Minimising and managing toxicity in Prostate Brachytherapy
Leeds UK
March 22 2019

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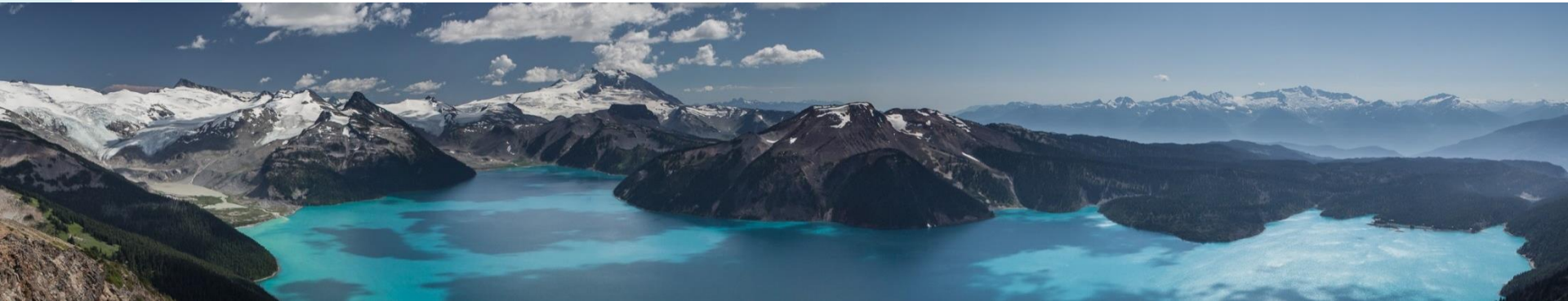

ACENDE RT - RTC 400 pts: 12 m ADT + EBRT ± LDR PB

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Clinical Investigation

Androgen Suppression Combined with Elective Nodal and Dose Escalated Radiation Therapy (the ASCENDE-RT Trial): An Analysis of Survival Endpoints for a Randomized Trial Comparing a Low-Dose-Rate Brachytherapy Boost to a Dose-Escalated External Beam Boost for High- and Intermediate-risk Prostate Cancer

W. James Morris, MD, FRCPC,*,† Scott Tyldesley, MD, FRCPC,*,† Sree Rodda, MBBS, MRCP, FRCR,* Ross Halperin, MD, FRCPC,*,‡ Howard Pai, MD, FRCPC,*,§ Michael McKenzie, MD, FRCPC,*,† Graeme Duncan, MB, ChB, FRCPC,*,† Gerard Morton, MB, MRCPI, FRCPC, FFRRCSI,‖ Jeremy Hamm, MSC,¶ and Nevin Murray, MD, FRCPC†,#

Clinical Investigation

ASCENDE-RT: An Analysis of Treatment-Related Morbidity for a Randomized Trial Comparing a Low-Dose-Rate Brachytherapy Boost with a Dose-Escalated External Beam Boost for High- and Intermediate-Risk Prostate Cancer

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Clinical Investigation

ASCENDE-RT: An Analysis of Health-Related Quality of Life for a Randomized Trial Comparing Low-Dose-Rate Brachytherapy Boost With Dose-Escalated External Beam Boost for High- and Intermediate-Risk Prostate Cancer

Sree Rodda, MBBS, MRCP, FRCR,* W. James Morris, MD, FRCPC,*,† Jeremy Hamm, MSC,‡ and Graeme Duncan, MB, ChB, FRCPC*,†

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BRACHYTHERAPY

Brachytherapy 17 (2018) 837–844

Prostate

Using a surgical prostate-specific antigen threshold of >0.2 ng/mL to define biochemical failure for intermediate- and high-risk prostate cancer patients treated with definitive radiation therapy in the ASCENDE-RT randomized control trial

W. James Morris*, Tom Pickles[1], Mira Keyes[1]

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Radiation Oncologist, Vancouver Cancer Centre, Vancouver, British Columbia, Canada

BC CANCER

UBC

Prostate cancer

Trial of radioactive implants offers improved prostate cancer survival

Treatment using permanently implanted radioactive 'seeds' doubles rates of five-year tumour-free survival compared with conventional high-dose radiotherapy

Scientists in Canada say low-dose-rate prostate brachytherapy has been more successful than dose-escalated external beam radiotherapy. Photograph: Jeff Pachoud/AFP/Getty

A prostate cancer treatment using permanently implanted radioactive "seeds" doubles rates of five-year tumour-free survival compared with conventional high-

A trial comparing the treatment with dose-escalated external beam radiotherapy found that it was much more successful at banishing cancer.
Men who underwent LDR-PB were twice as likely to be cancer-free five years later.
Scientists studied 398 men with cancer that had not spread outside the prostate gland who were judged to be at high risk of treatment failure based on standard test results.
Lead researcher Professor James Morris, from Vancouver Cancer Centre in Canada, said: "At five years follow-up, we saw a large advantage in progression-free survival in the LDR-PB group.
"Although, to date, overall survival and prostate cancer-specific survival do not appear to differ between the two groups, existing trends favour LDR-PB and an overall survival advantage is likely to emerge with longer follow-up."

ACENDE RT - RTC 400 pts: 12 m ADT + EBRT ± LDR PB

http://lmgtfy.com/?q=the+guardian+brachytherapy+prostate

Objectives

ASCENDE RT – toxicity

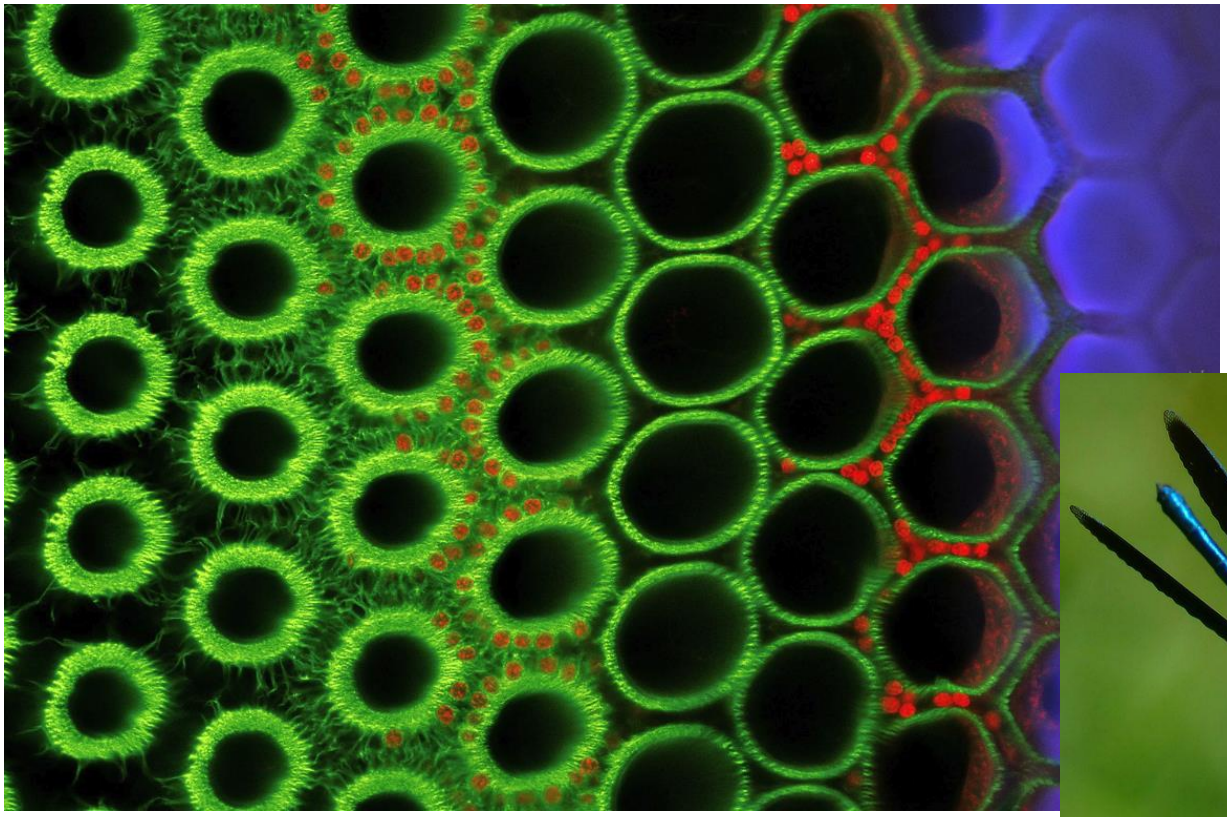
Interpretation can be in the eyes of beholder

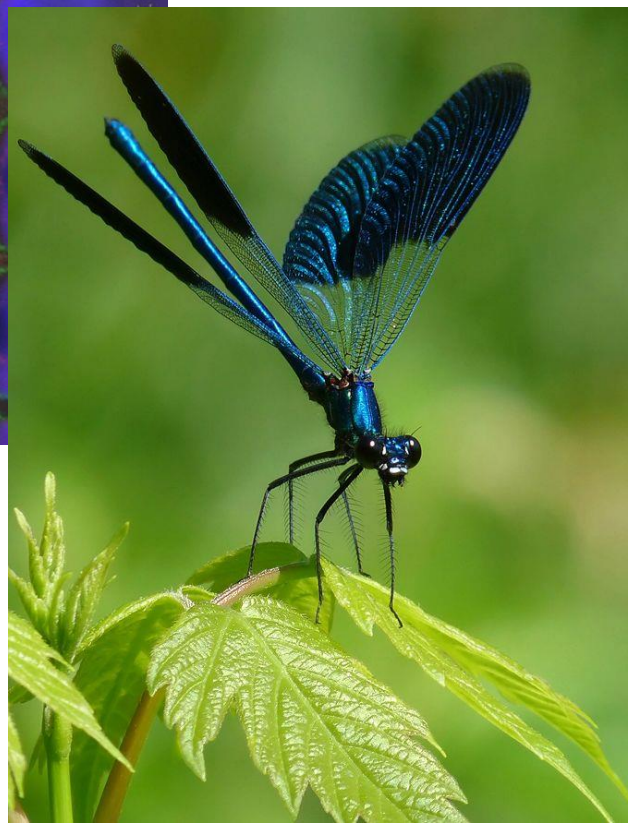
What was the cause of higher toxicity

How to move forward

Toxicity management

Fistulas and interventions

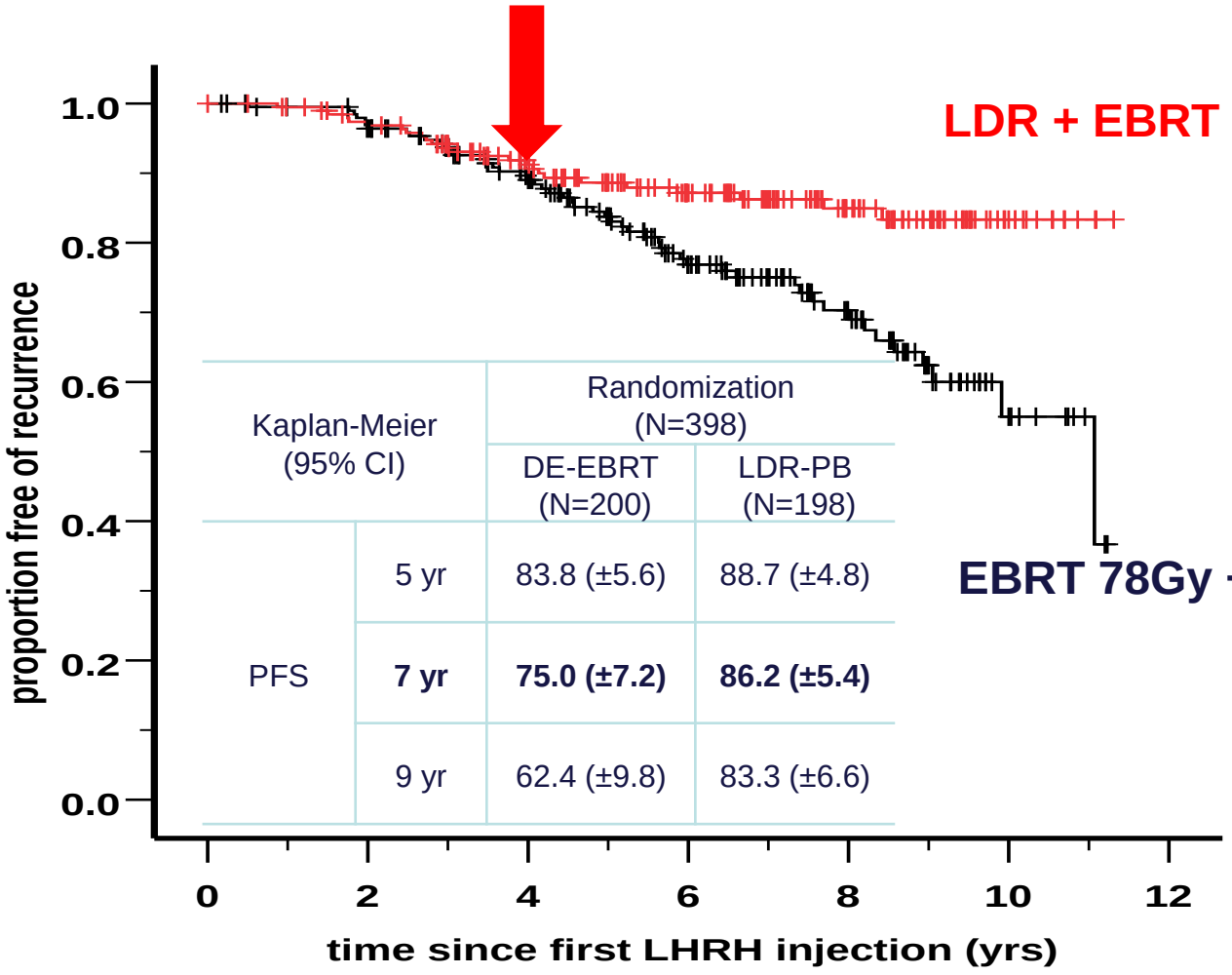




Eye of the dragonfly

ASCENDE RT

PSA PFS (Phoenix)at 5y – primary outcome



Kaplan-Meier (95% CI)		Randomization (N=398) DE-EBRT (N=200)	LDR-PB (N=198)
PFS	5 yr	83.8 (±5.6)	88.7 (±4.8)
	7 yr	**75.0 (±7.2)**	**86.2 (±5.4)**
	9 yr	62.4 (±9.8)	83.3 (±6.6)

LDR + EBRT + ADT bNED 83% @9y

EBRT 78Gy + ADT bNED 62% @ 9y

Absolute difference
5y – 4.9%
7y – 11.2%
9y – 20.95%

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Check for updates

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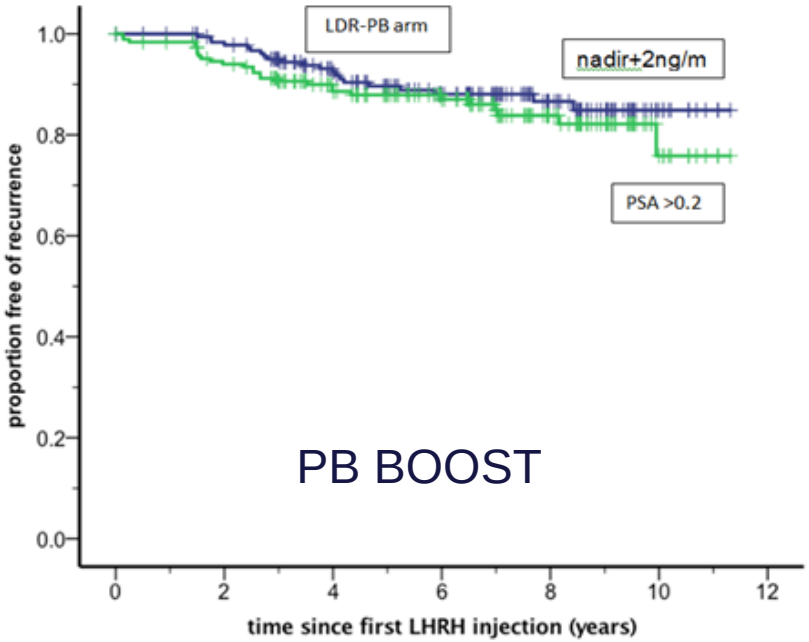
Brachytherapy 2018. Morris, Keyes Pickles

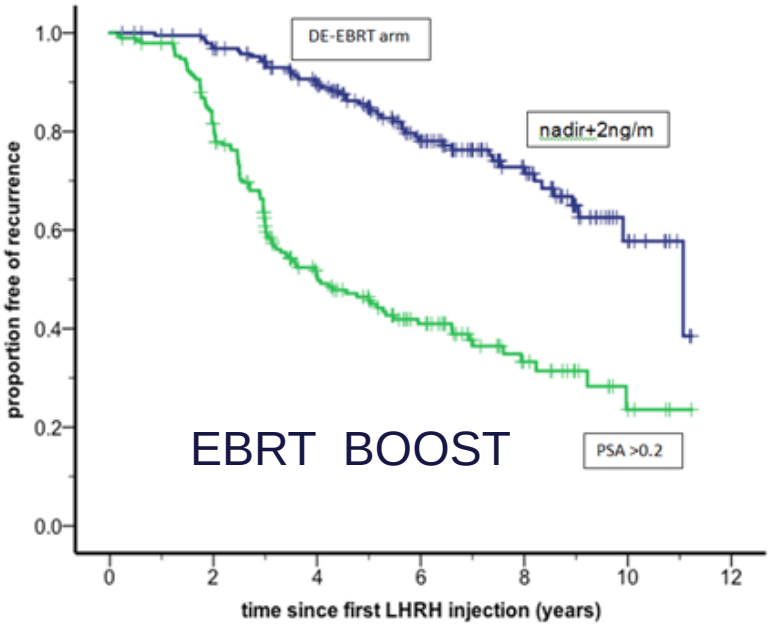
ASCENDE RT



PB BOOST

Numbers at risk:

Time (yrs)	0	2	4	6	8	10
Nadir+2mg/ml	188	177	137	98	55	11
>0.2 ng/mL	188	170	130	96	53	11



EBRT BOOST

Numbers at risk:

Time (yrs)	0	2	4	6	8	10
nadir+2ng/mL	195	181	141	95	53	11
>0.2 ng/mL	195	152	77	46	19	4

Nadir+2 vs. PSA>0.2 definition

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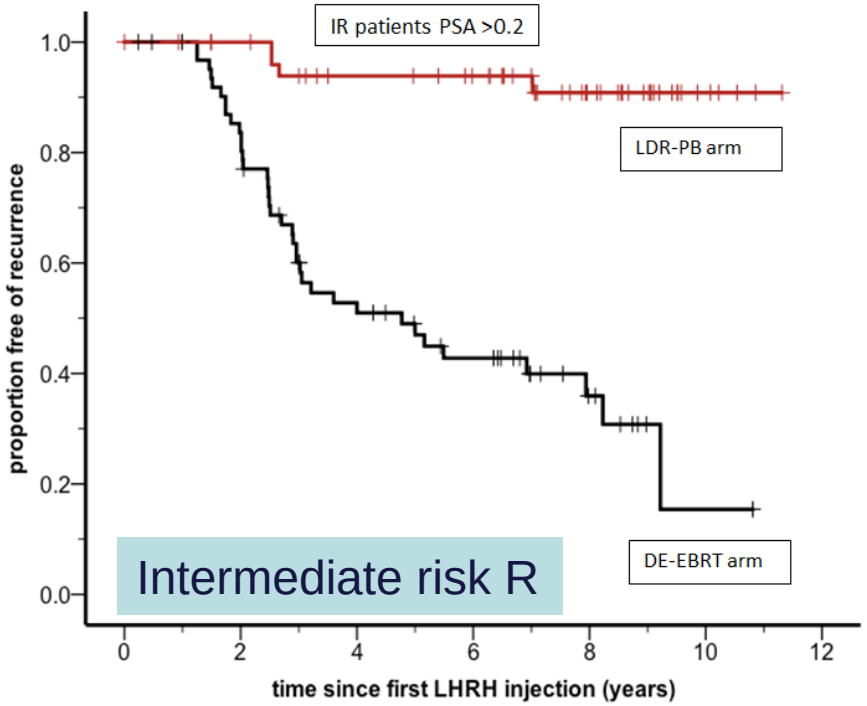
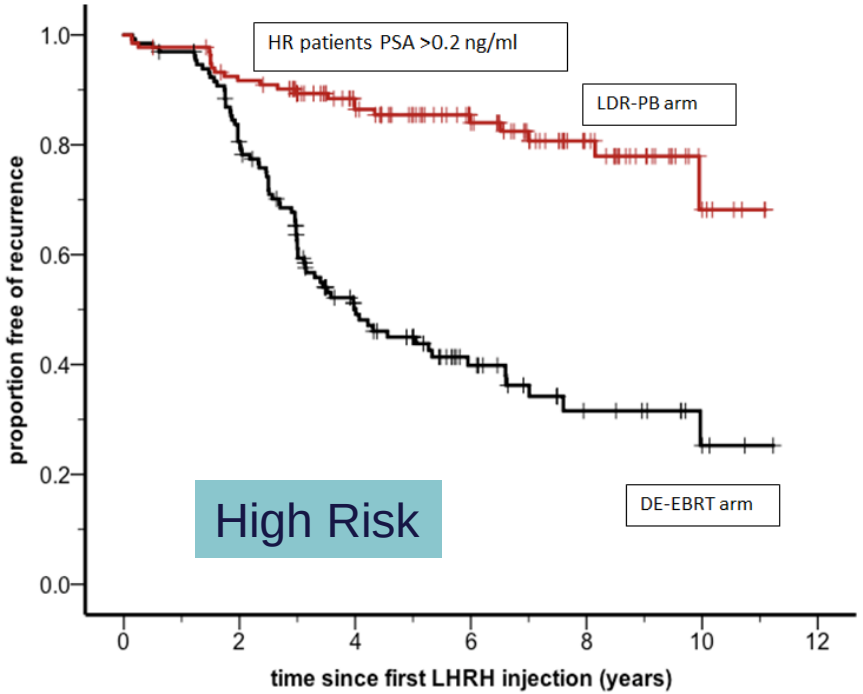
ACENDE RT



Time (yrs)	0	2	4	6	8	10
LDR-PB	54	50	41	37	22	4
DE-EBRT	64	50	28	20	8	-

Numbers at risk:



Time (yrs)	0	2	4	6	8	10
LDR-PB	131	120	87	58	31	6
DE-EBRT	134	101	48	26	10	3

PSA >0.2 failure definition for IR and HR

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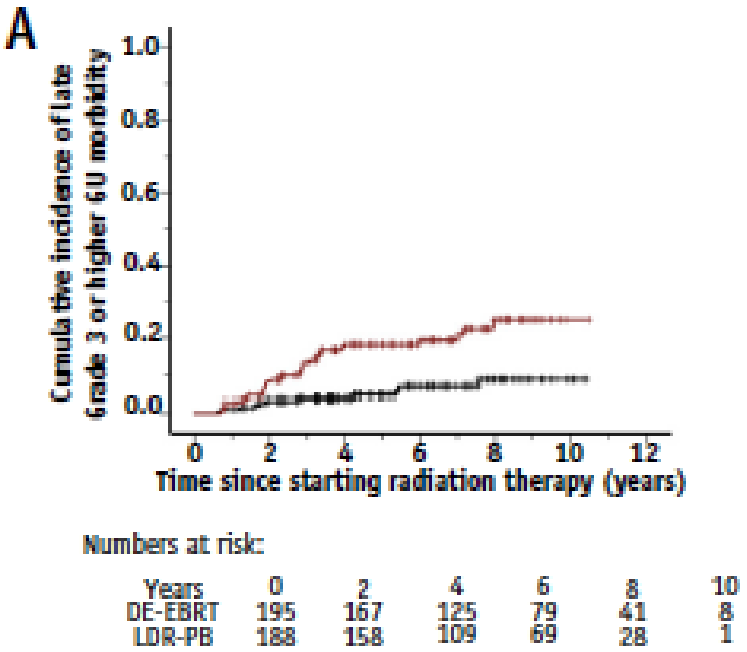
Late Gr 3 GU actuarial stats

LDR 32 – 18% pts

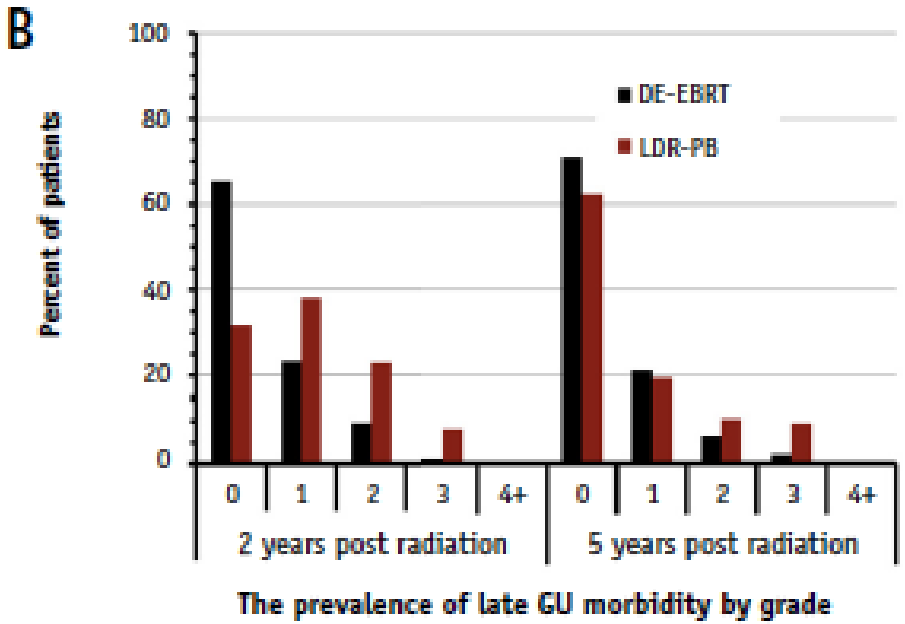
16 urethral strictures



31 pts LDR - 8.6% at 5y

EBRT 13- 5% pts

2 urethral strictures



10 pts EBRT – 2.2% at 5y

Incontinence - cumulative pad use

LDR - 35 - 16% pads

22 ≤ 2 pads per day
9 >2 pads per day
4 total incontinences

EBRT – 12 – 6.1% pads

7 ≤ 2 pads per day
3 >2 pads per day
2 total incontinences

Prevalence of pad use at 5 years

LDR 6.5%

EBRT 1.1%

Late catheterization

LDR 12%

EBRT 3%

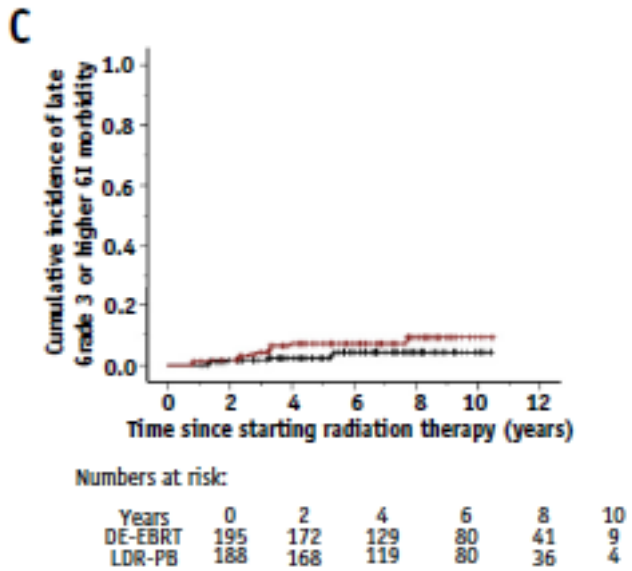
Predictors for ≥ Gr 2 GU toxicity?

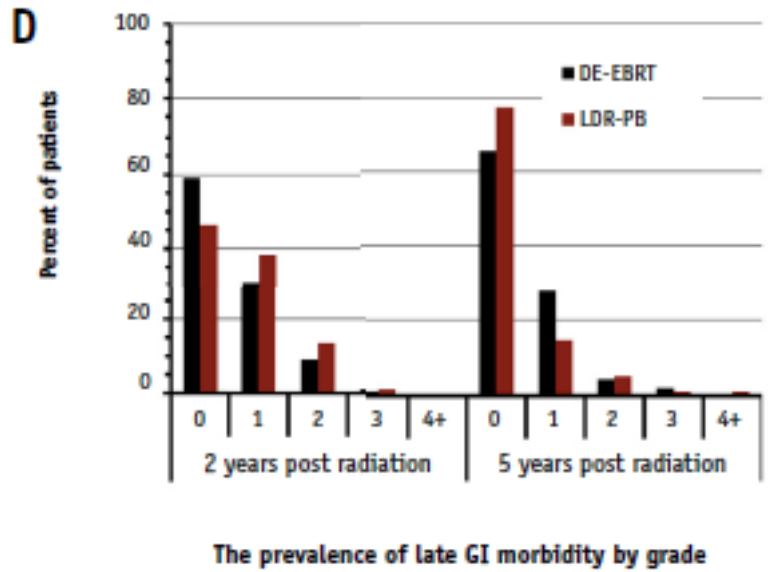
bIPSS >16 is only predictive factor

- HR 2.2 for LDR arm
- HR 1.37 EBRT arm (p=NS)

V100 and D90 were not predictive

5years late Gi Gr 3 toxicity





The prevalence of late GI morbidity by grade

Prevalence - NS

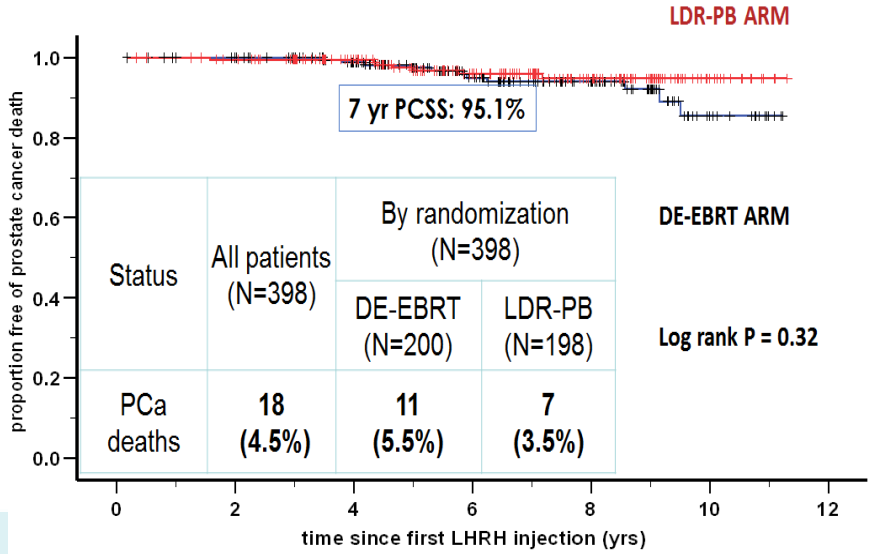
LDR - 2.2%

EBRT 1%

OS and PCSM – same

trial not powered to show the difference

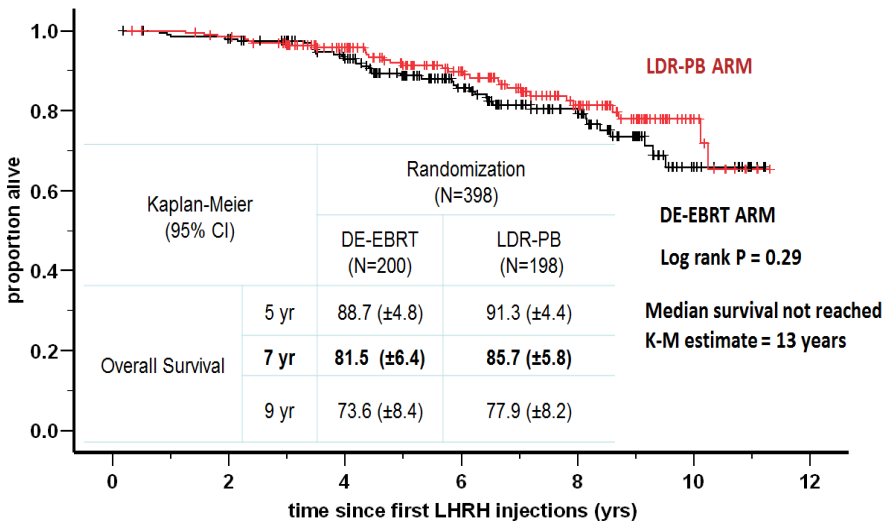
PSCM
N=398



Status	All patients (N=398)	By randomization (N=398)	
		DE-EBRT (N=200)	LDR-PB (N=198)
PCa deaths	**18 (4.5%)**	**11 (5.5%)**	**7 (3.5%)**

OS
N=398

OS 6% difference NS



Kaplan-Meier (95% CI)		Randomization (N=398)	
		DE-EBRT (N=200)	LDR-PB (N=198)
Overall Survival	5 yr	88.7 (±4.8)	91.3 (±4.4)
	7 yr	**81.5 (±6.4)**	**85.7 (±5.8)**
	9 yr	73.6 (±8.4)	77.9 (±8.2)

ASCENDE RT conclusions:

OS same	• 6% absolute difference p=ns
Mets Free survival - same	• 89 and 85% - p=ns • PB pts had mets early, - 2 y after PSA failure - **failing form occult metastatic disease**
PSA failure – 2x higher with EBRT	• 20% absolute difference • 1% per years for PB arm • 5% per year form EBRT arm
Toxicity higher in PB arm	

ASCENDE RT - toxicity

Toxicity – GU – worse in PB arm

- **5 y cumulative incidence GU** **18% vs. 5% - 50% strictures**
- 5 y prevalence 8% vs. 2%

Toxicity – GI - NS

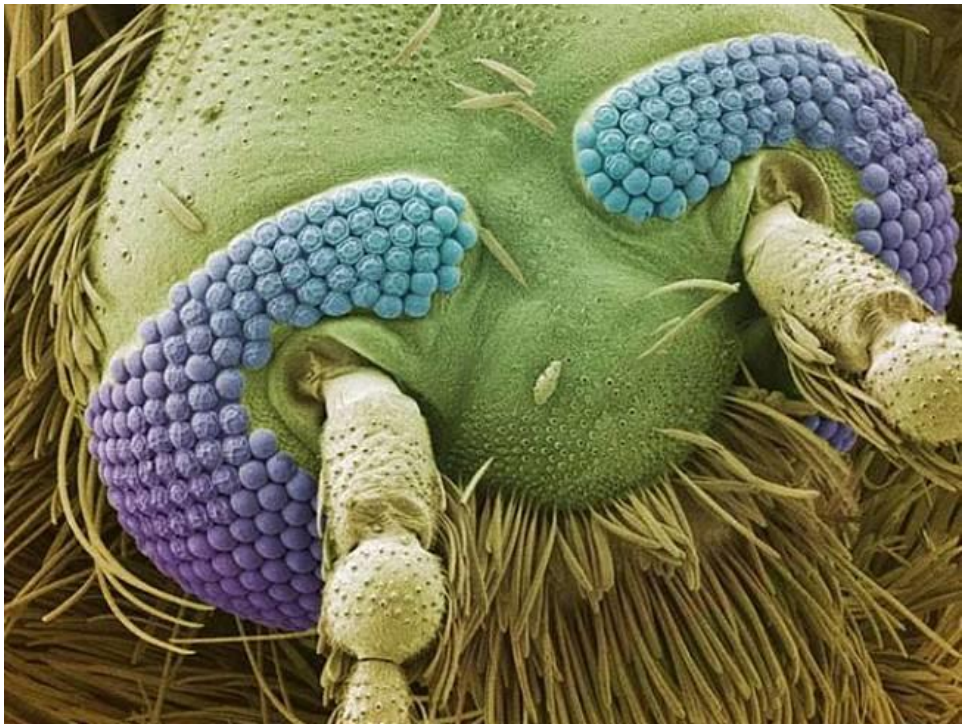
- 6 y cumulative incidence - 8 vs. 3%
- 5 y prevalence - 1 vs. 2%

EF - 5y - NS

- 45% for PB and 37% for EBRT

QOL

- Decline in mean scores both arms for physical and sexual
- Function scales, worse with LDR arm



- ASCENDE RT toxicity Very high?
- What went wrong?
- How dose it compare with HDR and with Surgery?
- What can be done to reduce it?

Toxicity Scale

ASCENDE RT Modified LENT- SOMA	CTCAE V3 or V4
Catheterization Gr3	**Catheterization Gr2 (<6w)**
Stricture any Gr3	**Stricture Gr1, Gr2, or G3** if altered organ function

- Toxicity scales differ
- Mostly reported as prevalence not a cumulative incidence
- RTC reporting is more strict than in institutional reporting

- Is having a stricture and dilatation reason to abandoned curative treatment?
- Is surgery providing better QOL?

What went wrong?
Imaging and Planning

Old US units
Poor images of Apex
115Gy
Large V150%
Planned large inf. margins

OR skills

Improvement:

New US units
Excellent imaging
MRI Imaging
Dose painting
Dose conformity at the apex
<110Gy? (100- 105Gy)

OR skills
EBRT Volume?

Comparisons of GU and GI morbidity between ASCENDE-RT limited by differences in morbidity scoring systems, follow-up, eligibility, pelvic vs. prostate-only EBRT, and the duration of ADT.

LDR - ASCENDE RT
Gr3 – 18%
Strictures - 9%

HDR - Hoskins
Gr3 – **30%**
Strictures – 13%
Not diff between arms

TROG RADAR trial
Stricture **13%**

HDR/Ir boost
Gr3 - **13%**

RTOG 2032 LDR ± EBRT
Overall gr 3: 12% vs 7%
GU: 7% vs 3%

RT - EBRT+ PB

Gr3 20-30%
Strictures ~8-13%


The NEW ENGLAND JOURNAL of MEDICI

ORIGINAL ARTICLE

Patient-Reported Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer

J.L. Donovan, F.C. Hamdy, J.A. Lane, M. Mason, C. Metcalfe, E. Walsh, J.M. Blazeby, T.J. Peters, P. Holding, S. Bonnington, T. Lennon, L. Bradshaw, D. Cooper, P. Herbert, J. Howson, A. Jones, N. Lyons, E. Salter, P. Thompson, S. Tidball, J. Blaikie, C. Gray, P. Bollina, J. Catto, A. Doble, A. Doherty, D. Gillatt, R. Kockelbergh, H. Kynaston, A. Paul, P. Powell, S. Prescott, D.J. Rosario, E. Rowe, M. Davis, E.L. Turner, R.M. Martin, and D.E. Neal, for the ProtecT Study Group*

Protect

Surgical Complications

Ac Gr 3 - 6%

- CVS events
- Transfusion >3units
- Anastomosis, rectal injury

Gr 3 RTC RP vs LDR

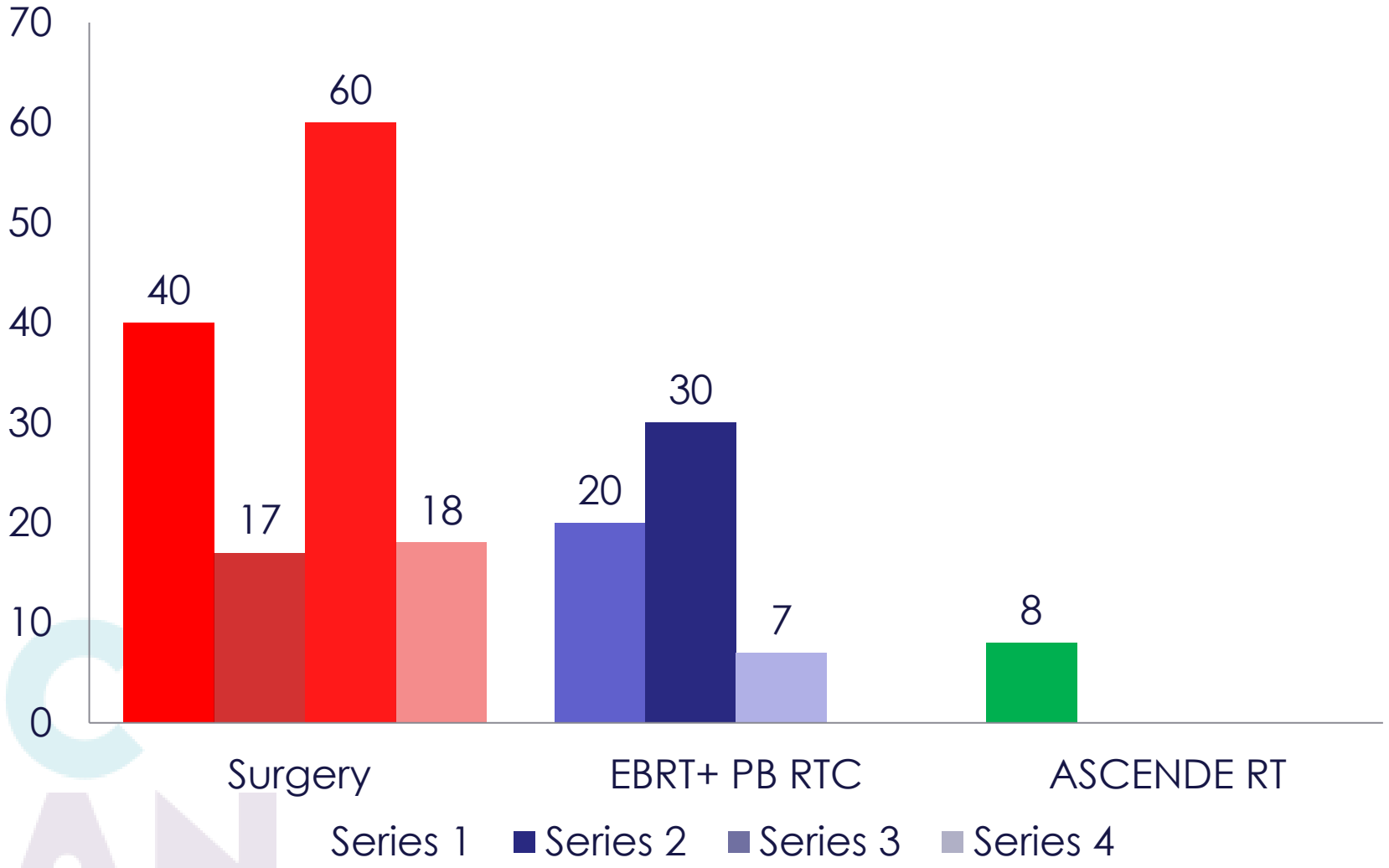
RP Incontinence 18%, Stricture 6.5%

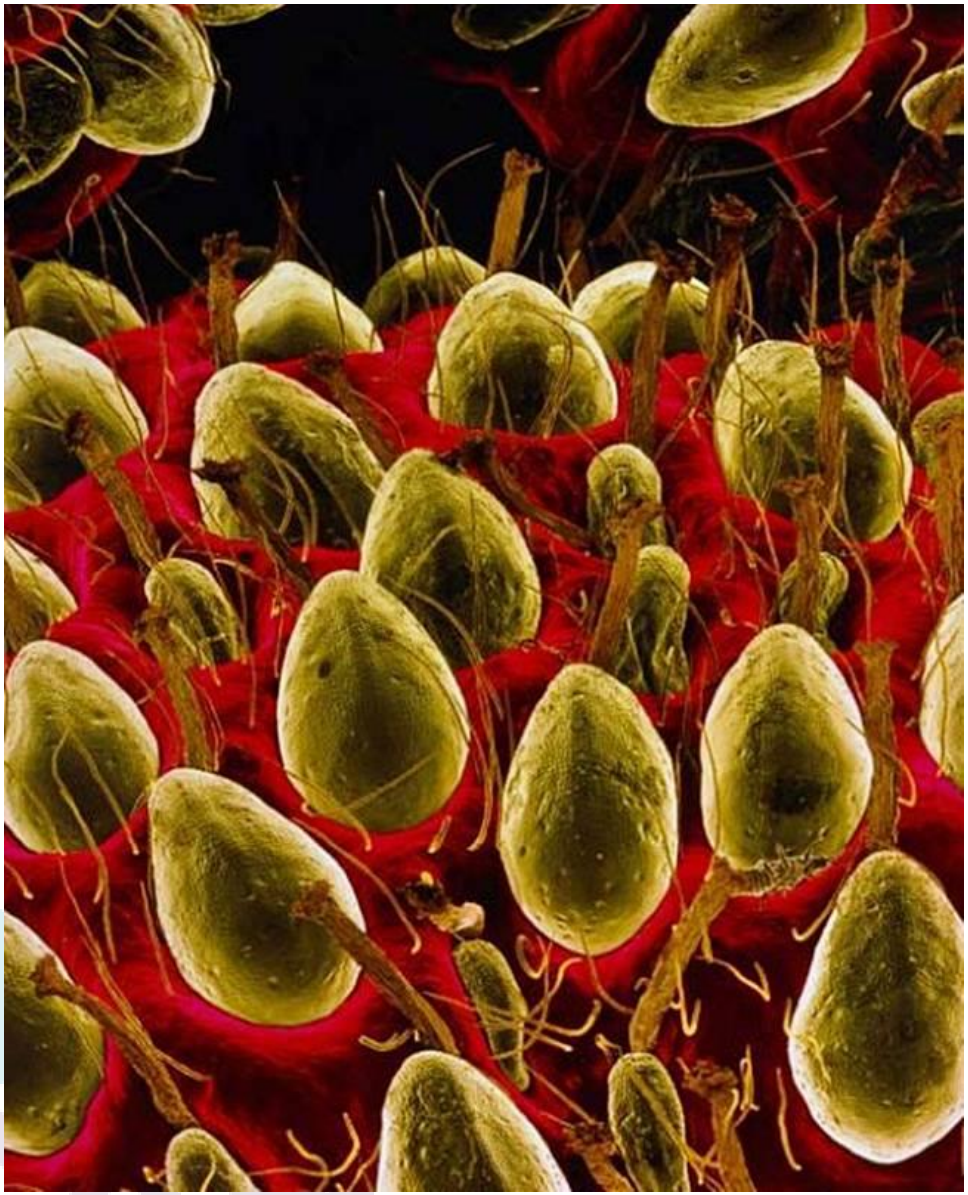
PB 2.5%

Incontinence RP RTCs

PIVOT	NEJM 2017	40%
PROTECT	NEJM 2017	17%
PCOS	NEJM 2013	18%
SPCG RTC	NEJM 2013	60%

Prevalence of Gr 3 toxicity with surgery vs EBRT + PB data from RTCs





Planning

How to avoid strictures

76 male

2011

TURPx2 2003
IR GS 4+3, PSA 9
LDR - 2011

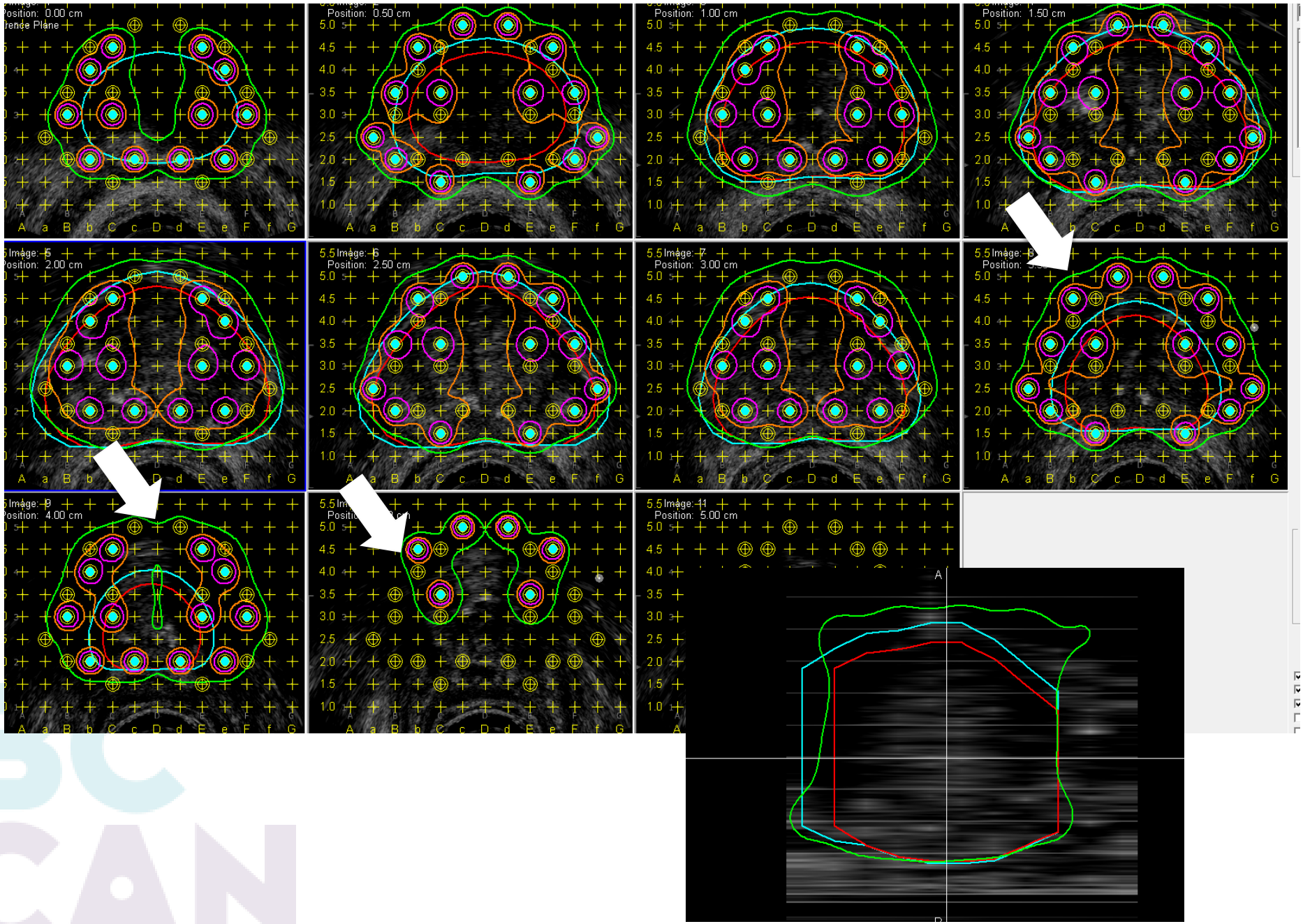
2012

++ urinary symptoms
Hematuria
Infection
Stricture
Blood per rectum

2018

Age 83
Self catheterize x2 day
Incontinent
Oncoming urinary symptoms
Rectal bleeding
- Severe telangiectasia
- PSA going up

Formal QA requested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A
B

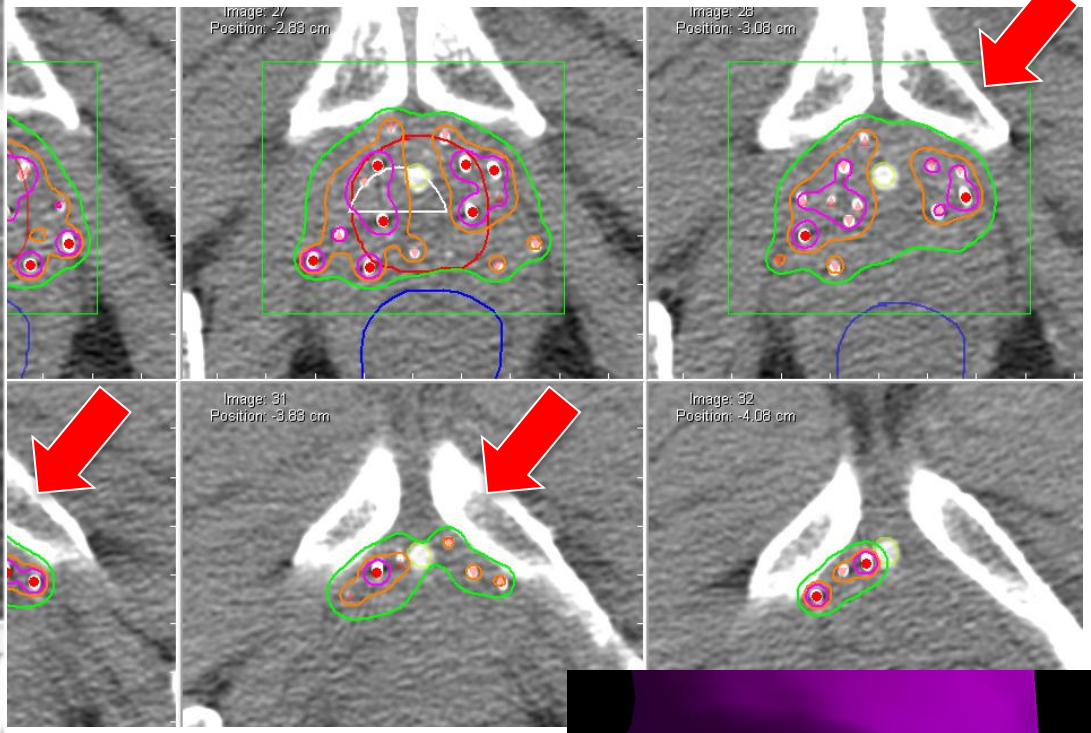
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Image: 32
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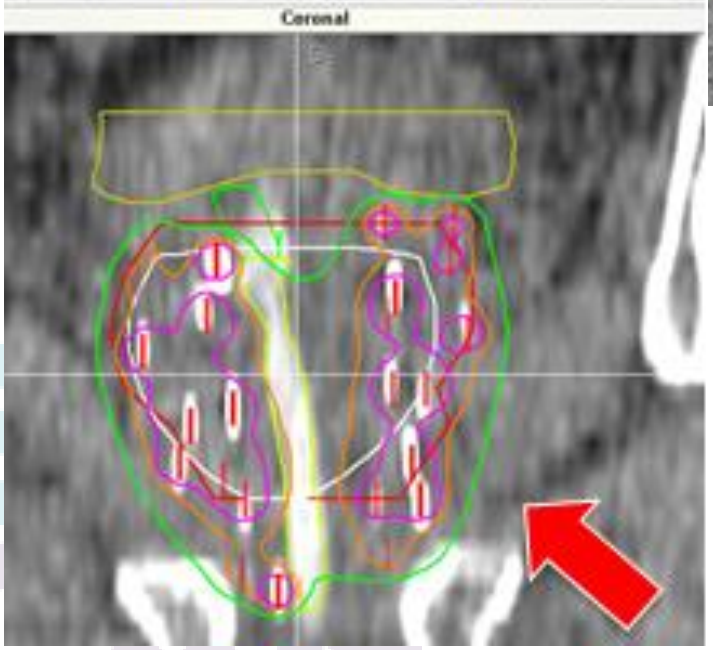
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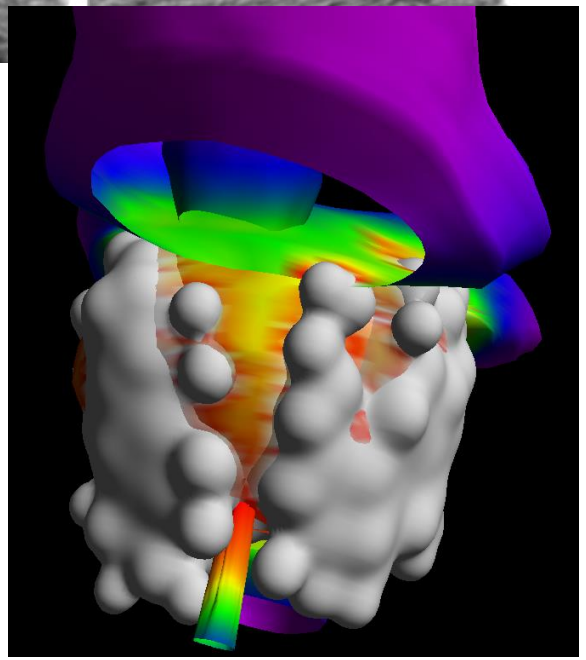


76 male

2014

70yold
GS 4+4, (4/10cores)
PSA 8
DRE - ?T3a
ADT + EBRT + PB

2015-2018

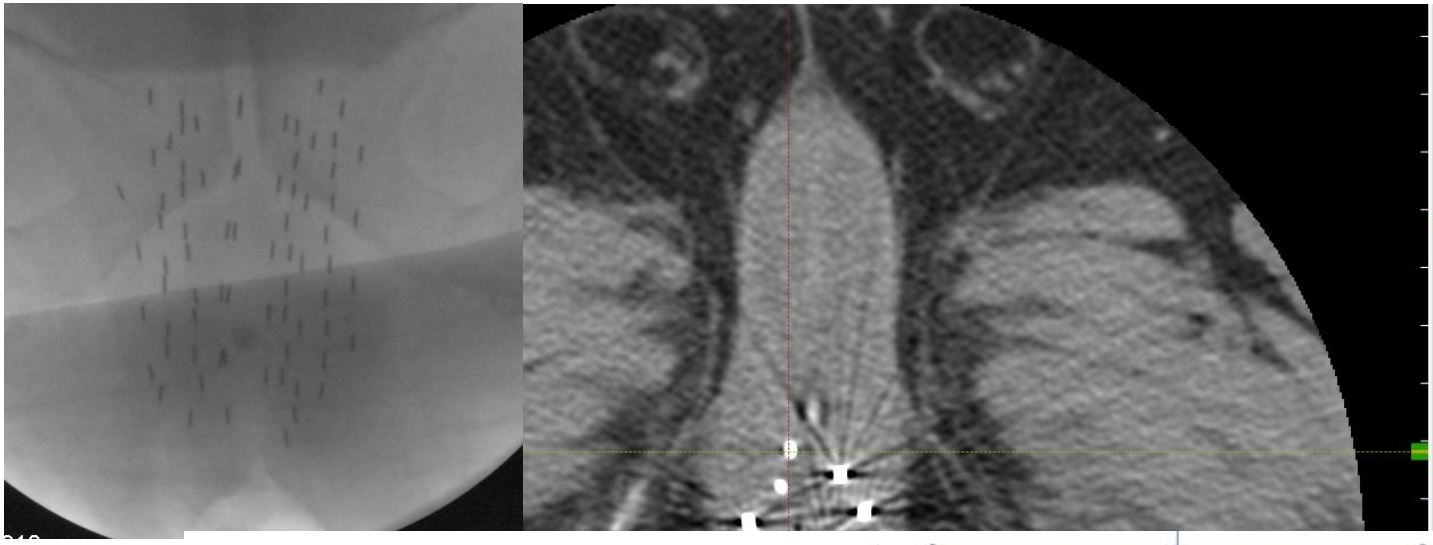
++ urinary symptoms
Urinary and fecal Incontinence
ED

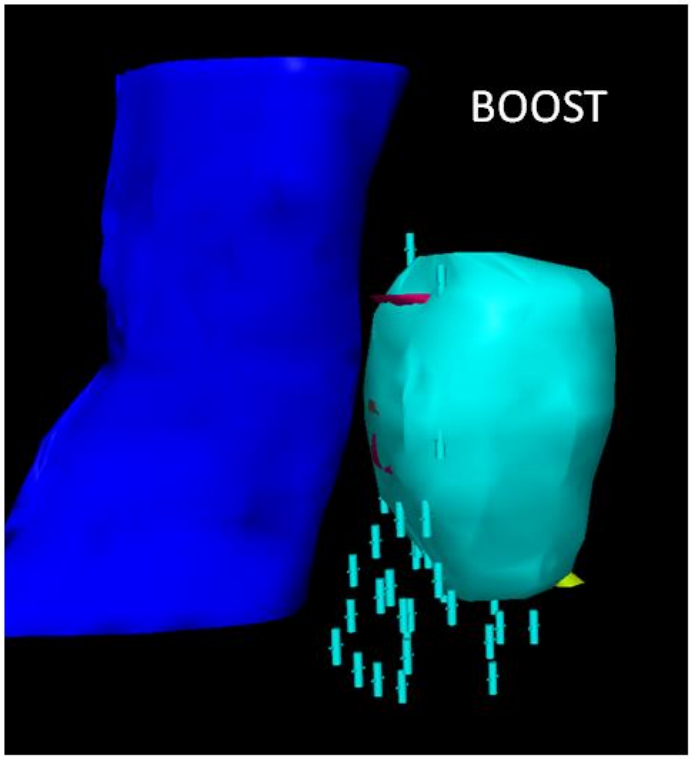
2018

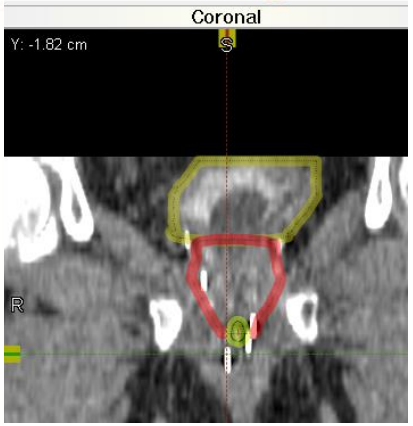
PSA 0.32
HBO
- Urinary obstruction
- Hematuria

Formal QA requested

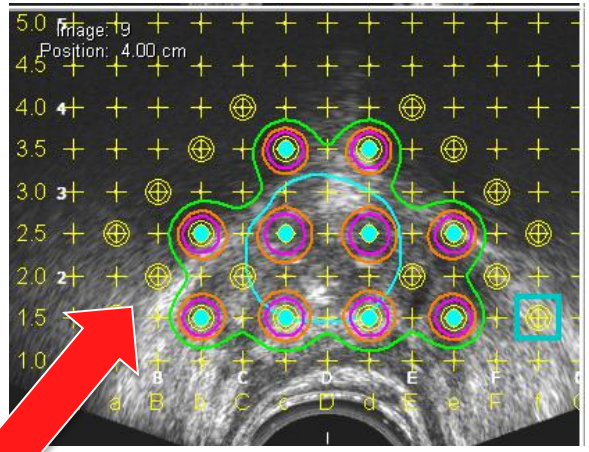
BCCA 1332840







APEX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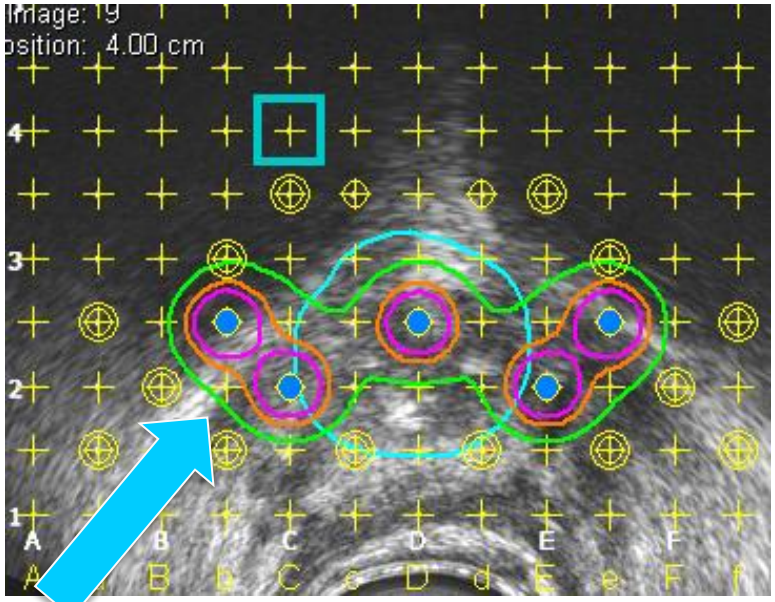
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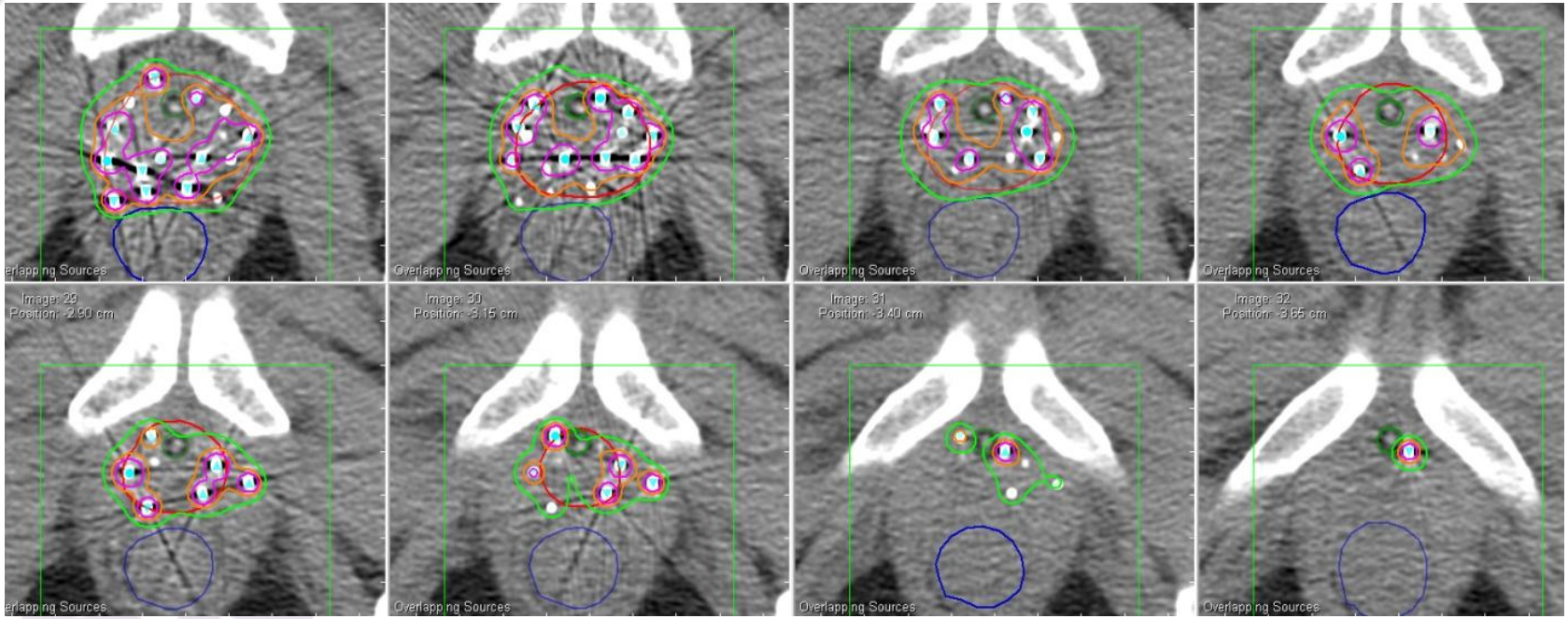
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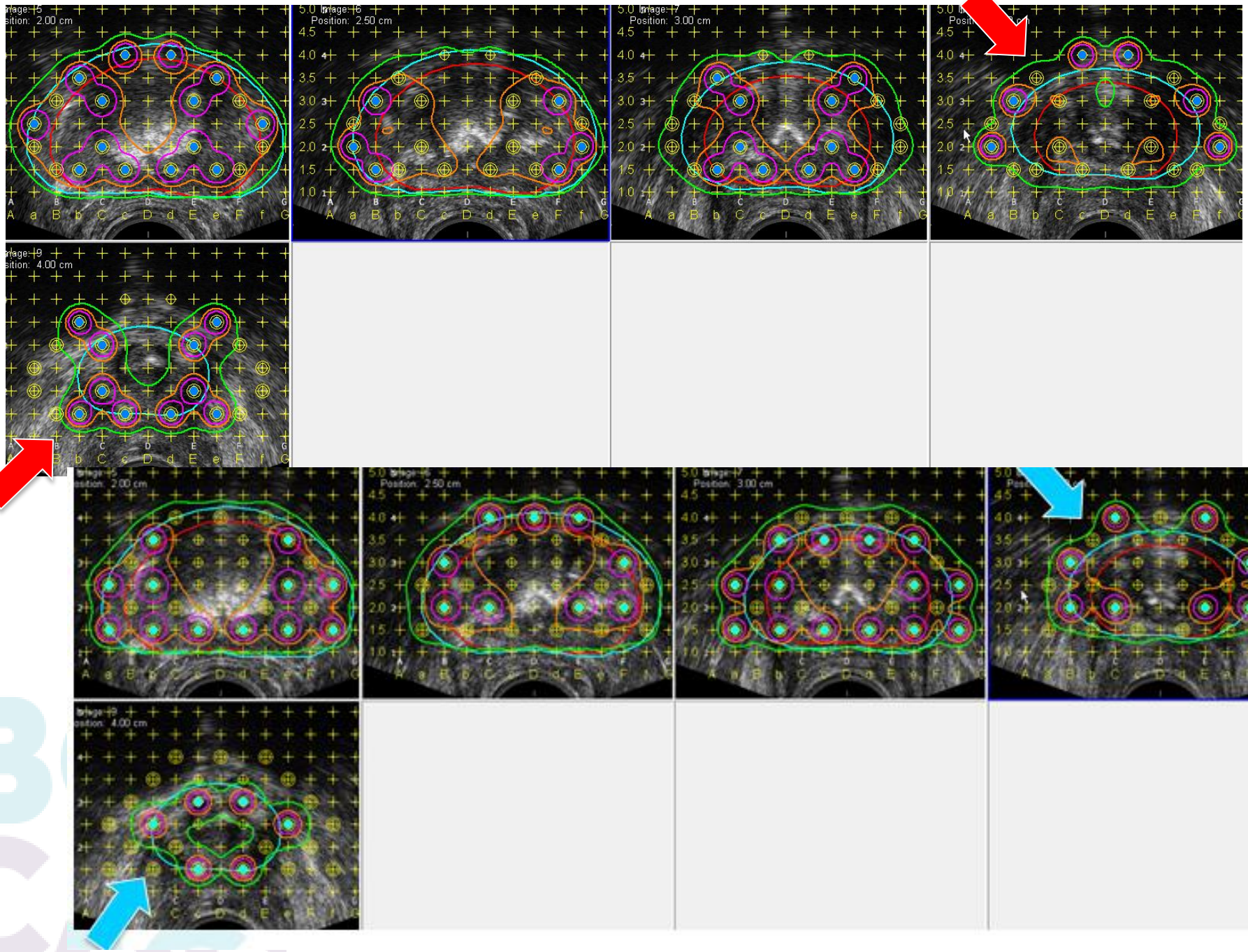
Image: 32
Position: -3.65 cm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Boost case **2016**

2016 – 60y man

High Tier IR

April 2016

EBRT + PB boost

No ADT

2018

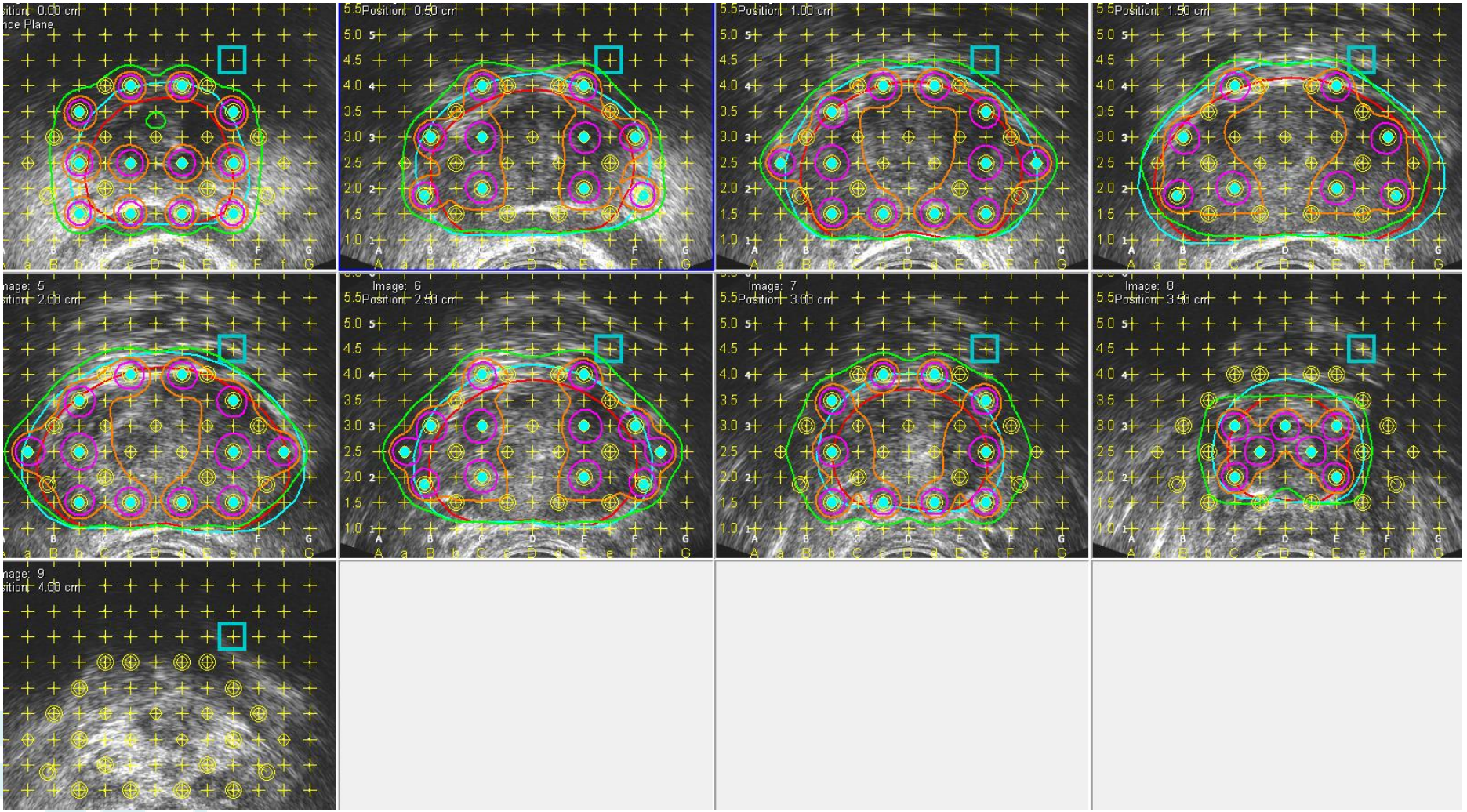
IPSS 3,

Bowel normal.

SHIM 24/25

PSA April 2017 - 0.23

PSA Jan 2018 - 0.18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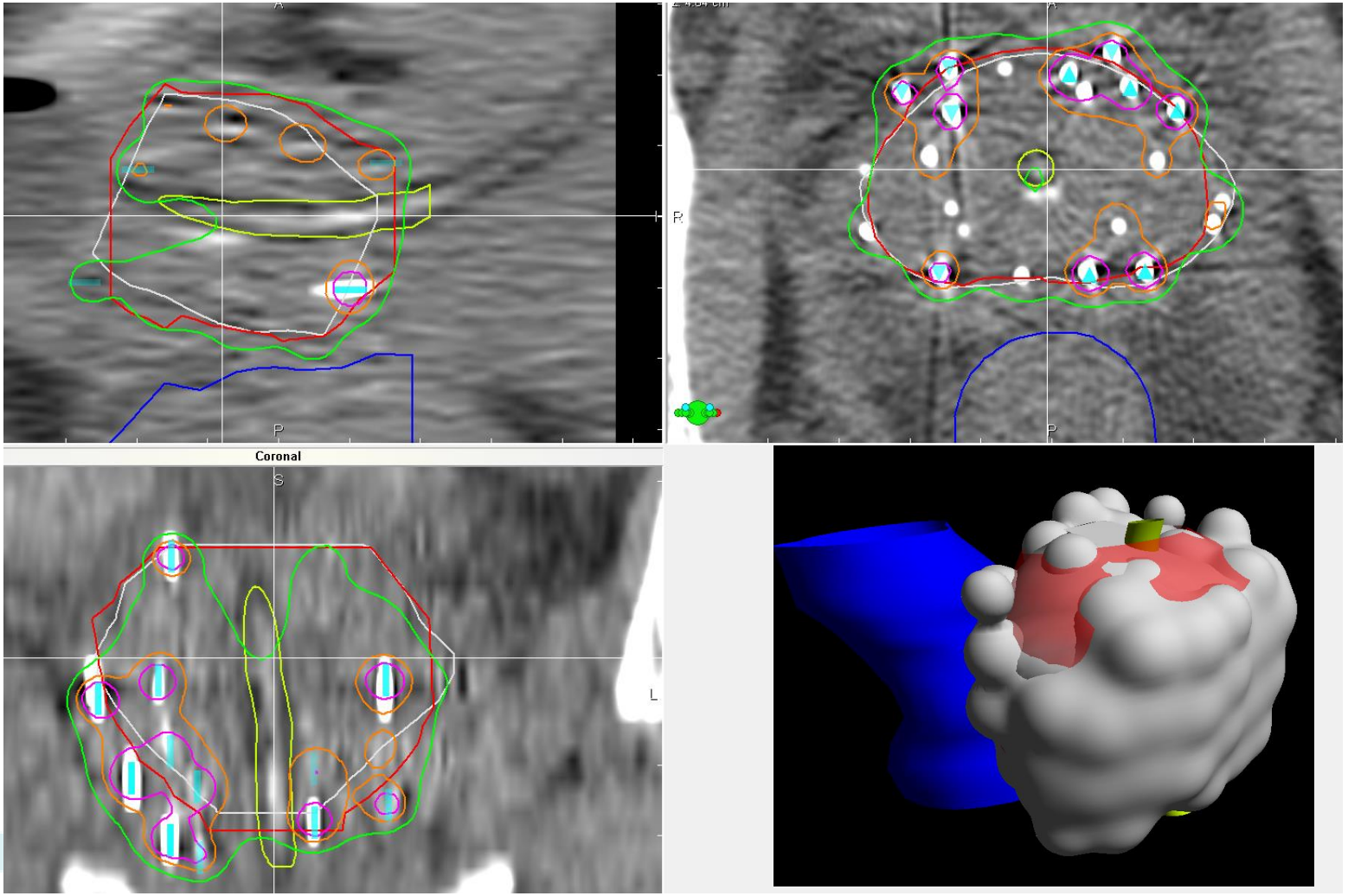
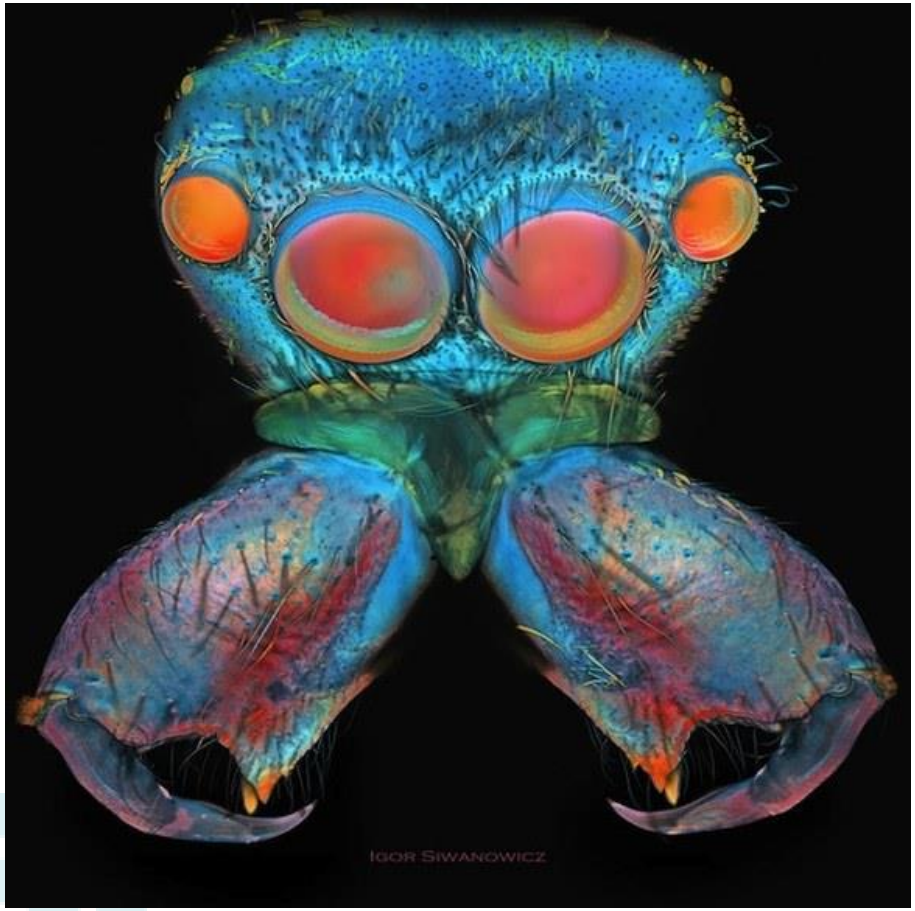
Position 0.50 cm
Position 1.00 cm
Position 1.50 cm
nage: 5
sition 2.00 cm
Image: 6
Position 2.50 cm
Image: 7
Position 3.00 cm
Image: 8
Position 3.50 cm
nage: 9
sition 4.00 cm



V100 - 92%
VR100 –0.00cc
UD50 - 100Gy



Spider head

Toxicity study in progress

No evidence of association between structures and large confluent volumes below apex

Side effects

Contraindications

Absolute

Life expectancy <10y

Large TURP defect

ATM

Good urinary function

Relative

IPSS >20

Poor max flow rates

Previous pelvic RT

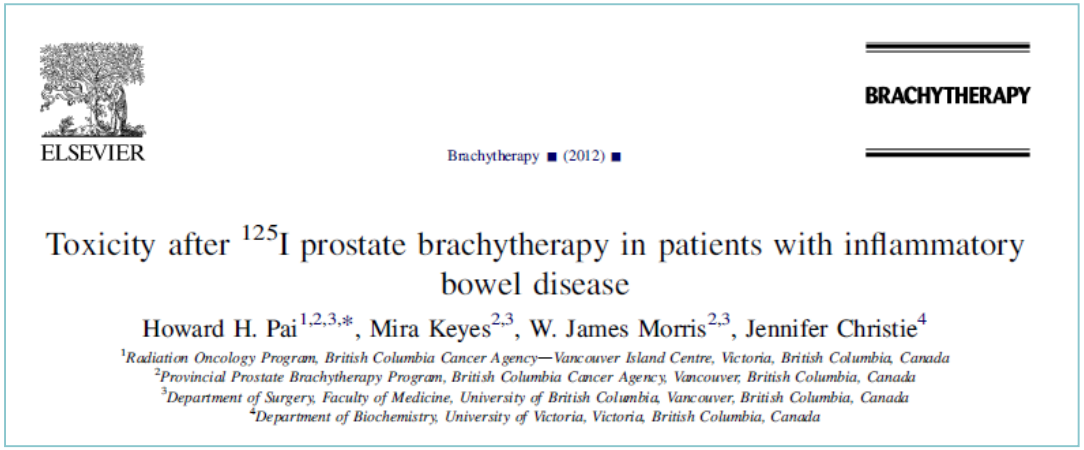
TURP

Large median lobe

IBD

>60-70cc

S.J. Frank Brachytherapy 2011
Pai - Brachytherapy 2012, J Urology 2015
Keyes IJROBP 2014
Crook IJROBP 2009
Davis, Brachytherapy 2012



ELSEVIER

Brachytherapy ■ (2012) ■

BRACHYTHERAPY

Toxicity after ^{125}I prostate brachytherapy in patients with inflammatory bowel disease

Howard H. Pai[1,2,3,*], Mira Keyes[2,3], W. James Morris[2,3], Jennifer Christie[4]

[1]Radiation Oncology Program, British Columbia Cancer Agency—Vancouver Island Centre, Victoria, British Columbia, Canada
[2]Provincial Prostate Brachytherapy Program, British Columbia Cancer Agency, Vancouver, British Columbia, Canada
[3]Department of Surgery, Faculty of Medicine, University of British Columbia, Vancouver, British Columbia, Canada
[4]Department of Biochemistry, University of Victoria, Victoria, British Columbia, Canada

IBD

26/3200 LDR med fu 4.3 years had IBD
13 IBD, 3 CD, 10 UC.

Acute Gr 3/4 - 3 pts
Late G gr 3/4 – 3 pts
3 pts with severe acute GI toxicity had rectal biopsies 3 m post implant

5 Pts with Gr3/4 toxicity Rectal dose
3 ≥ Gr2V100 >1 cc (2.7 - 4.2 cc)
2 pts had V100 of 0.00 cc.

major surgery with IBD 2/26
major surgery without IBD 4/3500

J Urology 2016

Rectal Ulcers and Rectoprostatic Fistulas after ^{125}I Low Dose Rate Prostate Brachytherapy

Nelson Leong, Howard H. Pai,* W. James Morris,† Mira Keyes, Tom Pickles, Scott Tyldesley, Jonn Wu and British Columbia Cancer Agency

From the British Columbia Cancer Agency, Vancouver Island Centre (NL, HHP), Victoria and British Columbia Cancer Agency, Vancouver Centre and Department of Radiotherapy and Developmental Radiotherapeutics, University of British Columbia (HHP), Vancouver (WJM, MK, TP, ST, JW), British Columbia, Canada

Rectal Ulcers and Fistulas

4,690 pts (1998 – 2013) Med fu 53 months

9 rectal ulcers (0.19%) and 12 cases of fistula (6 progressed form ulcers (0.26%)

12 with fistulas,

- 4 - Rectal biopsies,
- 5 - Urinary interventions (TURP, TUIP, debridement of strictures)
- 3 - APC

83% fistulas had some form of urological or rectal intervention.

No fistulas healed without surgical management, 2 died.

Review 238 patients with Gr 2-3 late rectal toxicity.

- **6.7%** APC
- **1.7%** Biopsies
- **1.7%** Urological interventions.

BC Cancer Agency
CARE + RESEARCH
An agency of the Provincial Health Services Authority

Surgical Oncology Network Newsletter

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In This Issue...

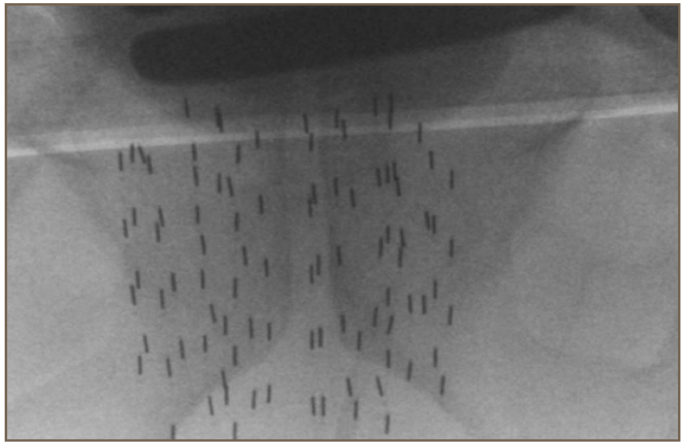
MARK YOUR CALENDARS!

SON FALL UPDATE ON COLORECTAL CANCERS

October 14, 2017
Four Seasons Hotel
Vancouver

BRACHYTHERAPY

ANTERIOR RECTAL WALL BIOPSY AND VIGOROUS APC ARE ASSOCIATED WITH RECTO-URETHRAL FISTULAS AFTER PROSTATE BRACHYTHERAPY



I-125 PERMANENT PROSTATE IMPLANT

Dr. Mira Keyes Clinical Professor Radiation Oncology Department of Surgery UBC

Brachytherapy refers to the placement of radioactive sources directly into cancerous tissue. As radiation dose gradients with brachytherapy are steep, the tumor receives a very high dose of radiation, while the surrounding normal tissues are largely spared; this offers the potential of a high cure rate and minimal toxicity to adjacent organs. Brachytherapy is the essential radiation modality used in many cancers including, prostate, cervix, lung, esophagus, eye, skin, and recently breast.

The "modern" era of LDR (Low Dose Rate) or seed prostate brachytherapy began in the 1980s with the development of trans- rectal US to plan and guide the placement of radioactive sources within the prostate. Prostate brachytherapy may be used either as monotherapy or combined with modest doses of external beam, for patients with higher risk disease. Patients treated with any form of brachytherapy had not only superior long-term PSA outcome but also showed remarkable durability of the results with a long follow-up, which may lead to cure in many patients[1,2]. BCCA Prostate Brachytherapy program is one of the largest in the world, with just over 5800 patinas implanted since 1998. We maintain a large database on all

Vigorous **APC** for rectal bleeding and **biopsies** of the anterior rectal wall are associated with very high incidence of rectal ulcers and fistulas in patients treated with prostate brachytherapy and **must be avoided if possible.**

1.Pai HH, Keyes Brachytherapy 2013 ,12
2. Leong N, Pai HH, Morris WJ, Keyes M, J.Urol 2016, 195(6)

Urinary toxicity

Acute GU Toxicity

AUR -	<5%
IPSS resolution	12 mo
RTOG gr2	~30%
RTOG gr3	~5% (AUR)

Late GU Toxicity

~10 % do not normalize IPSS to the baseline levels

Gr 2

Actuarial gr 2	30% with >10y - aging ?
Prevalence gr 2	< 5% at 10y

Gr3

Actuarial gr3	~5-10%
Prevalence gr3	<2% at 10y

Marshall RA, Urol Oncol 2014;32
Stone NN, J Urol 2012;187
Keyes M, IJROBP 2014
Chan E, Brachytherapy 2013

Predictive factors for worse GU toxicity And higher rate of AUR

Baseline IPSS

Large Prostate Volume *(no ADT)*

Higher D90 >180Gy /**EBRT**

AUR

- Higher bladder neck dose
- No Dexamethasone
- **Larger TZ**
- Post implant edema
- **Poor flow rate**
- **Trauma - # needles**

Tetsuhiro Ikeda IJ Urology 2009
Martnes Brachytherapy 2006
Keyes IJROBP 2014

Treatment: Ac. Obstructive symptoms

Flomax – 3-6 mo after PB	• 0.4 mg OD –(max 4-5 per day)
Cialis 5 mg qhs	
NSAIDS	
Flomax and Terazosin together	
Dexamethasone	• 4 mg OD x 10days than • 2 mg OD x10 days

Chronic Obstruction

Good patients selection	• Avoid patients with poor urinary function • Old age • Large volume Large medial lobe • **Combination of the above is the worst!**
AVOID TURP	• TUIP if necessary
Urethral necrosis and Repeated TURP	• Trental 400mg BID Vitamin E 800 IU • Daily x 4-6 mo • **Be Conservative**
Supra-pubic Catheter	• For chr. obstruction
Self catheterisation	• For strictures

GI toxicity

RTOG gr2	<5%
RTOG gr3	1-2%
RTOG gr4	<0.1%

Higher rectal dose

- VR100 >144Gy
- **EBRT**

Large Prostate Volume

Learning Curve

IBD

Fistulas

- TURP
- Argon Plasma
- IBD?

Keyes at al Brachytherapy 2011
Leong at all sublimed to Urology 2015
S.J. Frank ACR appropriateness Criteria Brachytherapy 2011

Treatment: Rectal symptoms

Gr 1/2 Rectal urgency and frequency	• Proctosedyl supp • Diet modification • Lomotil • Steroid enemas
Rectal bleeding **Observation**	• Aron Plasma Coagulation • HBO • Formalin enemas
Rectal Pain	• o+B supp
Be conservative LESS IS MORE	• **AVOID BIOPSY of ANTERIOR RECTAL Wall** • **Avoid APC**

Sexual Function

Snyder BJU 2011
Keyes M Brachytherapy 2015
Crook JCO 2011
Masashi Matsushima J Urology 2013

Overall 5 y EF - 50%
Young men (<60) EF >80%

Age, **ADT,** hypertension, and aging all have negative impact on long-term EF after LDR.

FIG. 1. Effect of age on potency.

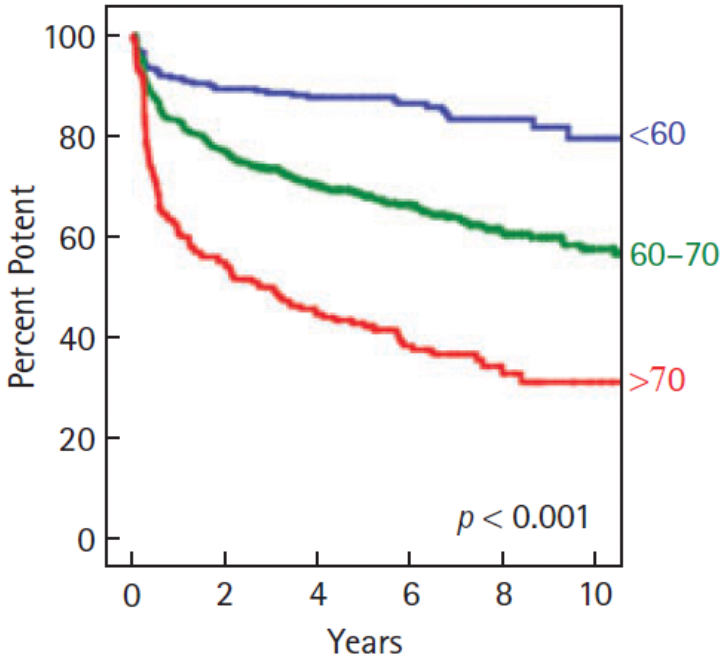
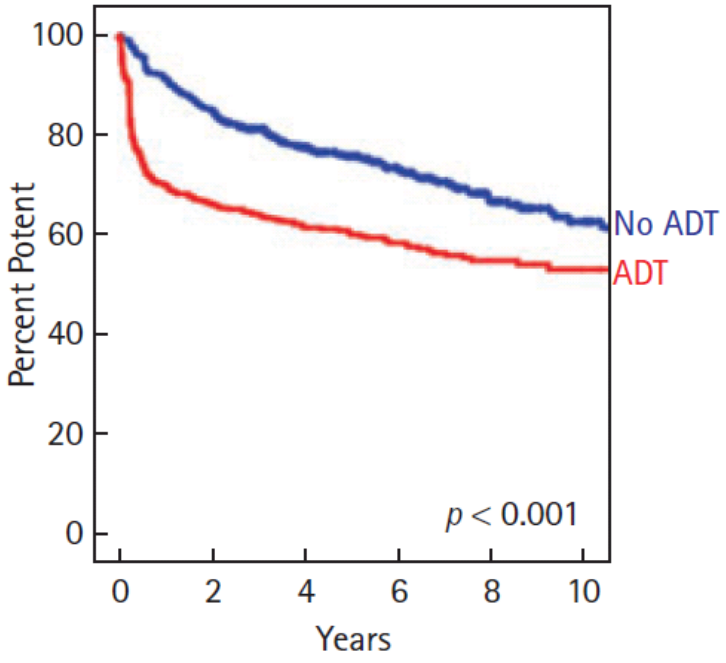


FIG. 3. Effect of ADT on potency.



ELSEVIER

Brachytherapy ■ (2015) ■

BRACHYTHERAPY

Effect of aging and long-term erectile function after iodine-125 prostate brachytherapy

Mira Keyes[1,*], Tom Pickles[1], Juanita Crook[2], Michael McKenzie[1], Arthur Cheung[3], Ingrid Spadinger[1], Vincent LaPointe[1], W. Francois Bachand[2], James Morris[1]

[1]*Vancouver Cancer Center, The British Columbia Provincial Prostate Brachytherapy Program, University of British Columbia, British Columbia Cancer Agency, Canada*

[2]*Cancer Centre for Southern Interior, The British Columbia Provincial Prostate Brachytherapy Program, University of British Columbia, British Columbia Cancer Agency, Canada*

[3]*Fraser Valley Cancer Centre, The British Columbia Provincial Prostate Brachytherapy Program, University of British Columbia, British Columbia Cancer Agency, Canada*

Aging process contributes ~50% to the decline in EF after PB in all age groups

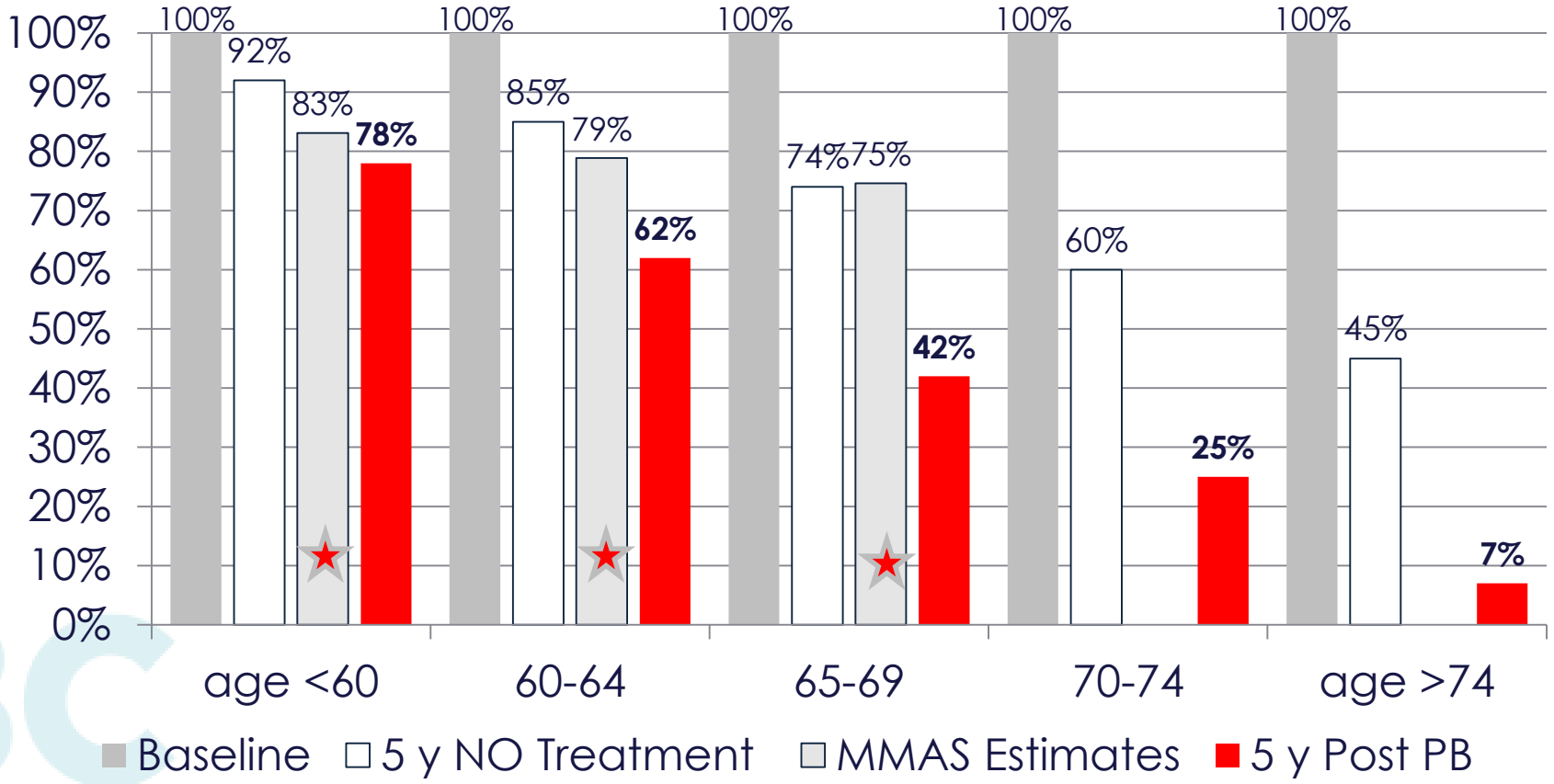
Prevention

Treatment

- Avoid ADT
- Avoid large high dose confluent areas below the apex
- Cialis 5 mg daily post op for several months

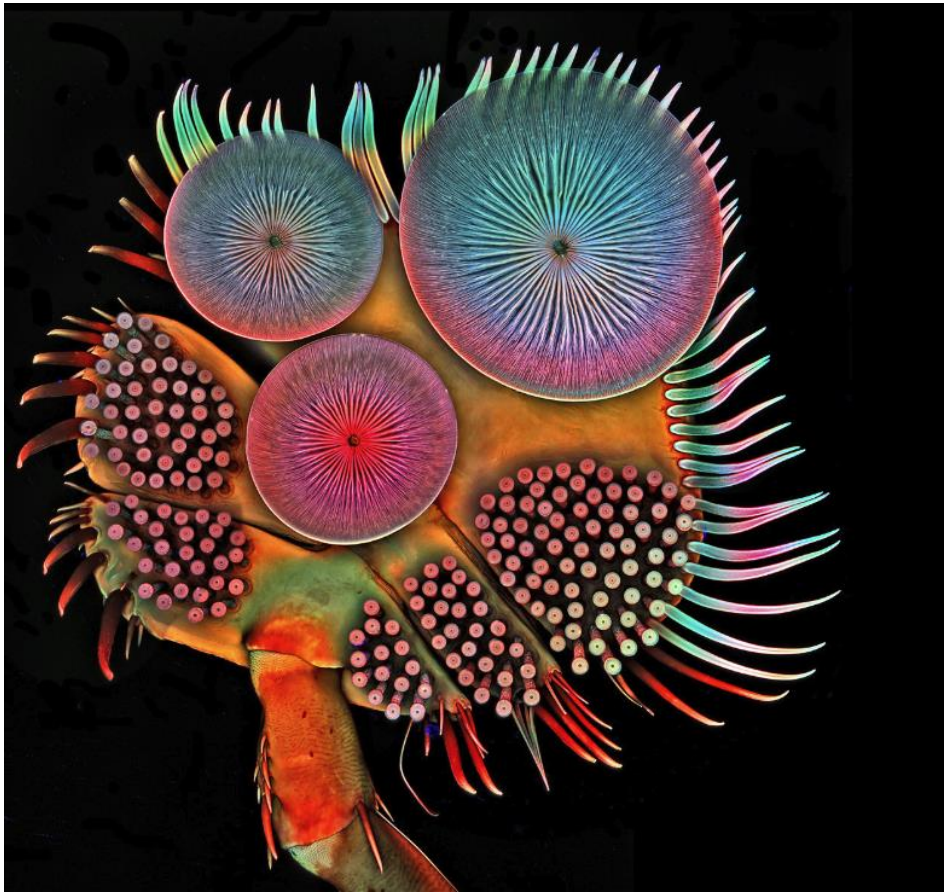
Proportional effects of aging on 5y EF decline

100% if EF is normal at baseline
BCCA pts aging process: without PB
MMAS aging process: MMAS prediction
PB effects of treatment



MMAS estimates ... *g linear regression*
MMAS[age<60] s...

Aging process contributes ~50% to the decline in EF after PB in all age groups



Male beetle

Almost any dose intensification in oncology has come with a price of higher toxicity

Patient selection

- Younger patents
- Good life expectancy
- Good urinary function

Planning is critical

OR skills

Conservative management of complications

It is not only what we do, but what we do not do, for which we are accountable

Moliere

Thank you!