Beth Israel Deaconess Medical Center

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

High Intensity Focused Ultrasound (HIFU) for Management of *SOME* Prostate Cancers

Aria F. Olumi, MD
Chief of Urologic Surgery at Beth Israel Deaconess Medical Center
Janet & William DeWolf Professor of Surgery at Harvard Medical School

Current Paradigm: Active Surveillance or Radical Therapy

Active Surveillance

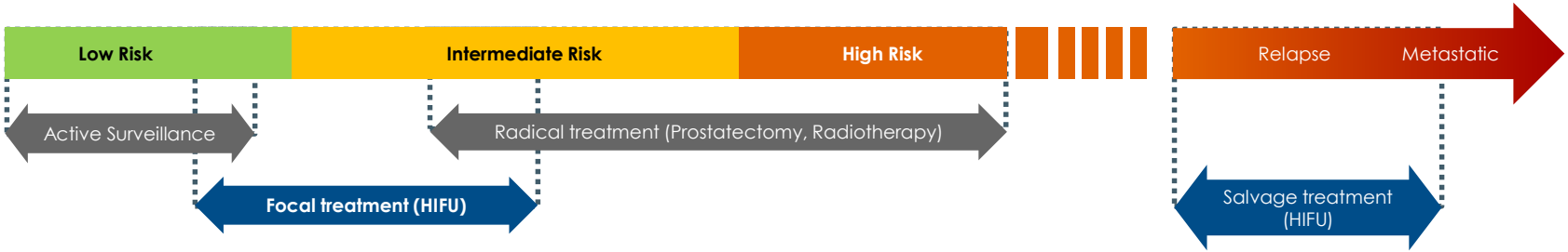
Vs

Radical therapy

- Temporarily preserves functi
- Delays Radical Therapy
- Cancer may spread without

Generally, but not always, effective
Increased morbidity
Reduced QoL

Focal therapy may fill an important treatment gap in prostate cancer



- Advanced imaging, targeted biopsies and genomic testing have changed the ability to localize disease and risk stratify prostate cancer
- Patients are seeking an option between active surveillance and radical therapy
- Focal therapy provides a safe, effective and minimally invasive option for patients with low and intermediate risk disease, as well as a salvage therapy

Goals of Focal therapy:

- Selective ablation of known disease
- Preserving function
- Minimizing morbidity
- Without compromising life expectancy

Focal Therapy: The Middle ground

Treat dangerous tissue

Observe the Rest

Ablate index lesion

Active Surveillance the others

Index Lesion

- While Pca is multifocal, the **Index Lesion** drives cancer biology

- **Index Lesion**: Largest lesion containing highest stage, grade, volume

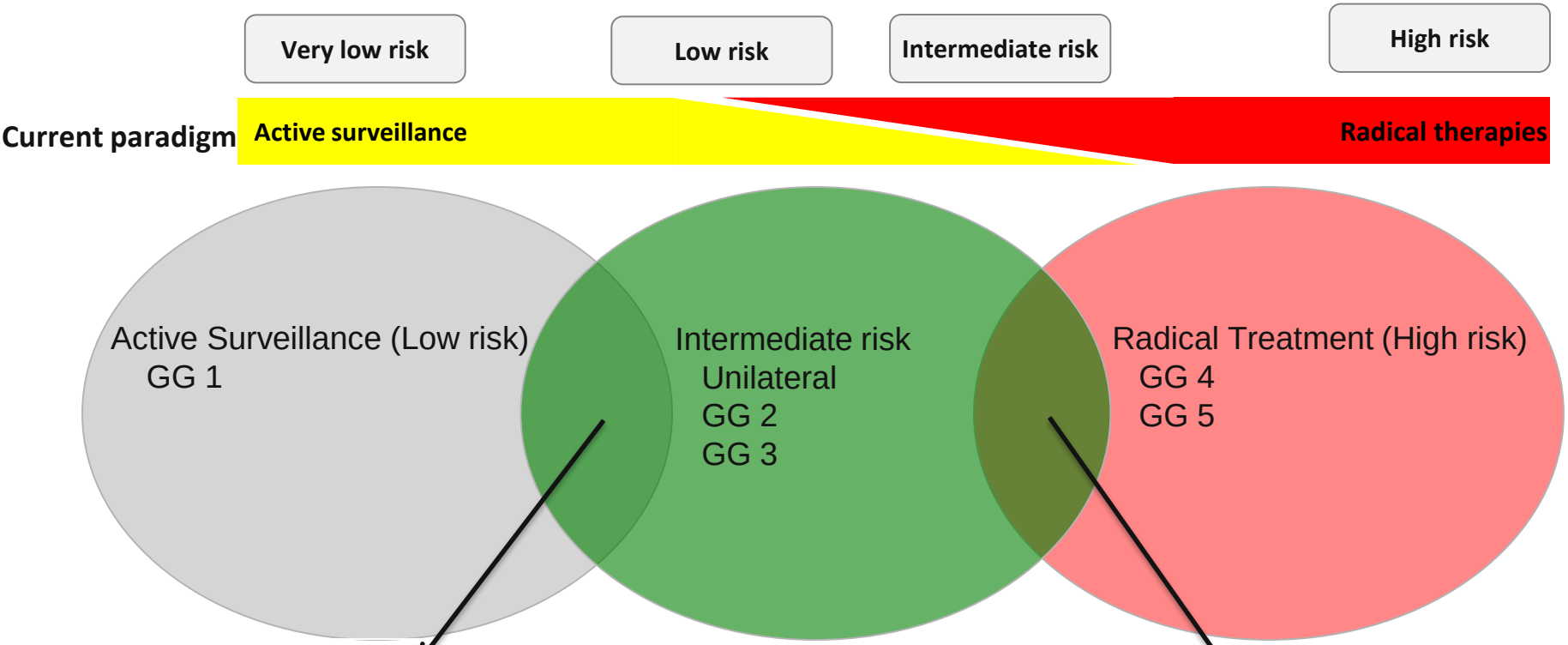
  - Accounts for 80% of the tumor bulk (Ohori et al, J Urol 175; 507, 2006)

  - Tumor volume, Gleason score, and pathological stage are almost invariably defined by the index lesion (Aihara et al, Urology 43: 60. 1994)

  - Most, if not all, metastatic PCa have monoclonal origins and arise from a single precursor cancer cell (*Liu et al, ,* Nat Med. 2009 May;15(5):559-65)

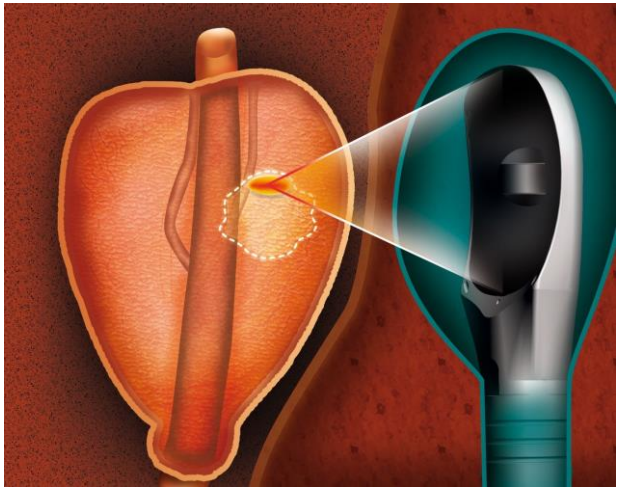
Patient Selection

- mpMRI
- Systematic + Target biopsy
- Markers – genomics (Oncotype Dx)
- PET PSMA (suspicion of advanced metastatic disease)


Very low risk
Low risk
Intermediate risk
High risk
Current paradigm
Active surveillance
Radical therapies
Active Surveillance (Low risk)
GG 1
Intermediate risk
Unilateral
GG 2
GG 3
Radical Treatment (High risk)
GG 4
GG 5
GG 1 who are not ideal for AS:
Markers: intermediate risk
Patient desires
Low volume GG 2
Small volume
Low PSA/PSAD
Patient desires

High Intensity Focused Ultrasound (HIFU)

- FDA approved novel modality of focal therapy for Prostate Cancer



Technology: Designed for Focal Ablation of Prostate

Fusion

HIFUsion® MRI / 3D Biopsy fusion

Targeting using MRI Fusion with live ultrasound image

Robotic Positioning System

Integrated workstation

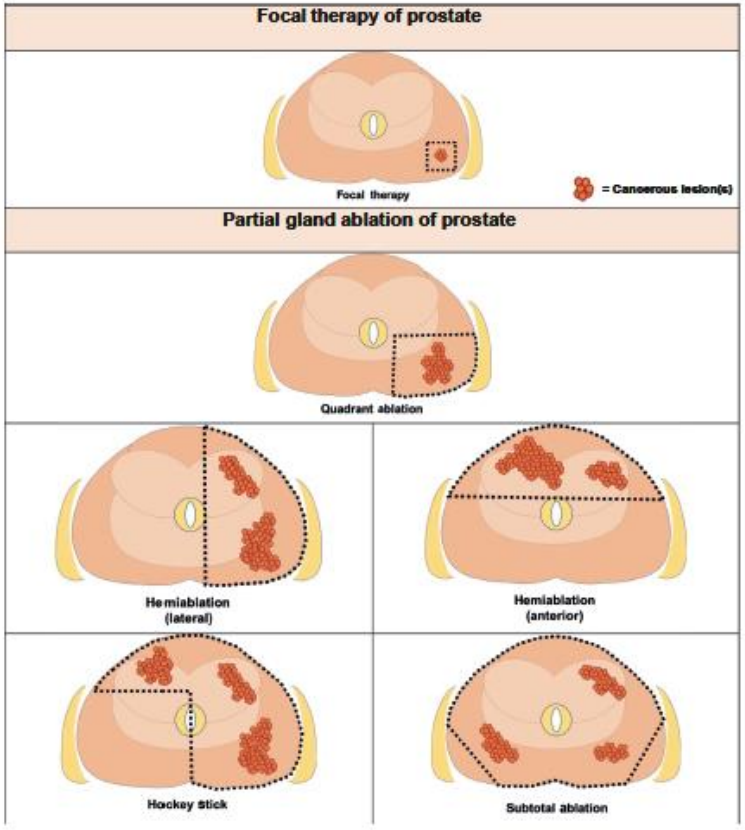
compatible with standard OR beds

Dynamic Focusing Probe

Faster treatments times: ~45 minutes for focal treatments

Focal ablative therapy options

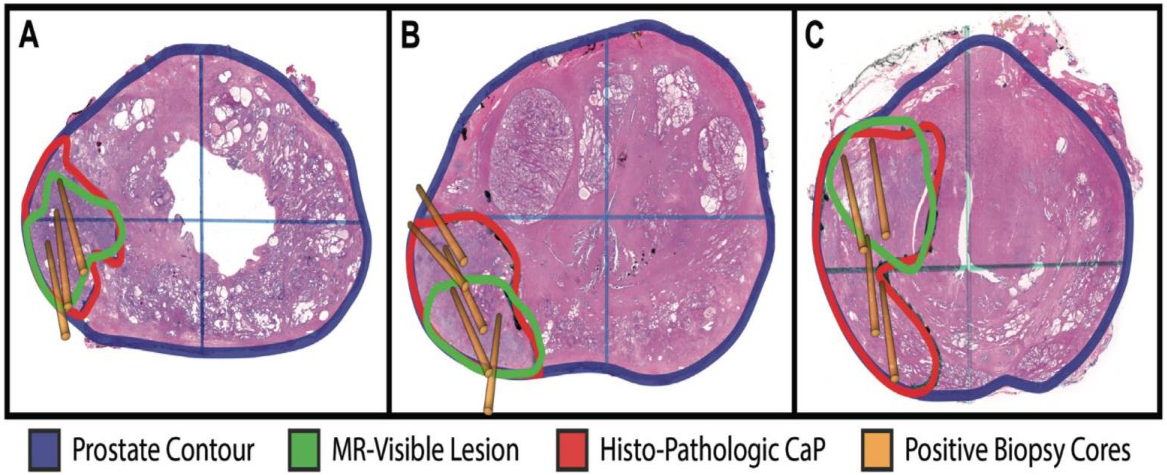
EUROPEAN UROLOGY 78 (2020) 371–378



Lebastchi et al European Urology 2020

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†



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European Association of Urology

Platinum Priority – Editorial
Referring to the article published on pp. x–y of this issue

Focal Therapy for Prostate Cancer: Getting Ready for Prime Time

Andre Luis Abreu [a,*], Masatomo Kaneko [a,b], Giovanni E. Cacciamani [a], Amir H. Lebastchi [a]

[a] USC Institute of Urology, Center for Image-Guided Surgery, Focal Therapy and Artificial Intelligence for Prostate Cancer, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [b] Department of Urology, Kyoto Prefectural University of Medicine, Kyoto, Japan

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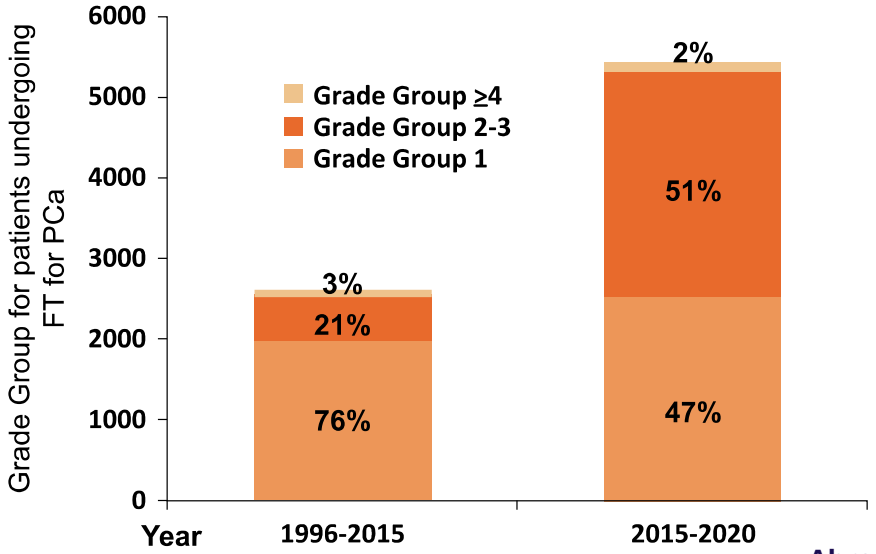

Abreu AL et al Eur Urol. 2022 Jan;81(1):34-36

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journal homepage: www.europeanurology.com

European Association of Urology

Prostate Cancer

Cancer Control Outcomes Following Focal Therapy Using High-intensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience

Failure-free survival
Intermediate risk
PCa:
93% - 3Y
83% - 5Y
68% - 7Y

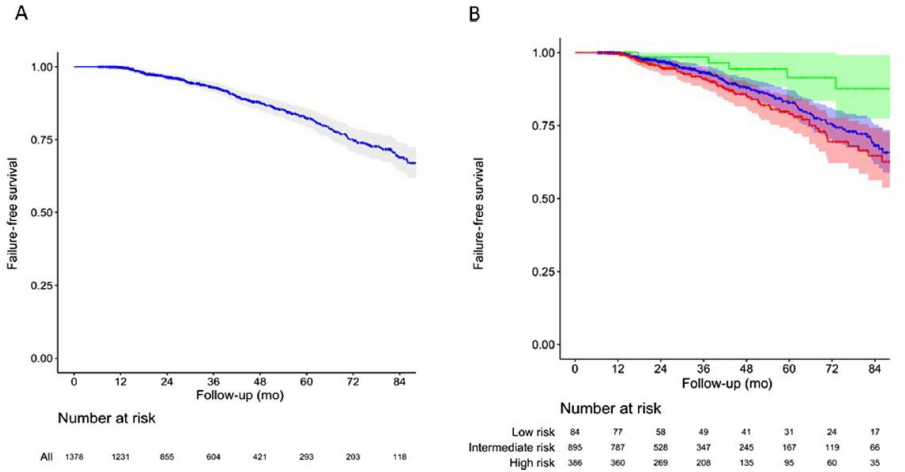

Fig. 1 – Kaplan-Meier curves of failure-free survival (FFS) with 95% confidence intervals. FFS is defined as transition to whole-gland salvage treatment or third focal therapy treatment, systematic treatment, and/or development of prostate cancer metastases and/or prostate cancer–specific death for (A) all patients with at least 6 mo of follow-up and (B) 1365 patients stratified per D'Amico low-risk (green line), intermediate-risk (blue line), and high-risk (red line) group (log-rank analysis of D'Amico intermediate- vs high-risk disease $p = 0.3$).

Kaplan-Meier estimate, % (95% confidence interval)

	1 yr	2 yr	3 yr	4 yr	5 yr	6 yr	7 yr
Failure-free survival [a]	100 (100–100)	96 (95–98)	93 (91–95)	88 (85–90)	82 (79–86)	75 (71–79)	69 (64–74)
By D'Amico risk class							
Low	100 (100–100)	99 (96–100)	99 (96–100)	94 (88–100)	91 (84–100)	91 (84–100)	88 (77–99)
Intermediate	100 (100–100)	97 (96–98)	93 (91–95)	88 (85–91)	83 (79–87)	75 (70–81)	68 (62–75)
High	100 (99–100)	95 (93–97)	91 (88–94)	85 (81–90)	79 (73–85)	69 (62–78)	65 (56–74)
Salvage local whole-gland or systemic treatment-free survival	100 (100–100)	97 (96–98)	93 (91–95)	89 (86–91)	85 (83–88)	80 (77–84)	75 (71–80)
By D'Amico risk class							
Low	100 (100–100)	99 (96–100)	99 (96–100)	99 (96–100)	99 (96–100)	99 (96–100)	95 (87– 100)
Intermediate	100 (100–100)	97 (96–99)	94 (91–96)	89 (86–92)	84 (80–88)	79 (74–84)	73 (67–80)
High	100 (99–100)	95 (93–98)	91(87–94)	86 (82–91)	84 (79–89)	78 (71– 85)	73 (65–82)

HIFU = high-intensity focused ultrasound.
[a] Failure-free survival defined by transition to whole-gland salvage treatment, third focal therapy treatment, systemic treatment, development of prostate cancer metastases, or prostate cancer–specific death.

Oncologic and Functional Outcomes of Partial Gland Ablation with High Intensity Focused Ultrasound for Localized Prostate Cancer

J Urol. 2019 Jan;201(1):113-119

Roman Bass,* Neil Fleshner, Antonio Finelli, Jack Barkin,† Liying Zhang and Laurence Klotz

From the Division of Urology, Sunnybrook Health Sciences Centre, University of Toronto (RB, LZ, LK), Division of Urology, Princess Margaret Hospital (NF, AF) and Humber River Hospital (JB), Toronto, Ontario, Canada

Table 4. *Functional outcomes*

	No. Pts (%)
Continence:	
No change	131 (94.9)
Insignificant deterioration	5 (3.6)
Significant deterioration	2 (1.4)
Lower urinary tract	
No changes	116 (84.1)
Mild deteriorati	10 (7.2)
Significant deter	6 (4.3)
Symptom improv	6 (4.3)
Erectile dysfunctior	
No change	115 (86.5)
Mild deteriorati	15 (11.3)
Significant deterioration	3 (2.2)

Continence: 95%

Potency: 87%

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Prostate Cancer

Cancer Control Outcomes Following Focal Therapy Using High-intensity Focused Ultrasound in 1379 Men with Nonmetastatic Prostate Cancer: A Multi-institute 15-year Experience

Multicentric study from 13 centers

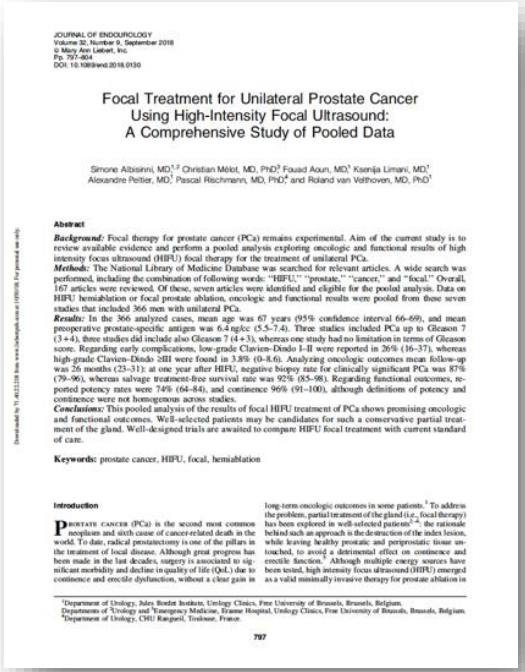
N = 1379 patients with ≥6 mo of follow-up after **focal HIFU**

- Post operative complications
  - Any complications: 83 pt (6%)
  - Clavien-Dindo >2: 7 pt (0.5%)
  - UTI: 52 pt (3.8%)
  - Epididymo-orchitis: 11 pt (0.8%)
  - Retention: 10 pt (0.7%)
  - Rectourethral fistula: 2 pt (0.1%)

Supplementary Table 6: Complication profile per Clavien-Dindo Score

Clavien Dindo Score	Frequency n/1379 (%)
I	11 (0.8)
II	65 (4.7%)
IIIa	2 (0.1)
IIIb	5 (0.3)

Reproducible early results of treating clinically significant cancer and avoiding progression to radical treatment while maintaining high urinary continence and sexual function



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Focal Treatment for Unilateral Prostate Cancer Using High-Intensity Focal Ultrasound: A Comprehensive Study of Pooled Data

Simone Albisinni, MD,[1,2] Christian Mélot, MD, PhD,[2] Fouad Aoun, MD,[1] Ksenija Limani, MD,[1] Alexandre Peltier, MD,[1] Pascal Rischmann, MD, PhD,[4] and Roland van Velthoven, MD, PhD[1]

Abstract

Background: Focal therapy for prostate cancer (PCa) remains experimental. Aim of the current study is to review available evidence and perform a pooled analysis exploring oncologic and functional results of high intensity focus ultrasound (HIFU) focal therapy for the treatment of unilateral PCa.

Methods: The National Library of Medicine Database was searched for relevant articles. A wide search was performed, including the combination of following words: "HIFU," "prostate," "cancer," and "focal." Overall, 167 articles were reviewed. Of these, seven articles were identified and eligible for the pooled analysis. Data on HIFU hemiablation or focal prostate ablation, oncologic and functional results were pooled from these seven studies that included 366 men with unilateral PCa.

Results: In the 366 analyzed cases, mean age was 67 years (95% confidence interval 66–69), and mean preoperative prostate-specific antigen was 6.4 ng/e (5.5–7.4). Three studies included PCa up to Gleason 7 (3+4), three studies did include also Gleason 7 (4+3), whereas one study had no limitation in terms of Gleason score. Regarding early complications, low-grade Clavien–Dindo I–II were reported in 26% (16–37), whereas high-grade Clavien–Dindo ≥III were found in 3.8% (0–8.6). Analyzing oncologic outcomes mean follow-up was 26 months (23–31): at one year after HIFU, negative biopsy rate for clinically significant PCa was 87% (79–96), whereas salvage treatment-free survival rate was 92% (85–98). Regarding functional outcomes, reported potency rates were 74% (64–84), and continence 96% (91–100), although definitions of potency and continence were not homogenous across studies.

Conclusions: This pooled analysis of the results of focal HIFU treatment of PCa shows promising oncologic and functional outcomes. Well-selected patients may be candidates for such a conservative partial treatment of the gland. Well-designed trials are awaited to compare HIFU focal treatment with current standard of care.

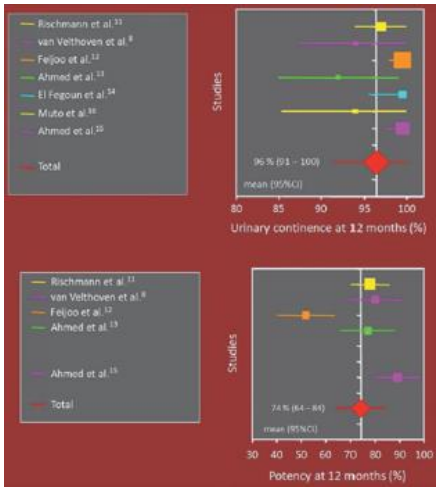
Keywords: prostate cancer, HIFU, focal, hemiablation

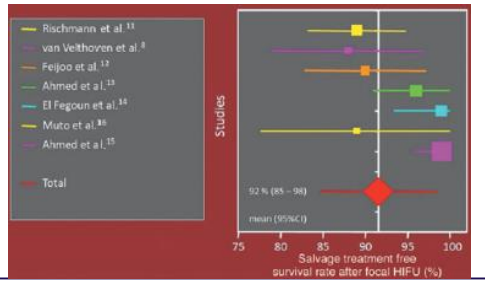
Introduction

PROSTATE CANCER (PCa) is the second most common neoplasm and sixth cause of cancer-related death in the world. To date, radical prostatectomy is one of the pillars in the treatment of local disease. Although great progress has been made in the last decades, surgery is associated to significant morbidity and decline in quality of life (QoL) due to continence and erectile dysfunction, without a clear gain in long-term oncologic outcomes in some patients.[1] To address the problem, partial treatment of the gland (i.e., focal therapy) has been explored in well-selected patients[2–4]: the rationale behind such an approach is the destruction of the index lesion, while leaving healthy prostatic and periprostatic tissue untouched, to avoid a detrimental effect on continence and erectile function.[5] Although multiple energy sources have been tested, high intensity focus ultrasound (HIFU) emerged as a valid minimally invasive therapy for prostate ablation in

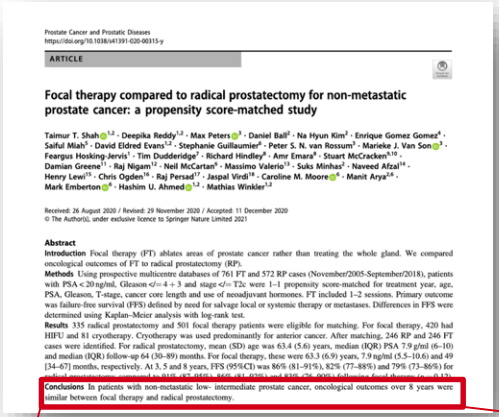
[1]Department of Urology, Jules Bordet Institute, Urology Clinics, Free University of Brussels, Brussels, Belgium.
Departments of [2]Urology and [3]Emergency Medicine, Etterbeek Hospital, Urology Clinics, Free University of Brussels, Brussels, Belgium.
[4]Department of Urology, CHU Rangueil, Toulouse, France.

- Systematic review, 7 studies
- 366 patients
- Focal primary HIFU
- 87% no clinically significant cancer found on biopsy
- 92% no progression to radical treatment
- 96% urinary continence (pad-free)
- 74% preservation of potency without drugs





Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity-score matching



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ARTICLE

Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity score-matched study

Taimur T. Shah[1,2] · Deepika Reddy[1,2] · Max Peters[1] · Daniel Ball[2] · Na Hyun Kim[2] · Enrique Gomez Gomez[4] · Saiful Miah[5] · David Eldred Evans[5,6] · Stephanie Guillaumier[4] · Peter S. N. van Rossum[7] · Marieke J. Van Son[3] · Feargus Hosking-Jervis[1] · Tim Dudderidge[2] · Richard Hindley[8] · Amr Emara[8] · Stuart McCracken[9,10] · Damian Greene[11] · Raj Nigam[12] · Neil McCartan[8] · Massimo Valerio[13] · Suks Minhas[2] · Naveed Afzal[14] · Henry Lewi[15] · Chris Ogden[16] · Raj Persad[17] · Jaspal Virdi[18] · Caroline M. Moore[8] · Manit Arya[2,8] · Mark Emberton[8] · Hashim U. Ahmed[1,8] · Mathias Winkler[1,2]

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Abstract

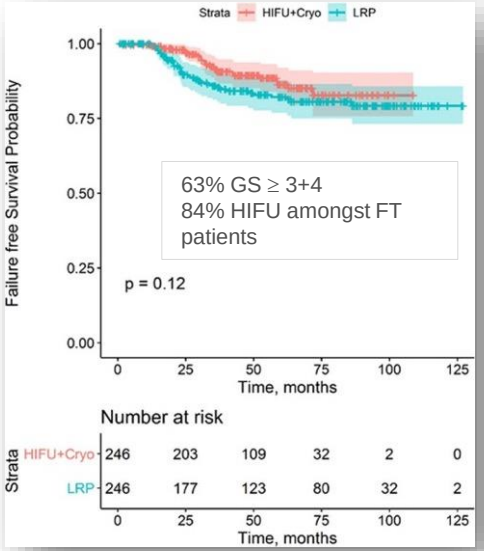
Introduction Focal therapy (FT) ablates areas of prostate cancer rather than treating the whole gland. We compared oncological outcomes of FT to radical prostatectomy (RP).

Methods Using prospective multicentre databases of 761 FT and 572 RP cases (November/2005-September/2018), patients with PSA < 20 ng/ml, Gleason </= 4 + 3 and stage </= T2c were 1–1 propensity score-matched for treatment year, age, PSA, Gleason, T-stage, cancer core length and use of neoadjuvant hormones. FT included 1–2 sessions. Primary outcome was failure-free survival (FFS) defined by need for salvage local or systemic therapy or metastases. Differences in FFS were determined using Kaplan–Meier analysis with log-rank test.

Results 335 radical prostatectomy and 501 focal therapy patients were eligible for matching. For focal therapy, 420 had HIFU and 81 cryotherapy. Cryotherapy was used predominantly for anterior cancer. After matching, 246 RP and 246 FT cases were identified. For radical prostatectomy, mean (SD) age was 63.4 (5.6) years, median (IQR) PSA 7.9 g/ml (6–10) and median (IQR) follow-up 64 (30–89) months. For focal therapy, these were 63.3 (6.9) years, 7.9 ng/ml (5.5–10.6) and 49 [34–67] months, respectively. At 3, 5 and 8 years, FFS (95%CI) was 86% (81–91%), 82% (77–88%) and 79% (73–86%) for radical prostatectomy, compared to 91% (87–95%), 86% (81–92%) and 83% (76–90%) following focal therapy (p = 0.12).

Conclusions In patients with non-metastatic low- intermediate prostate cancer, oncological outcomes over 8 years were similar between focal therapy and radical prostatectomy.

	RP	FT
N	246	246
Age, Mean (SD)	63.4 (5.6)	63.3 (6.9)
PSA, Median (IQR)	7.6 (6-10)	7.9 (5.5-10.6)
F/U, Median (IQR)	64 (30–89)	49 (34–67)
FFS % (95% CI)		
3 years	86% (81-91%)	91% (87–95%)
5 years	82% (77-88%)	86% (81–92%)
8 years	79% (73-86%)	83% (76–90%)



Conclusions In patients with non-metastatic low- intermediate prostate cancer, oncological outcomes over 8 years were similar between focal therapy and radical prostatectomy.

HIFU at BIDMC

33 Men treated with **HIFU** for intermediate risk PCa

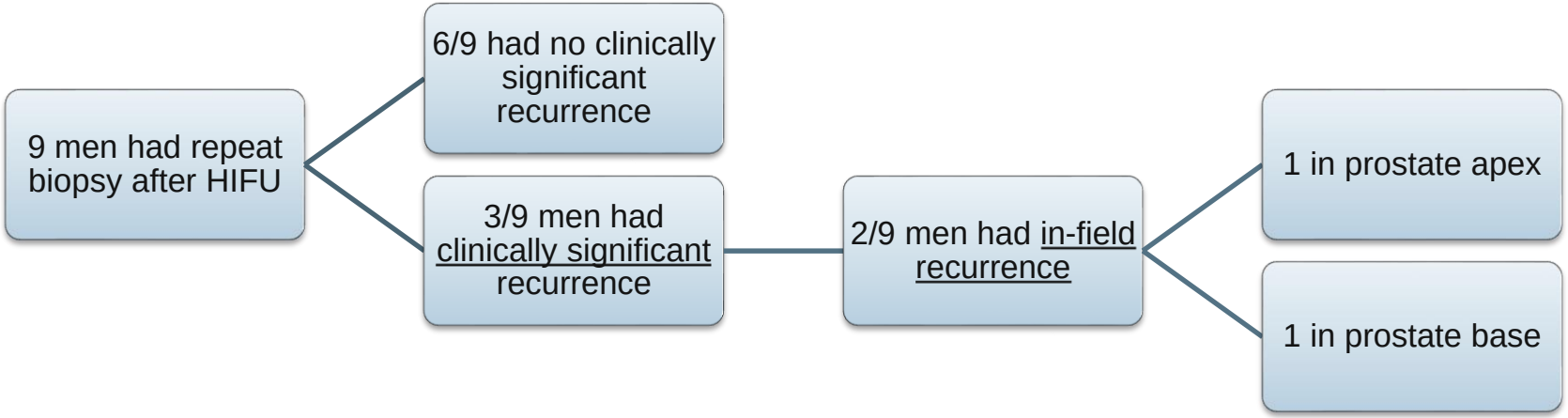
11 men had repeat imaging after HIFU

- Only 1/11 men had PIRADS>0 lesion on repeat imaging

9 men had repeat biopsy after HIFU

- 6/9 recurrence

HIFU at BIDMC



Clinically significant recurrence: Gleason ≥ 3+4

Baseline Patient Characteristics; 08/2022 – 05/2024

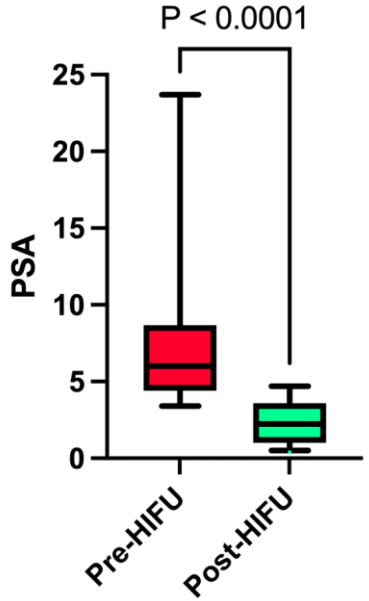
Table 1. Baseline Patient Characteristics	Mean (SD) / Counts (%)	Median	Range
Completed HIFU	**33**		
Age	65.83 (6.13) years	71 years	65.5-74 years
Genomic Prostate Score (Oncotype DX) (n=15)	29.9 (9.8)	28.5	26-39
Prostate size (MRI; cc)	50.4 (25.4) cc	53 cc	20-117 cc
Pre-HIFU PSA	6.8 (4.1)	6.4	3.4-23.7
Gleason grade		2	2-4
2 (3+4)	24 (73%)		
3 (4+3)	8(24%)		
4 (4+4)	1 (3%)		
Greatest cancer core %	64.1 (23.7)	63%	20-100%
Number of positive cores	5.3 (2.5)	5	2-10
Pre-HIFU AUASS (n=22)	8.07 (6.1)	6	4.5-11
Pre-HIFU EPIC QOL (n=22)	8.29 (7.66)	5	2.5-11.75

Post-HIFU Patient Characteristics

PSA and urinary symptom score Post-HIFU Treatment (n=22)

	Pre-HIFU	Post-HIFU
PSA	6.8±4.1	2.3±2.4
Urinary Symptoms	8±4	5±3

PSA Drops Post-HIFU Treatment (n=22)



HIFU patient Data

PSA		PIRADS Score		PCa location		Grade Group (Gleason)		Recurrence	
Pre-HIFU	Post-HIFU	Pre-HIFU	Post-HIFU	Pre-HIFU	Post-HIFU	Pre-HIFU	Post-HIFU	Infield Recurrence	External Field Recurrence
7.5	3.8	4	0	Left	Left	2 (3+4)	2 (3+4)	Yes	-
4.4	3.6	4	4	Left	Right	2 (3+4)	1 (3+3)	-	Yes
5	3.2	4	0	Right	Left	2 (3+4)	3 (4+3)	-	Yes
8.6	4.7	5	0	Left	Right+Left	2 (3+4)	2 (3+4)	-	Yes
9.3	1	5	0	Right	None	2 (3+4)	Normal	-	-
6.4	2.3	4	0	Left	None	2 (3+4)	Normal	-	-
5.8	0.4	4	0	Right	Right	3 (4+3)	1 (3+3)	Yes	-
7.8	2.2	4	0	Right	None	2 (3+4)	Normal	-	-
8	3.7	4	0	Right	Left	2 (3+4)	1 (3+3)	-	Yes

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BMC Urology

RESEARCH ARTICLE Open Access

Peri-operative, functional and early oncologic outcomes of salvage robotic-assisted radical prostatectomy after high-intensity focused ultrasound partial ablation

James E. Thompson[1,2*], Ashwin N. Sridhar[1,3], Greg Shaw[1,3], Prabhakar Rajan[1,4], Anna Mohammed[1], Timothy P. Briggs[1], Senthil Nathan[1,3], John D. Kelly[1,3] and Prasanna Sooriakumaran[1,3,5]

Table 2 – HIFU treatment technical details (n = 45)

Ideal according to consensus criteria, n (%)	26 (57.8)
Prostate volume, median (IQR)	35 (27–46)
Location of treatment (combined treatment fields for *n* = 5 with 2 HIFU treatments)	
Hemi-gland unilateral	
Hemi-gland with extension across midline or into SV	16
Hemi-gland anterior	7
Hemi-gland posterior	1
Quadrant (e.g. unilateral posterior)	1
Focal ablation (eg posterior right basal segment)	13
Subtotal (extended hemi-ablation, sparing lateral aspect of contralateral side)	6
	1
Number of HIFU treatments	
1	37
2	8
Known 'insignificant' cancer left untreated at HIFU	
Yes	21 (47.7)
No	23 (52.3)
Type of biopsy pre-HIFU:	
TTMB TP 5 mm Mapping + MRI-Targeted (if targets)	24 (53.3)
12–20 core TRUS + MR-targeted (if targets)	17 (37.8)
Targeted alone	3 (6.7)
Not documented	1 (2.2)

Table 3 - Early and Late complications after sRARP according to Clavien group (n = 45)

Early complications (< 90 days)	Number (%)	Description
Grade I	4 (8.9%)	(i) 1x AKI (self-limiting)
		(ii) 3 asymptomatic leaks on initial cystogram requiring prolonged catheterisation
Grade 2	3 (6.7%)	(i) 1x UTI 2 weeks post-op requiring oral antibiotics;
		(ii) 1x readmission for anastomotic leak and fever requiring IV antibiotics and observation (no intervention)
		(ii) 1x transfusion for retroperitoneal bleeding (did not require surgical/ radiologic intervention)
Grade 3a Grade 3b	1 (2.2%)	3b: Laparotomy, evacuation of clot and re-fashinoing of vesico-urethral anastomosis for haematoma causing anastomotic leak/ disruption
Grade 4	0	–
Grade 5 (Death)	0	–
Total	**8/45 (17.8%)**	–
Late complications (90 days – 12 months)*	5/33 (15.2%)	(i) 3x bladder neck contractures requiring 1 or more cystoscopy + optical dilation
		(ii) 1x Hemolock clip protruding into anastomosis causing LUTS
		(iii) 1x Small bowel obstruction (resolved with conservative management) due to adhesions in the same man who underwent laparotomy < 90 days.

***Note to Table: All 45 men completed 90-day peri-operative outcome follow-up; 12 men have not yet reached 12-months follow-up and therefore the sample size is *n* = 33**

Table 4 Summary of primary versus salvage RARP outcomes at our institution

Baseline or Outcome Variable	Primary RARP(16, 17)	Salvage RARP
Complication rate (Clavien-Dindo grade) (%)		
Early Grade 1–3	7–13	17.8
Early Grade 4	0.4*	0
Early Grade 5	0*	0
Anastomotic leak on cystogram	2*	11.1
Late bladder neck contracture/ clip	0.5*	10.5
Pre-RARP D'Amico risk group (%)		
Low	3	6.7
Intermediate	36	73.3
High	61	20.0
Pathologic T-stage (%)		
pT2	53	35.5
pT3	47	64.5
pT3a	33	46.6
pT3b	14	17.8
Positive surgical margin rate (%)		
Overall	17.3	44.4
pT2	9.6	37.5
pT3	26.1	48.3
Continence		
Pad-free at 3-months	67	33.3
Pad-free at 12-months	85.4	65.5
Socially continent at 12-mo (0–1 pad)	89.2	86.2
Proportion where nerve-sparing (NS) feasible		
Feasibility of bilateral NS (%)	18	6.7
Feasibility of unilateral NS (%)	34	22.2
Feasibility of bilateral NS in high-risk Ca	10	0.0
Proportion who received bilateral nerve-sparing and were potent at 12-months (potent pre-RARP)#	70	0 (0/2)

*Institutional audit data from latest institutional audit for calendar year 2017, $n = 605$ primary RARPs; #defined as erections adequate for intercourse at least half the time with or without the aid of PDE5Is

Salvage external beam radiotherapy after HIFU failure in localized prostate cancer: A single institution experience

Vanessa Di Lalla[1], Sara Elakshar[1,2], Maurice Anidjar[3], Marwan Tolba[1], Toufic Hassan[3], Boris Bahoric[1], Victor McPherson[3], Stephan Probst[4] and Tamim Niazi[1]*

[1]Department of Radiation Oncology, Jewish General Hospital, McGill University, Montreal, QC, Canada, [2]Department of Clinical Oncology, Tanta University, Tanta, Egypt, [3]Department of Urology, Jewish General Hospital, McGill University, Montreal, QC, Canada, [4]Department of Nuclear Medicine, Jewish General Hospital, McGill University, Montreal, QC, Canada

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Sexual and Urinary Function after sEBRT after HIFU

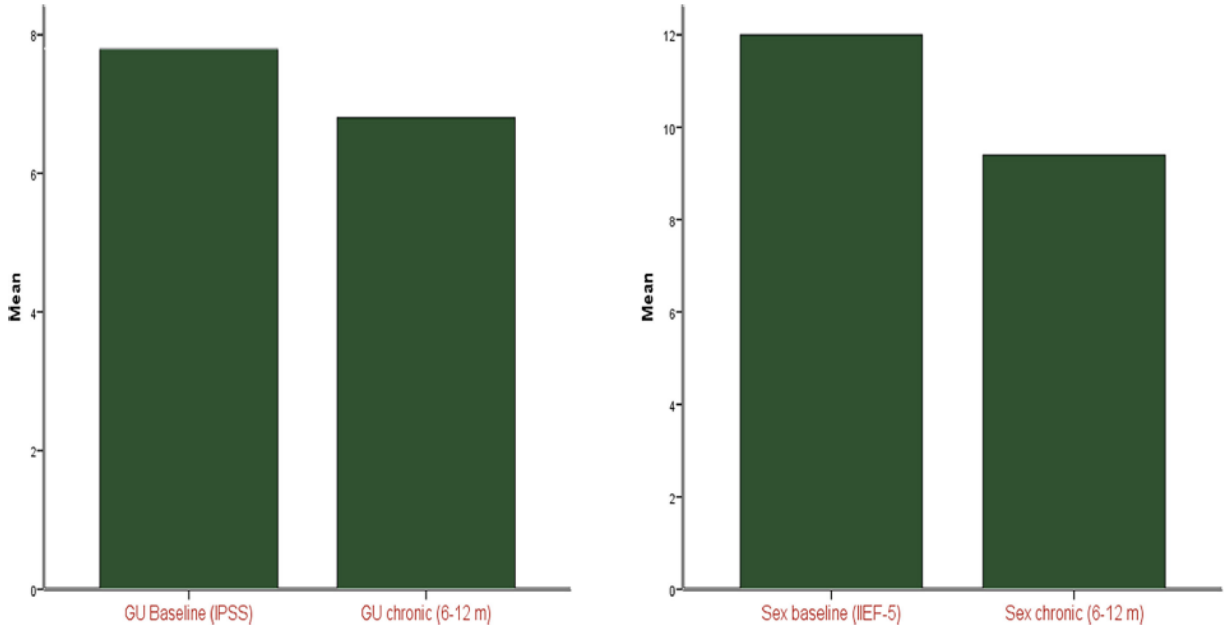

FIGURE 1
Change in IIEF and IPSS scores from baseline post-RT.

Acute GI Toxicity after sEBRT after HIFU

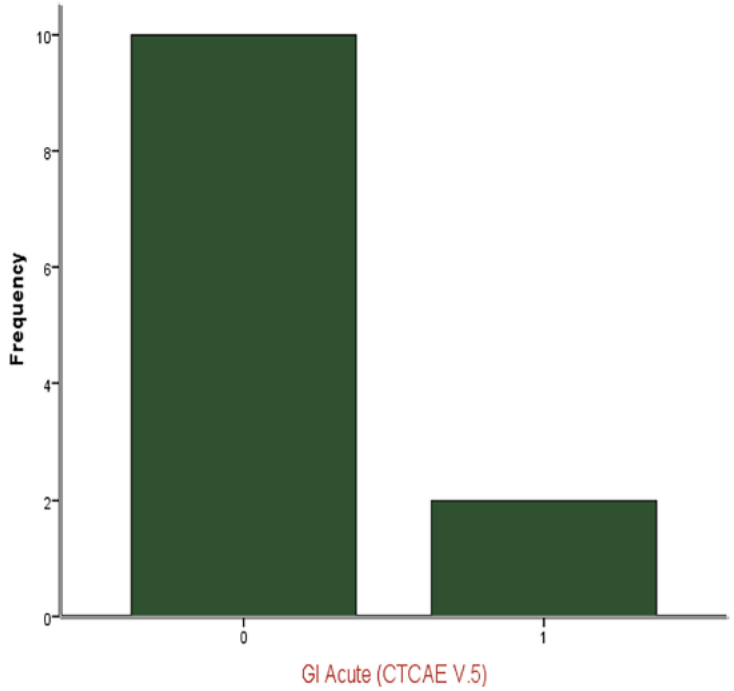

FIGURE 2
Acute GI Toxicity.

Conclusion

- As our understanding of Pca evolves, so will treatment options
- HIFU is a promising modality for the treatment of select patients with Pca.
- Follow up with prostate MRI is not sufficient to detect disease recurrence or progression
- BIDMC HIFU data repository to track functional and oncological outcomes