

BrachyNext



Working Together to Shape the Future of
Brachytherapy

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Brachytherapy

Challenges in Advancing Your Prostate Practice

Chairs: André-Guy Martin, Yasuo
Yoshioka, Mitchell Kamrava

Challenges Session B2



Session F2

Challenges in Advancing Your Prostate Practice

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GammaWest Cancer Services
Salt Lake City, Utah

Special thanks: C. Leland Rogers, M.D., Partner



Disclosures

John K. Hayes, Jr, MS, MD, has received consulting fees for the Elekta Advisory Board and has contracted research for Elekta.



Session F2: Challenges in Advancing Your Prostate Practice

Tasking: Are we going in the right direction? Expectations of a better cure and survival gain with brachytherapy (dose escalation)

**John K. Hayes, M.D., M.S.
GammaWest Cancer Services
Salt Lake City, Utah**



Challenges, Utah

Right direction to find and treat prostate cancer?

- Utah incidence: 176 cases/100,000
- U.S. average: 147 cases/100,000
- Cancer Deaths Utah Men:
 - Lung/bronchus 17.4%
 - Prostate 14.8%
 - Colon/rectum 8.4%
 - Pancreas 7.2%

Mortality

Lung/Pr Kentucky = 4.1

Lung/Pr Utah = 1.2



Challenges, PSA Screening Right Direction?

- PSA screening has lead to 1.3 M new diagnoses since 1986 and “only 56,000 deaths were averted.”¹ - Scott Hensley, NPR
- Benefits of PSA screening “are still open to question. There are some proven harms associated with screening. Screening, for example, leads to unnecessary treatment in some men who are diagnosed with localized disease.”² - Otis Brawley, CMO of ACS
- “The American Cancer Society does *not* recommend routine screening for prostate cancer, and has not since 1997.”³ - J. Leonard Litchenfield (ACS Deputy Chief Medical Officer) October 28, 2010

With friends like these who needs enemies?

NB: Most of the men diagnosed in the Göteborg study had early stage disease

1. Scott Hensley, Study: prostate cancer test leads to overtreatment. Shots, Health Blog National Public Radio. http://www.npr.org/blogs/health/2009/08/screening_for_prostate_cancer.html

2. Otis Brawley (CMO of ACS) <http://getbetterhealth.com/psa-screening-not-recommended-ny-daily-times-still-doesnt-care/2010.06.21>.

3. J. Leonard Litchenfield (Deputy CMO of ACS). ACS Dr. Len's Cancer Blog, Oct 8, 2010 <http://www.cancer.org/AboutUs/DrLensBlog/post/2010/10/28/Does-PSA-Testing-Really-Reduce-The-Risk-Of-Prostate-Cancer-Recurrence.aspx>.



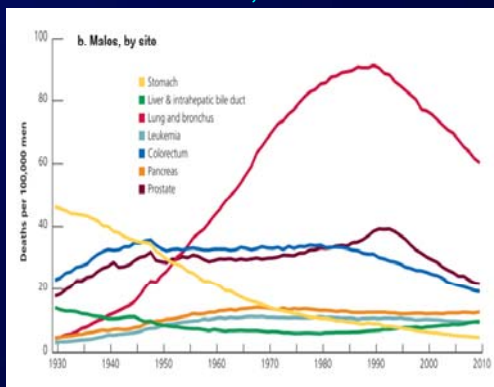
Challenges, Screening Right Direction?

“Cancer death rates have been continuously declining for the past 2 decades. Overall the risk of dying from cancer decreased by 20% between 1991 and 2010.”

“Death rates from prostate cancer are down by 45% as a result of improvements in early detection and treatment.”

“Progress has been most rapid among middle aged black men, among whom death rates have declined by approximately 50%.”

Death Rates Among Males for Selected Cancers
United States, 1930 to 2009

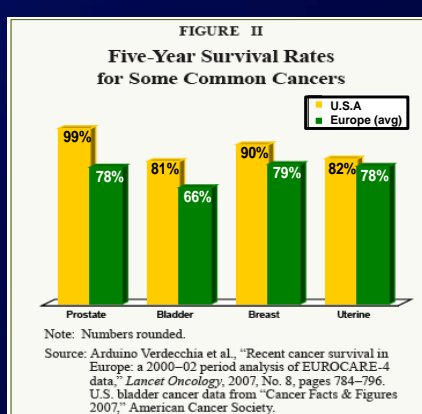
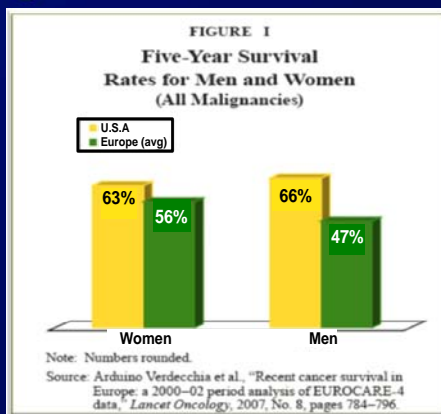


Rates age adjusted to the 2000 US std population. Due to changes in ICD coding, numerator info has changed over time. Rates for lung and bronchus, colorectum, liver, uterus, cervix, and ovary are affected

Siegel R, Ma J, Zou Z, Jemal A. Cancer Statistics, 2014. *CA CANCER J CLIN* 2014



Challenges, Right Direction? Better 5y Overall Survival USA vs Europe



Early detection and treatment?
A. Verdecchia, Istituto Superiore di Sanita



Challenges-Screening Right Direction?

- Utah SEER Data 2007-2011

Prostate cancer diagnosis by Gleason Score

Gleason <=6 45.7%

Gleason 7 37.4%

Gleason 8-10 12.6%

Unknown 4.2%

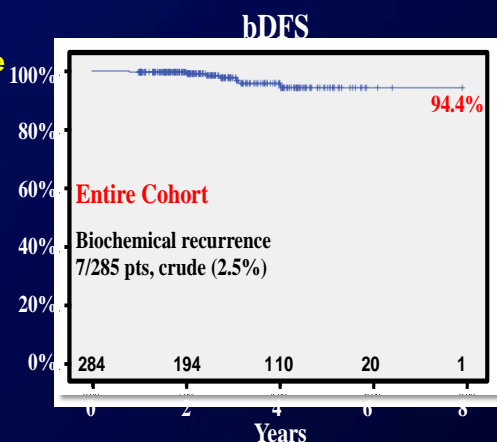
Gleason 7-10 = 50.0%!



Challenges- Screening HDR Monotherapy Intermediate-Risk CaPr

If HDR Monotherapy can cure
19 out of 20 men with
Intermediate risk CaPr, and
if 50% of new diagnoses are
Gleason 7-10 in Utah, does it
make sense to stop
PSA screening?

Right Direction?





Challenges, Toxicity

- The USPSTF downgrading of PSA Screening was a statement on toxicity related to surgery and to external beam radiation.
- As an HDR user, both monotherapy and as boost, FU clinics are in large part toxicity free.
- How does one convince a skeptical world that HDR brachytherapy is a solution to what is going to be a big public health problem in the next decade?



Challenges to HDR Program?

Not urinary toxicity!

Side Effects: IPSS Scores

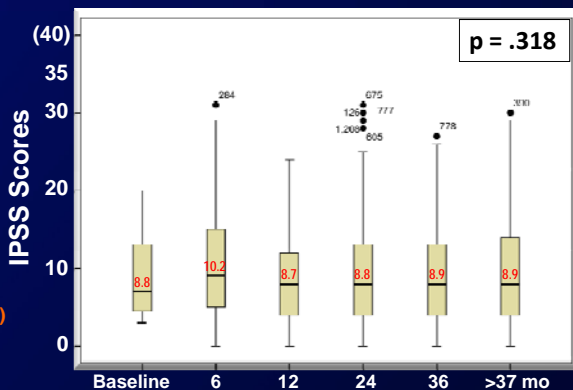
n = 284

Mean FU: 35.2 mo
(range 12.1-96.1)

Age: 70.2 yr (47-85)

PSA: 8.4 (1.0-19.7)

Box & Whiskers:
Box interquartile range (25-75%)
Line in the box is the median
Bottom of box 25th percentile
Top of Box is 75%



p = .318

If no dots: Top whisker highest in range. Bottom whisker is the lowest value.
If there are dots: whiskers only allowed to be as long as 1.5x length of box.
Dots are any values that lie outside of that, i.e. are outliers

Mean IPSS scores



Challenges, toxicity, HDR Monotherapy Not Urinary Incontinence

Side Effects: Incontinence (Pads)

New pad usage 22/284 (7.7%)

7 had TURP before HDR-MT (1 to 4 TURPs)

10 tremor, 2 stroke, and 1 had diffuse neuropathy

Grade 1	Grade 2	Grade 3	Grade 4
15 (68%)	5 (23%) [†]	2 (9%) [‡]	0

[†] 4 of 5 had TURP or tremor

[‡] 1 had 3 TURPs, the other 2 TURPs + tremor

7/284 (2.5%) with no TURP or neurologic compromise: 6 Gr 1, 1 Gr 2

Urinary Pad Grading Scale

Grade 0: none

Grade 1: occasional use of pads

Grade 2: ≤ daily intermittent use of pads

Grade 3: < 2 pads/day, regular use of pads, self cath

Grade 4: Refractory, permanent catheter

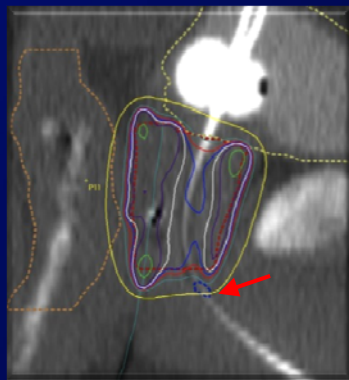


Challenges, Toxicity, HDR Monotherapy with rigorous dosing guidelines?

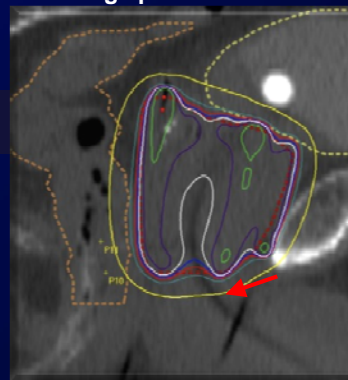
Side Effects

Bulbo-membranous Urethral Stricture

Small Prostate 15cc



Large prostate 100 cc



150%
120%
110%
105%
100%
60%



Challenges for HDR Program Sexual Dysfunction?

Side Effects: Erectile Function (IIEF-5)

Defining potency as IIEF-5 >10 (with or without aid), 67.9% were potent prior to HDR-MT. Of these **82.6%** maintained potency at 2y

Mean decrease in IIEF-5 score **6.1**

Erectile aid used by **9.2%** before vs **95.7%** after HDR-MT typically PDE-5 inhibitors alone

This result is similar to Vicini *et al*¹, who used 46Gy EBRT + HDRB, 5 Gy x 3 or 8.25-10.5 Gy x 2. With median f/u 2.8 y, potency was preserved in 73%.

1. Vicini FA, Kestin LL, Martinez AA. Use of conformal high-dose rate brachytherapy for management of patients with prostate cancer: optimizing dose escalation. *Tech Urol* 2000;6(2):135-145



Challenges to HDR Brachytherapy Program, Rectal Toxicity?

RTOG Grade 1 toxicity occurred in 12 patients (**4.2%**)
None experienced rectal toxicity beyond grade 1

ORGAN/ TISSUE	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
SMALL/LARGE INTESTINE	None	Mild diarrhea Mild cramping BM 5 times daily Slight rectal d/c or bleeding	Moderate diarrhea and colic BM >5 times daily Excessive mucus or intermittent bleeding	Obstruction or bleeding requiring surgery	Necrosis Perforation Fistula

97.9% of patients remain Hemocult® negative

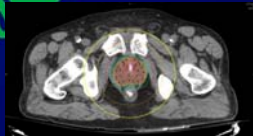
No patient required GI intervention for an HDR side effect

Rogers CL, Alder SC, Rogers RL, Hopkins SA, Platt, ML, Childs LC, Crouch RH, Hansen RS, Hayes JK. High Dose Brachytherapy as Monotherapy for Intermediate Risk Prostate Cancer. *J Urol* 2012; 187:109-116

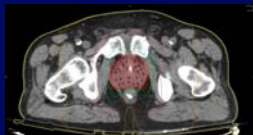


Are we going in the right direction?

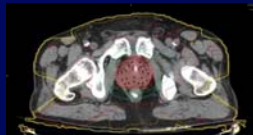
ALARA, Rad. Safety and Rx Gain



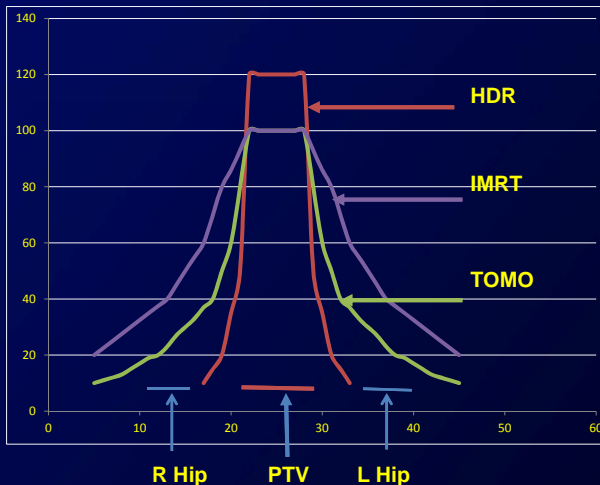
HDR



TOMO



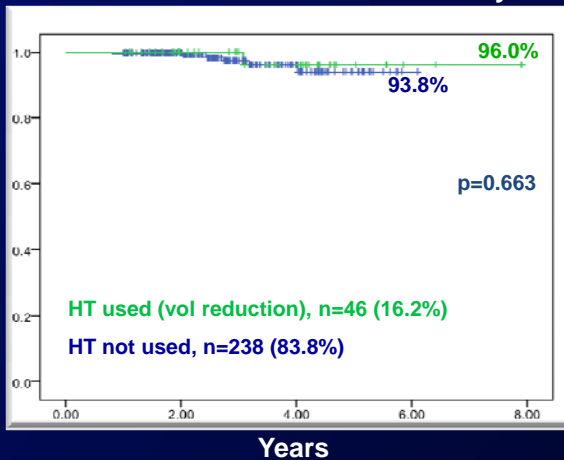
IMRT



HDR & Androgen Suppression

Going in the Right Direction?

Biochemical Disease-Free Survival by HT



Rogers CL, Alder SC, Rogers RL, Hopkins SA, Platt, ML, Childs LC, Crouch RH, Hansen RS, Hayes JK.
High Dose Brachytherapy as Monotherapy for Intermediate Risk Prostate Cancer. *J Urol* 2012; 187:109-116



HDR Lack of Benefit from Hormonal Therapy

WBH, CET, Kiel University

Biochemical Control Stratified by ADT

HDRB: 1260 patients

At least 1 "unfavorable characteristic"

$\geq cT2b$, $PSA \geq 10$, $GS \geq 7$

EBRT 36-50 Gy, 1.8-2 Gy fxs

Pelv (WBH, Kiel), Prost (CET)

HDR 22-24 Gy, 4 fxs, 1 implant

HDR Boost – varying protocols

HDR planning constraints:

urethral dose $\leq 125\%$

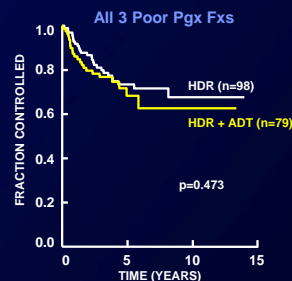
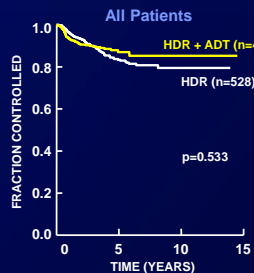
anterior rectal wall $\leq 75\%$

Androgen Deprivation:

406 pts ≤ 6 mo neoadj/concurrent

in most due to poor pgx fxs, but

discretionary, also for volume ↓



Martinez AA, Demanes DJ, Galalae R, Vargas C, Bertermann H, Rodriguez R, Gustafson G, Altieri G, Gonzalez J. Lack of benefit from a short course of androgen deprivation for unfavorable prostate cancer patients treated with an accelerated hypofractionated regime. IJROBP 2005;62(5):1322-1331



RTOG 0815

Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy with or without Short-Term (6 months) ADT For Patients with Intermediate-Risk Prostate Cancer

EBRT alone 79.2 Gy in 44 fractions of 1.8 Gy each

EBRT with brachy boost 45.0 Gy in 25 fractions of 1.8 Gy each

LDR seed boost if < 60 cc, $AUA \leq 15$, and no prior TURP

I-125 (110 Gy) or Pd-123 (100 Gy)

HDR boost, same constraints as LDR

21 Gy in 2 equal 10.5 Gy fractions separated ≥ 6 hr and ≤ 24 hr

Intermediate risk: Gleason Score 7, PSA > 10 but ≤ 20 , T-Stage T2b-T2c. Pts with all 3 intermediate risk factors and $\geq 50\%$ of their sampled biopsy cores involved will not be eligible for this study. Note: The percentage of biopsy cores involved will only be considered with respect to eligibility for those patients with all 3 of the above risk factors (i.e., patients with one or two of the above risk factors are eligible irrespective of the percentage of biopsy cores involved). Pts with Gleason score > 8 , PSA > 20 , or clinical stage $> T2c$ are ineligible for this study.



Right direction? EBRT+/-HDR Intermed-Risk Prostate Ca

Peter MacCallum Cancer Centre
Melbourne, Australia

2001-2006

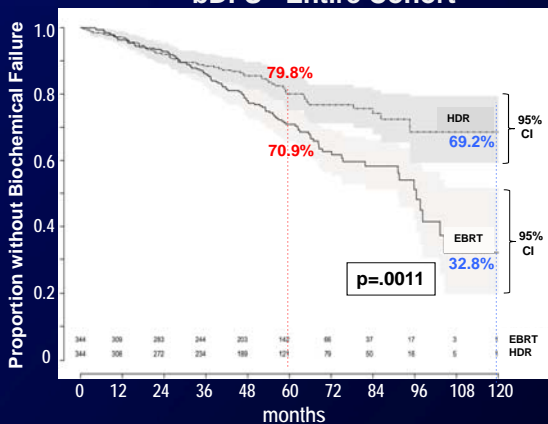
344 patients EBRT + HDR
46 Gy / 23 + 19.5 Gy / 3
344 matched cohort EBRT alone
74 Gy / 37

NCCN Risk Groups
Low Risk none
Intermediate 203 each group
High Risk 141 each group

Hormonal therapy 59% each arm

Median f/u 60.5 months

bDFS - Entire Cohort



Khor R, Duchesne G, Tai KH, Foroudi F, Chandler S, Van Dyk S, Garth M, Williams S. Direct 2-arm comparison shows benefit of high-dose-rate brachytherapy vs external beam radiation therapy alone for prostate cancer. *IJROBP* 2013;85(3):679-685



Comparison of PSA relapse-free survival in patients treated with ultra-high-dose IMRT versus combination HDR brachytherapy and IMRT

Ismael Deutsch¹, Michael J. Zelefsky¹, Zhigang Zhang², Qianxing Mo², Marco Zaider³, Gil'ad Cohen³, Oren Cahlon¹, Yoshiya Yamada^{1,*}

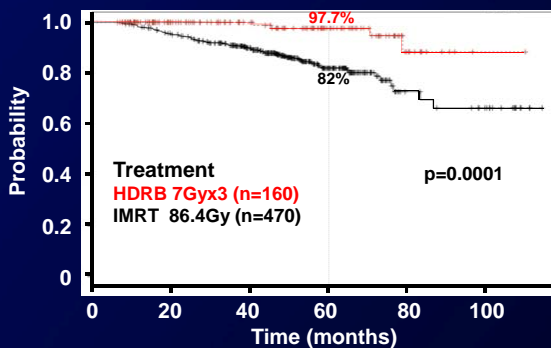
PSA Relapse-Free Survival (Nadir + 2)

MSKCC
IMRT 86.4Gy/48 (n=470) vs
HDRB 7Gyx3, then 1 mo later
50.4Gy/28 (n=160)

Med f/u: 53 mo IMRT
47 mo HDR + IMRT

Improved RFS on univariate analysis if: HDR, ↓T stage, ↓GS, ↓PSA, ↓NCCN risk group, no ADT

Improved on multivariate if: HDR
↓NCCN risk group, age





Spanish RCT (1999-2005)

445 Intermed or Hi-Risk (PSA>10 GS>6, T2b or T3)

EBRT 76 Gy/38 3D-CRT (n=222) v EBRT 46 Gy + HDR 16 Gy/2 (n=223)

	5y bDFS
EBRT	82.3%
EBRT+HDR	98.1%

p=<0.05

	RTOG Gr 2 Toxicity	
	Rectal	GU
EBRT	12.5%*	8.6%
EBRT+HDR	2.7%	8.6%

* p=<0.005

No grade 3 or 4 rectal or urinary complications in either arm

Conclusions: Acute and late rectal complications were significantly reduced with combined treatment, and short-term PSA control better

Guix B, Bartrina I, Tello J, Lacorte T, Henriquez I, Sole J, Guix I, Galdron G, Espino M. Dose escalation with high-dose 3D-conformal radiotherapy (HD-3D-CRT) or low-dose 3D-conformal radiotherapy plus HDR brachytherapy (LD-3D-CRT+HDR-B) for intermediate-or high-risk prostate cancer: Higher PSA control with lower toxicity. *JCO* 2011 (suppl 7; abstr 82). Also *JCO* 2010; 28:15s, abstr 4633



Right Direction vs. Surgery for Intermediate-Risk Prostate Ca

1746 patients

Baylor and MSKCC, 1983-2003

Single surgeon (Peter Scardino)

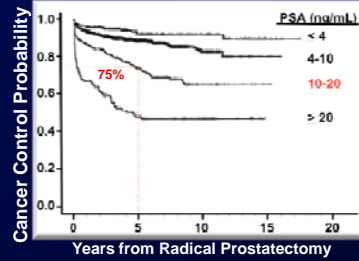
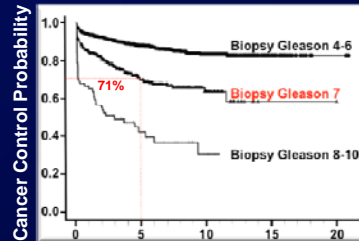
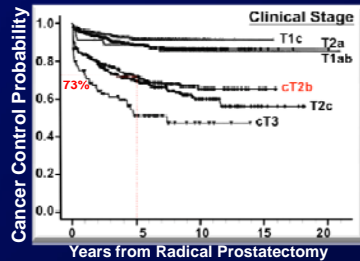
No EBRT, no neoadj hormonal tx

bDFS (PSA ≤0.4 a1996, ≤0.2 p1996)

from date of rad prostatectomy

by pre-op PSA, clinical stage,

biopsy Gleason score



Bianco FJ Jr., Scardino PT, Eastham JA. Radical prostatectomy: long-term cancer control and recovery of sexual and urinary function ("Trifecta"). *Urology* 2005; 66(Suppl 5A): 83-94



Systematic review

Comparison of three radiotherapy modalities on biochemical control and overall survival for the treatment of prostate cancer: A systematic review

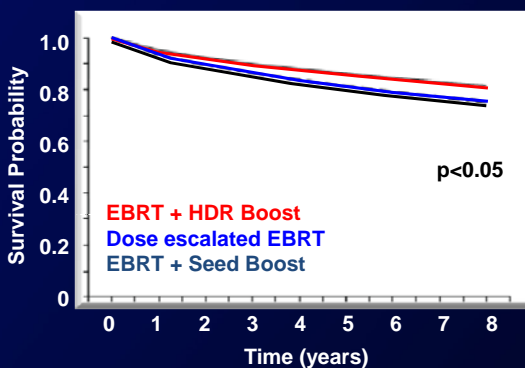
Bradley R. Pieters^{a*}, Djuna Z. de Back^a, Caro C.E. Koning^a, Aeilko H. Zwinderman^b

Systematic review 40 articles
bDFS and OS at 3,5, & 8 yrs

Treatment	HR bRecur
EBRT v HDR	1.40
	95% CI 1.31-1.51
Seeds v HDR	1.37
	95% CI 1.26-1.49

Treatment	HR OS
EBRT v HDR	1.50
	95% CI 1.29-1.73
Seeds v HDR	2.33
	95% CI 2.04-2.66

bDFS by Treatment



Radiotherapy and Oncology 2009;93:168-173



Systematic review

Comparison of three radiotherapy modalities on biochemical control and overall survival for the treatment of prostate cancer: A systematic review

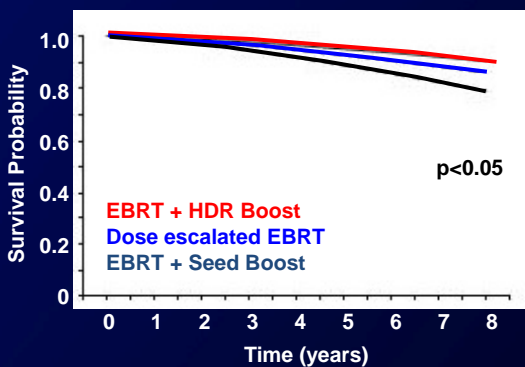
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Treatment	HR OS
EBRT v HDR	1.50
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Seeds v HDR	2.33
	95% CI 2.04-2.66

Overall Survival by Treatment



Radiotherapy and Oncology 2009;93:168-173



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Comparison of three radiotherapy modalities on biochemical control and overall survival for the treatment of prostate cancer: A systematic review

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Conclusion

“The combination of external beam radiotherapy and HDR brachytherapy results in a superior biochemical control and overall survival found in a systematic review on radiotherapy for prostate cancer. This outcome is mainly explained by the higher dose that can be prescribed when brachytherapy is used....”

Headed in the right direction with HDR Brachytherapy for prostate cancer?

Radiotherapy and Oncology 2009;93:168-173



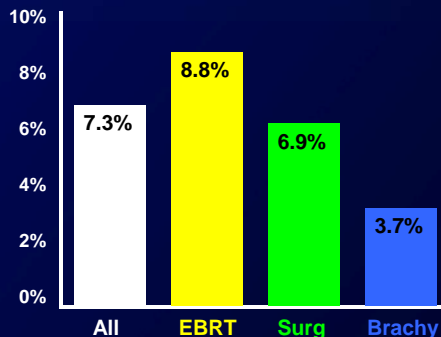
Right direction? Treatment Long-term Toxicity & Cost

SEER Medicare Database 1991-2007
n = 137,427 men ≥65 years old,
Prost Ca the only cancer diagnosis

Prostatectomy 59,559 (43.3%)
EBRT 60,806 (44.2%)
Brachytherapy 17,062 (12.4%)
No pt received combined therapy

Median f/u 71 months
7.3% toxic effects requiring intervention

Treatment Related Toxicities



Ciezki JP, Reddy CA, Angermeier K, Ulchaker J, Stephans KL, Tendulkar RD, Altman A, Chehade N, Klein EA. Long-term toxicity and associated cost of initial treatment and subsequent toxicity-related intervention for patients treated with prostatectomy, external beam radiotherapy, or brachytherapy: A SEER/Medicare database study. 2012 Genitourinary Cancers Symposium, San Francisco 2012. http://www.medscape.com/viewarticle/757895_print

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Right Direction? Modality Long-term Costs

Median FU 71 mo

EBRT
n=60,806 (44.3%)

Prostatectomy
n=59,559 (43.3%)

Brachytherapy
n=17,062 (12.4%)

\$10,000

\$8,000

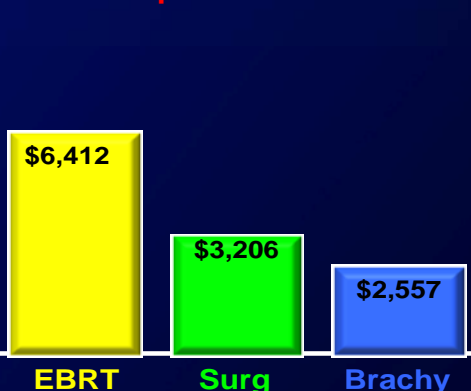
\$6,000

\$4,000

\$2,000

0

Cost per Patient Year



Ciezki JP, Reddy CA, Angermeier K, Ulchaker J, Stephans KL, Tendulkar RD, Altman A, Chehade N, Klein EA. Long-term toxicity and associated cost of initial treatment and subsequent toxicity-related intervention for patients treated with prostatectomy, external beam radiotherapy, or brachytherapy: A SEER/Medicare database study. 2012 Genitourinary Cancers Symposium, San Francisco 2012. http://www.medscape.com/viewarticle/757895_print



Right Direction for Program development?

<u>Year</u>	<u>77787* technical</u>	<u>77787* professional</u>
2008	\$ 1,163.64	\$ 243.31
2009	\$ 529.87	\$ 241.55
2013	\$ 653.41	\$ 238.14
2014	\$ 476.33	\$ 249.87

**Thus this year technical reimbursement
for 77787 decreased another 27.1%**

* in 2008 there was no CPT 77787, rather 77784; Utah Medicare Data



Challenges, Right Direction?

“Take part or be taken apart!”

Hon. Alan K. Simpson, R-WY 1979-96

“We took part and got taken apart!”

**Hon. David Wazer, Socio-economics
Chair, ABS**



Right Direction? HDR for CaPr

HDR Brachytherapy

- Unmatched long-term biochemical control for the majority of patients with prostate cancer
- Very favorable side effect profile
- Few adverse events. Urinary incontinence is more likely in pts with TURP, or with neurologic compromise
- Every study, including randomized trials and a large systematic review, making a direct comparison has shown advantages to HDR brachytherapy
- Androgen ablation may be unimportant, less important, or appropriate in shorter courses (e.g. GW 4 months) with HDR. This will demand further study. RTOG 0815 will help
- HDR delivers superb outcomes, optimized dosimetry, limited side effects, lack of rad exposure to others, short tx course, min time out of work, and affordability.



Right Direction? HDR for CaPr

HDR Brachytherapy

- Eliminates the need to clone Peter Grimm and Greg Merrick. I.E., the technique eliminates the need for brachytherapy superheroes. The technology can be transferred brachytherapy teams while maintaining high quality.
- Adaptable to Multiple planning methods and techniques.
- Although very high dose-fractionation schedules have been reported, 45 Gy IMRT plus 3X6.5 Gy or 6X6.5 Gy HDR MT (or its BED GY2 equivalent, is sufficient to eradicate a very high percentage of prostate tumors. Dose escalation beyond that BED is therefore not recommended.
- Medicare and the USPSTF have failed the American public as regards HDR BT for Prostate Cancer (Gleason 7-10 = 50% of new prostate diagnoses in Utah)
- Radiation oncologists working with urologists can be a powerful public health team in the upcoming epidemic of advanced prostate cancer if they incorporate HDR BT into treatment.



Challenges, Right direction in Socio-economic policy?

- | | |
|-------------------|--------------------|
| • Pro + Tech IMRT | • Pro+Tech HDR |
| • 40 fractions | • 6 fx, 3 implants |
| • Utah Medicare | • Utah Medicare |
| • \$20,662 | • \$4,357 |

What is your radiation therapy department administrator going to say when you ask for money to build and staff an HDR program?



Right Direction, Radio-Protection?

43 X 1.8 Gy = 77.4 Gy

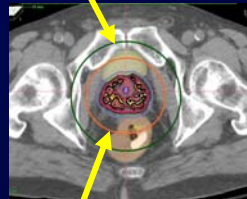
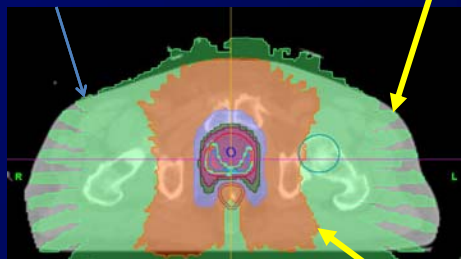
6 X 6.5 Gy = 39.0 Gy

12.5 % of prescription dose

About 500-1000 pelvic CT scans

9.7 Gy (10.76 Gy₂)

4.9 Gy (6.85 Gy₂)



19.4 Gy (23.70 Gy₂)

9.75 Gy (17.67 Gy₂)

25% of prescription dose

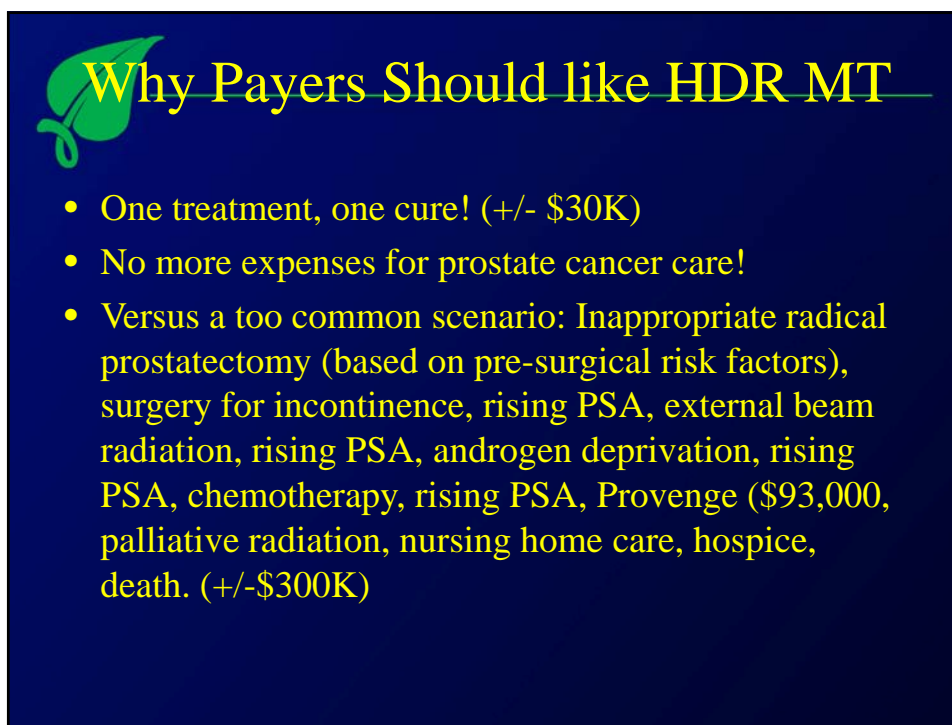
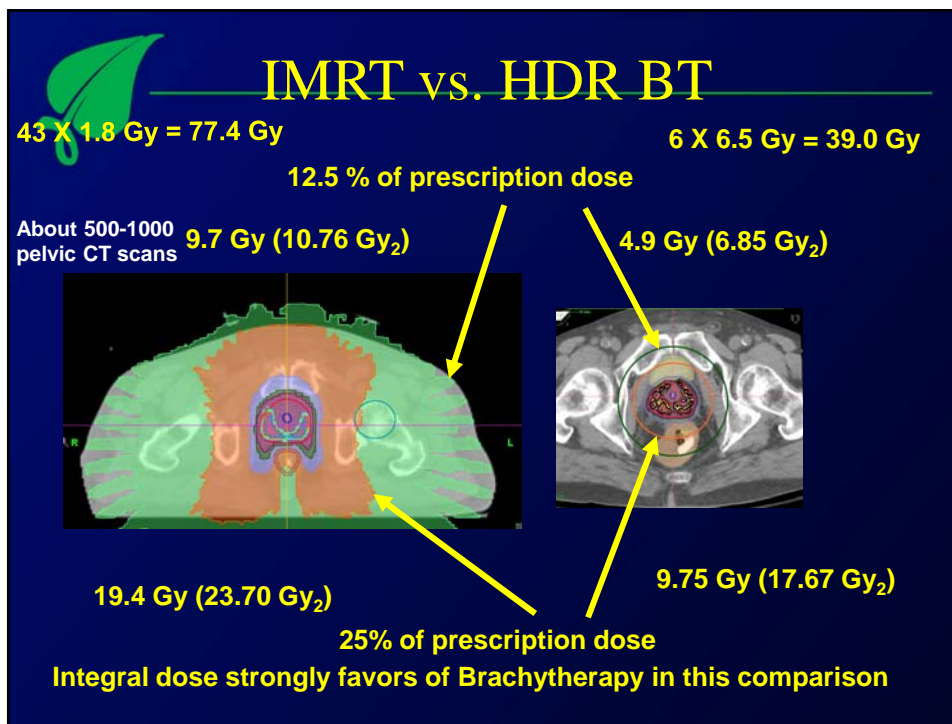
Integral dose strongly favors of Brachytherapy in this comparison



Tale of Two Doctors

- | | |
|--|--|
| <ul style="list-style-type: none"> • Doctor A 2002 • Age 56 • PSA 60 ng/ml • Gleason 3+4, 3/6 sext. • MAB+EBRT+HDR BT • PSA 8/14/10 = 0.01 ng/ml | <ul style="list-style-type: none"> • Doctor B 2004 • Age 56 • PSA 13.7 ng/ml • Gleason 3+3, 6/6 sext. 30-80% in each core • MAB+EBRT+HDR BT • PSA 10/07 = 0.03 ng/ml • PSA 04/08 = 0.02 • PSA 03/10 = 0.01 |
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Cost effective medicine?





Tale of Two Doctors

- | | |
|--|--|
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Cost effective medicine?



Urologic Détente?



Before Brachytherapy



After Brachytherapy





Are we going in the right direction?

Conclusions

- In world since 1986 vs. 1995 for IMRT
- Several studies now suggest benefits over other modern modalities
- May lessen the need for androgen ablation
- More accurate dose delivery vs. LDR
- Fewer Side effects vs. LDR



Are We Going in the Right Direction?

HDR Brachytherapy

- Truly Robotic vs. Robot Assisted
- Highly potent against CaP (Very favorable radiobiology, Brenner and Hall)
- In world, since 1986 vs. 1995 for IMRT
- Precise and Accurate? Yes
- Fewer Side effects than almost all treatments for prostate cancer



How to change made up minds?

- Reasoning is suffused with emotion
- The two are inseparable
- Positive and negative feelings arise faster than conscious thoughts
- By the time we are consciously reasoning, we may instead be rationalizing prior emotional commitments

Chris Mooney in "Made-up minds" In THE WEEK May 20, 2011



Made-up minds

Attitudes toward issues like the date the world will end, global warming, capital punishment, vaccines and autism, etc. are influenced by pre-existing emotional biases, as are attitudes toward prostate cancer treatment depending on one's training and experience.

True believers in their area of expertise critique each new study that challenges their views.

Chris Mooney in "Made-up minds" In THE WEEK May 20, 2011



Challenges, Prostate Cancer: How can patients get HDR BT?

- Buy in by CMS**
- Buy in by radiation oncologists**
- Buy in by urologists**
- Buy in by patients and media**
- Political support by ASTRO**
- Political support by AUA**
- Buy in by Hospitals**
- Investment in HDR brachytherapy teams**
- Buy in by patient care organizations**
- Buy in by insurance companies**
- Buy in by USPSTF**



Made-up minds

- Giving partisans scientific data that is relevant to their beliefs is like unleashing them in the motivated reasoning equivalent of a candy store.**
- Political sophisticates are prone to be more biased than those who know less about the issues. They generate more and better reasons to explain why they are right**
- If you want to convince, don't lead with the facts, lead with the values, so as to give the facts a fighting chance.**

Chris Mooney in "Made-up minds" In THE WEEK May 20, 2011