Contemporary Diagnosis and Treatment of Localized Prostate Cancer

Jim C. Hu M.D., M.P.H.

Ronald Lynch Professor in Urologic Oncology

Director of the LeFrak Center for Robotic Surgery

Outline

- Prostate cancer epidemiology
- Contemporary approach prostate cancer Dx
- Improving prostate cancer risk stratification
- Current treatment options for prostate cancer
- Challenges to partial gland ablation

Trends in Metastatic Breast and Prostate Cancer — Lessons in Cancer Dynamics

H. Gilbert Welch M.D., M.P.H., David H. Gorski, M.D., Ph.D., and Peter C. Albertsen, M.D.

Prostate Specific Antigen (PSA)

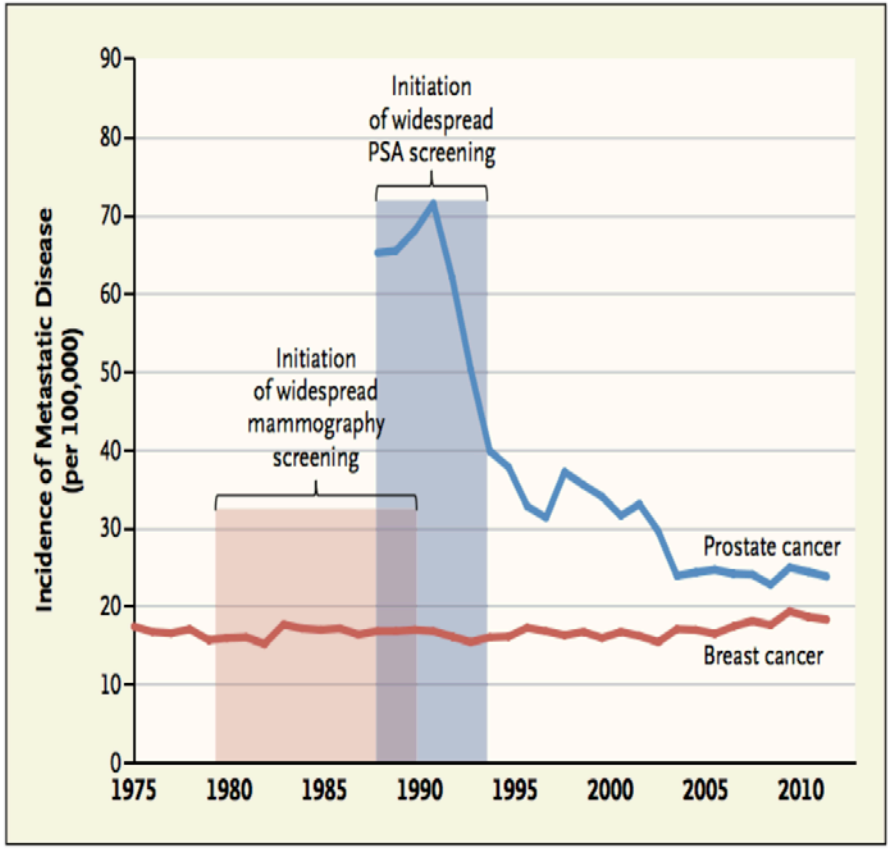
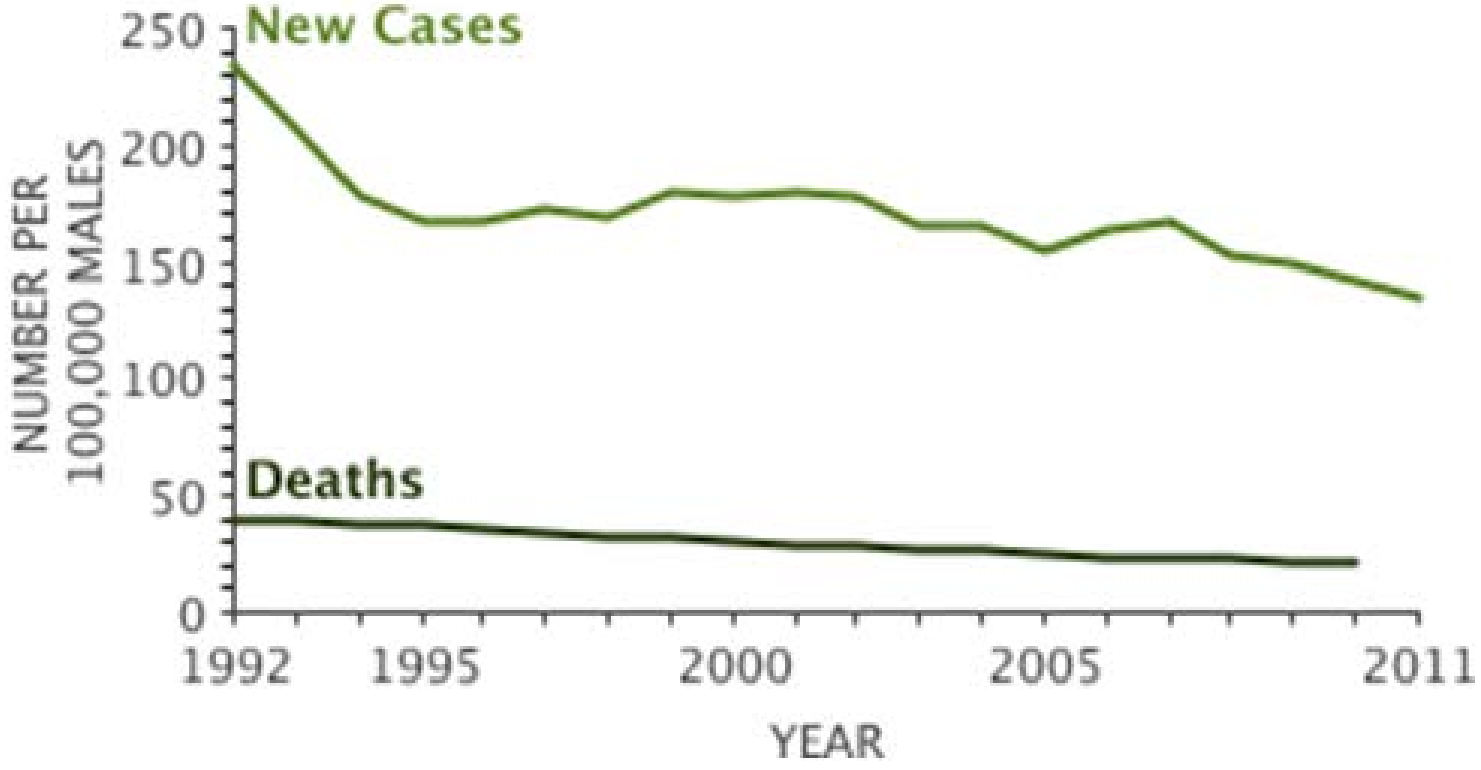


Figure 1 from Welch HG et al. Trends in Metastatic Breast and Prostate Cancer—Lessons in Cancer Dynamics. New Eng J Med 2016 373: 1685–1687.

Comparison to other Cancers

Prostate Cancer Deaths Were Declining Since 1992



https://seer.cancer.gov/data

U.S. Epidemiology

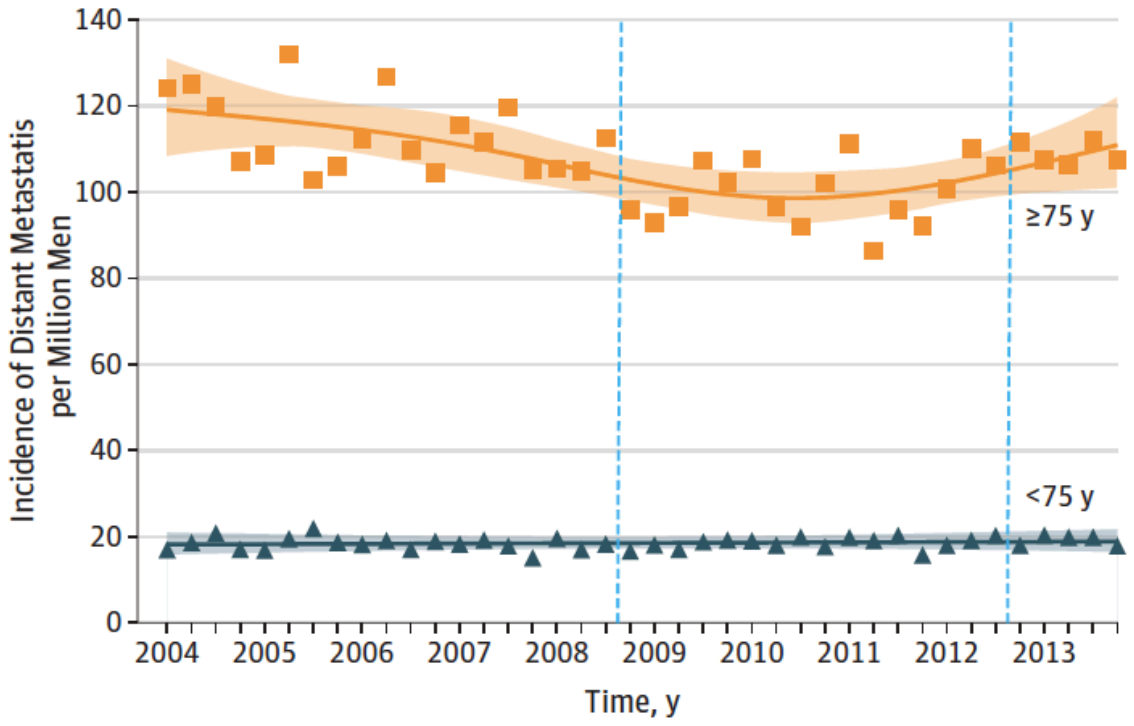
American Cancer Society Statistics

- **Incidence**
  - 2017: 161,360
  - 2019: 175,650
  - 2020: 191,930
- **Deaths**
  - 2017: 26,730
  - 2019: 31,620
  - 2020: 33,330
- Lifetime risk of diagnosis is 1 in 9
- Prevalence: 3.1 million

Increase in Incidence of Prostate Cancer Distant Metastases at Diagnosis in the U.S.

Jim C. Hu, MD, MPH
Paul Nguyen, MD
Jialin Mao, MD, MSc
Joshua Halpern, MD
Jonathan Shoag, MD
Jason D. Wright, MD
Art Sedrakyan, MD, PhD

Figure. Standardized Incidence of Prostate Cancer Distant Metastasis at Diagnosis by Quarter Between 2004 and 2013 Among Men Aged 75 Years and Older and Younger Than 75 Years



p<0.01

Dashed vertical blue lines demonstrate the release of the 2008 and 2012 screening recommendations.

Hu JC, Nguyen P, Mao J, et al. Increase in Incidence of Prostate Cancer Distant Metastases at Diagnosis in the U.S. JAMA Oncol, 2017 May 1;3(5):705-707. doi: 10.1001/jamaoncol.2016.5465.

PSA screening recommendations

- 2012 USPSTF Grade D recommendation
- 2018 USPSTF Grade C recommendation

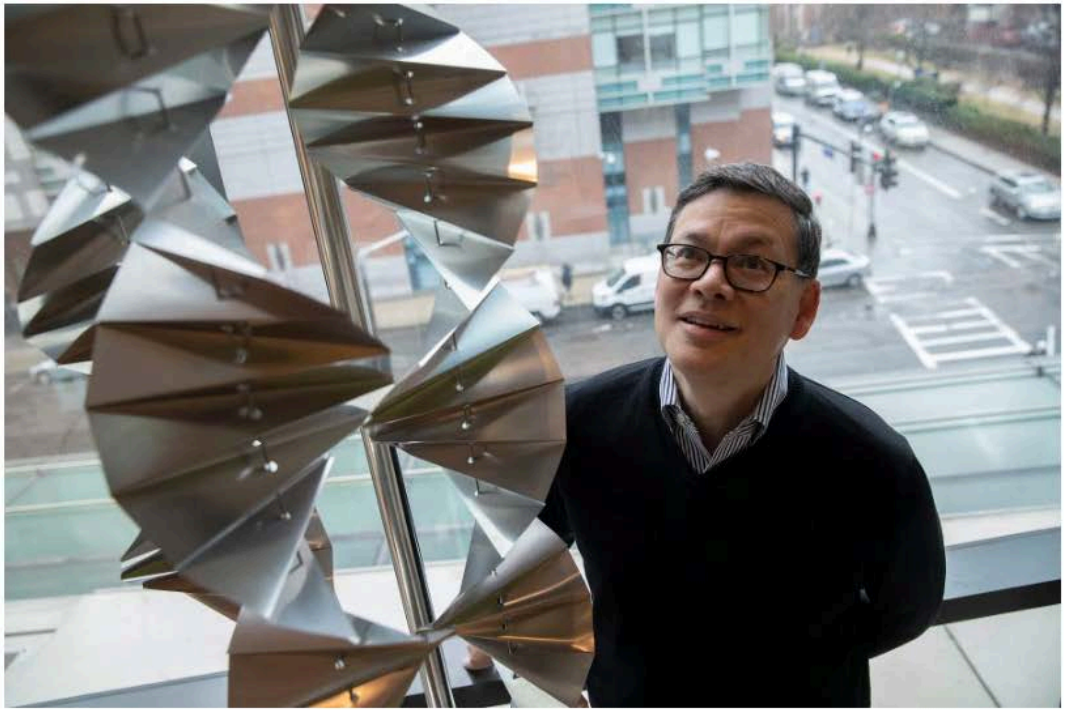
https://news.harvard.edu/gazette/story/2020/02/u-s-life-expectancy-goes-up-as-cancer-deaths-go-down/

The Harvard Gazette

Drop in cancer deaths lifts U.S. life expectancy

Professor Timothy Rebbeck looks at the reduction in deaths from cancer, the nation's No. 2 killer.

Kris Snibbe/Harvard Staff Photographer

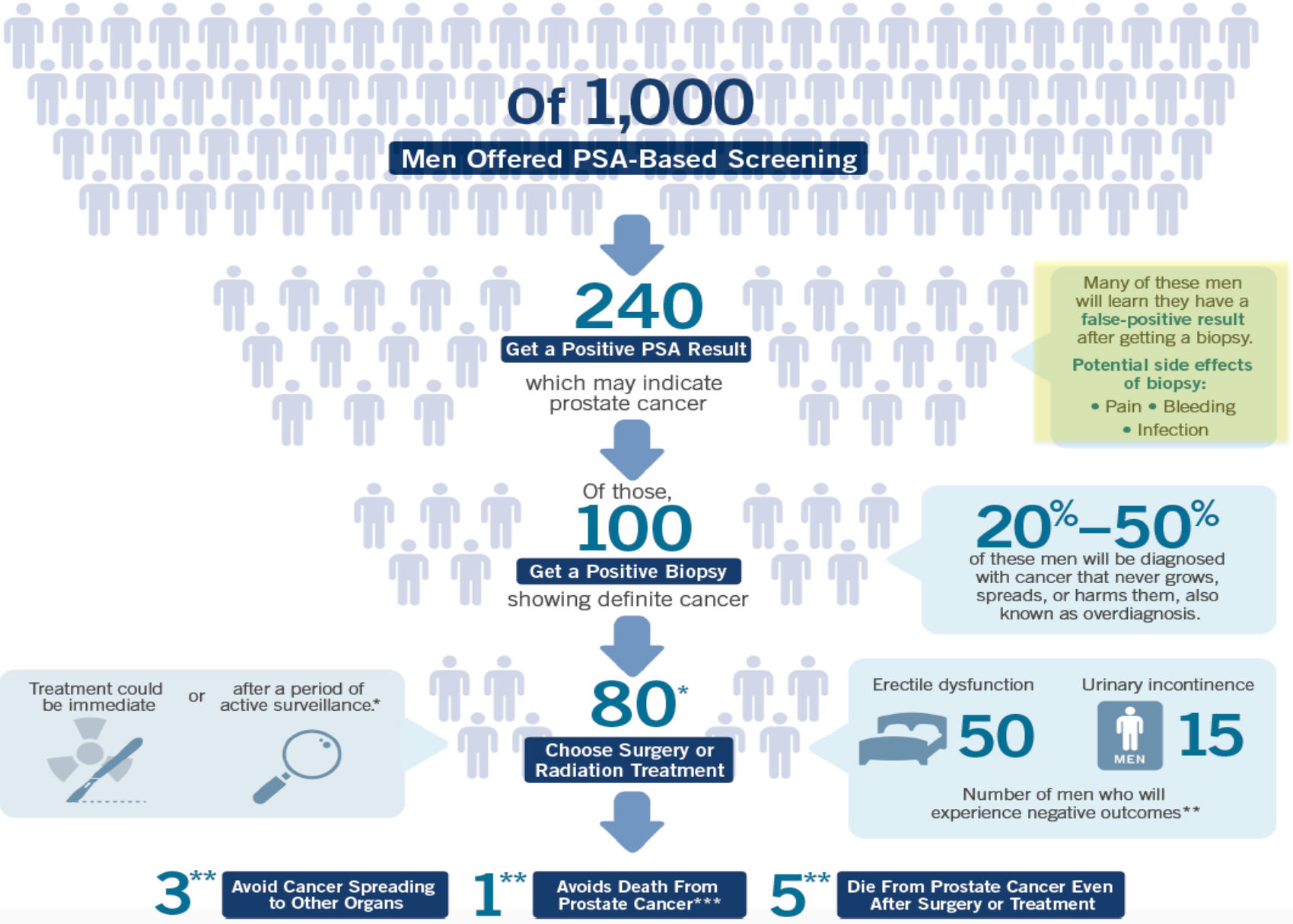


"In 2020, *rates of aggressive prostate cancer going up*, and *more men are dying of prostate cancer*. So that's an example where, even though we have better therapeutic options, *we're still really not doing a good job in screening....we may see more mortality in the coming years*"

Is Prostate Cancer Screening Right for You?

Understanding the Potential Benefits vs. Harms for Men 55–69

USPSTF INFOGRAPHIC



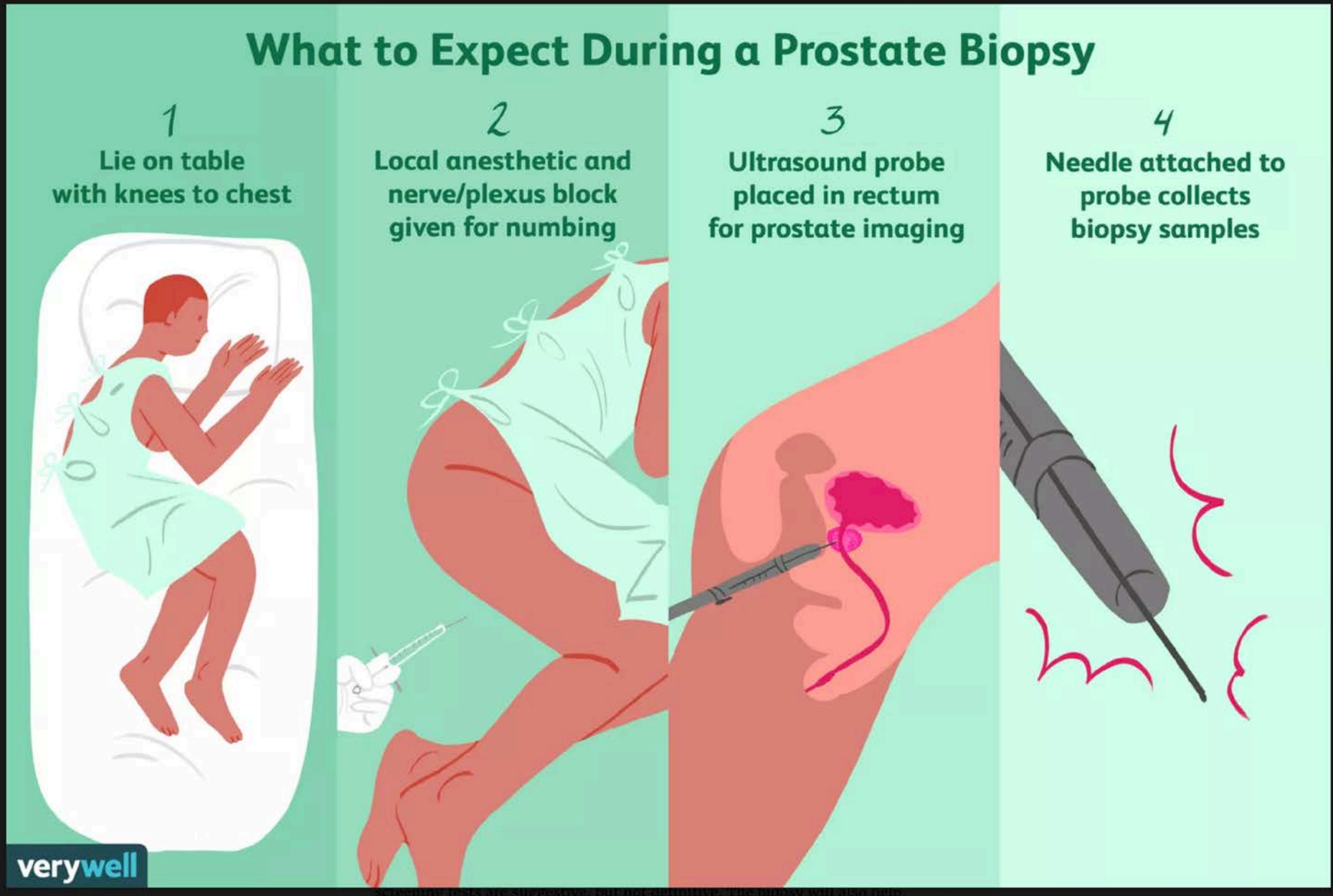


Illustration by Emily Roberts, Verywell

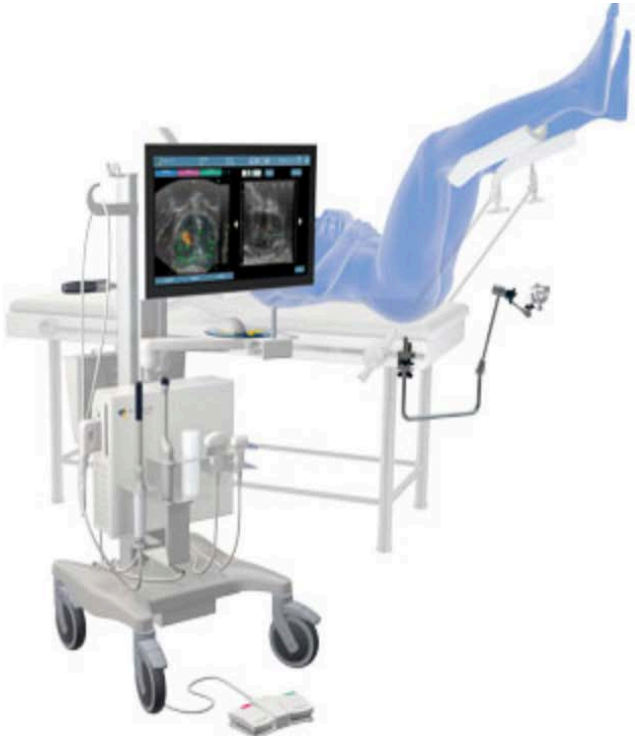
The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MAY 10, 2018 VOL. 378 NO. 19

MRI-Targeted or Standard Biopsy for Prostate-Cancer Diagnosis

V. Kasivisvanathan, A.S. Rannikko, M. Borghi, V. Panebianco, L.A. Mynderse, M.H. Vaarala, A. Briganti, L. Budäus, G. Hellawell, R.G. Hindley, M.J. Roobol, S. Eggener, M. Ghei, A. Villers, F. Bladou, G.M. Villeirs, J. Virdi, S. Boxler, G. Robert, P.B. Singh, W. Venderink, B.A. Hadaschik, A. Ruffion, J.C. Hu, D. Margolis, S. Crouzet, L. Klotz, S.S. Taneja, P. Pinto, I. Gill, C. Allen, F. Giganti, A. Freeman, S. Morris, S. Punwani, N.R. Williams, C. Brew-Graves, J. Deeks, Y. Takwoingi, M. Emberton, and C.M. Moore, for the PRECISION Study Group Collaborators*

MRI scans could revolutionise prostate cancer diagnosis (Image: E+)



Weill Cornell Medicine

NewYork-Presbyterian

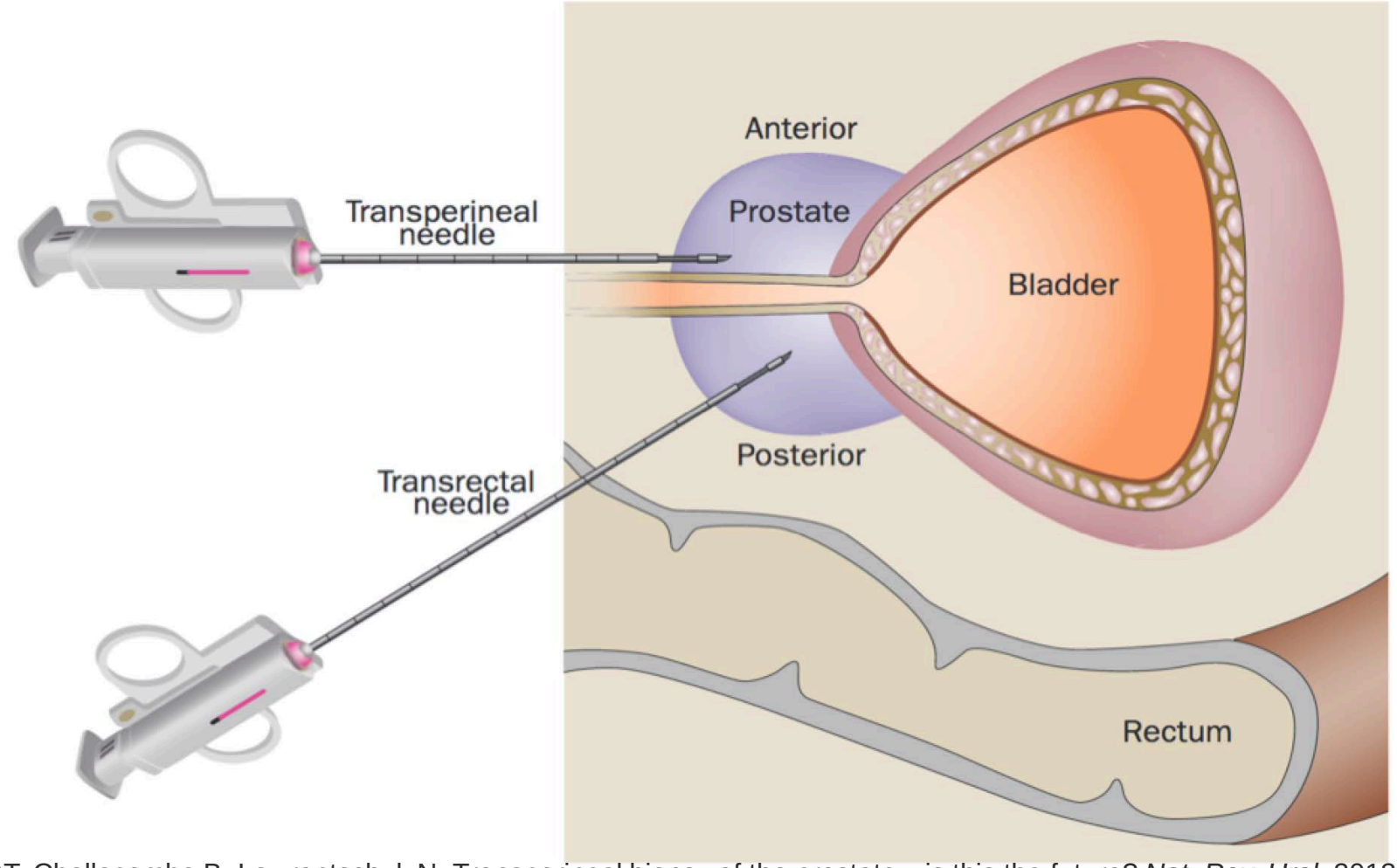
28% of men avoid Biopsy
Increased detection (+12%) of Clinically Significant Prostate Cancer Decreased detection (-13%) of Indolent Prostate Cancer

Table 2. Comparison of Cancer Detection between Groups.*

Outcome	MRI-Targeted Biopsy Group (N=252)	Standard-Biopsy Group (N=248)	Difference†	P Value
Biopsy outcome — no. (%)			—	—
No biopsy because of negative result on MRI	71 (28)	0		
Benign tissue	52 (21)	98 (40)		
Clinically significant cancer¶				
Intention-to-treat analysis — no. (%)	95 (38)	64 (26)	12 (4 to 20)	0.005
Clinically insignificant cancer — no. (%)	23 (9)	55 (22)	−13 (−19 to −7)	<0.001

TREXIT

Figure 3. Improved sampling of anterior zone for transperineal (clean) vs. transrectal (contaminated) approach.[48]

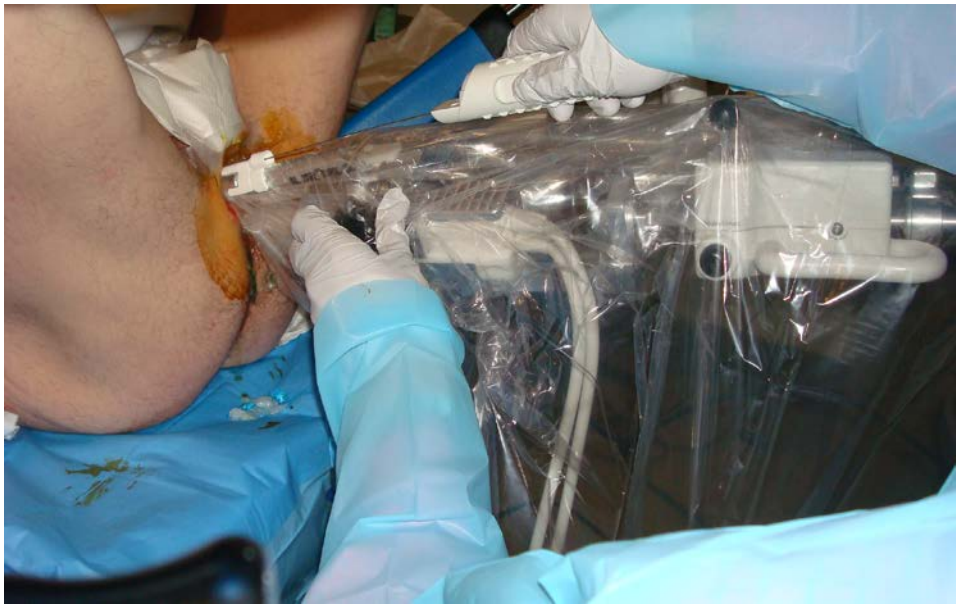


Chang DT, Challacombe B, Lawrentschuk N. Transperineal biopsy of the prostate—is this the future? *Nat. Rev. Urol.* 2013 Dec;10(12):690-702. doi: 10.1038/nrurol.2013.195. Epub 2013 Sep 24.

BMJ Surgery, Interventions, & Health Technologies

IDEAL Stage 2a experience with in-office, transperineal MRI/ultrasound software fusion targeted prostate biopsy

Michael Tzeng ,[1] Eliza Cricco-Lizza,[1] Bashir Al Hussein Al Awamlh,[1] Morgan Pantuck,[1] Daniel J Margolis,[2] Miko Yu,[1] Jim Hu[1]



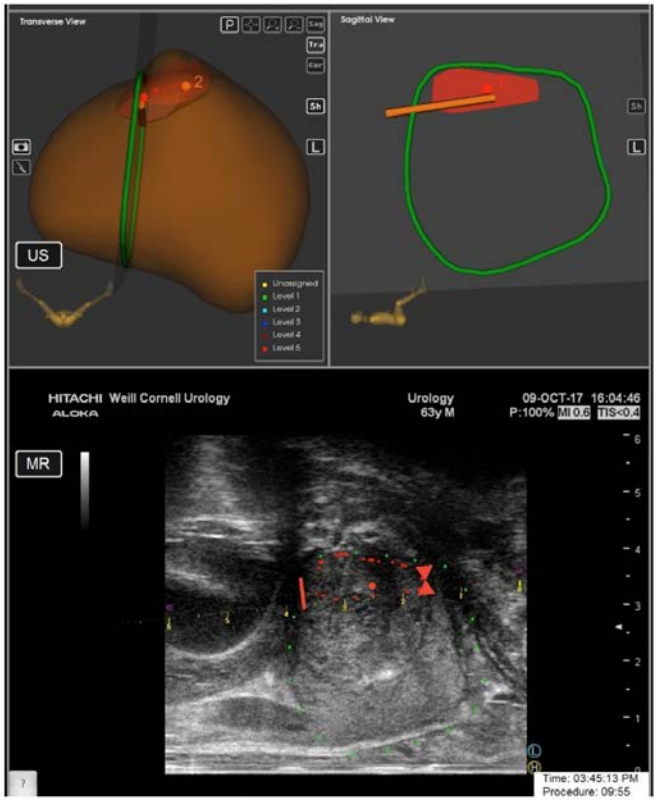


Figure 2 Transperineal MRI/ultrasound software fusion and targeting of an anterior Prostate Imaging-Reporting and Data System four lesion for biopsy.

1 R01 CA241758-01A1

PI Name: Gorin, Michael ; Hu, Jim (Contact); Schaeffer, Edward Matthew

NIH Appl. ID: 9973695

Application ID: 1 R01 CA241758-01A1

Application

Award Document Number: RCA241758A

FSR Accepted Code: N

Snap Indicator Code:

Impact Score: 18

Percentile: 4.0

For information about next steps: Click here

Early Stage Investigator Eligible: N

New Investigator Eligible: N

Eligible for FFATA Reporting: Yes

Study Section

Scientific Review Group: NRCS

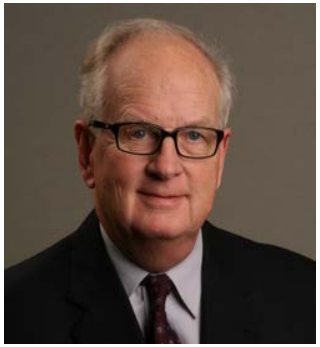
Council Meeting Date (YYYY/MM): 2020/01

Meeting Date: 10/31/2019

Meeting Time: 08:00

Study Roster: View Meeting Roster






Is Prostate Cancer Screening Right for You?

Understanding the Potential Benefits vs. Harms for Men 55–69

Of 1,000

Men Offered PSA-Based Screening

240

Get a Positive PSA Result

which may indicate prostate cancer

Many of these men will learn they have a **false-positive result** after getting a biopsy.

Potential side effects of biopsy:

- Pain
- Bleeding
- Infection

Of those,

100

Get a Positive Biopsy

showing definite cancer

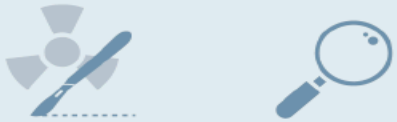
20%–50%

of these men will be diagnosed with cancer that never grows, spreads, or harms them, also known as overdiagnosis.

80*

Choose Surgery or Radiation Treatment

Treatment could be immediate or after a period of active surveillance.*



Erectile dysfunction

50

Urinary incontinence

15

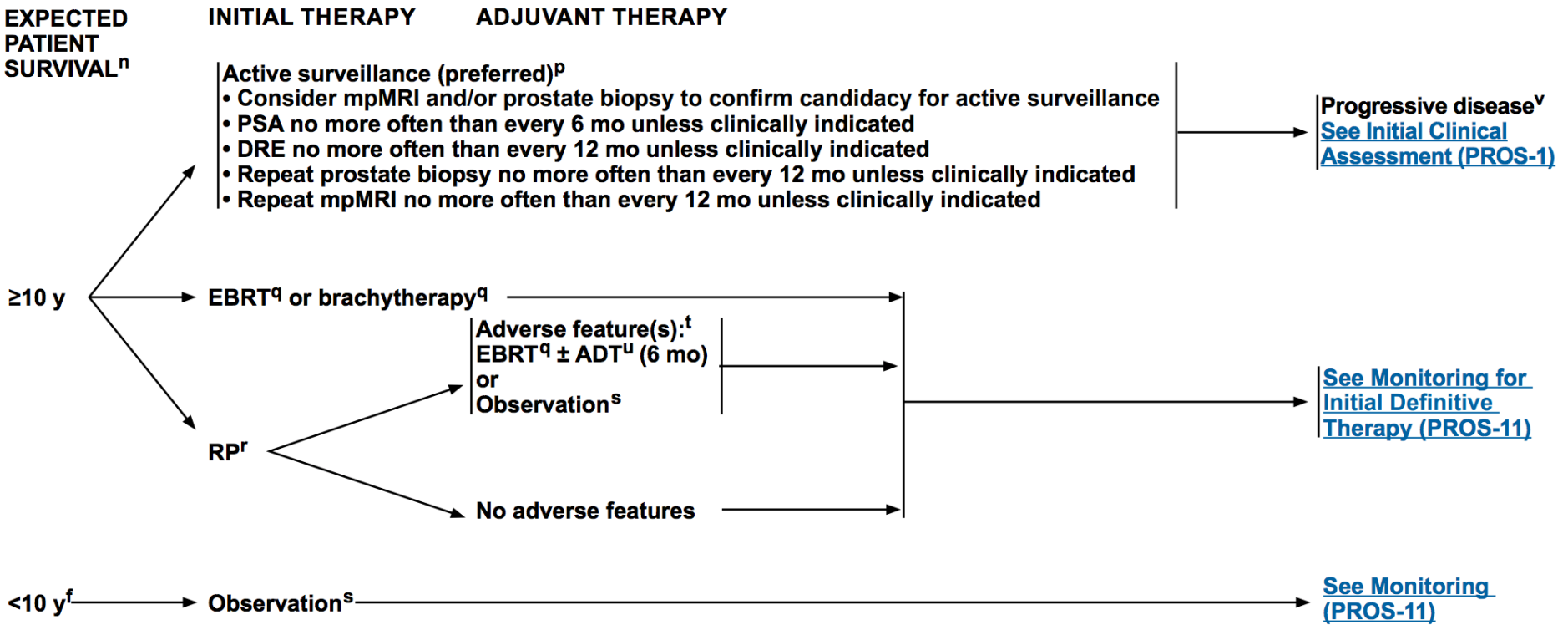
Number of men who will experience negative outcomes**

3** **Avoid Cancer Spreading to Other Organs**

1** **Avoids Death From Prostate Cancer*****

5** **Die From Prostate Cancer Even After Surgery or Treatment**

LOW RISK GROUP

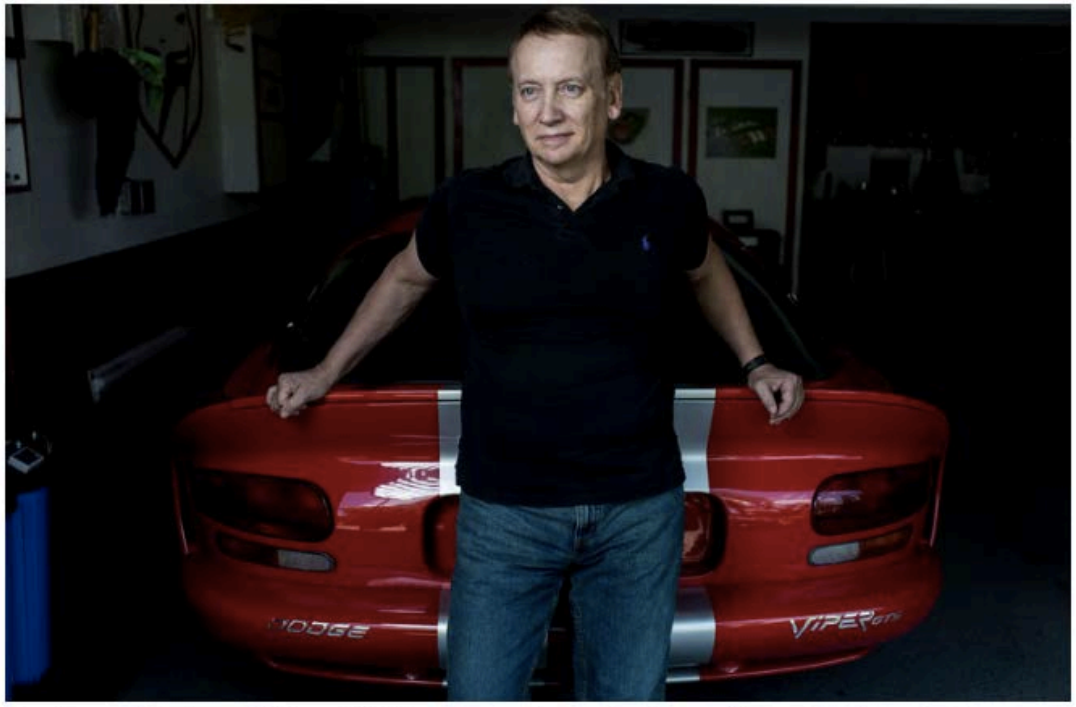


https://www.nytimes.com/2016/05/25/health/prostate-cancer-active-surveillance-surgery-radiation.html

HEALTH

More Men With Early Prostate Cancer Are Choosing to Avoid Treatment

By GINA KOLATA MAY 24, 2016



Bruce Perry of Charleston, W.Va., said his doctors never discussed active surveillance when he received his diagnosis. Raymond Thompson Jr., for The New York Times

Seemingly overnight, treatment of men with early-stage prostate cancer has undergone a sea change. Five years ago, nearly all opted for surgery or radiation; now, nearly half are choosing no treatment at all.

Five years ago, **nearly all** of men with localized prostate cancer opted for surgery or radiation; now, **nearly half** are choosing no treatment at all.

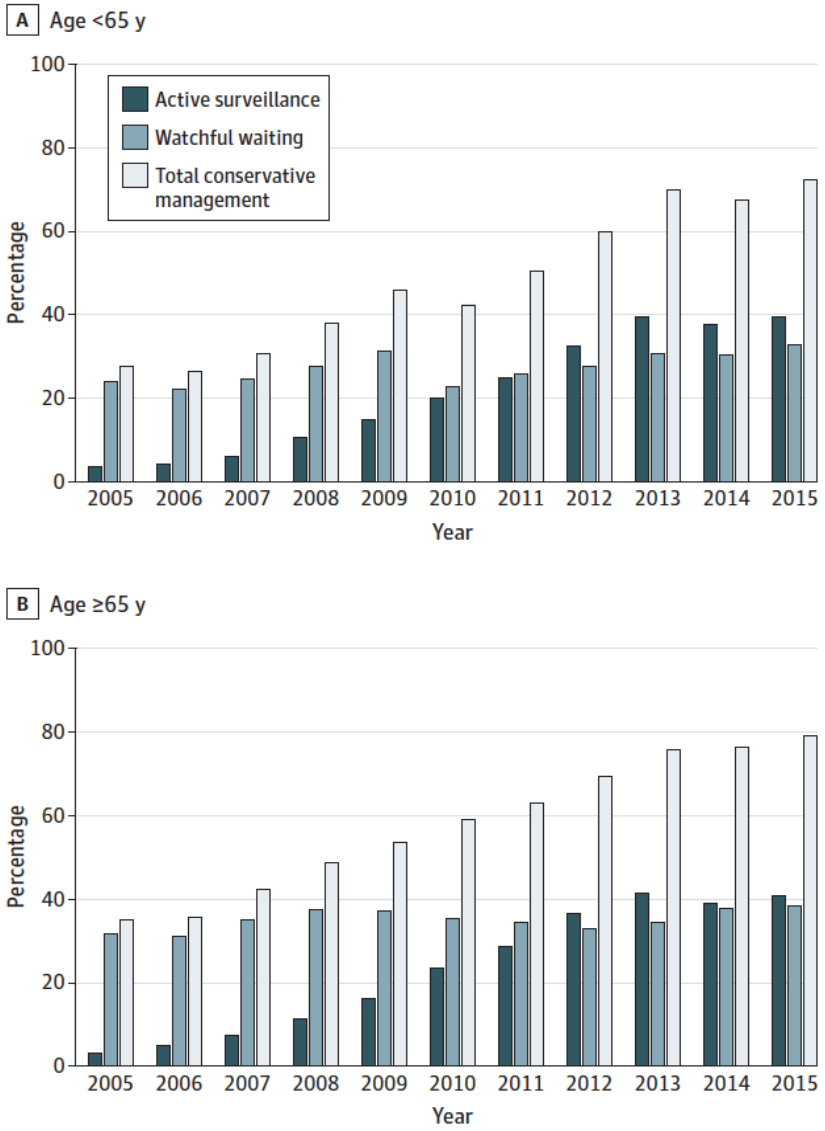
RESEARCH LETTER

Use of Conservative Management for Low-Risk Prostate Cancer in the Veterans Affairs Integrated Health Care System From 2005-2015

Stacy Loeb, MD, MSc
Nataliya Byrne, BA
Danil V. Makarov, MD, MHS
Herbert Lepor, MD
Dawn Walter, MPH

2232 JAMA June 5, 2018 Volume 319, Number 21

Figure. Proportion of US Veterans With Low-Risk Prostate Cancer Receiving Conservative Management (Active Surveillance or Watchful Waiting) From 2005-2015, by Age[a]



[a] In the total cohort (N = 125 083), 68 463 were <65 y, of whom 43% received conservative management; 56 620 of men were ≥65 y, of whom 54% received conservative management.

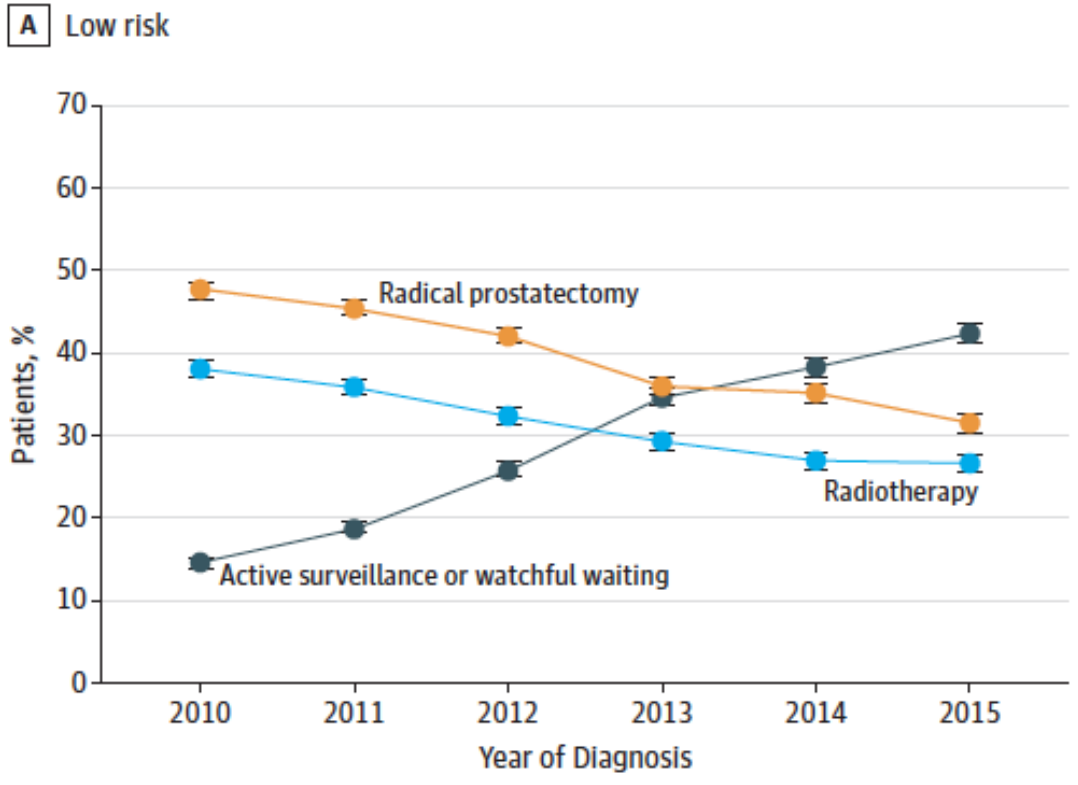
RESEARCH LETTER

Use of Active Surveillance or Watchful Waiting for Low-Risk Prostate Cancer and Management Trends Across Risk Groups in the United States, 2010-2015

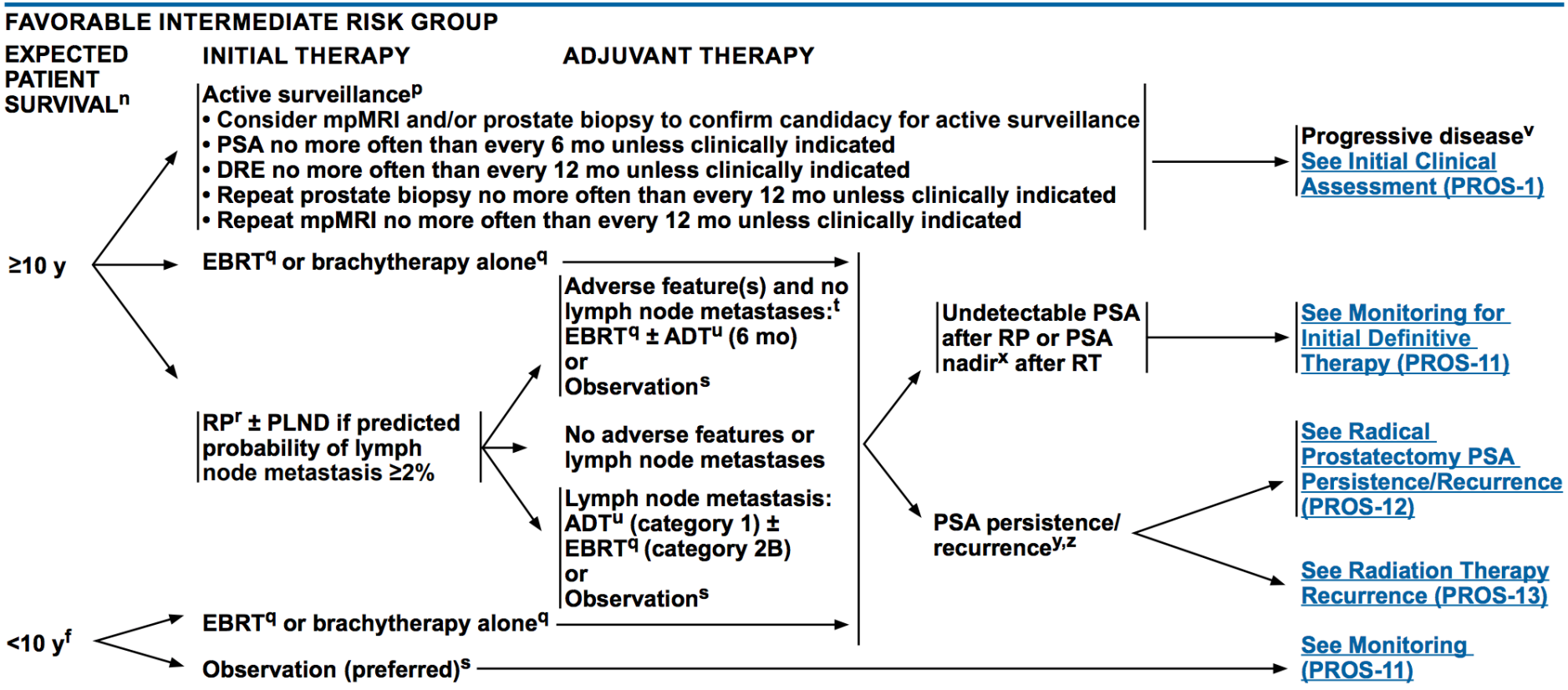
Brandon A. Mahal, MD
Santino Butler, BA
Idalid Franco, MD, MPH
Daniel E. Spratt, MD
Timothy R. Rebbeck, PhD
Anthony V. D'Amico, MD
Paul L. Nguyen, MD

JAMA February 19, 2019 Volume 321, Number 7 705

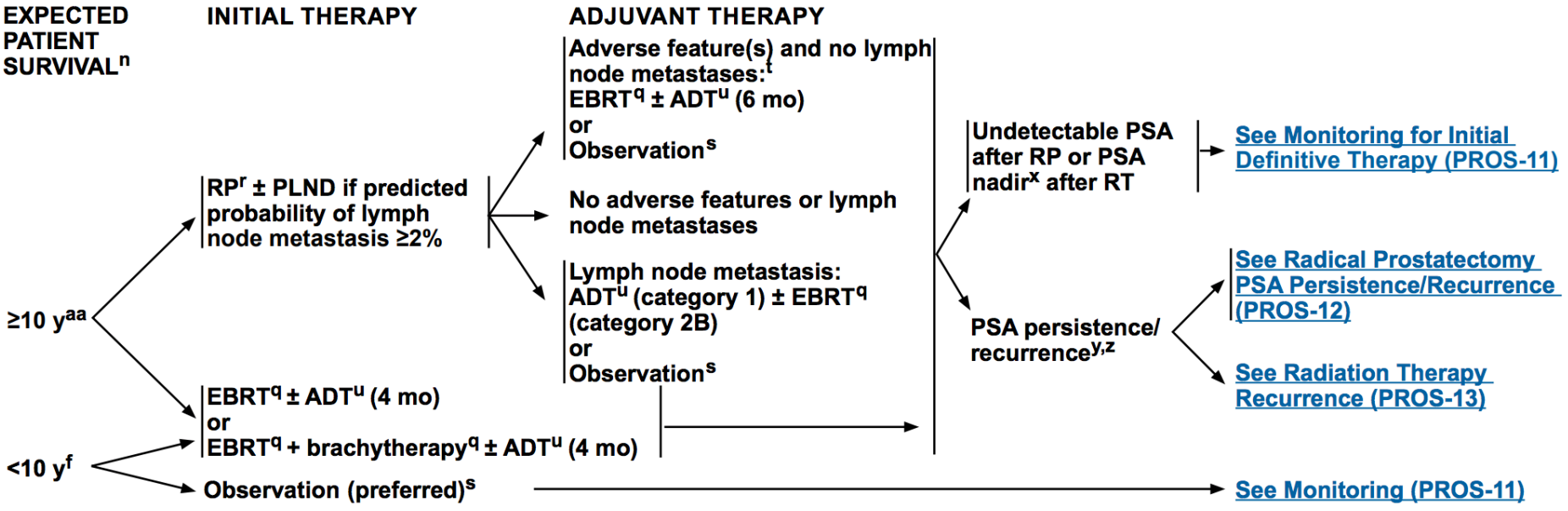
Figure. Initial Management Trends Among Patients Diagnosed as Having Low-, Intermediate-, and High-Risk Prostate Cancer in the United States From 2010 to 2015 in the Surveillance, Epidemiology, and End Results Prostate Active Surveillance/Watchful Waiting Database

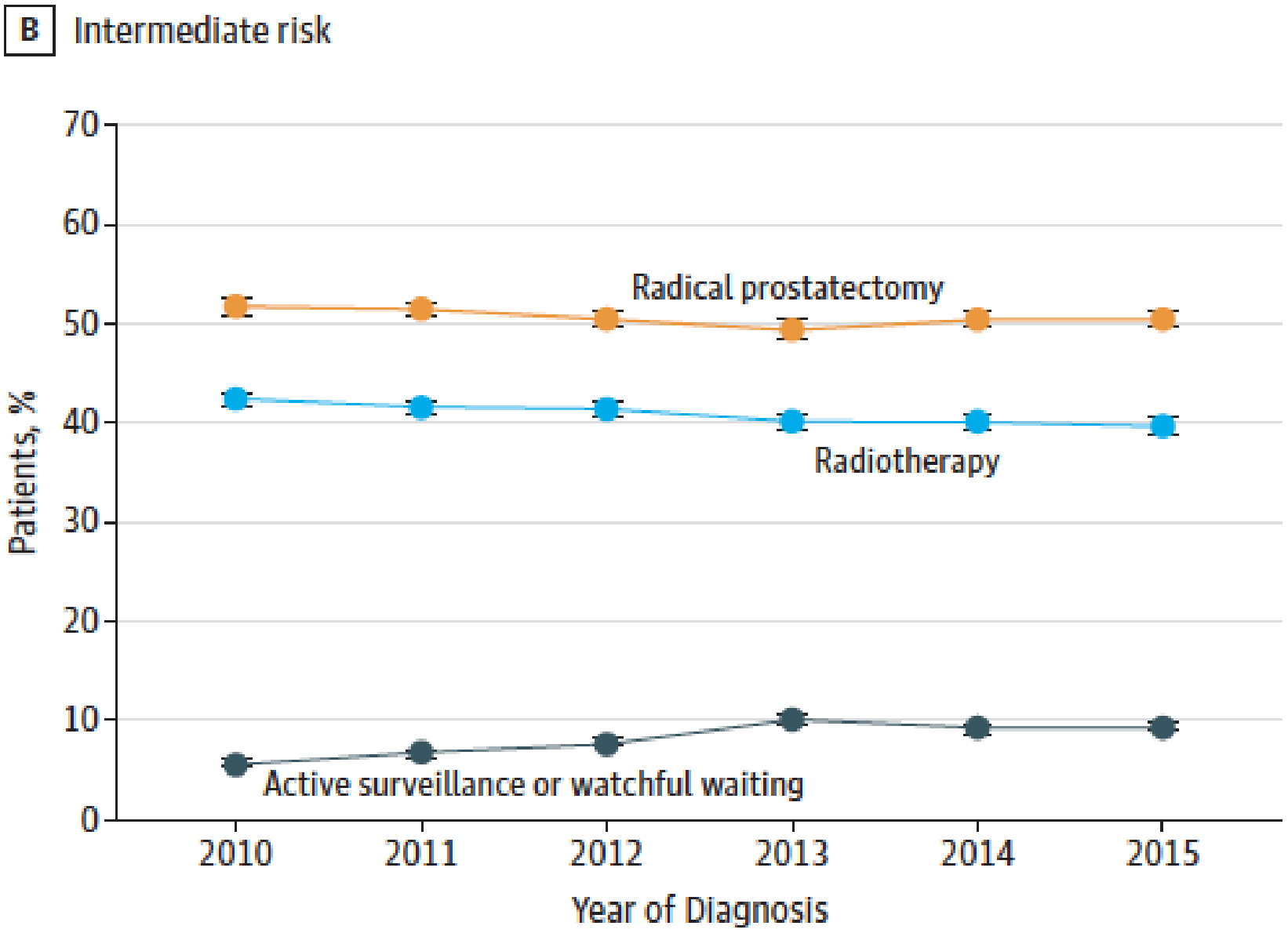


FAVORABLE INTERMEDIATE RISK GROUP



UNFAVORABLE INTERMEDIATE RISK GROUP





National Comprehensive Cancer Network®

NCCN Guidelines Version 4.2019
Prostate Cancer

- **Footnote m was modified: Men with low or favorable intermediate risk disease may consider the use of the following tumor-based molecular assays: Decipher, Oncotype DX Prostate, Prolaris, and ProMark.**

Retrospective studies have shown that molecular assays performed on prostate biopsy or radical prostatectomy specimens provide prognostic information independent of NCCN *or CAPRA* risk groups. These include, but are not limited to, likelihood of death with conservative management, likelihood of biochemical progression after radical prostatectomy or external beam therapy, and likelihood of developing metastasis after radical prostatectomy or salvage radiotherapy. See Discussion.

Improving Risk Stratification

HEALTH

Prostate Cancer Surgery or Not?

Genomics tests help doctors figure out which patients can follow 'active surveillance' and which ones need treatment

BY LUCETTE LAGNADO

IN 37 YEARS as a police officer, Edwin Michel coped with a plane crash, a sniper, wildfires and three bullet wounds.

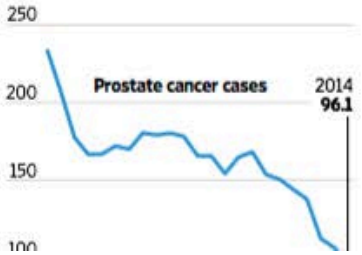
Nothing much rattled him until he was diagnosed with prostate cancer in November 2016. His doctor said the cancer wouldn't kill him but Mr. Michel, now 76 years old, wasn't entirely reassured.

He felt more confident after a genomics test later revealed his prostate cancer was very low risk. The test, known as Oncotype DX, takes a sample from a prostate biopsy and analyzes 17 genes in it to

RY FOR THE WALL STREET JOURNAL; MICHIGAN PHOTOGRAPHY

Sleuthing Out Sickness

Deaths from prostate cancer have decreased due to better treatments and early detection, doctors say. At the same time the number of cases has fallen, which many attribute to a decline in screening.

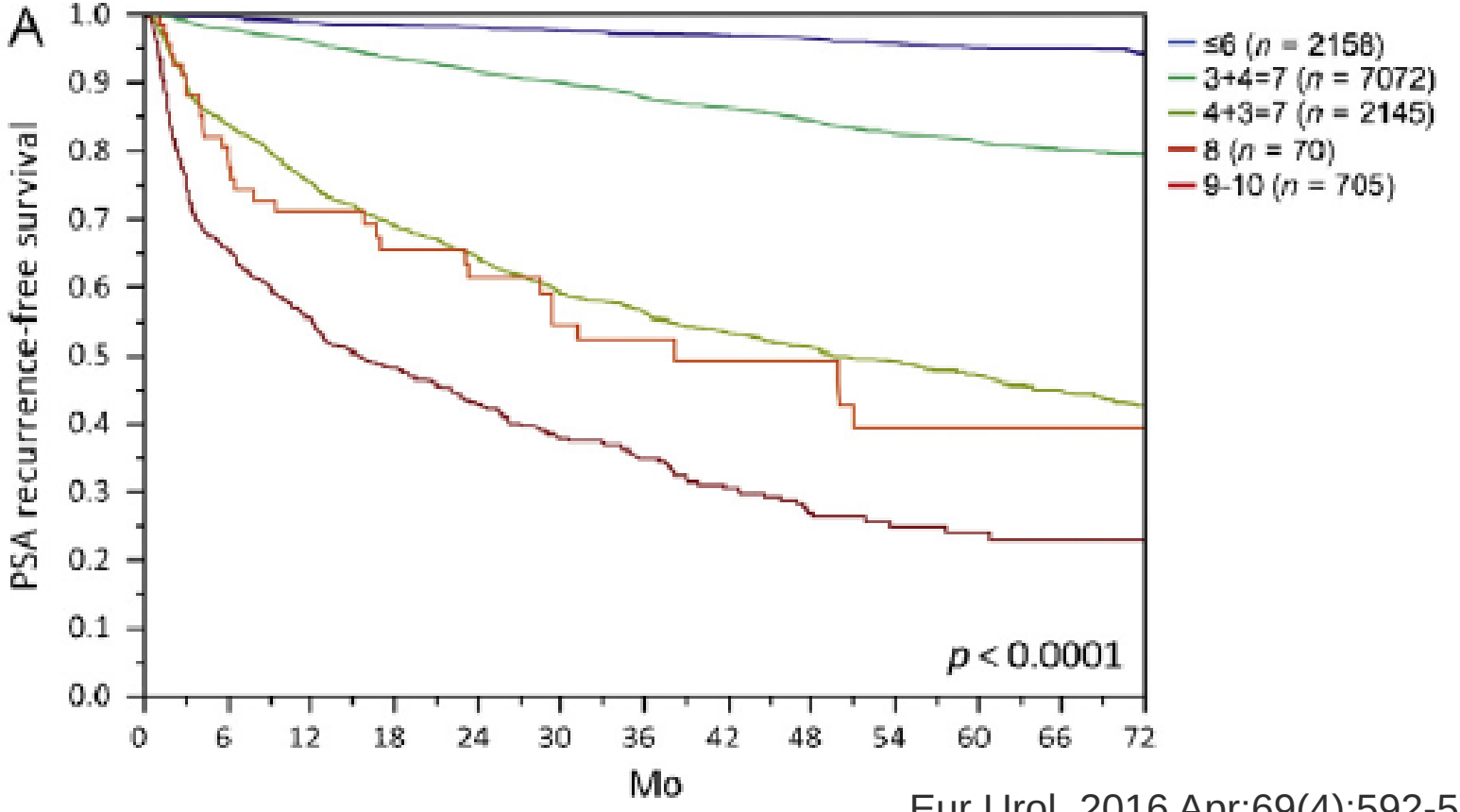


https://www.wsj.com/articles/prostate-cancer-gene-test-helps-patients-decide-on-treatment-1522494300

Clinical Utility of Quantitative Gleason Grading in Prostate Biopsies and Prostatectomy Specimens

Guido Sauter[a,], Stefan Steurer[a], Till Sebastian Clauditz[a], Till Krech[a], Corinna Wittmer[a], Florian Lutz[a], Maximilian Lennartz[a], Tim Janssen[a], Nayira Hakimi[a], Ronald Simon[a], Mareike von Petersdorff-Campen[a], Frank Jacobsen[a], Katharina von Loga[a], Waldemar Wilczak[a], Sarah Minner[a], Maria Christina Tsourlakis[a], Viktoria Chirico[a], Alexander Haese[b], Hans Heinzer[b], Burkhard Beyer[b], Markus Graefen[b], Uwe Michl[b], Georg Salomon[b], Thomas Steuber[b], Lars Henrik Budäus[b], Elena Hekeler[a], Julia Malsy-Mink[a], Sven Kutzera[a], Christoph Fraune[a], Cosima Göbel[a], Hartwig Huland[b], Thorsten Schlomm[b,c]*

[a] *Institute of Pathology, University Medical Center Hamburg-Eppendorf, Germany;* [b] *Martini-Klinik, Prostate Cancer Center, University Medical Center Hamburg-Eppendorf, Germany;* [c] *Department of Urology, Section for translational Prostate Cancer Research, University Medical Center Hamburg-Eppendorf, Germany*



Eur Urol. 2016 Apr;69(4):592-598

Clinical Utility of Quantitative Gleason Grading in Prostate Biopsies and Prostatectomy Specimens

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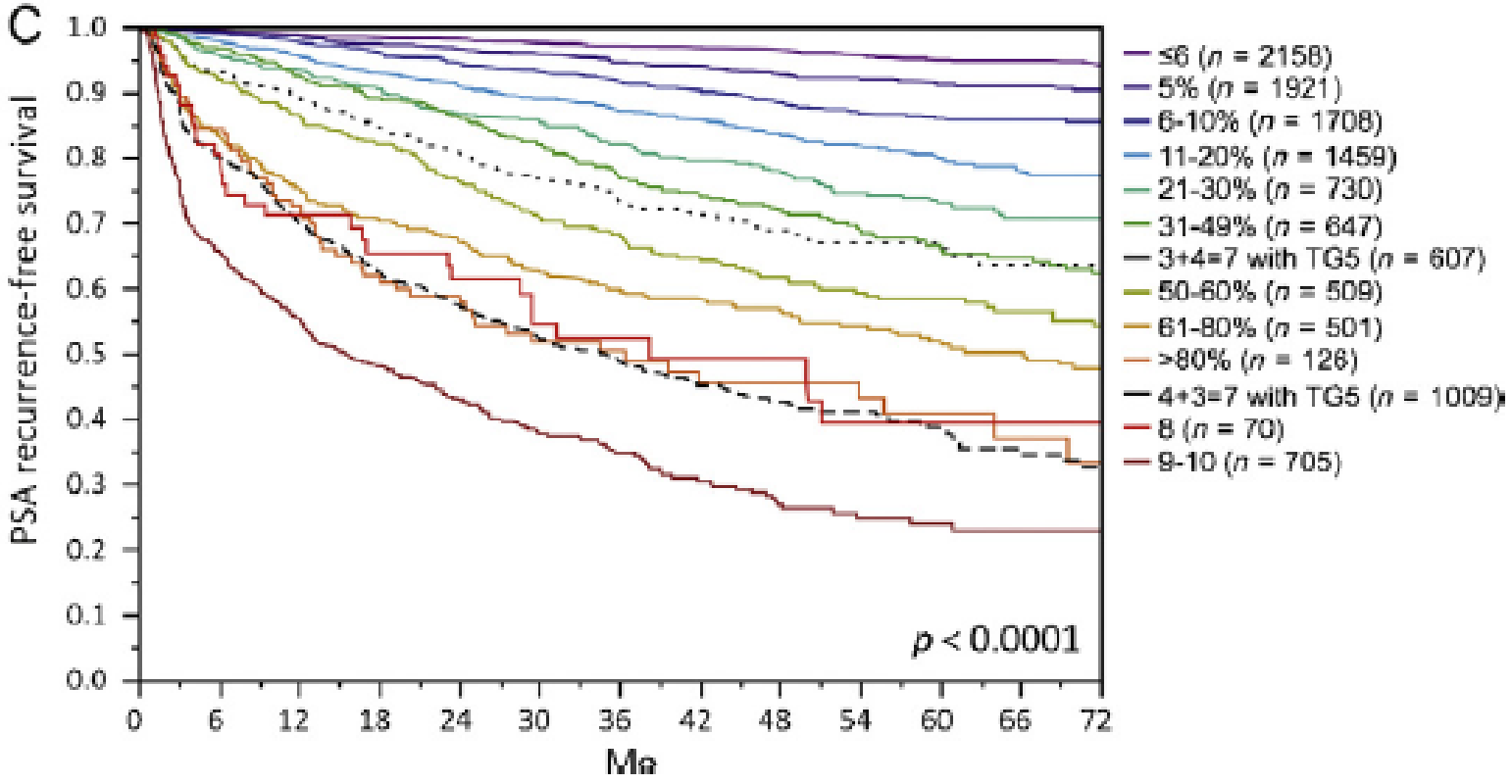


Biopsy to Radical Prostatectomy Pathology

NCCN risk. : ↑34%, ↓12%
Grade group: ↑25%, ↓22%
Upstaging in: 29%

Persistent Discordance in Grade, Stage, and NCCN Risk Stratification in Men Undergoing Targeted Biopsy and Radical Prostatectomy

Mark N. Alshak, Neal Patel, Michael D. Gross, Daniel Margolis, and Jim C. Hu

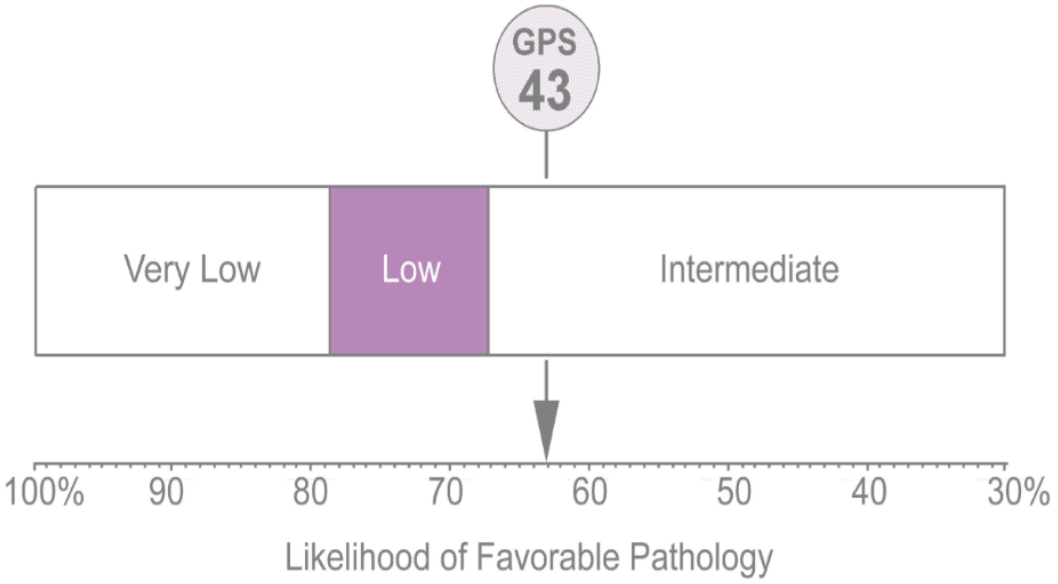
Urology. 2020 Jan;135:117-123

Table 3. Multivariable regression assessing independent clinical characteristics associated with Gleason grade upgrading, upstaging, increase in NCCN risk stratification, decrease in NCCN risk stratification, and downgrading at RP

	Upgrade			Upstage		
	OR	95% CI	*P* value	OR	95% CI	*P* value
Age	1.05	0.98-1.11	0.154	1.04	0.98-1.10	0.216
BMI	1.01	0.90-1.12	0.923	1.04	0.93-1.16	0.510
PSAD*	0.74	0.33-1.64	0.453	3.92	1.60-9.62	0.003
Diameter of Index Lesion	0.71	0.33-1.53	0.379	1.16	0.59-2.29	0.669
PI-RADS**						
4	0.26	0.08-0.81	0.020	0.68	0.21-2.28	0.535
5	0.56	0.14-2.14	0.391	0.83	0.20-3.35	0.789

Genomic Testing, Precision Medicine
Oncotype DX Genomic Prostate Score

Interpretation of GPS for this clinical NCCN LOW risk patient:



Likelihood of Favorable Pathology

63% (95% CI: 51%-73%)

LESS FAVORABLE than by clinical criteria alone. In the expected range of NCCN INTERMEDIATE risk.

more favorable ⟷ **less favorable**

Freedom from High-Grade Disease *(dominant Gleason pattern 4 or any pattern 5):* **72%** (95% CI: 60%-82%)
Freedom from Non-Organ-Confined Disease *(pathologic T3 stage):* **70%** (95% CI: 58%-79%)

A 17-Gene Genomic Prostate Score as a Predictor of Adverse Pathology in Men on Active Surveillance

Zachary Kornberg,* Matthew R. Cooperberg,* Janet E. Cowan, June M. Chan,† Katsuto Shinohara, Jeffry P. Simko, Imelda Tenggara and Peter R. Carroll‡,§

From the Department of Urology, University of California-San Francisco Helen Diller Family Comprehensive Cancer Center (ZK, MRC, JEC, JMC, KS, IT, PRC) and Departments of Epidemiology and Biostatistics (MRC, JMC) and Pathology (JPS), University of California-San Francisco, San Francisco, California

J Urol. 2019 Oct;202(4):702-709

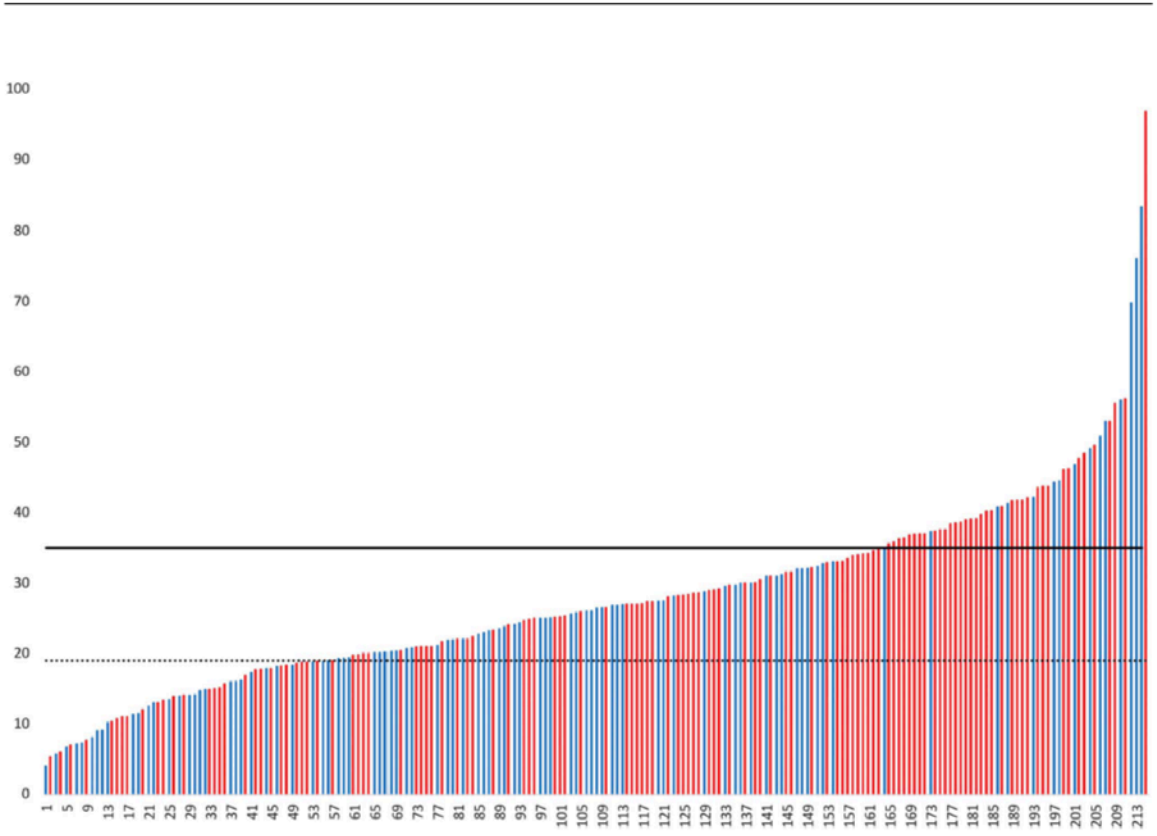


Figure 2. Waterfall plot shows GPS and adverse surgical pathology (red bars) outcome in 215 men enrolled on AS who later underwent delayed RP at UCSF. Blue bars indicate favorable pathology. Dotted horizontal line indicates 25th percentile. Solid horizontal line indicates 75th percentile.

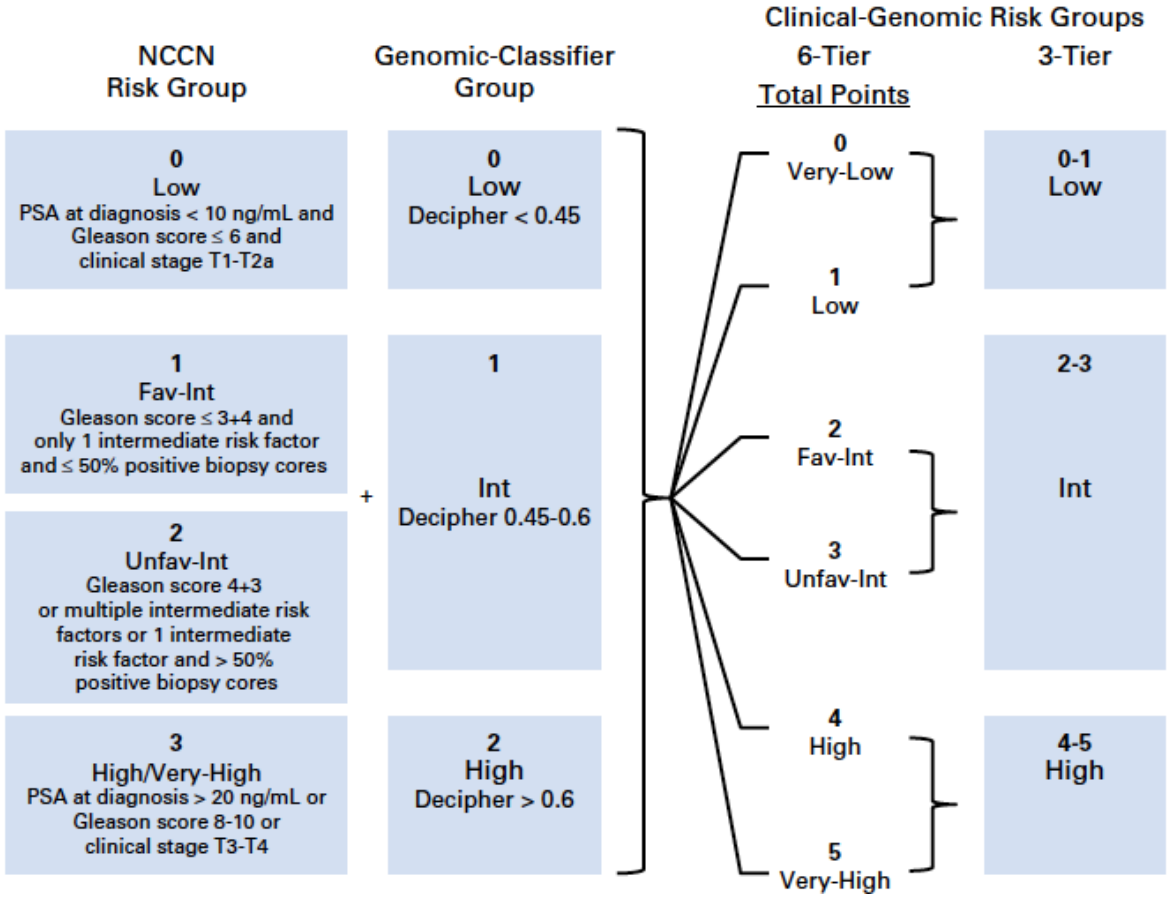
Table 2. *Inverse probability of censoring weighted multivariable Cox proportional hazards regression of GPS on risk of adverse surgical pathology and multivariable Cox proportional hazards regression of GPS on risk of biochemical recurrence after surgery in 215 men on active surveillance who later underwent delayed radical prostatectomy at UCSF*

	Adverse Pathology Risk		Biochemical Recurrence Risk	
	p Value	HR (95% CI)	p Value	HR (95% CI)
GPS/5 units	<0.01	1.16 (1.06–1.26)	0.04	1.10 (1.00–1.21)
At diagnosis:				
Age	<0.01	1.07 (1.03–1.11)	0.41	0.98 (0.94–1.02)
Clinical CAPRA score	0.60	0.92 (0.66–1.27)	0.19	1.29 (0.88–1.90)
Log PSA density at GPS	0.06	1.70 (0.97–2.96)	0.65	0.88 (0.49–1.57)
GPS at confirmatory vs diagnostic biopsy	<0.01	0.53 (0.34–0.82)	0.08	1.80 (0.94–3.45)
Biopsy source (UCSF vs elsewhere)	0.77	0.93 (0.58–1.49)	0.59	0.86 (0.50–1.49)
GPS clinical testing group vs research protocol:				
Lead pathologist	<0.01	2.42 (1.41–4.14)	0.14	0.60 (0.28–1.30)
Other pathologist	—	2.57 (1.45–4.55)	—	0.20 (0.03–1.46)

Development and Validation of a Novel Integrated Clinical-Genomic Risk Group Classification for Localized Prostate Cancer

Daniel E. Spratt, Jingbin Zhang, María Santiago-Jiménez, Robert T. Dess, John W. Davis, Robert B. Den, Adam P. Dicker, Christopher J. Kane, Alan Pollack, Radka Stoyanova, Firas Abdollah, Ashley E. Ross, Adam Cole, Edward Uchio, Josh M. Randall, Hao Nguyen, Shuang G. Zhao, Rohit Mehra, Andrew G. Glass, Lucia L.C. Lam, Jijumon Chelliserry, Marguerite du Plessis, Voleak Choeurng, Maria Aranes, Tyler Kolisnik, Jennifer Margrave, Jason Alter, Jennifer Jordan, Christine Buerki, Kasra Yousefi, Zaid Haddad, Elai Davicioni, Edouard J. Trabulsi, Stacy Loeb, Ashutosh Tewari, Peter R. Carroll, Sheila Weinmann, Edward M. Schaeffer, Eric A. Klein, R. Jeffrey Karnes, Felix Y. Feng, and Paul L. Nguyen

J Clin Oncol 36:581-590.



Integrated Clinical-Genomic Risk Group Classification increases AUC to 0.84, compared to 0.73 for NCCN and 0.74 for CAPRA

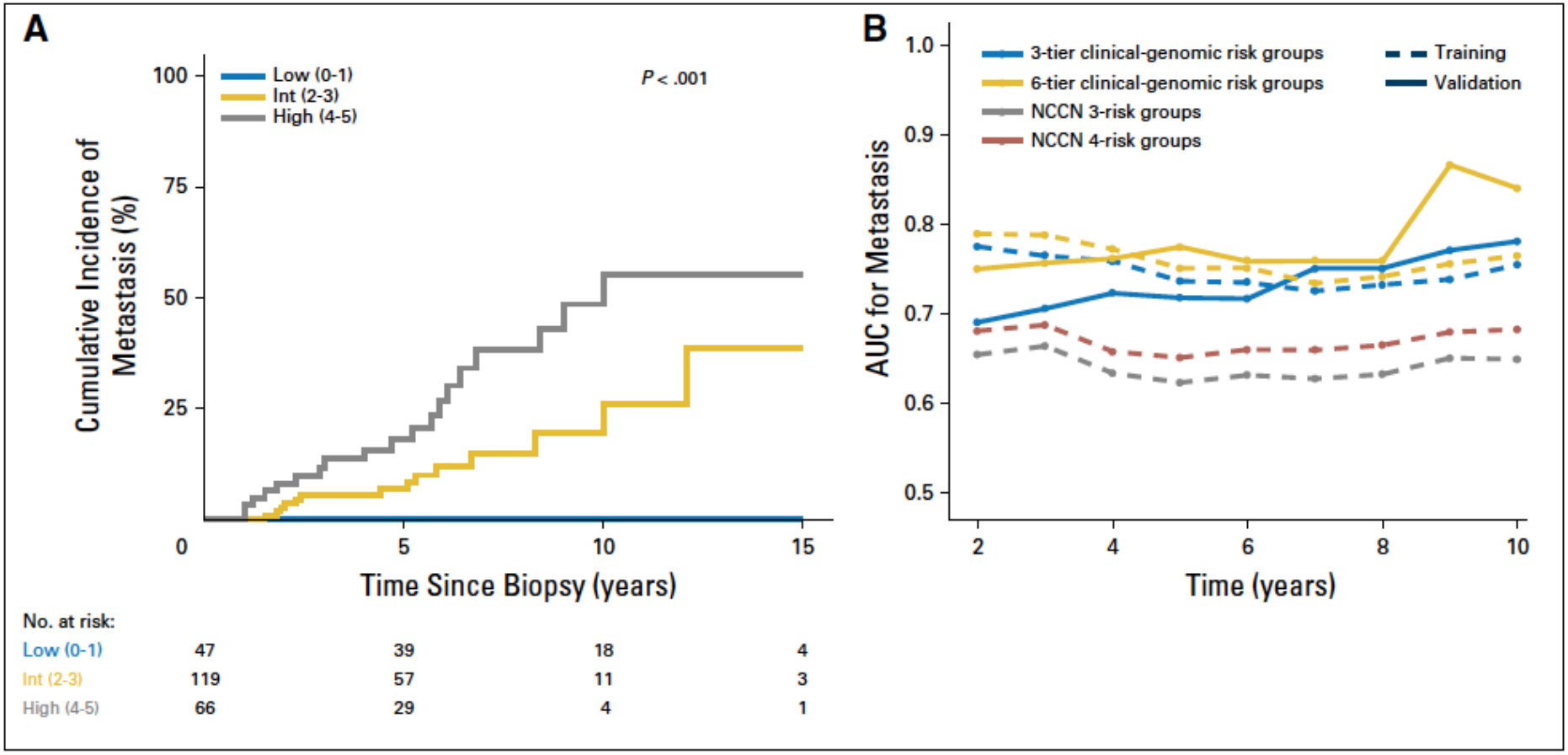


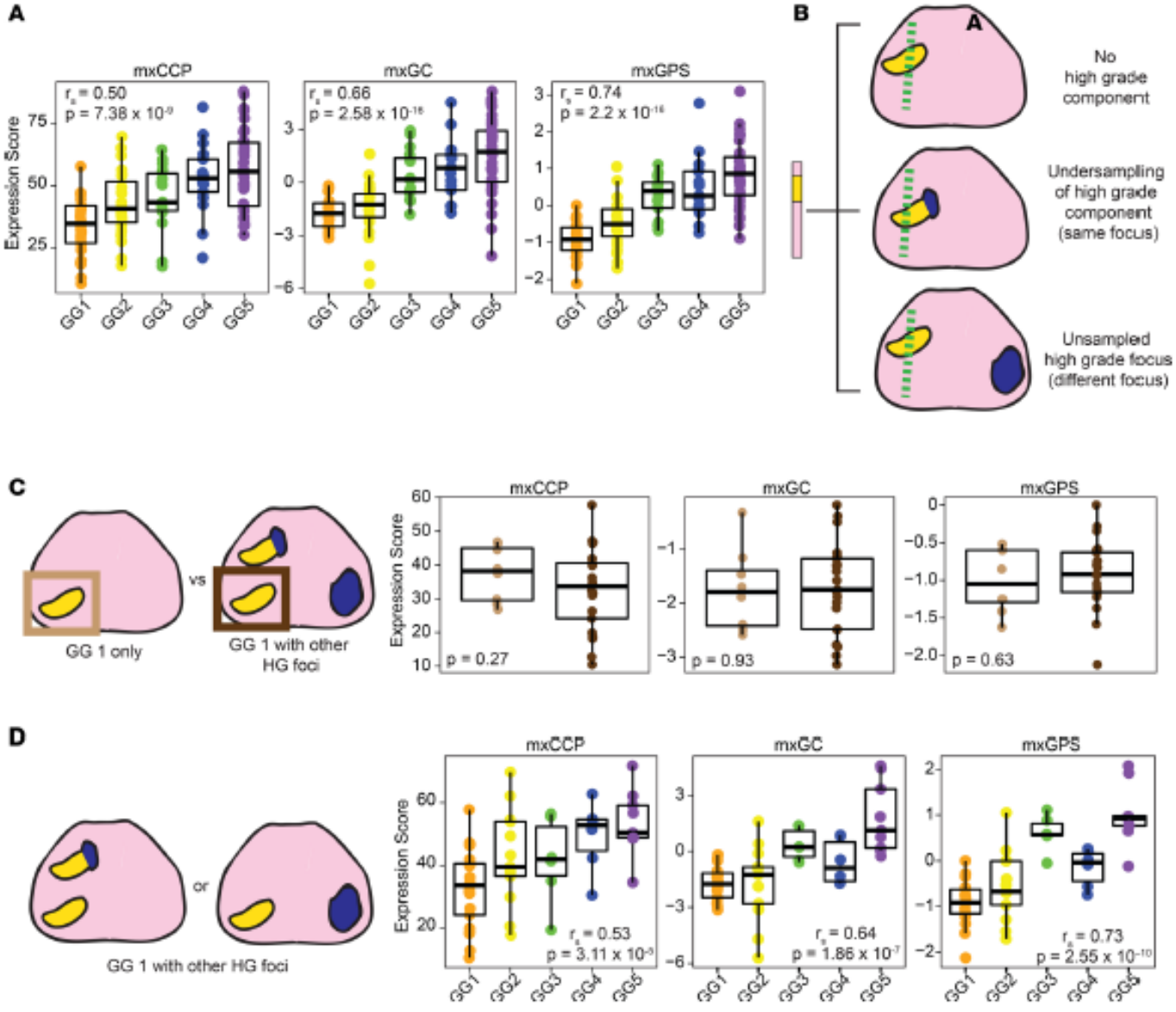
Fig 3. (A) Cumulative incidence curves using the validation cohort for distant metastasis by the clinical-genomic risk groups. (B) Discriminatory analysis of c-indices over time for metastasis of the training and validation cohorts comparing National Comprehensive Cancer Network (NCCN) and clinical-genomic risk groups. AUC, area under the curve.

J Clin Oncol 36:581-590.

Transcriptomic heterogeneity in multifocal prostate cancer

Simpa S. Salami,[1,2] Daniel H. Hovelson,[3] Jeremy B. Kaplan,[3] Romain Mathieu,[4,5] Aaron M. Udager,[3] Nicole E. Curci,[6] Matthew Lee,[1] Komal R. Plouffe,[3] Lorena Lazo de la Vega,[3] Martin Susani,[7] Nathalie Rioux-Leclercq,[8] Daniel E. Spratt,[2,9] Todd M. Morgan,[1,2] Matthew S. Davenport,[1,6] Arul M. Chinnaiyan,[1,2,3,10] Joanna Cyrta,[11] Mark A. Rubin,[11,12] Shahrokh F. Shariat,[4] Scott A. Tomlins,[1,2,3,10] and Ganesh S. Palapattu[1,2,4]

JCI Insight. 2018;3(21):e123468. https://doi.org/10.1172/jci.insight.123468.



Is Prostate Cancer Screening Right for You?

Understanding the Potential Benefits vs. Harms for Men 55–69

Of 1,000

Men Offered PSA-Based Screening

240

Get a Positive PSA Result

which may indicate prostate cancer

Many of these men will learn they have a **false-positive result** after getting a biopsy.

Potential side effects of biopsy:

- Pain
- Bleeding
- Infection

Of those,

100

Get a Positive Biopsy

showing definite cancer

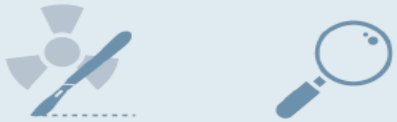
20%–50%

of these men will be diagnosed with cancer that never grows, spreads, or harms them, also known as overdiagnosis.

80*

Choose Surgery or Radiation Treatment

Treatment could be immediate or after a period of active surveillance.*



Erectile dysfunction **50**

Urinary incontinence **15**

Number of men who will experience negative outcomes**

3** Avoid Cancer Spreading to Other Organs

1** Avoids Death From Prostate Cancer***

5** Die From Prostate Cancer Even After Surgery or Treatment

Example of Internet DTCA

The CyberKnife Treatment Advantage

CyberKnife surgery is completely non-invasive and has transformed radiosurgeries of the brain, prostate gland, breast, spine and soft-tissue (lungs, liver, pancreas and kidneys) into painless, bloodless outpatient procedures. Patients who undergo CyberKnife treatment typically resume normal activities soon after the procedure.

With high-tech, cruise-missile-guidance technology and ultra-flexible, computer-controlled robotics, CyberKnife delivers extraordinarily accurate, precisely targeted radiation to tumors throughout the body when radiation therapy is indicated. The beams can be sculpted to reach small, deeply embedded, complex masses, minimizing damage to healthy tissue.

CyberKnife surgery advantages include:

- Treatment for tumors inoperable by conventional surgery or other stereotactic radiosurgery.
- Additional treatment option for tumors that have received maximum allowed radiation.
- Painless, bloodless and non-invasive.
- High-dose radiation delivered accurately.
- Ability to treat multiple tumors at different locations during a single session.
- Healthy tissue unharmed.
- No need for invasive, uncomfortable head frame or skull pins.
- Usually no more than five treatments of 35 minutes each.
- Full-body treatment capability CyberKnife is cleared by the FDA for treatment of tumors and lesions anywhere in the body when radiation therapy is indicated. However, patients should consult their physicians to determine if this treatment approach is right for them.

JAMA Network Open

JAMA Netw Open. 2020;3(2):e1920471

Original Investigation | Urology

Trends in the Use of Stereotactic Body Radiotherapy for Treatment of Prostate Cancer in the United States

Sean S. Mahase, MD; Debra D'Angelo, MS; Josephine Kang, MD, PhD; Jim C. Hu, MD, MPH; Christopher E. Barbieri, MD, PhD; Himanshu Nagar, MD

SBRT most used for lower risk disease

Table 2. Trend of SBRT vs Other RT by Risk Group and Year (2010-2015)

Risk Category	RT Group	Year of Diagnosis, No. (%)						*P* Value[a]
		2010	2011	2012	2013	2014	2015	
Low	SBRT	258 (3.8)	273 (4.3)	270 (6.5)	327 (8.8)	310 (9.0)	363 (12.2)	<.001
	Other	6531 (96.2)	6134 (95.7)	3900 (93.5)	3393 (91.2)	3136 (91.0)	2605 (87.8)	
Intermediate								
Favorable	SBRT	190 (3.6)	246 (4.6)	231 (5.7)	294 (7.0)	348 (7.8)	486 (10.2)	<.001
	Other	5069 (96.4)	5116 (95.4)	3814 (94.3)	3919 (93.0)	4088 (92.2)	4284 (89.8)	
Unfavorable	SBRT	124 (2.9)	141 (3.3)	142 (4.0)	235 (6.3)	257 (6.0)	327 (6.8)	<.001
	Other	4165 (97.1)	4139 (96.7)	3420 (96.0)	3524 (93.8)	4010 (94.0)	4476 (93.2)	
High	SBRT	72 (1.6)	91 (2.0)	90 (2.5)	99 (2.6)	121 (2.6)	100 (2.0)	.046
	Other	4453 (98.4)	4493 (98.0)	3577 (97.6)	3714 (97.4)	4590 (97.4)	4981 (98.0)	
All patients	SBRT	644 (3.1)	751 (3.6)	733 (4.8)	955 (6.2)	1036 (6.1)	1276 (7.2)	<.001
	Other	20 218 (96.9)	19 882 (96.4)	14 711 (95.3)	14 550 (93.8)	15 824 (93.9)	16 346 (92.8)	

Abbreviations: RT, radiation therapy; SBRT, stereotactic body radiation therapy.

[a] Trend analyzed using the Cochran-Armitage test.

AUA-FDA-SUO PARTIAL GLAND ABLATION FOR PROSTATE CANCER WORKSHOP MAY 2015

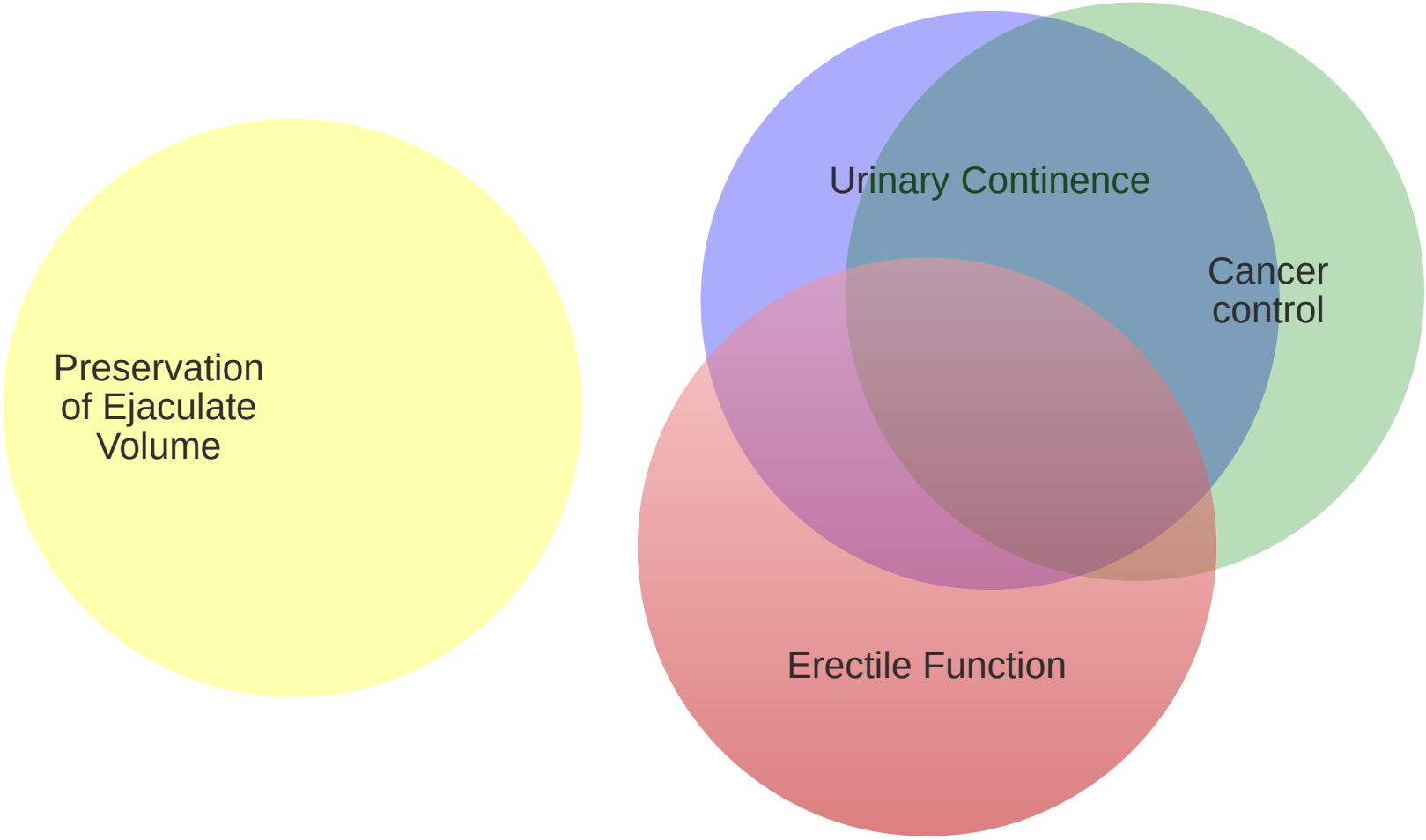
Jim Kiefert: “ablate the cancer cells within the gland and still maintain the safety of your gland, seems like a promise from heaven, something that we would really -- every man would like to have happen….

The guys who have chosen to have active surveillance, many of them really dread the biopsies…

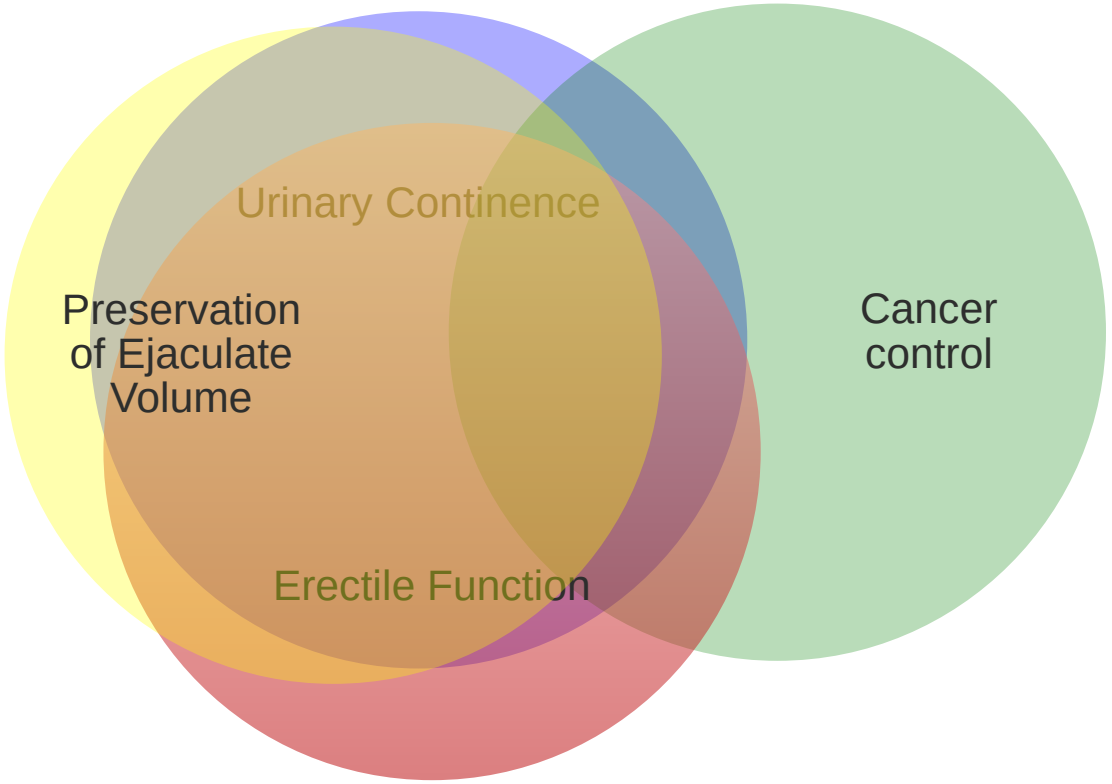
Our hope is that the men with low-risk cancer would say…I would go on active surveillance, but I would much rather have partial ablation than to have the full gland either surgically removed or radiated or frozen….

American Urological Association & U.S. Food & Drug Administration. Public Workshop – American Urological Association-Food and Drug Administration-Society of Urologic Oncology Workshop on Partial Gland Ablation for Prostate Cancer, May 17, 2015.

Optimization of Radical Prostatectomy Outcomes Predicated on Patient Selection



Optimization of Partial Gland Ablation Outcomes Predicated on Patient Selection



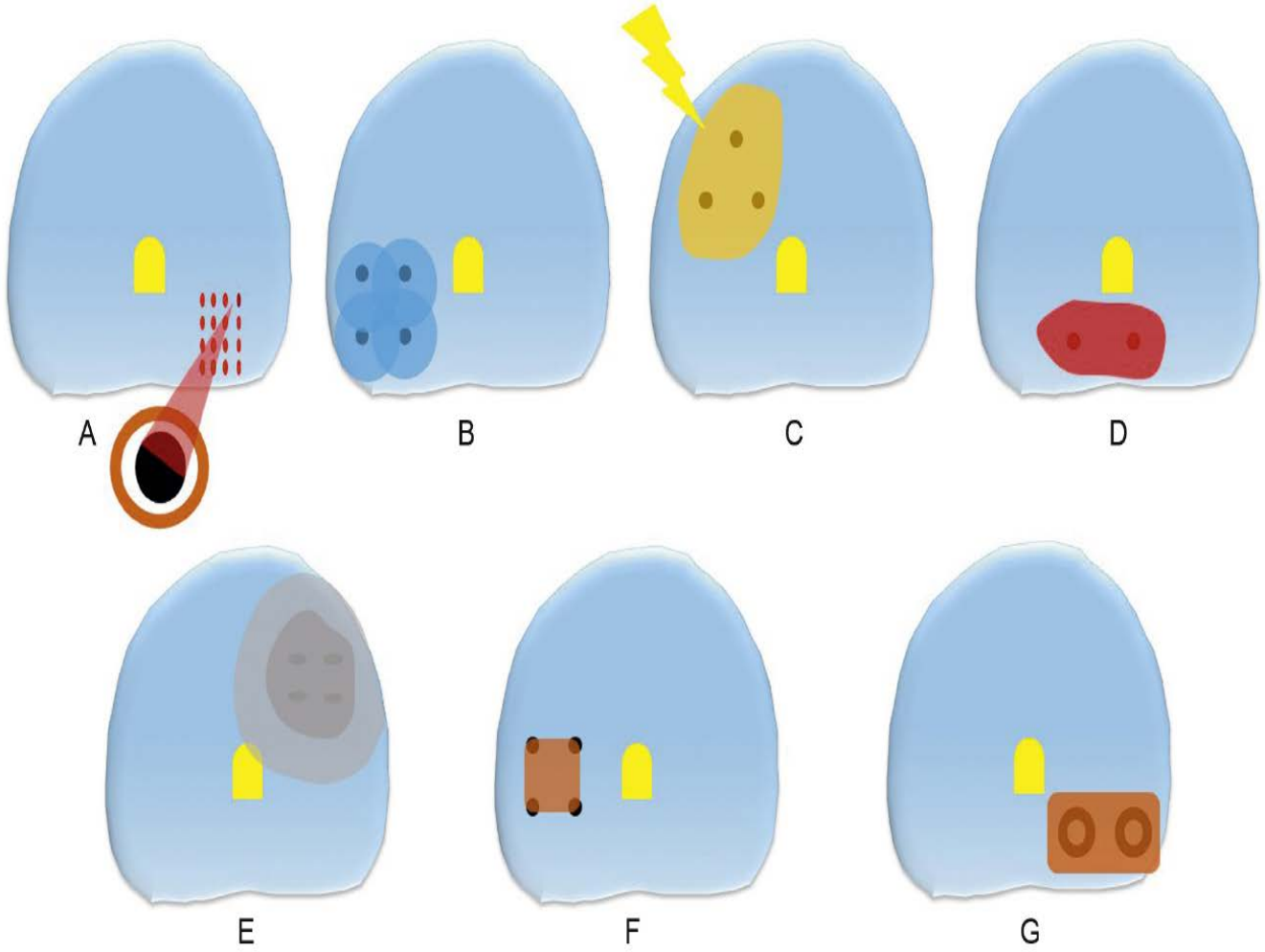


Fig. 2 – Schematic representation of the sources of energy used in actual series: (A) high-intensity focused ultrasound, (B) cryotherapy, (C) photodynamic therapy, (D) laser-induced interstitial thermotherapy, (E) brachytherapy, (F) irreversible electroporation, and (G) radiofrequency ablation.

Valerio M, et al. New and Established Technology in Focal Ablation of the Prostate: A Systematic Review. Eur Urol (2016), http://dx.doi.org/10.1016/j.eururo.2016.08.044

Magnetic Resonance Imaging Underestimation of Prostate Cancer Geometry: Use of Patient Specific Molds to Correlate Images with Whole Mount Pathology

Alan Priester, Shyam Natarajan, Pooria Khoshnoodi, Daniel J. Margolis, Steven S. Raman, Robert E. Reiter, Jiaoti Huang, Warren Grundfest and Leonard S. Marks*

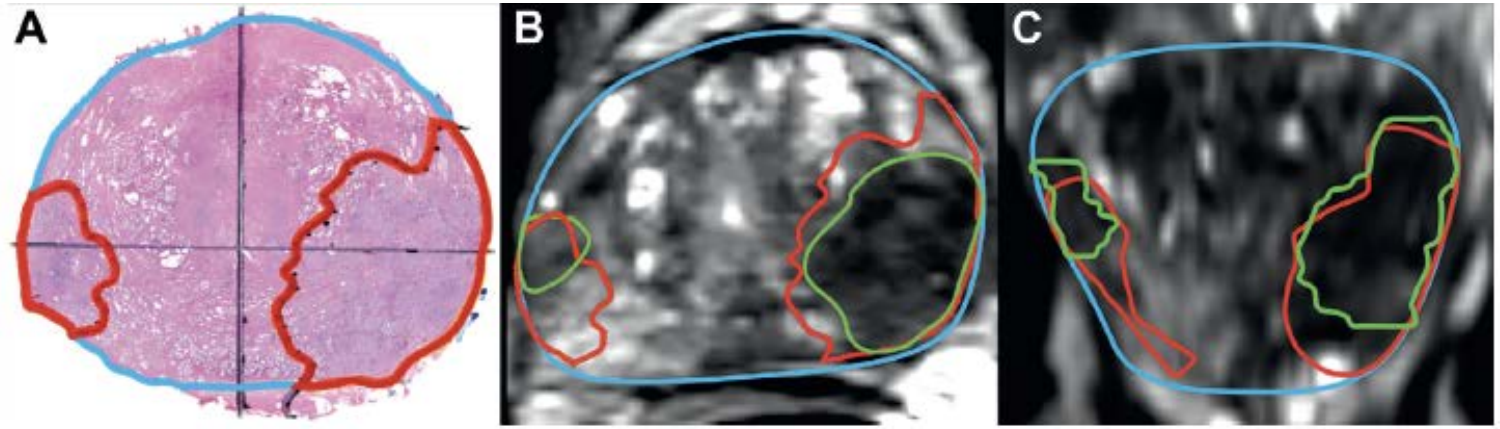


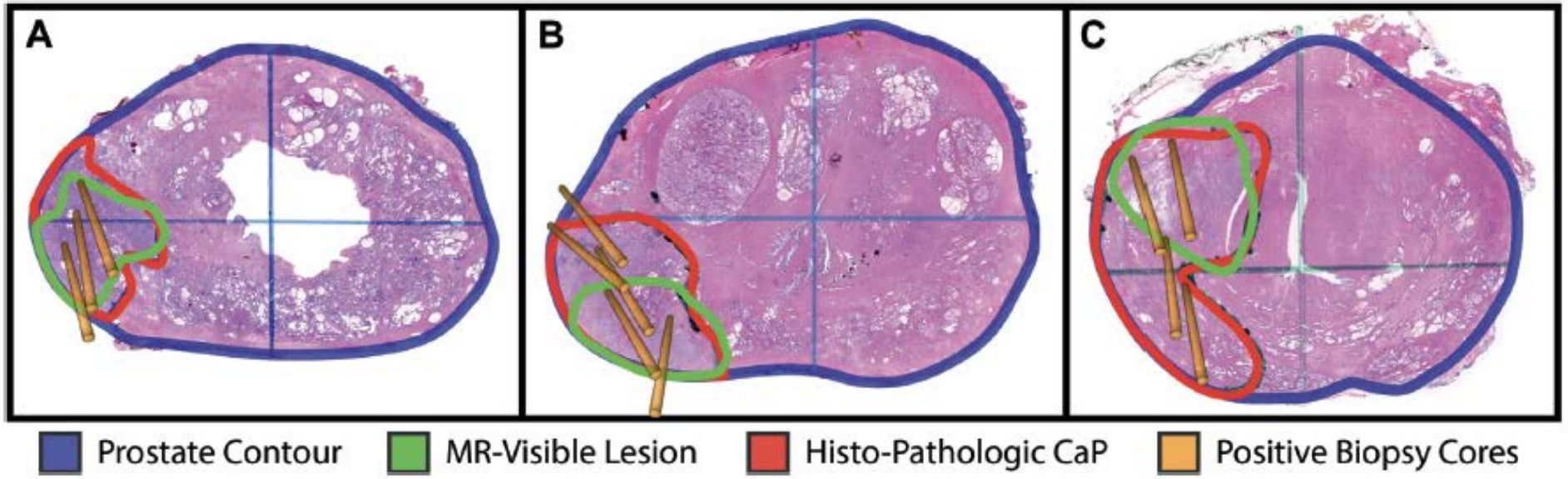
Figure 2. Example of registration of tumors (red outlines) to T2 MRI ROI (green outlines). *A*, whole mount prostate section with 2 tumors delineated. *B*, tumor contours registered to corresponding axial MRI with 2 ROIs. *C*, tumor contours overlaid on coronal MRI. Note underestimation of actual tumor size by ROI.

Priester A, Natarajan S, Khoshnoodi, et al. Magnetic Resonance Imaging Underestimation of Prostate Cancer Geometry: Use of Patient Specific Molds to Correlate Images with Whole Mount Pathology. J Urol. 2017 Feb;197(2):320-326. doi: 10.1016/j.juro.2016.07.084. Epub 2016 Jul 30.

Focal Therapy Eligibility Determined by Magnetic Resonance Imaging/Ultrasound Fusion Biopsy

Nima Nassiri,* Edward Chang,* Patricia Lieu, Alan M. Priester, Daniel J. A. Margolis, Jiaoti Huang, Robert E. Reiter, Frederick J. Dorey, Leonard S. Marks and Shyam Natarajan†

From the Department of Urology, David Geffen School of Medicine (NN, EC, PL, RER, FJD, LSM) and Department of Bioengineering (AMP), University of California-Los Angeles (SN), Los Angeles, California, Department of Radiology, Weill Cornell at New York Presbyterian (DJAM), New York, New York, and Department of Pathology, Duke University School of Medicine (JH), Durham, North Carolina



Using intermediate risk eligibility criteria, 39% of men with a targeted biopsy proven lesion identified on MRI would have been *eligible for focal therapy*. Eligibility determined by *fusion biopsy was concordant with whole mount histology* in 75% of cases. Improved selection criteria are needed to reliably determine focal therapy eligibility

Nassiri N, Chang E, Lieu P, et al. Focal Therapy Eligibility Determined by Magnetic Resonance Imaging/Ultrasound Fusion Biopsy. J Urol. 2018 Feb;199(2):453-458. doi: 10.1016/j.juro.2017.08.085. Epub 2017 Aug 19.

Extensive Histological Sampling following Focal Therapy of Clinically Significant Prostate Cancer with High Intensity Focused Ultrasound

Ashkan Mortezavi, Johanna Krauter, Alexander Gu, Julian Sonderer, Julia Bruhin, Kelly A. Reeve, Leonhard Held, Olivio F. Donati, Niels J. Rupp, Holger Moch, Tullio Sulser and Daniel Eberli*

From the Departments of Urology (AM, JK, AG, JS, JB, TS, DE) and Pathology and Molecular Pathology (NJR, HM) and Institute of Diagnostic and Interventional Radiology (OFD), University Hospital Zurich and Epidemiology, Biostatistics and Prevention Institute (KAR, LH), University of Zurich, Zurich, Switzerland

Table 2. *Histology outcomes in 75 men who qualified for followup biopsy 6 months after focal HIFU*

No. refused biopsy/total No. (%)	7/75	(9.3)
No. TRUS guided mpMRI fusion TTSPB/total No. (%)	68/75	(90.7)
Median No. biopsies (IQR)	44	(36–44)
Clinically significant PCa pos biopsies:		
No./total No. (%)	28/68	(41.2)
Median ng/ml pre-biopsy serum PSA (IQR)	2.09	(1.21–2.93)
No. pre-biopsy mpMRI Likert score 3 or greater/total No. (%)	4/28	(14.3)
Median No. pos cores (IQR)	2	(1–3)
Median mm max Ca core length (IQR)	3	(1–4)
No. post-HIFU Gleason score 3 + 4/total No. (%)	17/28	(60.7)
No. post-HIFU Gleason score 4 + 3/total No. (%)	4/28	(14.3)
No. post-HIFU Gleason score 4 + 4/total No. (%)	7/28	(25.0)
No. untreated area clinically significant PCa (%)	14/28	(50.0)
No. treated area clinically significant PCa (%)	8/28	(28.6)
No. untreated + treated area clinically significant PCa (%)	6/28	(21.4)
No. clinically significant PCa pre-HIFU Gleason score/total No. (%):		
3 + 3	1/5	(20.0)
3 + 4	21/48	(43.8)
4 + 3	6/15	(40.0)

Use of MRI-Guided Biopsy for Selection and Follow-up of Men Undergoing Hemi-gland Cryoablation of Prostate Cancer

Steve R. Zhou, Demetrios N. Simopoulos, Rajiv Jayadevan, Ely R. Felker, Merdie K. Delfin, Danielle E. Barsa, Lorna Kwan, and Leonard S. Marks

OBJECTIVE To investigate safety, efficacy, and quality of life impact of hemi-gland cryotherapy for clinically-significant prostate cancer (CaP), when patient selection and follow-up includes MRI-guided biopsy.

METHODS Twenty-nine men with unilateral CaP (all clinically significant with prostate volume <60 cc) were enrolled in a prospective observational trial of hemi-gland cryotherapy. Mean patient age was 68.7 years. Median prostate-specific antigen (PSA) was 6.6 ng/mL. MRI-guided biopsy (3T-MRI, Artemis US fusion) was used for diagnosis and repeated at 6-month follow-up in all men. Treatment was under general anesthesia using the BTG/Galil system. Validated questionnaires were used to determine effects of treatment on urinary and sexual function and quality of life.

RESULTS Cryotherapy was completed satisfactorily in all 29 cases in <60 minutes with no intraoperative complications. Significant decreases in PSA (median decrease 5.6 ng/mL) and PSA density (median decrease 0.14 ng/mL/cc) were observed ($P < .01$). At 6 months, 23 patients (79%) demonstrated no residual cancer on follow-up MRI-guided biopsy of the treated side. Three patients (10%) revealed micro-residual disease. Three patients (10%) had residual cancer and underwent further treatment. Ipsilateral MRI lesions were present before treatment in 26 patients and after treatment in only 2, reflecting the gross ablative effect; however, MRI showed disappearance of lesions in 4 patients with residual tumor on biopsy. The single complication was 1 case of transient urinary retention; 85% of men who were sexually active continued without change after treatment. Voiding function was unchanged.

CONCLUSION Hemi-gland cryoablation for clinically-significant CaP is well-tolerated, and when patients are selected and followed by MRI/US fusion biopsy, cancer control appears promising at 6 months.
UROLOGY 126: 158–164, 2019.

Zhou SR, Simopoulos DN, Jayadevan R, et al. Use of MRI-Guided Biopsy for Selection and Follow-up of Men Undergoing Hemi-gland Cryoablation of Prostate Cancer. Urology, 2019 Apr;126:158-164. doi: 10.1016/j.urology.2018.11.052. Epub 2019 Jan 16.

6-month IPSI-LATERAL Targeted and Systematic Biopsies Performed, Mean 10 (range 4-16)

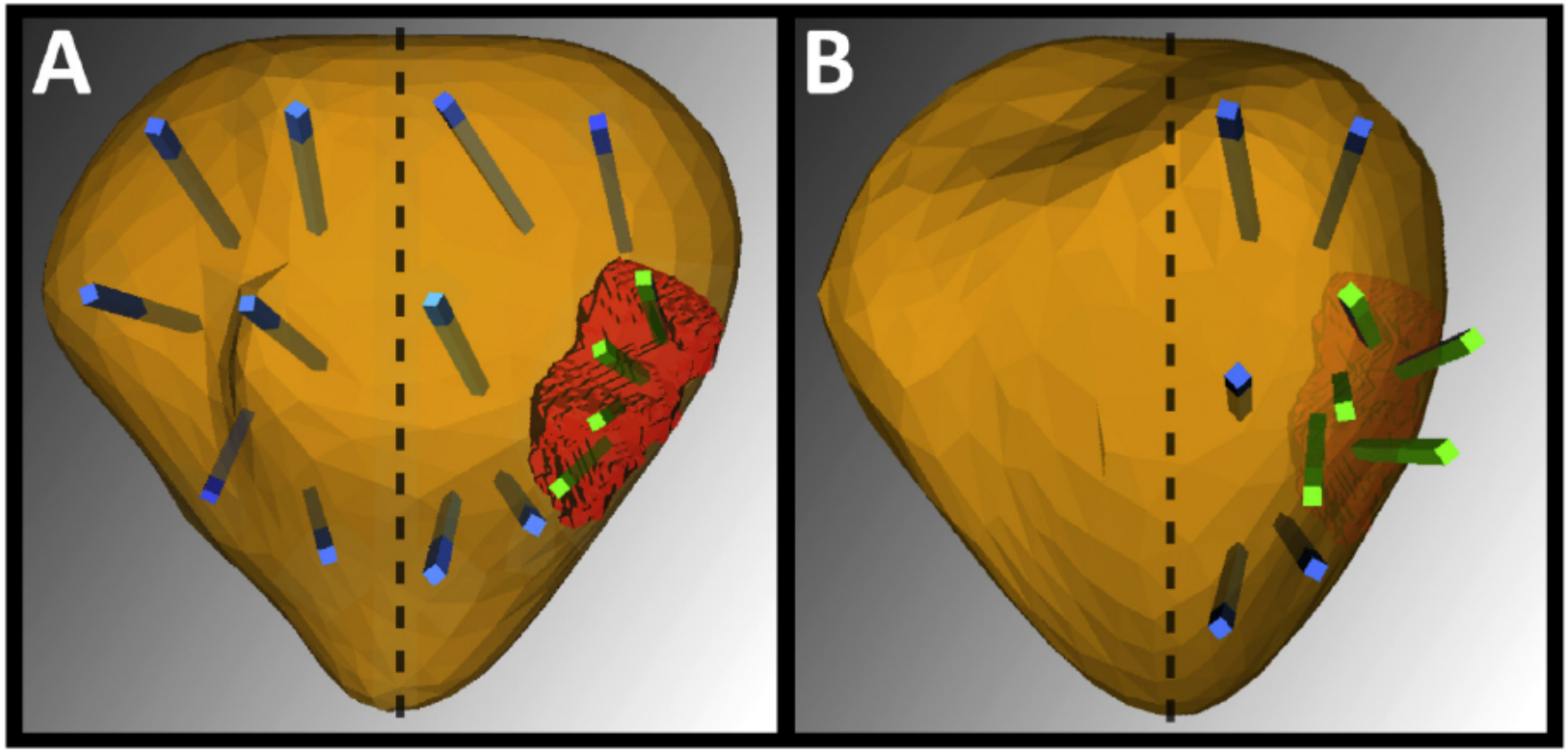


Figure 1. Illustration of biopsy method: (**A**), baseline and (**B**) 6-months after successful hemi-gland ablation. Before treatment (**A**) patient has an MRI-visible lesion on the left (red spot). Targeted cores taken from the lesion (shown in green) were found to contain csCaP. Systematic cores (blue) were found to contain no csCaP outside the lesion, making the patient eligible for focal therapy. After hemi-gland ablation (**B**), biopsy cores are guided by MRI/US fusion tracking to the region of the prior positive spots; the lesion, which was seen previously, has receded. All cores are now negative for cancer, both targeted and systematic ipsilaterally. In this study of hemi-gland ablation, 6-month biopsy samples were taken from the treated side of the prostate (see text).

Zhou SR, Simopoulos DN, Jayadevan R, et al. Use of MRI-Guided Biopsy for Selection and Follow-up of Men Undergoing Hemi-gland Cryoablation of Prostate Cancer. Urology, 2019 Apr;126:158-164. doi: 10.1016/j.urology.2018.11.052. Epub 2019 Jan 16.

Table 2. Individual patient metrics before and after treatment

	Gleason Score		PI-RADS v2 Grade		PSA (ng/mL)			Prostate Volume (cc)		PSAD (ng/mL/cc)	
Patient ID	Baseline	6 MO	Baseline	6 MO	Baseline	3 MO	6 MO	Baseline	6 Months	Baseline	6 Months
1-VC	4 + 4	Benign	Negative	Negative	7.2	–	1.1	‡	23	–	0.05
2-DW	4 + 4	Benign	5	Negative	3.8	1.0	1.0	53	26	0.07	0.04
3-AS	4 + 4	Benign	5	Negative	12.3	3.9	3.1	58	42	0.21	0.07
4-DC	4 + 3	Benign	5	Negative	6.2	0.7	1.0	23	20	0.27	0.05
5-DJ	4 + 3	Benign	5	Negative	17.0	0.9	0.3	50	36	0.34	0.01
6-SM	4 + 3	Benign	5	Negative	9.8	0.7	1.2	31	17	0.32	0.07
7-EA	4 + 3	Benign	4	Negative	10.3	1.0	1.3	21	20	0.49	0.07
8-DL	3 + 4	Benign	Negative	Negative	15.7	2.9	3.3	25	17	0.64	0.19
9-BV	3 + 4	Benign	Negative	Negative	6.7	0.7	0.7	31	25	0.22	0.03
10-MW	3 + 4	Benign	5	Negative	5.9	0.3	0.3	24	14	0.25	0.02
11-GB	3 + 4	Benign	5	Negative	6.5	-	2.4	40	26	0.16	0.09
12-SS	3 + 4	Benign	5	Negative	2.4	0.2	0.3	19	16	0.13	0.02
13-JP	3 + 4	Benign	5	Negative	10.3	0.6	0.9	40	22	0.26	0.04
14-AN	3 + 4	Benign	4	Negative	11.8	3.9	5.2	66	59	0.18	0.09
15-RT	3 + 4	Benign	4	Negative	6.4		4.5	44	28	0.15	0.16
16-AS	3 + 4	Benign	4	Negative	4.9		2.1	40	27	0.12	0.08
17-MW	3 + 4	Benign	4	Negative	6.6		0.9	33	23	0.20	0.04
18-WT	3 + 4	Benign	3	Negative	7.9		1.7	50	31	0.16	0.06
19-JB	3 + 4	Benign	3	Negative	1.4		0.6	29	21	0.05	0.03
20-RG	3 + 4	Benign	3	Negative	5.2		1.3	50	44	0.10	0.03
21-PW	3 + 4	Benign	4	Negative	4.1		1.8	38	23	0.11	0.08
22-PB	3 + 4	Benign	4	3	4.6		1.7	24	31	0.19	0.06
23-LM	3 + 3	Benign	5	Negative	8.2		5.8	52	34	0.16	0.17
24-GD	4 + 4	3 + 4*	5	Negative	14.4		4.8	55	44	0.26	0.11
25-JS	3 + 4	3 + 4*	4	Negative	4.7		1.7	31	24	0.15	0.07
26-KL	3 + 3	3 + 3*	5	5	8.3		1.5	28	22	0.30	0.07
27-BV	4 + 3	3 + 4†	5	–	5.5		1.4	59	–	0.09	–
28-PM	3 + 4	3 + 4†	5	Negative	6.0		2.0	27	15	0.22	0.13
29-DL	3 + 4	3 + 4†	5	Negative	13.2		5.0	37	26	0.36	0.19

PSA, prostate-specific antigen; PSAD, prostate-specific antigen density.
* Micro-residual or clinically-insignificant cancer on follow-up biopsy.
† Follow-up biopsy positive for csCaP.
‡ Dash indicates missing data.

6/29 (21%) had persistent disease

Zhou SR, Simopoulos DN, Jayadevan R, et al. Use of MRI-Guided Biopsy for Selection and Follow-up of Men Undergoing Hemi-gland Cryoablation of Prostate Cancer. Urology, 2019 Apr;126:158-164. doi: 10.1016/j.urology.2018.11.052. Epub 2019 Jan 16.

Prostate Multiparametric Magnetic Resonance Imaging Features Following Partial Gland Cryoablation

Bashir Al Hussein Al Awamlh, Daniel J. Margolis, Michael D. Gross, Shyam Natarajan, Alan Priester, Stefanie Hectors, Xilu Ma, Juan Miguel Mosquera, Joseph Liao, and Jim C. Hu

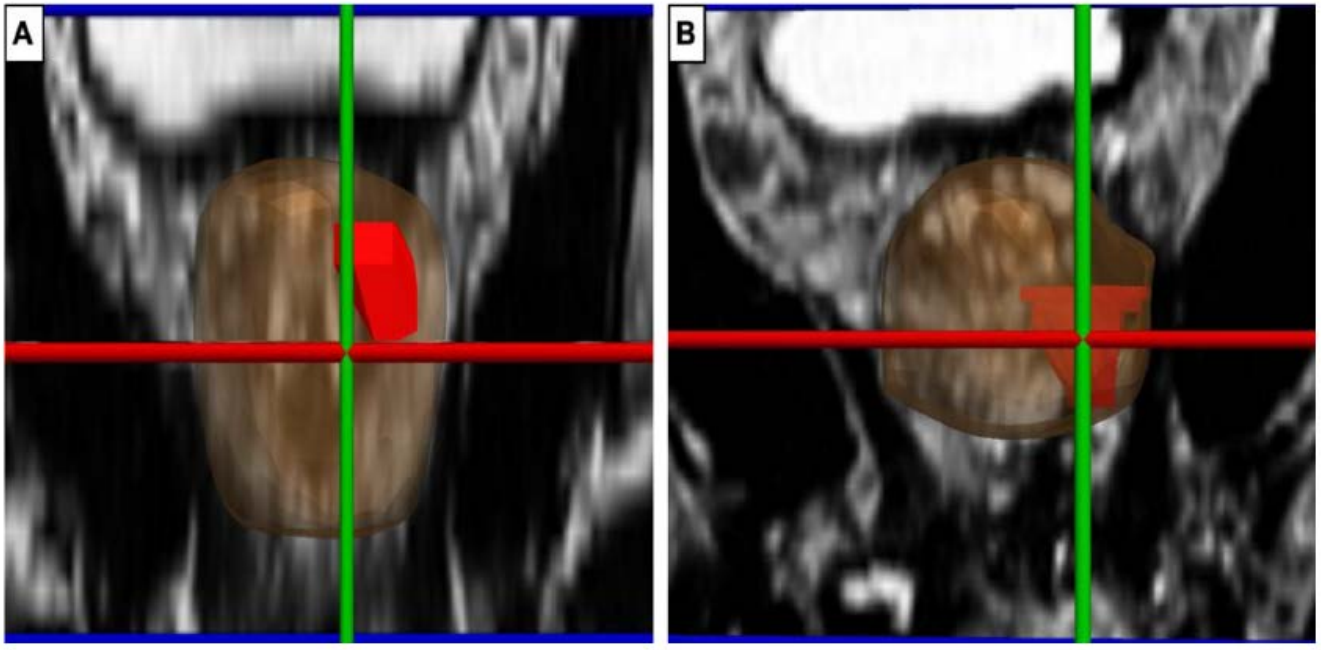


Figure 1. Pre- and post-treatment multiparametric MRI reformatted images of the prostate and region of interest. The figure shows reformatted (**A**) pretreatment (gland size 43 mL) and (**B**) post-treatment (gland size 28 mL) T2 multiparametric MRI coronal images for subject 4. The red is the target (region of interest) and the brown is the prostate. The cross hairs in the 2 images show the center of the image as acquired. In reference to the prostate, the bladder lies superiorly and the obturator muscles (which are black) laterally. (Color version available online.)

Al Hussein Al Awamlh B, Margolis DJ, Gross MD, et al. Prostate Multiparametric Magnetic Resonance Imaging Features Following Partial Gland Cryoablation. Urology, 2020 Jan 15. pii: S0090-4295(20)30022-4. doi: 10.1016/j.urology.2020.01.005.

Table 2. Post-treatment mpMRI and pathologic characteristics of the treated regions of interest

	mpMRI Features of Treated ROI			Pathologic Features of Treated ROI				
Subject	PI-RADS	ROI Changes	Treatment Response	Grade Group	Volume Reduction (mm)	Treatment Effect in Targeted Cores*	Adjacent Systematic Grade Group	Treatment Effect in Adjacent Systematic Cores*
1	5	Persistent focal enhancement	Viable	1	−10.5 (80%)	Present	1	Present
2	2	Nonenhancement	Nonviable	1	−7 (78%)	Present	2	Absent
3	2	Resolution of restricted diffusion and enhancement	Nonviable	-	-	Present	-	Present
4	2	Hypointensity without abnormal enhancement	Nonviable	-	-	Present	-	Present
5	3	Decrease in restricted diffusion	Equivocal	2	−3 (60%)	Present	-	Present
6	2	Not identified	Nonviable	-	-	Present	4	Present
7	3	Signal abnormality with nonfocal enhancement	Equivocal	2	−3 (27%)	Absent	2	Present
8	2	T2-hypointensity with mildly restricted diffusion and increased perfusion	Equivocal	2	−9 (60%)	Absent	1	Absent
9	2	Markedly decreased T2 signal and hypointensity on DWI	Nonviable	-	-	Present	-	Present
10	2	T2 hypointensity and parenchymal loss, no restricted diffusion or enhancement	Nonviable	-	-	Present	1	Present

* Fibrosis, Hemosiderin-laden pigment.

Al Hussein Al Awamlh B, Margolis DJ, Gross MD, et al. Prostate Multiparametric Magnetic Resonance Imaging Features Following Partial Gland Cryoablation. Urology, 2020 Jan 15. pii: S0090-4295(20)30022-4. doi: 10.1016/j.urology.2020.01.005.

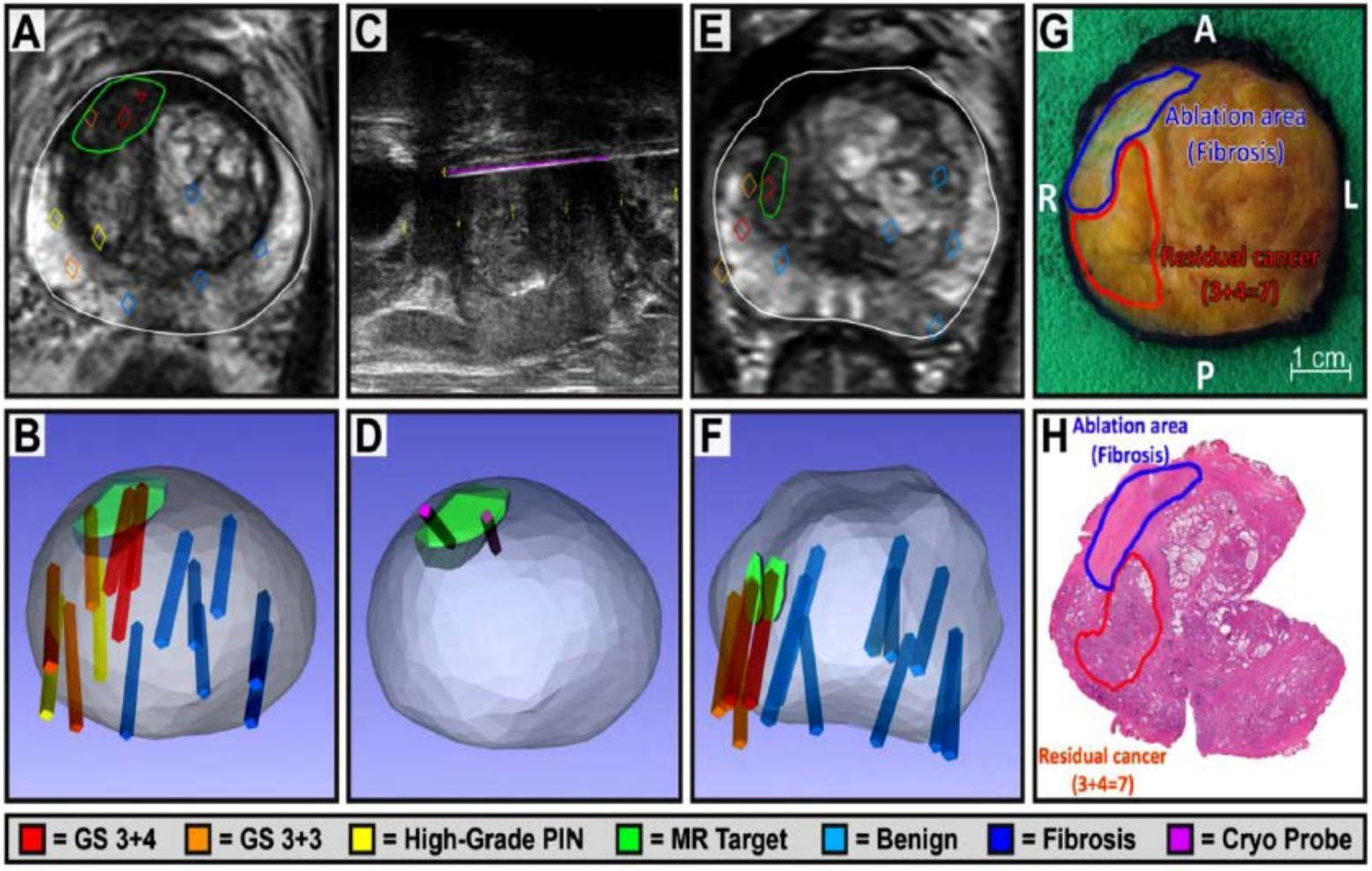


Figure 2. Imaging and pathology before, during, and after partial gland ablation with cryotherapy for subject 8. **(A-B)** Fusion biopsy prior to cryoablation, seen on T2 mpMRI (top) and 3D model (bottom). **(C-D)** Cryoablation probe location during focal therapy, seen on real-time ultrasound (top) and 3D model (bottom). **(E-F)** Fusion biopsy of residual MRI target following cryoablation, seen on T2 mpMRI (top) and 3D model (bottom). **(G-H)** Fibrosis and residual disease on gross radical prostatectomy specimen and whole mount prostate histology. (Color version available online.)

Al Hussein Al Awamlh B, Margolis DJ, Gross MD, et al. Prostate Multiparametric Magnetic Resonance Imaging Features Following Partial Gland Cryoablation. Urology, 2020 Jan 15. pii: S0090-4295(20)30022-4. doi: 10.1016/j.urology.2020.01.005.

Developing Studies for Prostate Ablation Related Energy Devices (SPARED)

Science, Infrastructure, and Coordinating

Weill Cornell Medicine

Meetings to Date:

July 22, 2016
September 25, 2017
May 3, 2018
July 10, 2018
May 3, 2019
July 16, 2019

1-U01-FD-005478-01

Courtesy of *Michael Gorin*

Development of a Nationally Representative Coordinated Registry Network for Prostate Ablation Technologies

Ron Golan, Adrien Bernstein, Art Sedrakyan, Timothy J. Daskivich, Dongyi T. Du, Behfar Ehdaie, Benjamin Fisher, Michael A. Gorin, Ivan Grunberger, Bradley Hunt, Hongying H. Jiang, Hyung L. Kim, Danica Marinac-Dabic, Leonard S. Marks, Timothy D. McClure, Jeffrey S. Montgomery, Dipen J. Parekh, Sanoj Punnen, Stephen Scionti, Charles J. Viviano, John T. Wei, Sven Wenske, James S. Wysock, John Rewcastle,* Mark Carol,† Marc Oczachowski‡ and Jim C. Hu§

From the Departments of Urology, New York Presbyterian-Weill Cornell Medical College (RG, AB, TDM, JCH), New York Presbyterian-Columbia University Medical Center (SW) and New York University Langone Medical Center (JSW), Department of Healthcare Policy and Research, Weill Cornell Medical College (AS) and Urology Service, Memorial Sloan Kettering Cancer Center (BE), New York and Division of Urology, New York Presbyterian-Brooklyn Methodist Hospital (IG), Brooklyn, New York, Division of Urology, Cedars Sinai Medical Center (TJD, HLK) and Departments of Urology, University of California-Los Angeles (LSM) and University of Southern California (JR), Los Angeles, California, Center for Devices and Radiological Health, United States Food and Drug Administration (DTD, BF, BH, HHJ, DM-D, CJV), Silver Spring and Department of Urology, Johns Hopkins University School of Medicine (MAG), Baltimore, Maryland, Department of Urology, University of Michigan (JSM, JTW), Ann Arbor, Michigan, Department of Urology, University of Miami (DJP, SP), Miami and Vituro Health (SS), Sarasota, Florida, SonaCare Medical (MC), Charlotte, North Carolina, and EDAP-TMS (MO), Vaulx-en-Velin, France

J Urol. 2018 Jun;199(6):1488-1493. doi: 10.1016/j.juro.2017.12.058.

SPARED Collaboration: Patient Selection for Partial Gland Ablation in Men with Localized Prostate Cancer

Michael D. Gross, Art Sedrakyan, Fernando J. Bianco,* Peter R. Carroll, Timothy J. Daskivich,† Scott E. Eggener,‡ Behfar Ehdaie, Benjamin Fisher, Michael A. Gorin, Bradley Hunt, Hongying Jiang, Eric A. Klein, Danica Marinac-Dabic, Jeffrey S. Montgomery, Thomas J. Polascik,§ Alan M. Priester,‖ Ardeshir R. Rastinehad, Charles J. Viviano, James S. Wysock and Jim C. Hu¶

From the Department of Urology, New York Presbyterian-Weill Cornell Medical College (MDG, JCH), Department of Healthcare Policy and Research, Weill Cornell Medical College, (AS), Urology Service, Department of Surgery, Memorial Sloan Kettering Cancer Center (BE), Department of Interventional Radiology, Mount Sinai Health System (ARR) and Department of Urology, New York University Langone Medical Center (JSW), New York, New York, Urological Research Network (FJB), Miami Lakes, Florida, Department of Urology, University of California-San Francisco (PRC), San Francisco and Division of Urology, Cedars Sinai Medical Center (TJD) and Department of Bioengineering, University of California-Los Angeles (AMP), Los Angeles, California, Section of Urology, Department of Surgery, University of Chicago Medical Center (SEE), Chicago, Illinois, Center for Devices and Radiological Health, United States Food and Drug Administration (BF, BH, HJ, DM-D, CJV), Silver Spring and Department of Urology, Johns Hopkins University School of Medicine (MAG), Baltimore, Maryland, Department of Urology, Glickman Urology and Kidney Institute, Cleveland Clinic (EAK), Cleveland, Ohio, Department of Urology, University of Michigan (JSM), Michigan, and Duke Cancer Institute, Duke Medical Center (TJP), Durham North Carolina

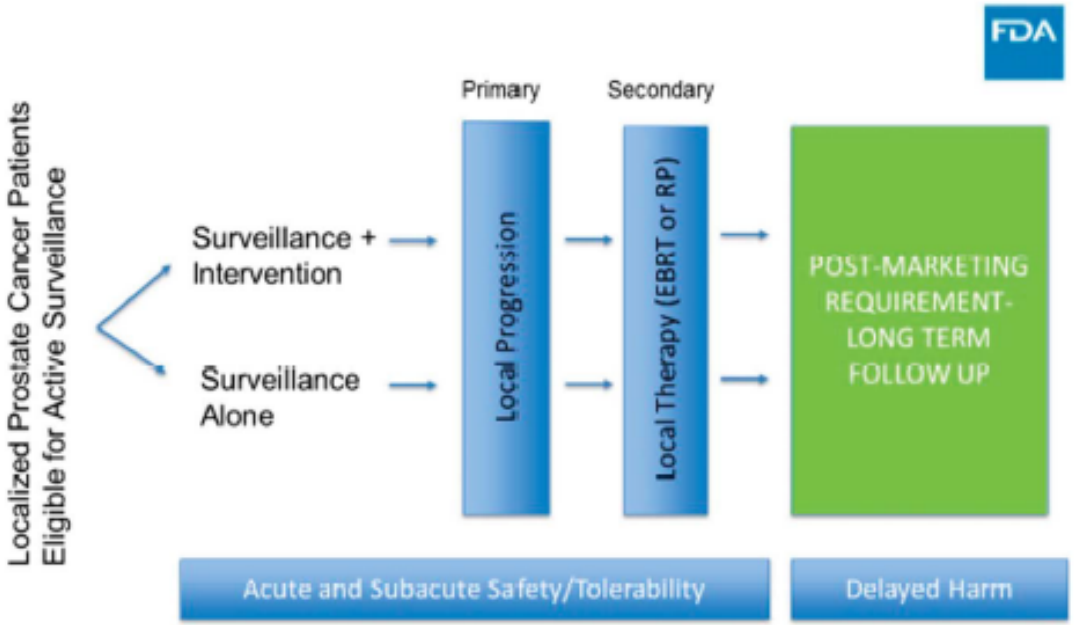
J Urol. 2019 Nov;202(5):952-958. doi: 10.1097/JU.0000000000000357.

Development of Treatments for Localized Prostate Cancer in Patients Eligible for Active Surveillance: U.S. Food and Drug Administration Oncology Center of Excellence Public Workshop

Chana Weinstock,* Daniel Suzman, Paul Kluetz, John Baxley, Charles Viviano, Amna Ibrahim, Jonathan Jarow, Raejshwari Sridhara, Ke Liu, Peter Carroll,† Scott Eggener, Jim C. Hu, Maha Hussain, Martin King, Eric Klein, Terry Kungel, Danil Makarov, Peter A. Pinto, Brian Rini, Mack Roach, Howard Sandler, Peter N. Schlegel, Daniel Song, Kirsten Goldberg, Richard Pazdur and Julia A. Beaver

From the United States Food and Drug Administration (CW, DSu, PK, JB, CV, AI, JJ, RS, KL, KG, RP, JAB), Silver Spring, The Johns Hopkins Medical Institutions (DSo), Baltimore and National Cancer Institute (PAP), Bethesda, Maryland, University of California-San Francisco Helen Diller Comprehensive Cancer Center (PC, MR), San Francisco and Cedars-Sinai Medical Center (HS), Los Angeles, California, University of Chicago Medicine (SE) and Robert H. Lurie Comprehensive Cancer Center Northwestern University Feinberg School of Medicine (MH), Chicago, Illinois, Weill Cornell Medicine (JCH), New York University School of Medicine (DM) and New York Presbyterian/Weill Cornell Medical Center (PNS), New York, New York, Maine Coalition to Fight Prostate Cancer (TK), Augusta, Maine, Dana Farber Cancer Institute, Harvard Medical Center (MK). Boston. Massachusetts. and Cleveland Clinic (EK. BR). Cleveland. Ohio

0022-5347/20/2031-0115/0
THE JOURNAL OF UROLOGY®
https://doi.org/10.1097/JU.0000000000000532
Vol. 203, 115-119, January 2020



Trial design example shows how patients would be randomized to AS vs AS plus focal intervention and follow standard biopsy and clinical followup surveillance. Objective pathological and clinical progression criteria would be established to support primary end point. Key secondary end point would be reduction in number of patients who proceed to curative external beam radiation therapy (*EBRT*) or radical prostatectomy (*RP*). Safety and tolerability would be measured throughout and continue into postmarketing requirement followup.

Can we deliver randomized trials of focal therapy in prostate cancer?

Hashim U. Ahmed, Viktor Berge, David Bottomley, William Cross, Rakesh Heer, Richard Kaplan, Tom Leslie, Chris Parker, Clare Relton, Richard Stephens, Matthew R. Sydes, Lindsay Turnbull, Jan van der Meulen, Andrew Vickers, Timothy Wilt, Mark Emberton and the Prostate Cancer RCT Consensus Group

Ahmed, H. U. *et al. Nat. Rev. Clin. Oncol.* **11**, 482–491 (2014); published online 22 April 2014; corrected online 12 September 2017; doi:10.1038/nrclinonc.2014.44

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Prostate Cancer Comparative Outcomes of New Conceptual Paradigms for Treatment (PC CONCEPT)

Project Details

Principal Investigator

Jim C. Hu, MD, MPH, and Ronald C. Chen, MD, MPH

Project Status

Awarded; Contract pending

Board Approval Date

November 2019

Project End Date

April 2023

Organization

Joan & Sanford I. Weill Medical College of Cornell University

Year Awarded

2019

State

New York

Project Type

Research Project

Health Conditions

Cancer
Prostate Cancer

Intervention Strategies

Device Interventions
Other Clinical Interventions

Funding Announcement

Assessment of Prevention, Diagnosis, and Treatment Options

Project Budget *

$3,411,846





Is Prostate Cancer Screening Right for You?

Understanding the Potential Benefits vs. Harms for Men 55–69

Of 1,000

Men Offered PSA-Based Screening

240

Get a Positive PSA Result

which may indicate prostate cancer

Many of these men will learn they have a **false-positive result** after getting a biopsy.

Potential side effects of biopsy:

- Pain
- Bleeding
- Infection

Of those,

100

Get a Positive Biopsy

showing definite cancer

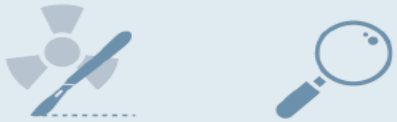
20%–50%

of these men will be diagnosed with cancer that never grows, spreads, or harms them, also known as overdiagnosis.

80*

Choose Surgery or Radiation Treatment

Treatment could be immediate or after a period of active surveillance.*



Erectile dysfunction **50**

Urinary incontinence **15**

Number of men who will experience negative outcomes**

3** Avoid Cancer Spreading to Other Organs

1** Avoids Death From Prostate Cancer***

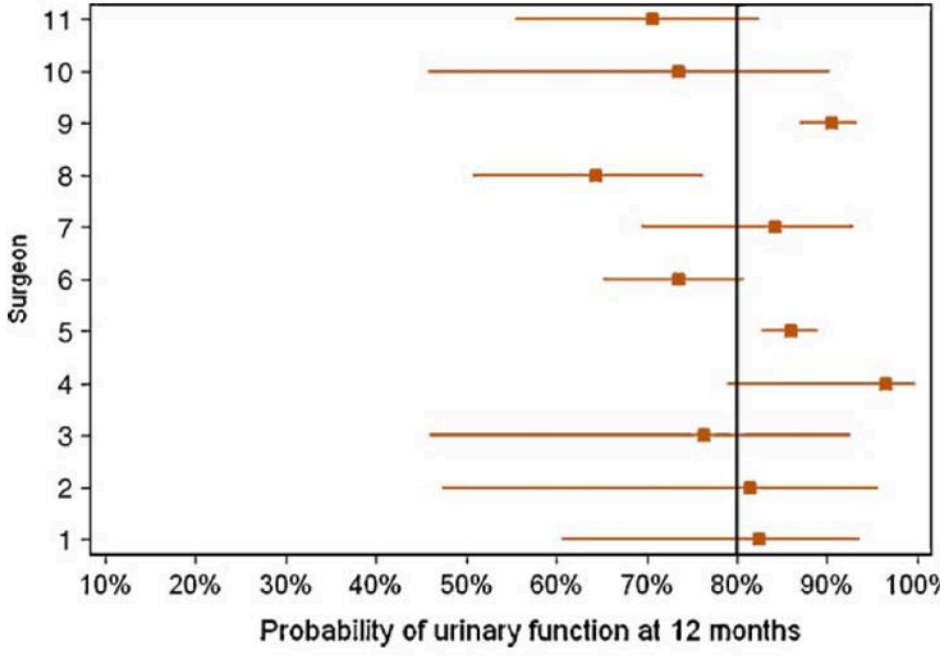
5** Die From Prostate Cancer Even After Surgery or Treatment

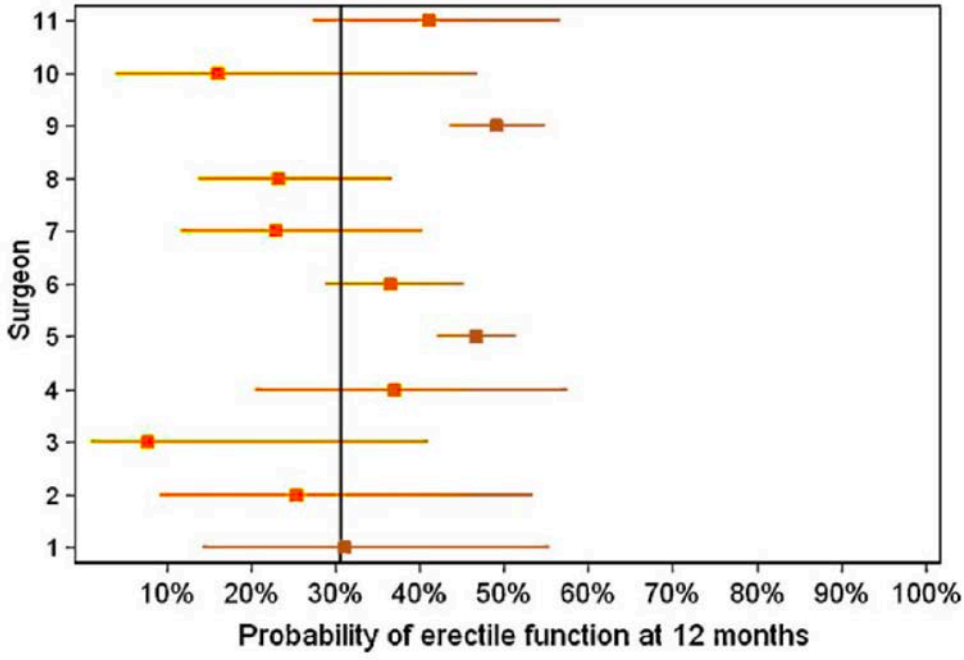
Cancer Control and Functional Outcomes After Radical Prostatectomy as Markers of Surgical Quality: Analysis of Heterogeneity Between Surgeons at a Single Cancer Center

Andrew Vickers[a,*], *Caroline Savage*[a], *Fernando Bianco*[b], *John Mulhall*[c], *Jaspreet Sandhu*[c], *Bertrand Guillonneau*[c], *Angel Cronin*[d], *Peter Scardino*[c]

[a] *Department of Surgery and Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center, New York, NY, USA*
[b] *Columbia University Division of Urology at Mount Sinai Medical Center, New York, NY, USA*
[c] *Department of Surgery and Department of Urology, Memorial Sloan-Kettering Cancer Center, New York, NY, USA*
[d] *Department of Medical Oncology, Dana-Farber Cancer Institute, Boston, MA, USA*

EUROPEAN UROLOGY 59 (2011) 317–322





Surgery in Motion

Anatomic Bladder Neck Preservation During Robotic-Assisted Laparoscopic Radical Prostatectomy: Description of Technique and Outcomes

Marcos P. Freire[a], Aaron C. Weinberg[a], Yin Lei[a], Jane R. Soukup[b], Stuart R. Lipsitz[b], Sandip M. Prasad[a], Fernando Korkes[d], Tiffany Lin[a], Jim C. Hu[a,b,c,]*

Surgery in Motion

The Impact of Prostate Size, Median Lobe, and Prior Benign Prostatic Hyperplasia Intervention on Robot-Assisted Laparoscopic Prostatectomy: Technique and Outcomes

Andy C. Huang[a,1], Keith J. Kowalczyk[a,1], Nathanael D. Hevelone[b], Stuart R. Lipsitz[b], Hua-yin Yu[a], Blakely A. Plaster[a], Channa A. Amarasekara[a], William D. Ulmer[a], Yin Lei[a], Stephen B. Williams[a], Jim C. Hu[a,b,]*

Surgery in Motion

Athermal Division and Selective Suture Ligation of the Dorsal Vein Complex During Robot-Assisted Laparoscopic Radical Prostatectomy: Description of Technique and Outcomes

Yin Lei[a,1], Mehrdad Alemozaffar[a,1], Stephen B. Williams[a], Nathanael Hevelone[b], Stuart R. Lipsitz[b,c], Blakely A. Plaster[a], Channa A. Amarasekera[c], William D. Ulmer[c], Andy C. Huang[a], Keith J. Kowalczyk[a], Jim C. Hu[a,b,c,]*

Surgery in Motion

Randomized Controlled Trial of Barbed Polyglyconate Versus Polyglactin Suture for Robot-Assisted Laparoscopic Prostatectomy Anastomosis: Technique and Outcomes

Stephen B. Williams[a,1], Mehrdad Alemozaffar[a,1], Yin Lei[a], Nathanael Hevelone[b], Stuart R. Lipsitz[b], Blakely A. Plaster[a], Jim C. Hu[a,b,]*

Technique and outcomes of bladder neck intussusception during robot-assisted laparoscopic prostatectomy: A parallel comparative trial

Hung-Jui Tan, M.D.[a,b], Siwei Xiong, M.D.[b], Aaron A. Laviana, M.D.[b], Ryan J. Chuang, B.S.[b], Eric Treat, M.D.[b], Patrick C. Walsh, M.D.[c], Jim C. Hu, M.D., M.P.H.[b,d,*]

Surgery in Motion

Technical Refinement and Learning Curve for Attenuating Neurapraxia and Improving Sexual Function Outcome During Robot-Assisted Radical Prostatectomy

M. Alemozaffar[a], A. Duclos[b], N.D. Hevelone[b], S.R. Lipsitz[b], T. Borza[a], H.Y. Yu[a], K.J. Kowalczyk[c], J.C. Hu[d,]*

Surgery in Motion

Posterior, Anterior, and Periurethral Surgical Reconstruction of Urinary Continence Mechanisms in Robot-assisted Radical Prostatectomy: A Description and Video Compilation of Commonly Performed Surgical Techniques

André N. Vis[a,], Henk G. van der Poel[b], Annebeth E.C. Ruiter[a], Jim C. Hu[c], Ashutosh K. Tewari[d], Bernardo Rocco[e], Vipul R. Patel[f], Sanjay Razdan[g], Jakko A. Nieuwenhuijzen[a]*

Stepwise Description and Outcomes of Bladder Neck Sparing During Robot-Assisted Laparoscopic Radical Prostatectomy

David F. Friedlander, Mehrdad Alemozaffar, Nathanael D. Hevelone, Stuart R. Lipsitz and Jim C. Hu*

Surgery in Motion

Stepwise Approach for Nerve Sparing Without Countertraction During Robot-Assisted Radical Prostatectomy: Technique and Outcomes

Keith J. Kowalczyk[a], Andy C. Huang[a], Nathanael D. Hevelone[b], Stuart R. Lipsitz[b], Hua-yin Yu[a], William D. Ulmer[a], Joshua R. Kaplan[a], Sunil Patel[a], Paul L. Nguyen[c], Jim C. Hu[a,b,]*

Can we deliver randomized trials of focal therapy in prostate cancer?

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Value (Outcomes/Cost) Based Care

VIEWPOINT

Jim C. Hu, MD, MPH
Department of Urology, Weill Cornell Medicine, New York, New York.

Aaron Lavlana, MD
Department of Urology, David Geffen School of Medicine at UCLA, Los Angeles, California.

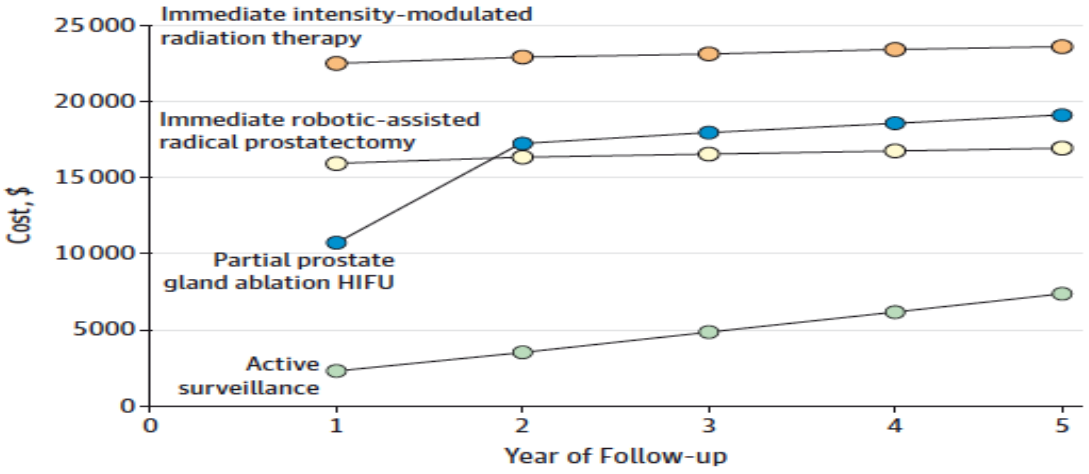
Art Sedrakyan, MD, PhD
Department of Healthcare Policy and Research, Weill Cornell Medicine, New York, New York.

INNOVATIONS IN HEALTH CARE DELIVERY

High-Intensity Focused Ultrasound for Prostate Cancer
Novelty or Innovation?

JAMA June 28, 2016 Volume 315, Number 24

Figure. Examples of Estimated Comparative Costs of High-Intensity Focused Ultrasound Partial Gland Ablation



Costs modeled assuming 50% failure and progression and crossover to definitive therapy with intensity-modulated radiotherapy, through 5 years of follow-up. Costs for active surveillance and high-intensity focused ultrasound (HIFU) include preoperative multiparametric magnetic resonance imaging (mp-MRI) followed by annual mp-MRI and repeat biopsy as well as biannual prostate-specific antigen (PSA) testing and office visits. Biannual PSA testing and office visits are also modeled in surgery and radiotherapy costs.

Conclusions

- Elevated PSA - prostate MRI to assess risk
- TREXIT – shift to transperineal biopsy
- Precision medicine and MRI as biomarkers to improve risk stratification
- Increased use of SBRT (fewer fractions)
- Challenges of partial gland ablation
    - Patient selection
    - Follow-up endpoints
- Challenges to conduct a RCT for part gland abl.