

GROWTH AREAS IN IO - PROSTATE

SHIVANK BHATIA M.D.

CHAIRMAN

DEPARTMENT OF INTERVENTIONAL RADIOLOGY
PROFESSOR, INTERVENTIONAL RADIOLOGY AND UROLOGY

UNIVERSITY
OF MIAMI



UNIVERSITY OF MIAMI
MILLER SCHOOL
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Disclosures

- Consultant: Merit Medical, Mentice, Embolx
- Speaker: Merit Medical, Terumo, Siemens

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Prostate Cancer Statistics

At a Glance

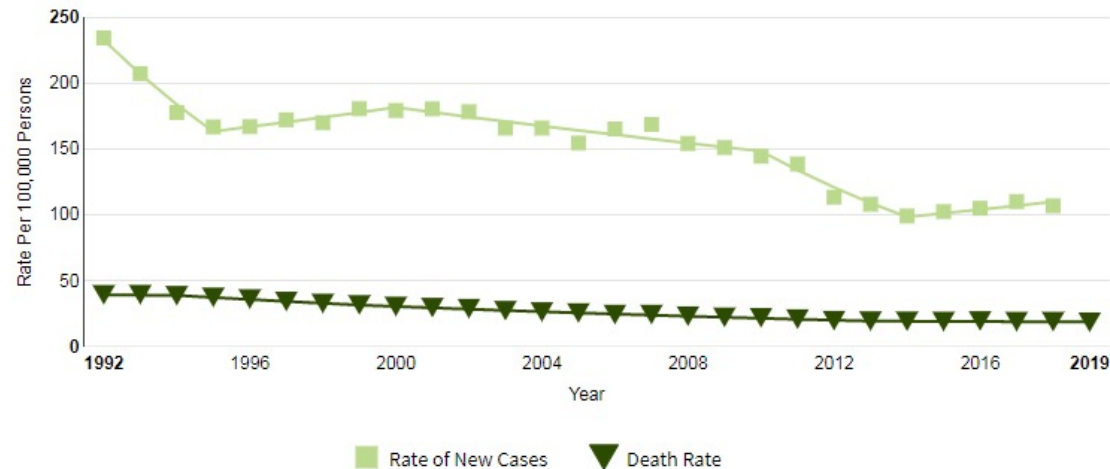
Estimated New Cases in 2021	248,530
% of All New Cancer Cases	13.1%

Estimated Deaths in 2021	34,130
% of All Cancer Deaths	5.6%

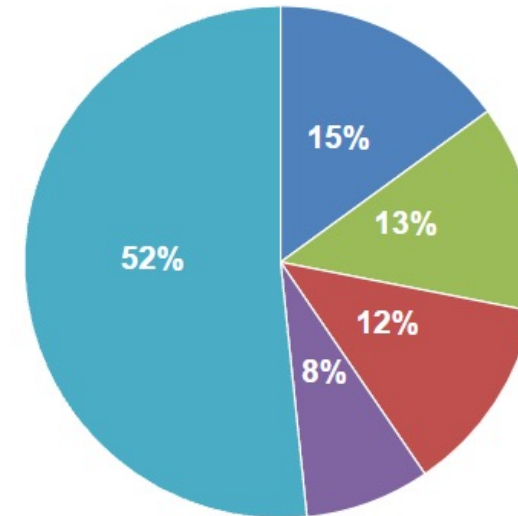
5-Year Relative Survival

97.5%

2011-2017



New Cancer Cases, 2021

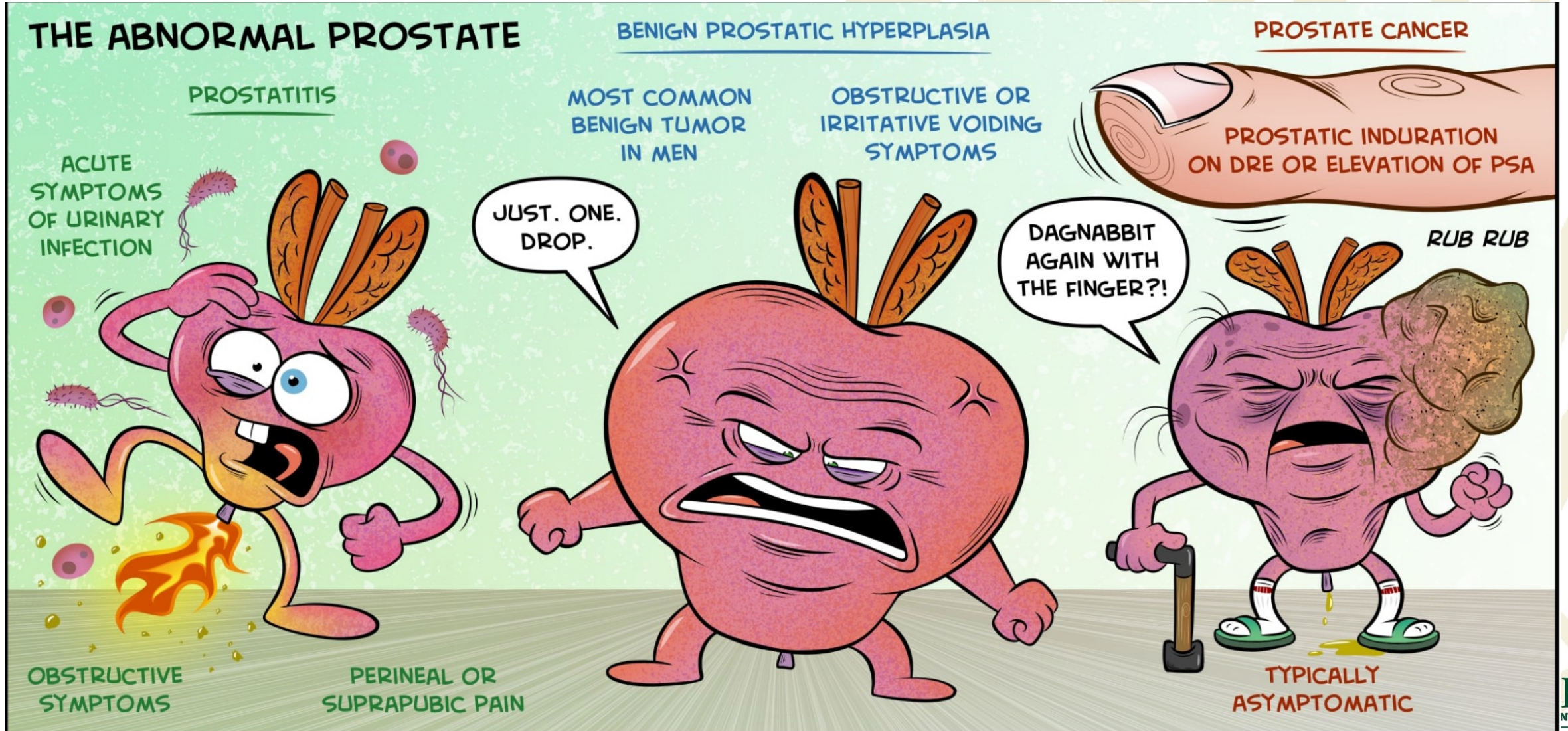


- Breast: 284,200 (15%)
- Prostate: 248,530 (13%)
- Lung and bronchus: 235,760 (12%)
- Colon and rectum: 149,500 (8%)
- Other: 980,170 (52%)

<https://seer.cancer.gov/statfacts/html/prost.html>



Prostate Cancer Presentation



Prostate Cancer Management



For the past 30 years:
Surgery
Radiotherapy
Active Surveillance



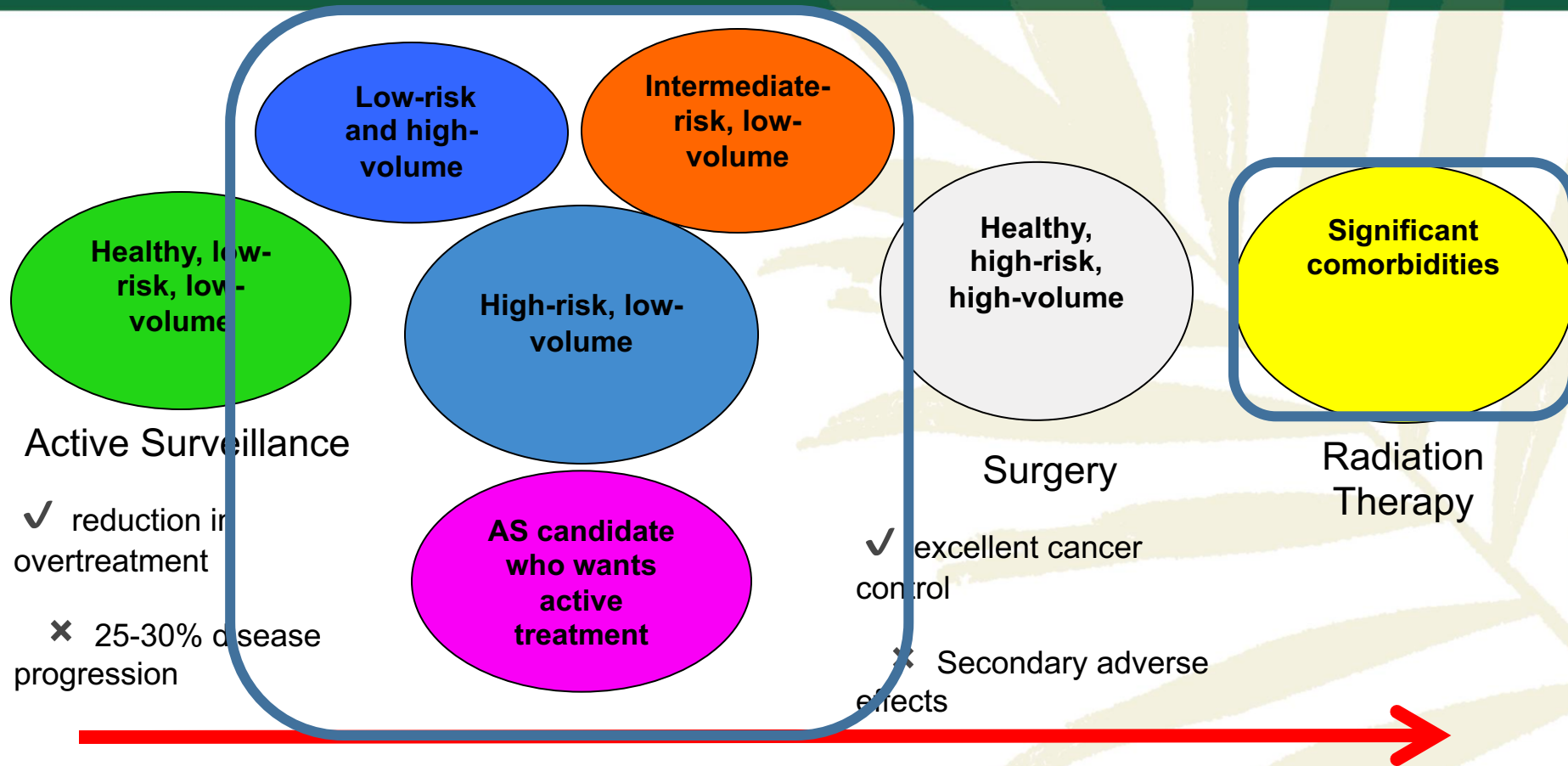
No difference in prostate
cancer specific mortality,
overall mortality, or
metastases between surgery
and radiotherapy



Decisions are driven by risks
of urinary, erectile, and
bowel dysfunction –
functional outcomes



Prostate Cancer Treatment Menu – Urologist perspective



Focal Therapy

Future Intra-arterial therapies



Focal Therapy – Energy Sources

- Cryotherapy
- High-Intensity Focused Ultrasound (HIFU)
- Irreversible Electroporation (IRE)
- Laser Ablation Therapy
- Vascular-targeted Photodynamic Therapy (VTP)
- Brachytherapy



Focal Therapy for PCa

✓ Primary treatment with significantly fewer side effects

↓ Incontinence
↓ ED

✓ Fewer Complications

✓ Short-term oncological outcomes are promising

✗ Lack of long-term data

✗ Multifocal disease

✗ Indication overlaps with patients on AS

✗ No standardized definition for eligibility criteria, failure/success, and follow-up



Focal Therapy and Index Lesion

- Focal therapy is based on the treatment of the **Index lesion**

- Index lesion is the **largest, dominant** lesion associated with the **highest Gleason Score**

- Drives **clinical progression**

- Prostate Cancer is a **multifocal disease!**
 - 86% multifocal disease, 14% unifocal

Masterson et al., 2010

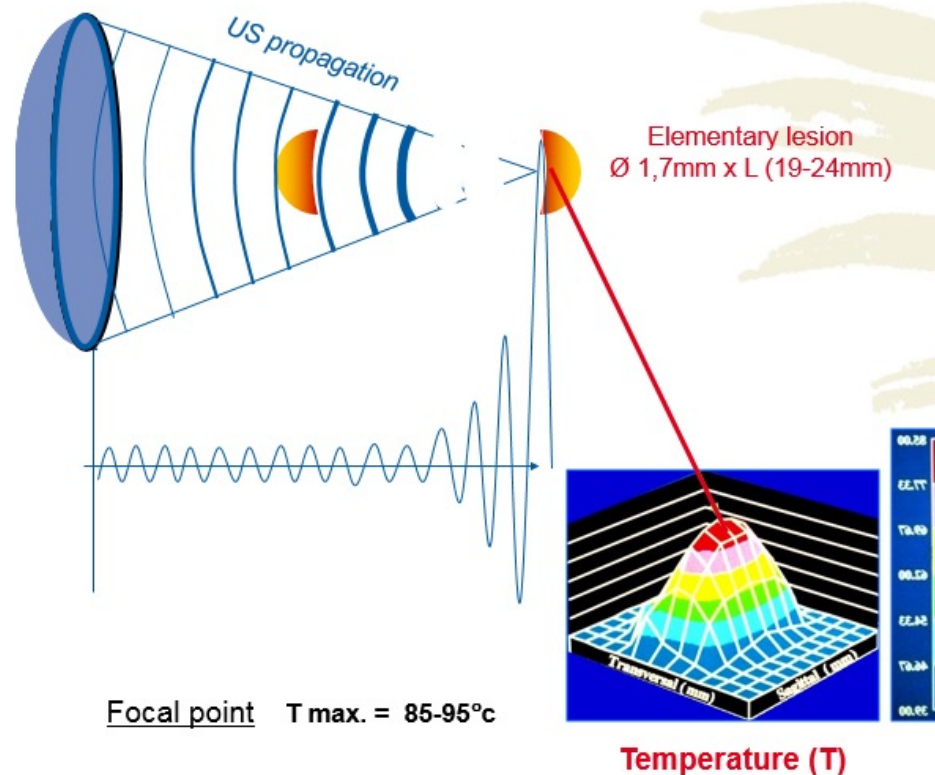
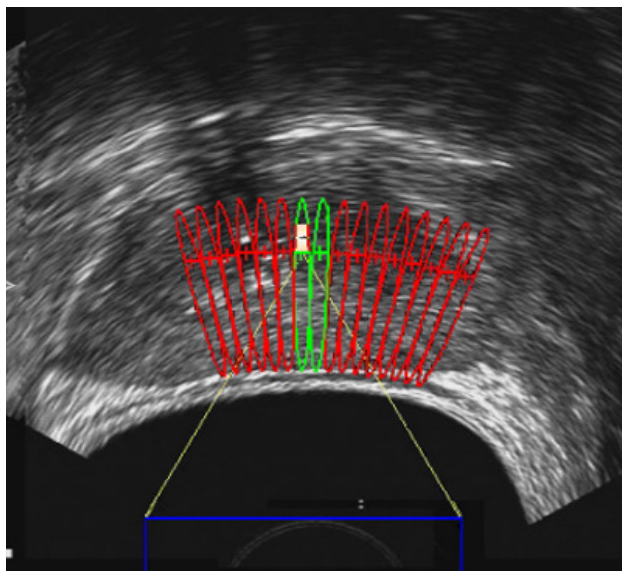
- ... but 99% of **satellite lesions** are **Gleason 6** and 87% are **< 0.5ml in volume** *Karavitis et al., 2011*



HIFU Principles

HIFU Therapy

- 3 MHz
- Focused ultrasound
- Very high power (200W)
10,000 times more than imaging



- Coagulative necrosis in 24h
- Fibrosis in 3 months



HIFU Outcomes

available at www.sciencedirect.com
journal homepage: www.europeanurology.com



Platinum Priority – Prostate Cancer
Editorial by XXX on pp. x–y of this issue

A Multicentre Study of 5-year Outcomes Following Focal Therapy in Treating Clinically Significant Nonmetastatic Prostate Cancer

Stephanie Guillaumier^{a,b,†}, Max Peters^{c,†}, Mani Arya^{b,d,e}, Naveed Afzal^f, Susan Charman^a, Tim Dudderidge^g, Feargus Hosking-Jervis^{a,h}, Richard G. Hindleyⁱ, Henry Lewi^j, Neil McCartan^{a,b}, Caroline M. Moore^{a,b}, Raj Nigam^k, Chris Ogden^l, Raj Persad^m, Karishma Shah^a, Jan van der Meulenⁿ, Jaspal Virdi^e, Mathias Winkler^d, Mark Emberton^{a,b}, Hashim U. Ahmed^{a,d,h,*}

^a Division of Surgery and Interventional Sciences, University College London, London, UK; ^b Department of Urology, UCLH NHS Foundation Trust, London, UK; ^c Department of Radiotherapy, University Medical Centre, Utrecht, The Netherlands; ^d Imperial Urology, Charing Cross Hospital, Imperial College Healthcare NHS Trust, London, UK; ^e Department of Urology, The Princess Alexandra Hospital NHS Trust, Harlow, UK; ^f Department of Urology, Dorset County Hospital NHS Trust, Dorset, UK; ^g Department of Urology, University Hospital Southampton NHS Trust, Southampton, UK; ^h Division of Surgery, Department of Surgery and Cancer, Faculty of Medicine, Imperial College London, London, UK; ⁱ Department of Urology, Basingstoke and North Hampshire Hospital, Hampshire Hospitals NHS Foundation Trust, Basingstoke, UK; ^j Springfield Hospital, Chelmsford, UK; ^k Department of Urology, Royal County Surrey Hospital NHS Trust, Guildford, UK; ^l Department of Academic Urology, The Royal Marsden Hospital NHS Foundation Trust, London, UK; ^m Department of Urology, Southmead Hospital, North Bristol NHS Trust, Bristol, UK; ⁿ London School of Hygiene and Tropical Medicine, London, UK

Article info

Article history:
Accepted June 1, 2018

Associate Editor:
James Catto

Statistical Editor:
Andrew Vickers

Keywords:
High-intensity focused ultrasound
Focal therapy
Transperineal biopsy
Multiparametric magnetic resonance imaging
Targeted biopsy

Abstract

Background: Clinically significant nonmetastatic prostate cancer (PCa) is currently treated using whole-gland therapy. This approach is effective but can have urinary, sexual, and rectal side effects.

Objective: To report on 5-yr PCa control following focal high-intensity focused ultrasound (HIFU) therapy to treat individual areas of cancer within the prostate.

Design, setting, and participants: This was a prospective study of 625 consecutive patients with nonmetastatic clinically significant PCa undergoing focal HIFU therapy (Sonablate) in secondary care centres between January 1, 2006 and December 31, 2015. A minimum of 6-mo follow-up was available for 599 patients. Intermediate- or high-risk PCa was found in 505 patients (84%).

Intervention: Disease was localised using multiparametric magnetic resonance imaging (mpMRI) combined with targeted and systematic biopsies, or transperineal mapping biopsies. Areas of significant disease were treated. Follow-up included prostate-specific antigen (PSA) measurement, mpMRI, and biopsies.

Outcome measurements and statistical analysis: The primary endpoint, failure-free survival (FFS), was defined as freedom from radical or systemic therapy, metastases, and cancer-specific mortality.

Results and limitations: The median follow-up was 56 mo (interquartile range [IQR] 35–70). The median age was 65 yr (IQR 61–71) and median preoperative PSA was 7.2 ng/ml (IQR 5.2–10.0). FFS was 99% (95% confidence interval [CI] 98–100%) at 1 yr, 92% (95% CI 90–95%) at 3 yr, and 88% (95% CI 85–91%) at 5 yr. For the whole patient cohort, metastasis-free, cancer-specific, and overall survival at 5 yr was 98% (95% CI 97–99%), 100%, and 99% (95% CI 97–100%), respectively. Among patients who returned validated questionnaires, 241/247

[†] These authors contributed equally to this work and share first authorship.

* Corresponding author. Imperial Urology, Charing Cross Hospital Campus, Imperial College London, Fulham Palace Road, London, UK.

E-mail address: hashim.ahmed@imperial.ac.uk (H.U. Ahmed).

Guillaumier S, et al. Eur Urol June 2018

- Multicenter, prospective study
- 625 patients (84% intermediate or high-risk)
- 5-y failure-free survival 88%
- 5-y metastasis-free survival 98%
- Pad-free continence 98%
- UTI 10.4%
- AUR needing TURP 10%

MRI-Guided Transurethral Ultrasound Ablation (TULSA)

Transurethral directional US ablation

- Sweeping ultrasound, continuous rotation, no cold spots between sonications
- Capable of large or small ablation volumes

Real-time MR imaging and control

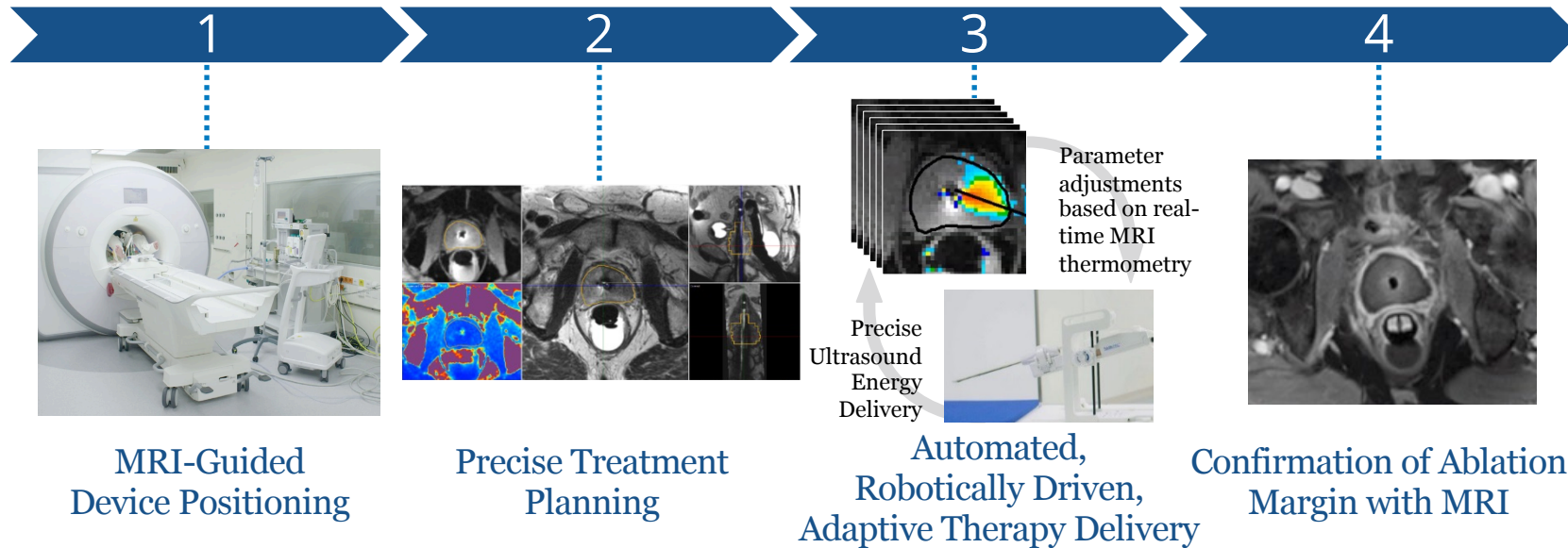
- Customized, predictable treatment planning
- MR thermal dosimetry enables closed-loop feedback control for millimeter precision

Designed for safety

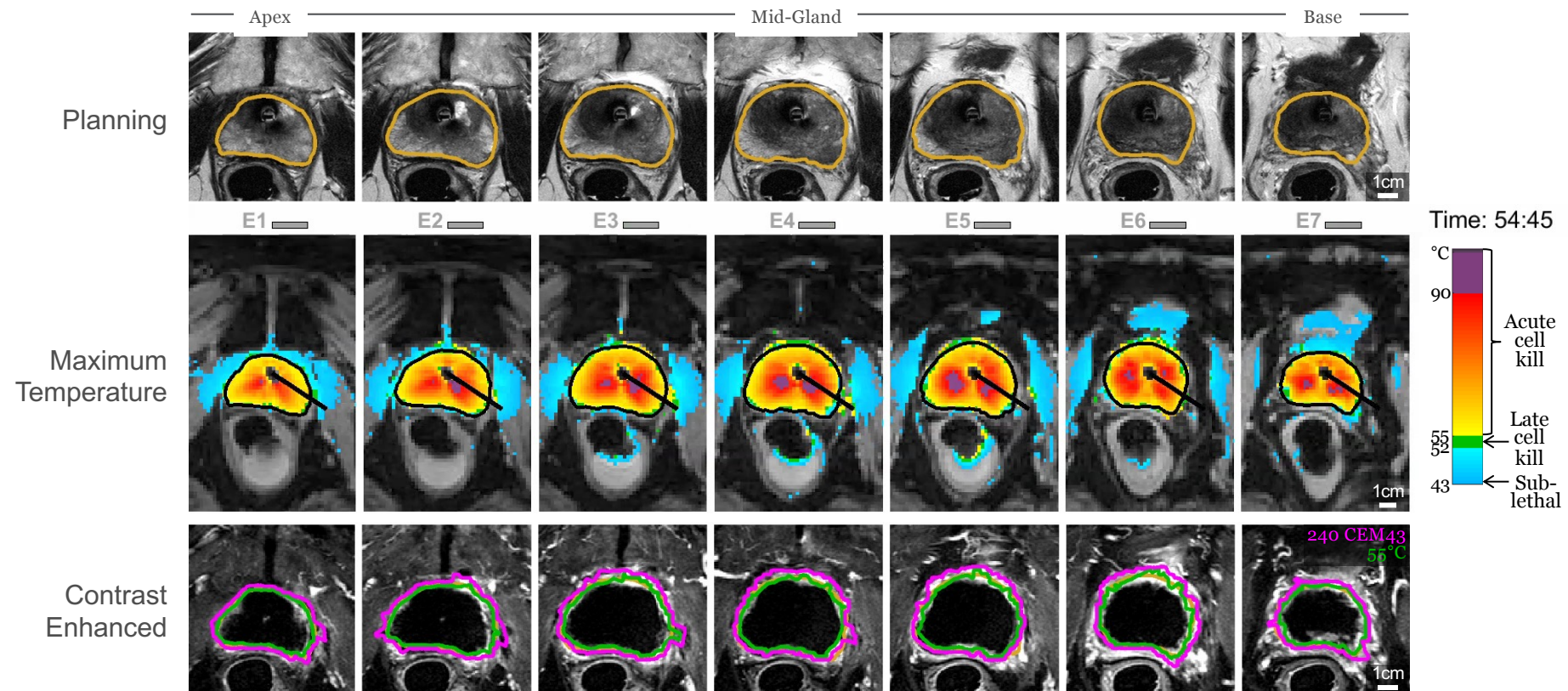
- No energy through rectum
- Active cooling protects urethra and rectum



MRI-Guided Transurethral Ultrasound Ablation



Real-Time MRI Thermometry and Feedback Control



Transurethral Prostate Cancer Ablation

TACT summary, **Literature review** of other trials provided for context

	TACT Study	Literature Review		
	TULSA	Prostatectomy	Radiation	HIFU
Biopsy / Histology	21% Clinically significant 14% Insignificant disease (GG1, ≤2 cores, < 50% CCL) 65% Negative	16 – 24% +Margin ¹ (Meta-Analysis) 10 – 15% +Margin ² (RCT) 24% +Margin ³ (ProtecT)	28% Clinically significant ⁴ 20% Insignificant disease ⁴ (Positive w. treatment effect) 52% Negative ⁴	59 – 61% Negative ⁵⁻⁶ (Intent to treat) 63% Negative, after 40% having repeat HIFU and 39% ADT ⁷
Erectile Dysfunction erections insufficient for penetration	23% Grade 2 medication indicated. No Grade 3 ED	79% ⁹ (Range: 25 – 100%) ¹⁻⁴	63% ⁹ (Range: 7 – 85%) ¹⁻⁵	58% ⁷ (Range: 44 – 67%) ⁶⁻⁸
Urinary Incontinence moderate to severe	2.6% Grade 2 pads indicated. No Grade 3 Incontinence	15% ⁹ (Range: 0 – 50%) ¹⁻⁴	4% ⁹ (Range: 2 – 15%) ¹⁻⁵	3% ⁵ (Range: 3 – 22%) ⁶⁻⁸
Urethral Stricture moderate to severe	2.6%	9% ¹¹ (Range: 3 – 26%) ¹⁻⁴	2% ¹¹ (Range: 1 – 9%) ¹⁻⁵	35% ⁵ (Range: 9 – 35%) ⁶⁻⁸
GI Toxicity, moderate to severe diarrhea, urgency, incontinence, fistula	No GI Toxicity	15% ⁹ (Range: 0 – 24%) ¹⁻⁴	25% ^{9, 12} (Range: 0 – 40%) ¹⁻⁵	7% ⁵ (Range: 1 – 21%) ⁶⁻⁸

1. Tewari et al 2012 (Meta-Analysis)
2. Yaxley et al 2016 (RCT)
3. Hamdy et al 2016 (ProtecT)
4. Radiation Meta-Analysis (publication pending)

6. FDA IDE Study DEN150011
7. Crouzet et al, Eur Urol 2014 (1000+ patients, Whole-gland HIFU)
8. Thompson (Chair) et al, AUA prostate cancer clinical guideline update panel 11 Urol 2007

10. Potosky et al, Prostate Cancer Outcomes Study (PCOS), J NCI 2004
11. Elliott et al, CaPSURE database, J Urol 2007
12. Budaus et al, Review, Eur Urol 20012

Focal therapy for localized prostate cancer: Where do we stand?

Bruno Nahar ^{*}, Dipen J. Parekh

Department of Urology, University of Miami Miller School of Medicine, Miami, FL, USA



Table 1 – Ongoing trials on focal therapy as of February 2019.

	Name, number and location of the trial	Trial design
HIFU	Intervention trial evaluating focal therapy using high intensity focused ultrasound for the treatment of prostate cancer (NCT02265159) Zurich, Switzerland	<ul style="list-style-type: none"> • Phase 2/3 trial investigating low- to intermediate-risk PC patients (n = 100) • Primary outcome: oncological safety • Secondary outcome: PSA dynamics, MRI accuracy, cost-effectiveness, functional outcomes, rate of salvage treatment • Follow-up: 3 yr
	Phase 3, multicenter, randomized study, evaluating the efficacy and tolerability of focused HIFU therapy compared to active surveillance in patients with significant low risk prostate cancer (HIFUSA) (NCT03531099) Lyon, France	<ul style="list-style-type: none"> • Phase 3 trial randomizing patients to active surveillance vs HIFU (n = 146) • Primary outcome: proportion of patients who need radical treatment • Secondary outcome: pathologic progression, appearance of metastasis, survival outcomes, functional outcomes • Follow-up: 4 yr
	Focal prostate ablation versus radical prostatectomy (FARP) (NCT03668652) Oslo, Norway	<ul style="list-style-type: none"> • Phase 3 trial randomizing patients with low- to intermediate-risk PC to radical prostatectomy vs HIFU (n = 250) • Primary outcome: proportion of patients who need salvage treatment • Secondary outcome: functional outcomes, rate of secondary interventions, PSA dynamics, cost-effectiveness • Follow-up: 3 yr
	A multi-center prospective single arm intervention trial evaluating focal therapy using high intensity focused ultrasound for localized prostate cancer (INDEX) (NCT01194648) London, UK	<ul style="list-style-type: none"> • Phase 2 trial investigating low- to intermediate-risk PC patients (n = 354) • Primary outcome: conversion to radical treatment and/or need for systemic therapy and/or developing metastasis and/or dying from PC • Secondary outcome: functional outcomes, survival outcomes, appearance of metastasis, focal ablation failure • Follow-up: 10 yr
Cryotherapy	Regional cryoablation for localized adenocarcinoma of the prostate (NCT00877682) Houston, TX, USA	<ul style="list-style-type: none"> • Phase 2 trial investigating low- to intermediate-risk PC patients (n = 48) • Primary outcome: positive biopsy rates at 6 mo • Secondary outcome: not applicable • Follow-up: 3 yr
PDT	Study of the efficacy, safety and quality of life after TOOKAD [®] soluble (VTP) for intermediate risk prostate cancer (NCT03315754) New York, NY, USA	<ul style="list-style-type: none"> • Phase 2 trial investigating intermediate-risk PC patients (n = 50) • Primary outcome: absence of Gleason 4 or 5 on biopsy at 12 mo • Secondary outcome: absence of Gleason 4 or 5 at 24, 36, 48, and 60 mo, need for salvage therapy, PSA dynamics, functional outcomes, adverse events • Follow-up: 5 yr
	Study of erectile dysfunction, urinary incontinence and related QoL after TOOKAD [®] VTP for low risk prostate cancer (NCT03849365) Angers, France	<ul style="list-style-type: none"> • Phase 4 trial investigating low-risk PC patients (n = 200) • Primary and secondary outcome: occurrence and timing of side effects such as erectile dysfunction and urinary incontinence • Follow-up: 12 mo

	Name, number and location of the trial	Trial design
FLA	A phase II study to evaluate outpatient magnetic resonance image-guided laser focal therapy for prostate cancer, a 20-year survival study (NCT02243033) Indian Wells, CA, USA	<ul style="list-style-type: none"> • Phase 2 trial investigating low- to intermediate-risk PC patients (n = 1000) • Primary outcome: safety and adverse events at 1 yr • Secondary outcome: Oncological efficacy evaluated by MRI targeted biopsy at 12 mo, time to biochemical recurrence, metastasis at 20 yr • Follow-up: up to 20 yr
	MRI guided focal laser ablation of prostate cancer (NCT03650595) Toronto, Canada	<ul style="list-style-type: none"> • Phase 2 trial investigating low- to intermediate-risk PC patients (n = 23) • Primary outcome: clinically significant cancer-free survival at 6- and 24-mo follow-up biopsy • Secondary outcome: functional outcomes • Follow up: 2 years
	Magnetic resonance imaging (MRI) guided focal laser interstitial thermal ablation of localized prostate cancer (NCT03634579) Atlanta, GA, USA	<ul style="list-style-type: none"> • Phase 2 trial investigating low- to intermediate-risk PC patients (n = 20) • Primary outcome: recurrence rates at 1 yr, safety, functional outcomes • Secondary outcome: recurrence at 2 yr • Follow up: 2 yr
IRE	Multi-center randomized clinical trial irreversible electroporation for the ablation of localized prostate cancer (NCT01835977)	<ul style="list-style-type: none"> • Phase 2 trial randomizing patients with low- to intermediate-risk PC to focal vs extended ablation (n = 200) • Primary outcome: recurrence rates at 1 yr • Secondary outcome: oncological outcomes • Follow-up: 5 yr
Focal BT	Focal brachytherapy in patients with selected "low-risk" prostate cancer: a phase II trial (FOKAL-BT) (NCT02391051) Erlangen, Germany	<ul style="list-style-type: none"> • Phase 2 feasibility trial investigating low-risk PC patients (n = 50) • Primary outcome: adverse events at 6 wk • Secondary outcome: tumor regression, PSA recurrence, correlation of molecular markers with PSA-free survival • Follow-up: 10 yr
	Phase II study of feasibility of focal therapy for prostate cancer of good prognosis with permanent 1125 localized implant (CURIEFOCALE) (NCT01902680) Toulouse, France	<ul style="list-style-type: none"> • Phase 2 feasibility trial investigating low risk patients (n = 18) • Primary outcome: efficacy of focal BT evaluated via MRI at 30 d • Secondary outcome: functional outcomes, progression-free survival, toxicity • Follow-up: 3 yr
	Prospective evaluation of focal brachytherapy using cesium-131 for patients with low risk prostate cancer (NCT02290366) Pittsburgh, PA, USA	<ul style="list-style-type: none"> • Phase 2 trial investigating low-risk PC patients (n = 100) • Primary outcome: biochemical disease-free survival • Secondary outcome: not applicable • Follow-up: 5 yr
	A prospective stage 2S clinical trial evaluating hemi-ablative low dose rate (LDR) brachytherapy for localized prostate cancer (HAPpy) (NCT02632669) Guildford, UK	<ul style="list-style-type: none"> • Phase 2 trial investigating low-risk PC patients (n = 31) • Primary outcome: toxicity and functional outcomes • Secondary outcome: Oncological control assessed via transperineal biopsy • Follow-up: 2 yr



Unanswered Questions

- **Patient selection:**

Who is the ideal candidate? **Not defined**

- **Definition of what constituted focal therapy:**

Unifocal? Multifocal? Hemiablation? Hockey Stick?

Not defined

- **How to define which lesion to target?**

TRUS-guided biopsies / MRI-US fusion biopsies

Not defined

- **Do we have a definition of success?**

PSA – Is PSA a good marker?

Biopsy – When? Does infield Gleason 6 or contralateral positive biopsy mean failure?

MRI – Accuracy for detecting failure?

Success or Failure → UNDEFINED!



Conclusion – Focal Therapy

- Focal therapy of the prostate is safe with low impact on QoL.
- Short-term oncological outcomes are promising.
- Future directions:
 - Standardized definitions of eligibility criteria, failure/success, and follow-up are needed.
 - Long-term oncological effectiveness warrants further studies.



TRANSARTERIAL THERAPIES

- BLAND EMBOLIZATION
- CHEMOEMBOLIZATION
- RADIOEMBOLIZATION
- MANAGE BPH IN PCA SETTING



CLINICAL STUDY

Prostatic Artery Embolization in the Treatment of Localized Prostate Cancer: A Bicentric Prospective Proof-of-Concept Study of 12 Patients

Livio Mordasini, MD, Lukas Hechelhammer, MD, Pierre-André Diener, MD, Joachim Diebold, MD, Agostino Mattei, MD, Daniel Engeler, MD, Gautier Müllhaupt, MD, Suk-Kyum Kim, MD, Hans-Peter Schmid, MD, and Dominik Abt, MD

From the Department of Urology (L.M., A.M.) and Department of Pathology (J.D.), Luzerner Kantonsspital, Spitalstrasse, 6000 Luzern, Switzerland; and Department of Radiology (L.H., S.-K.K.), Department of Pathology (P.-A.D.), and Department of Urology (D.E., G.M., H.-P.S., D.A.), Kantonsspital St. Gallen, St. Gallen, Switzerland. Received November 20, 2017; final revision received and accepted January 6, 2018. Address correspondence to L.M.; E-mail: livio.mordasini@luks.ch

None of the authors have identified a conflict of interest.

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J Vasc Interv Radiol 2018; 29:589–597

<https://doi.org/10.1016/j.jvir.2018.01.766>

EDITORS' RESEARCH HIGHLIGHTS

- Prostate artery embolization before robotic-assisted radical prostatectomy was performed in 12 patients with biopsy-proven prostate cancer; bilateral embolization with the use of 100 μ m Embosphere microspheres (Boston Scientific, Natick, Massachusetts) was started in the proximal prostatic arteries and finished distally in all patients.
- Two patients (17%) developed partial bladder wall necrosis requiring surgery. Histology of the 12 specimens showed microspheres and ischemia with fibrosis, mainly in the central gland and around the prostatic urethra, but also in the seminal glands.
- All patients had residual viable tumor in the resected prostate specimens.
- PAE with small-sized microspheres and this embolization approach led to some severe nontarget ischemic complications without clear evidence of complete tumor control.



PACE for Prostate Cancer

PROSPECTIVE
STUDY – 20
PATIENTS

GLEASON SCORE
6-9

T2N0M0

PRE-PROCEDURE

1.5 ML OF – CHELIDONIUM MAJUS

DOCETAXEL 1.5 ML (30MG)

100-300 UM EMBOSPHERES – 1.5ML

LIPIODOL 0.5MG

MRI

TRUS

PSA

Prostate arterial chemoembolization for prostate cancer

J. Pisco¹, T. Bilhim¹, M. Ribeiro¹, L. Fernandes², N. Costa³, A. Oliveira¹; ¹N/A, Lisbon, Portugal; ²N/A, Lisboa, Portugal; ³Hospital Saint Louis, Lisboa, Portugal

Purpose: To evaluate the safety, morbidity and preliminary results of Prostate Arterial Chemoembolization (PACE) in patients with prostate cancer.

Materials: Single-center cohort prospective study, approved by the Institutional Review Board, was conducted between March 2015 to July 2016. It includes 20 patients with prostate cancer refusing other treatments due to fear or suffering of complications of their therapy. The diagnosis was confirmed by prostate biopsy. Gleason score ranged 6 to 9 and staging was T2N0M0 in all patients. Magnetic Resonance (MR), prostatic transrectal ultrasound (TRUS), digital rectal examination and prostatic specific antigen (PSA) were carried out before PACE. At baseline the following parameters were evaluated: IPSS, QoL, Qmax, IIEF, PVR and PV; and bone scintigraphy in all patients with PSA > 10ng/mL. Pelvic computed tomographic angiography evaluated the prostatic arteries. These vessels were selectively catheterized under local anesthesia and we used Plant Mother-Tinctures (Chelidonium majus) 1.5mL, Docetaxel 1.5 ml (30mg) mixed with 1.5 ml of Embospheres 100 µ to 300 µ plus ultra-fluid Lipiodol 0.5 mL for the PACE. All patients were discharged 4-6 hours after the procedure and PSA was evaluated monthly for 6 months, and then every 3 months. The other parameters were evaluated at 1, 3, 6 months and every 6 months thereafter. MRI was performed at 6 months' follow-up.

Results: Twenty patients aged 57-78 years (mean age 64.7 years) underwent PACE. 4 were technical failures and 16 were technical successes. Out of the 4 technical failures, 1 was treated by brachytherapy, 2 by radical prostatectomy and 1 refused any treatment. Of the 16 technical successes, 13 (81.3%) had PSA decrease below 2ng/mL and were called 'initial biochemical successes'. In the remaining 3 (18.7%) patients, PSA didn't change significantly and were considered 'initial biochemical failures'. They were treated with other therapies. PSA before PACE in cases of biochemical success ranged from 0.2ng/mL to 23.4 ng/mL (mean 7.6ng/mL) and after PACE from 0.2 ng/mL to 1.8 ng/mL (mean 0.9 ng/mL). Biochemical successes were evaluated between 6 and 18 months. In one patient PSA increase to 6.14 ng / mL at 4. There was one major complication: a bladder wall ischemia that was cured by a simple surgical intervention. 1 acute urinary retention after PACE needed an indwelling catheter for a week and another 1 reported urinary urgency for a week.

Conclusions: PACE for prostate cancer is a new, safe and effective outpatient procedure for prostate cancer with good preliminary results.



Results

20 PATIENTS; MEAN AGE 64.7 YEARS

16 TECHNICAL SUCCESS

INITIAL BIOCHEMICAL SUCCESS
– PSA < 2 MG/ML (N=13)

6-18 MONTHS – 1 PATIENT: PSA OF 6 MG/ML

- Biochemical success at 12 to 18 months was seen in 10 of 16 patients. Adverse events were few and mostly minor.
- MRI @ 12 months (N=10) with biochemical successes showed that of the seven patients with a Gleason Score of 6, no changes were seen in the lesions, whereas the three patients with a Gleason Score > 7 had > 50% tumor size reduction



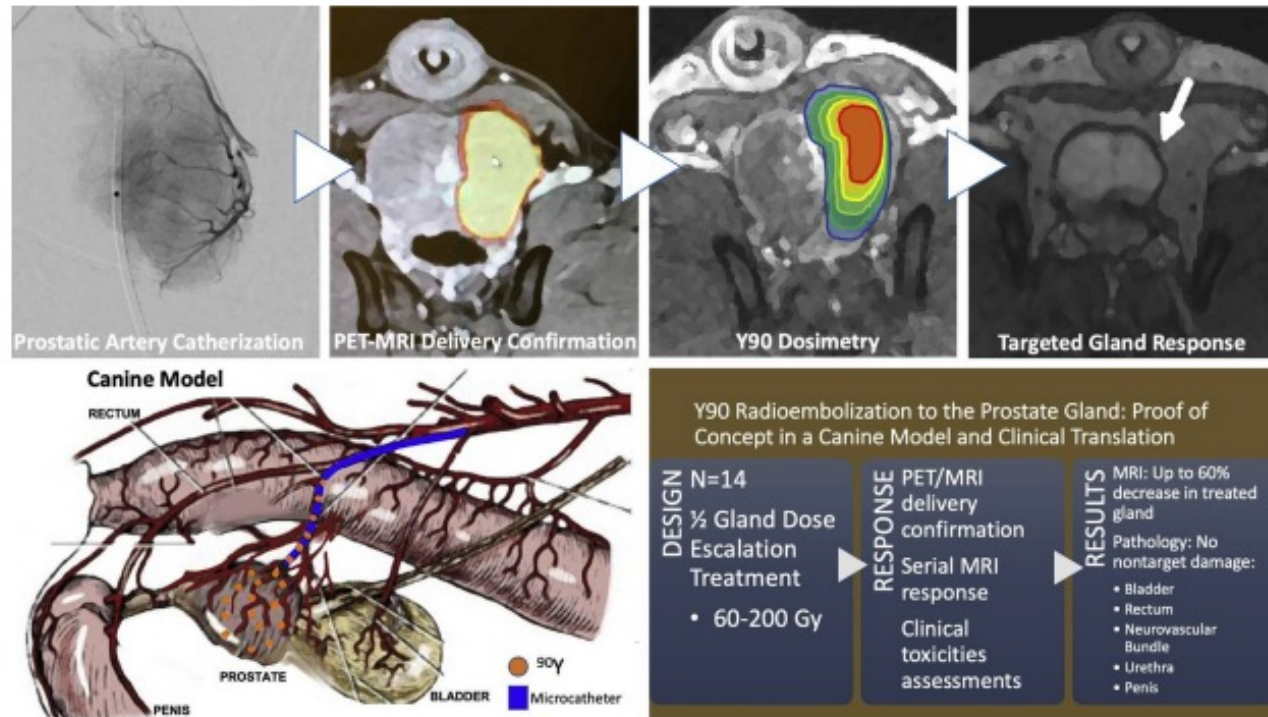
Yttrium-90 Radioembolization to the Prostate Gland: Proof of Concept in a Canine Model and Clinical Translation

Samdeep K. Mouli, MD, MS, Simone Raiter, MS, Kathleen Harris, BA, Amrutha Mylarapu, BS, Malcolm Burks, BS, Weiguo Li, PhD, Andrew C. Gordon, MD, PhD, Ali Khan, BS, Monica Matsumoto, MD, Keith L. Bailey, DVM, PhD, Alexander S. Pasciak, MD, PhD, Sasicha Manupipatpong, BS, Clifford R. Weiss, MD, David Casalino, MD, Frank H. Miller, MD, Vanessa L. Gates, PhD, Elias Hohlastos, MD, Robert J. Lewandowski, MD, Dong-Hyun Kim, PhD, Matthew R. Dreher, PhD, and Riad Salem, MD, MBA

SIR ABSTRACT OF THE YEAR

VISUAL SYNOPSIS

Next application of Y-90?





Effectiveness and Safety of Prostatic Artery Embolization for the Treatment of Lower Urinary Tract Symptoms from Benign Prostatic Hyperplasia in Men with Concurrent Localized Prostate Cancer

Nainesh Parikh, MD, MBA, Edward Keshishian, MD, Brandon Manley, MD, G. Daniel Grass, MD, PhD, Javier Torres-Roca, MD, David Boulware, MS, MBA, Sebastian Feuerlein, MD, Julio M. Pow-Sang, MD, Sandeep Bagla, MD, Kosj Yamoah, MD, PhD, and Shivank Bhatia, MD

Purpose: To assess the effectiveness and safety of prostatic artery embolization (PAE) on lower urinary tract symptoms (LUTS) in the setting of localized prostate cancer (PCa).

Materials and Methods: This was a retrospective, single-center, institutional review board-approved study from December 2016 to June 2020 of 21 patients (median age, 72; range, 63–83 years) with moderate LUTS and localized PCa. Clinical effectiveness was evaluated at 6 and 12 weeks using International Prostate Symptom Score (IPSS) and quality of life (QoL) improvement. Seventeen patients were scheduled to receive definitive radiotherapy (RT) after PAE; 13 patients completed RT. Short-term imaging signs of oncologic progression were evaluated at 6 and 12 weeks defined by at least one of the following on magnetic resonance imaging: increased Prostate Imaging-Reporting and Data System score of index lesion(s) to at least 4, new extracapsular extension, seminal vesicle involvement, or pelvic lymphadenopathy. Nonparametric Wilcoxon signed-rank test was used for analysis.

Results: IPSS improved by a median of 12 ($n = 19$, $P < .0001$) and 14 ($n = 14$, $P < .0001$) at 6 and 12 weeks, respectively. QoL improved by a median of 2 ($n = 19$, $P < .0001$) and 3 ($n = 3$, $P < .0001$) at 6 and 12 weeks. Prostate volume decreased by a median of 24% ($n = 19$, $P < .0001$) and 36% ($n = 12$, $P = .015$) at 6 and 12 weeks. No patients demonstrated disease progression at 6 ($n = 16$) or 12 ($n = 8$) weeks by imaging. No patients experienced increased prostate-specific antigen after RT, grade ≥ 3 adverse events, or greater genitourinary toxicity.

Conclusions: PAE is effective and safe for the treatment of men with LUTS from benign prostatic hyperplasia in the setting of concomitant, localized, non-obstructive PCa.



SUMMARY

- Prostate cancer treatment presents a promising opportunity for minimally invasive options
- Focal therapy will remain mainstay of the next-gen therapies with HIFU and TULSA as promising options.
- Intra-arterial therapies are still in innovation phase and we have at least a decade worth of work ahead of us