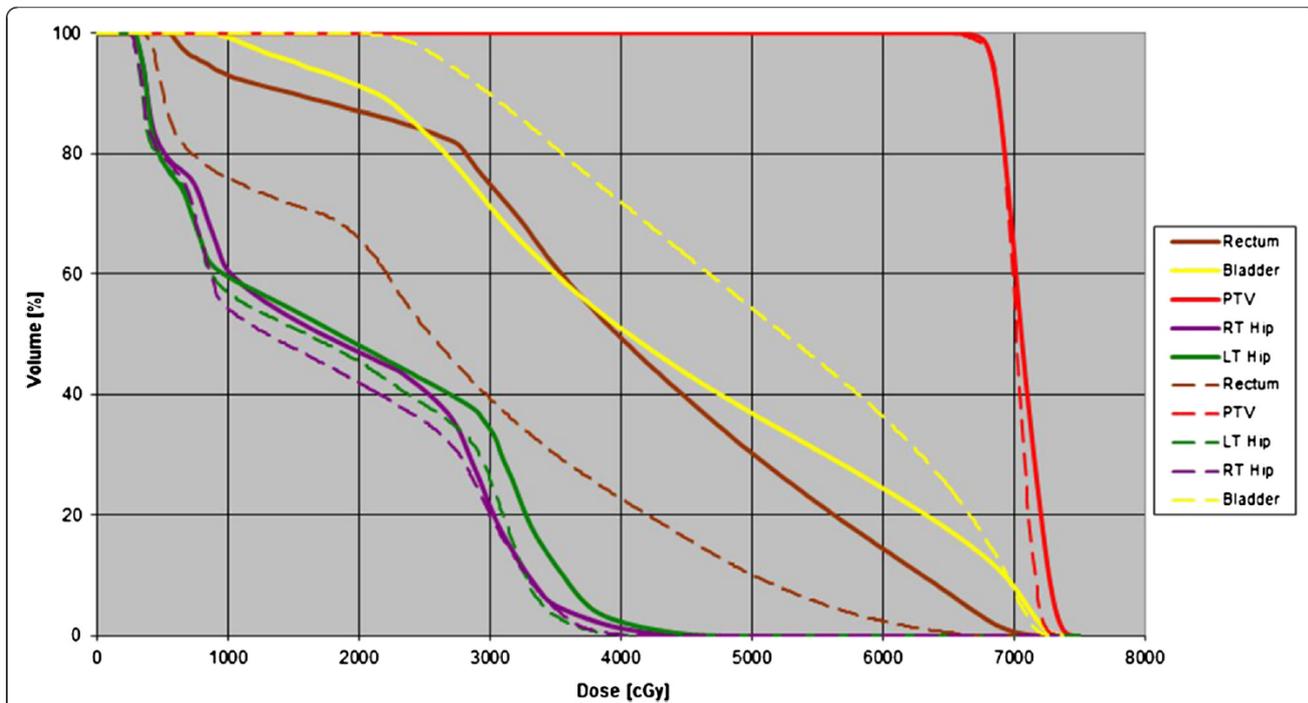
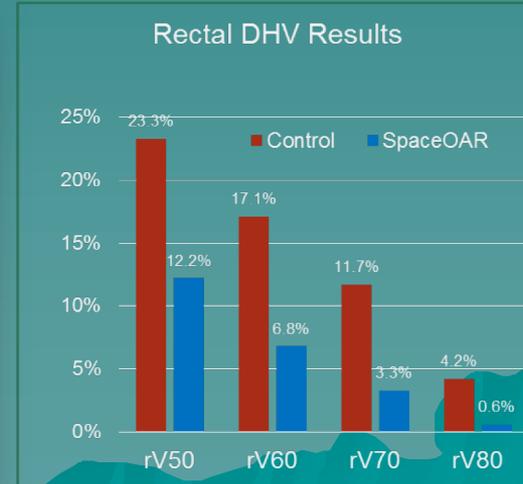
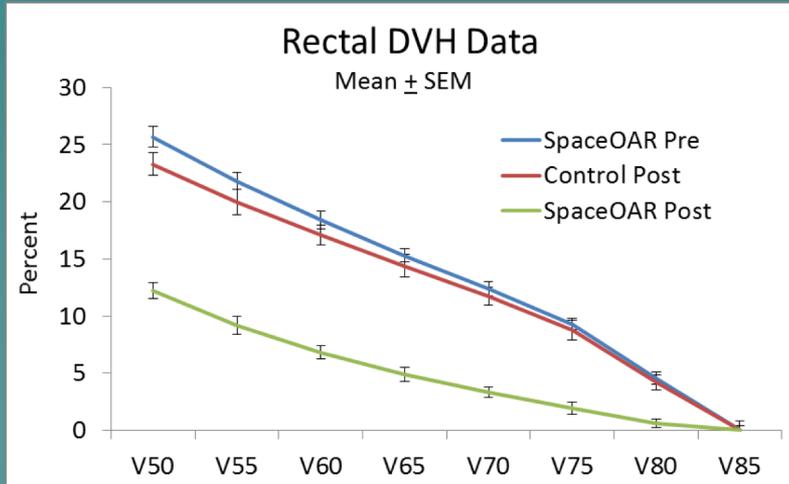
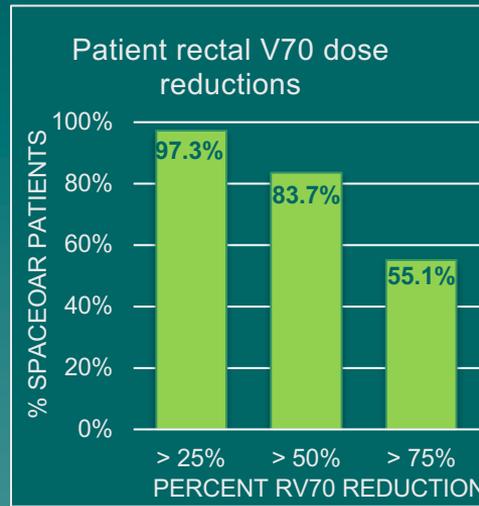


Figure 3 DVHs pre and post balloon implant of a single patient: Continuous line pre and dashed line post balloon implant.

## Hydrogel Spacer Prospective Multicenter Randomized Controlled Pivotal Trial: Dosimetric and Clinical Effects of Perirectal Spacer Application in Men Undergoing Prostate Image Guided Intensity Modulated Radiation Therapy

Neil Mariados, MD,\* John Sylvester, MD,† Dhiren Shah, MD,‡ Lawrence Karsh, MD,§ Richard Hudes, MD,|| David Beyer, MD,¶ Steven Kurtzman, MD,# Jeffrey Bogart, MD,\*\* R. Alex Hsi, MD,†† Michael Kos, MD,‡‡ Rodney Ellis, MD,§§ Mark Logsdon, MD,||| Shawn Zimberg, MD,¶¶ Kevin Forsythe, MD,## Hong Zhang, MD, PhD,\*\*\* Edward Soffen, MD,††† Patrick Francke, MD,††† Constantine Mantz, MD,§§§ Peter Rossi, MD,|||| Theodore DeWeese, MD,¶¶¶ Daniel A. Hamstra, MD, PhD,### Walter Bosch, DSc,\*\*\*\* Hiram Gay, MD,\*\*\*\* and Jeff Michalski, MD, MBA\*\*\*\*\*

Int J Radiation Oncol Biol Phys, Vol. 92, No. 5, pp. 971–977, 2015



# Absorbable Hydrogel Spacer Use in Prostate Radiotherapy: A Comprehensive Review of Phase 3 Clinical Trial Published Data

Lawrence I. Karsh, Eric T. Gross, Christopher M. Pieczonka, Philip J. Aliotta, Christopher J. Skomra, Lee E. Ponsky, Peter T. Nieh, Misop Han, Daniel A. Hamstra, and Neal D. Shore  
UROLOGY ■■■: ■■■–■■■, 2017.

**Table 1.** Statistically significant clinical differences resulting from polyethylene glycol (PEG) hydrogel spacer use during prostate radiotherapy: percent difference relative to nonspacer patients and number needed to treat (NNT) with PEG hydrogel spacer to prevent 1 event

Clinical Outcome	Spacer Arm (%)	Control Arm (%)	P-Value	Difference Relative to Control (%)	NNT
Rectal pain adverse events (0-3 mo)	2.7	11.1	.022	76	11.9
Late G1+ rectal toxicity (3-37 mo)	2.0	9.2	.028	78	13.9
Late G2+ rectal toxicity (3-37 mo)	0.0	5.7	.015	100	17.5
Late G1+ urinary incontinence (3-37 mo)	4	15	.046	73	9.1
Percentage of patients experiencing MID declines in bowel QOL (at 37 mo)	14	41	.002	66	3.7
Percentage of patients experiencing MID declines in urinary QOL (at 37 mo)	17	30	<.05	43	7.7
Potent men at baseline retaining erections sufficient for intercourse (at 37 mo)	66.7	37.5	.046	78	3.4
Men experiencing MID declines in all 3 QOL domains (bowel, urinary, and sexual) (at 37 mo)	2.5	20.0	.002	88	5.7

MID, minimally important difference; QOL, quality of life.