

UC San Diego Health

Management of localized prostate cancer

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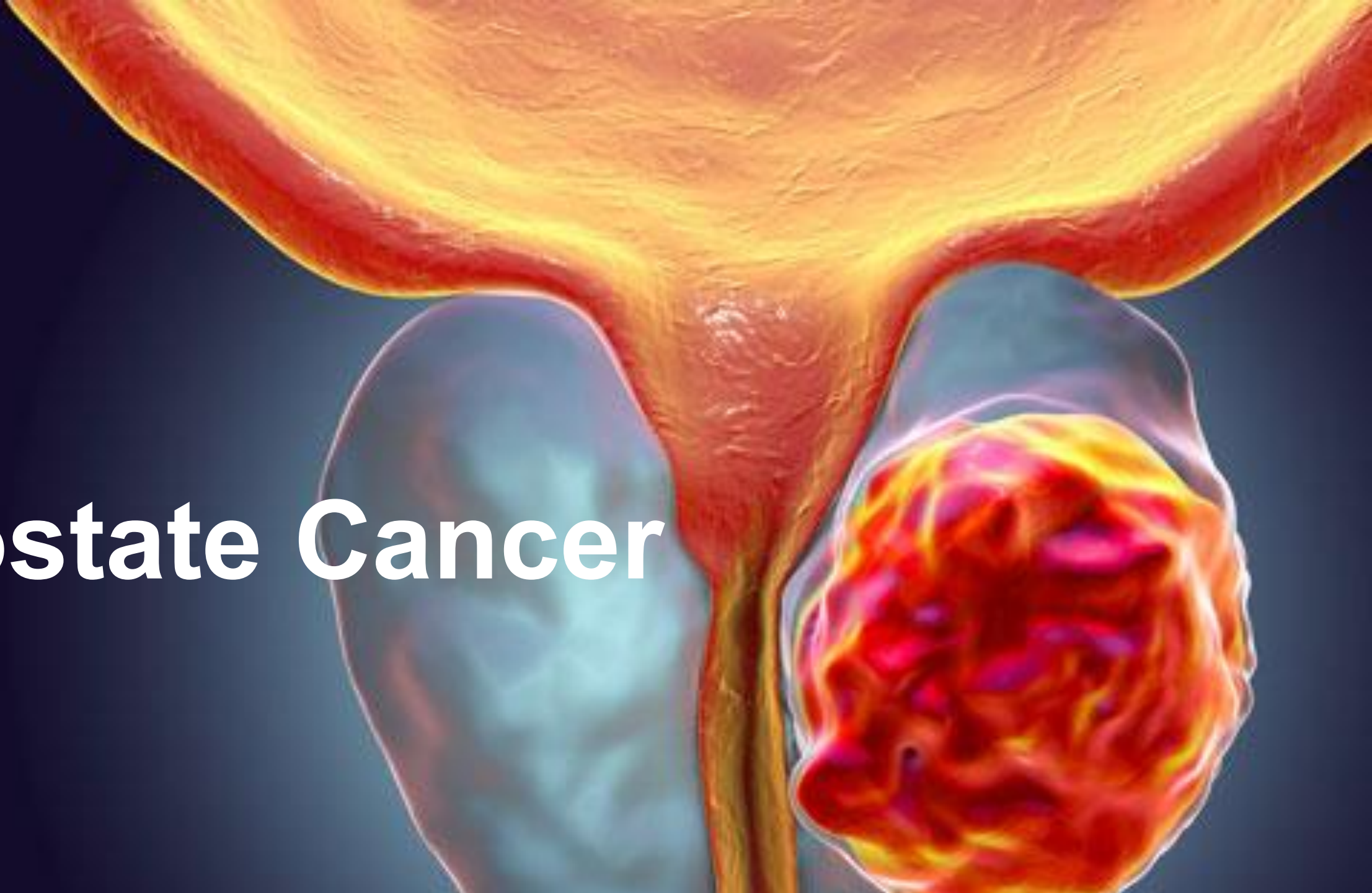
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[@adityabagrodia](#)



Prostate Cancer



Prostate cancer in the press

The Washington Post

To Your Health

Almost all men with early prostate cancer survive 10 years, regardless of treatment

By Laurie McGinley September 14



TIME

LATEST MAGAZINE VIDEO

HEALTH CANCER

Prostate Cancer Treatment Doesn't Save More Lives Than Active Surveillance

Prostate Cancer Treatment Doesn't Save More Lives Than Active Surveillance

The New York Times

ARCH

Teaching Your Child Emotional Agility

Copper Sinks and Faucets May Stem Hospital Infections

Toxins Linger in Homes Long After Smokers Quit

HEALTH

Prostate Cancer Study Details Value of Treatments

By DENISE GRADY SEPT. 14, 2016



A new [study](#) offers important information to men who are facing difficult decisions about how to treat [prostate cancer](#) in its early stages, or whether to treat it at all.

Researchers followed patients for 10 years and found no difference in death rates between men who were picked at random to have surgery or radiation, or to rely on “active monitoring” of the [cancer](#), with treatment only if it progressed.

Death rates from the cancer were low over all: only about 1 percent of patients 10 years after diagnosis.

But the disease was more likely to progress and spread in the men who opted for monitoring rather than for early treatment. And about half the patients in the study who had started out being monitored wound up having surgery or radiation.

Robert Boulton, a prostate cancer patient, was initially assigned to receive active monitoring but switched to radiation treatment after four years, when his P.S.A. went up.
Alexander Azark for The New York Times

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- U.S.
- With Early Prostate Cancer, Forgoing Treatment Makes No Difference

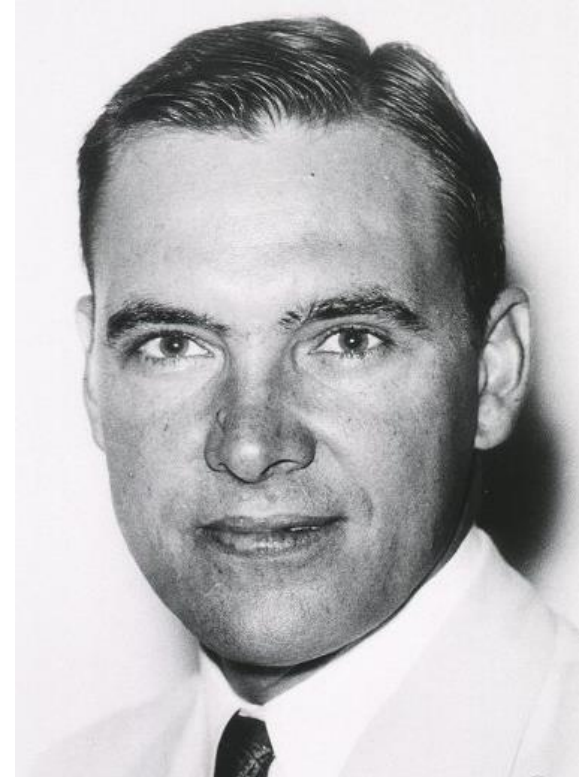
Skepticism even within Urologic Oncologists

WHITMOREISMS: MEMORABLE QUOTES FROM WILLET F. WHITMORE, JR, M.D.

JAMES E. MONTIE AND JOSEPH A. SMITH, JR

The current state of prostate cancer may not be good medicine but it sure is good business.

There are more people making a living from prostate cancer than there are dying from it.



Prostate Cancer: Epidemiology

In the United States

- #1 cause of cancer in men
- ~250,000 new cases per year
- 26% of all cancer diagnoses!
- 12% lifetime risk of prostate cancer

- #2 cause of cancer death in men
- ~34,130 deaths / year

Estimated New Cases

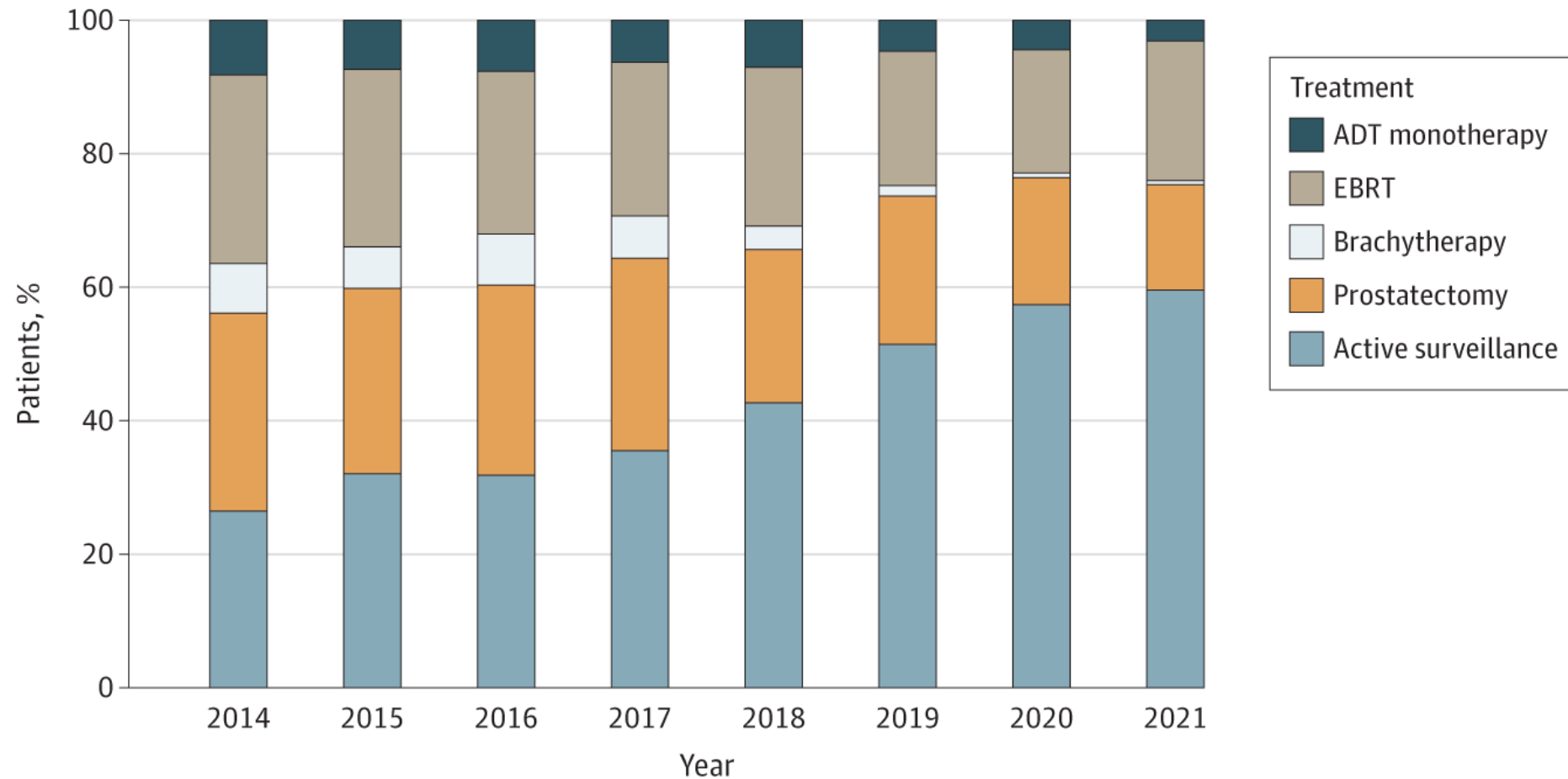
			Males	Females			
Prostate	248,530	26%			Breast	281,550	30%
Lung & bronchus	119,100	12%			Lung & bronchus	116,660	13%
Colon & rectum	79,520	8%			Colon & rectum	69,980	8%
Urinary bladder	64,280	7%			Uterine corpus	66,570	7%
Melanoma of the skin	62,260	6%			Melanoma of the skin	43,850	5%
Kidney & renal pelvis	48,780	5%			Non-Hodgkin lymphoma	35,930	4%
Non-Hodgkin lymphoma	45,630	5%			Thyroid	32,130	3%
Oral cavity & pharynx	38,800	4%			Pancreas	28,480	3%
Leukemia	35,530	4%			Kidney & renal pelvis	27,300	3%
Pancreas	31,950	3%			Leukemia	25,560	3%
All Sites	970,250	100%			All Sites	927,910	100%

Estimated Deaths

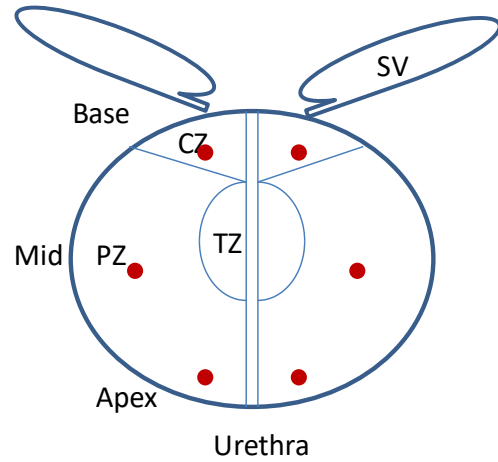
			Males	Females			
Lung & bronchus	69,410	22%			Lung & bronchus	62,470	22%
Prostate	34,130	11%			Breast	43,600	15%
Colon & rectum	28,520	9%			Colon & rectum	24,460	8%
Pancreas	25,270	8%			Pancreas	22,950	8%
Liver & intrahepatic bile duct	20,300	6%			Ovary	22,950	5%
Leukemia	13,900	4%			Uterine corpus	12,940	4%
Esophagus	12,410	4%			Liver & intrahepatic bile duct	9,930	3%
Urinary bladder	12,260	4%			Leukemia	9,760	3%
Non-Hodgkin lymphoma	12,170	4%			Non-Hodgkin lymphoma	8,550	3%
Brain & other nervous system	10,500	3%			Brain & other nervous system	8,100	3%
All Sites	319,420	100%			All Sites	289,150	100%

From: **Time Trends and Variation in the Use of Active Surveillance for Management of Low-risk Prostate Cancer in the US**

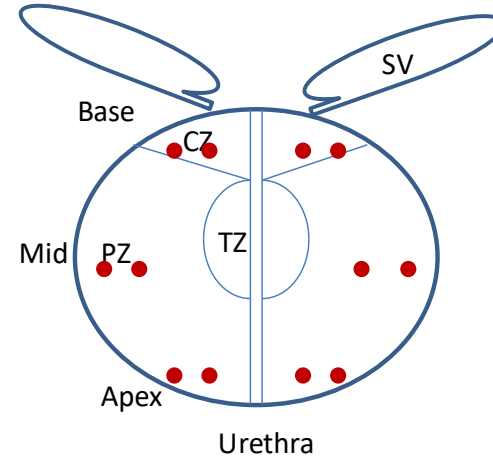
JAMA Netw Open. 2023;6(3):e231439. doi:10.1001/jamanetworkopen.2023.1439



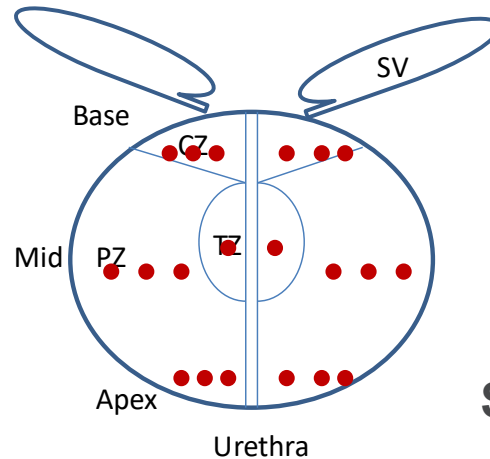
PSA/Diagnosis of prostate cancer



Sextant



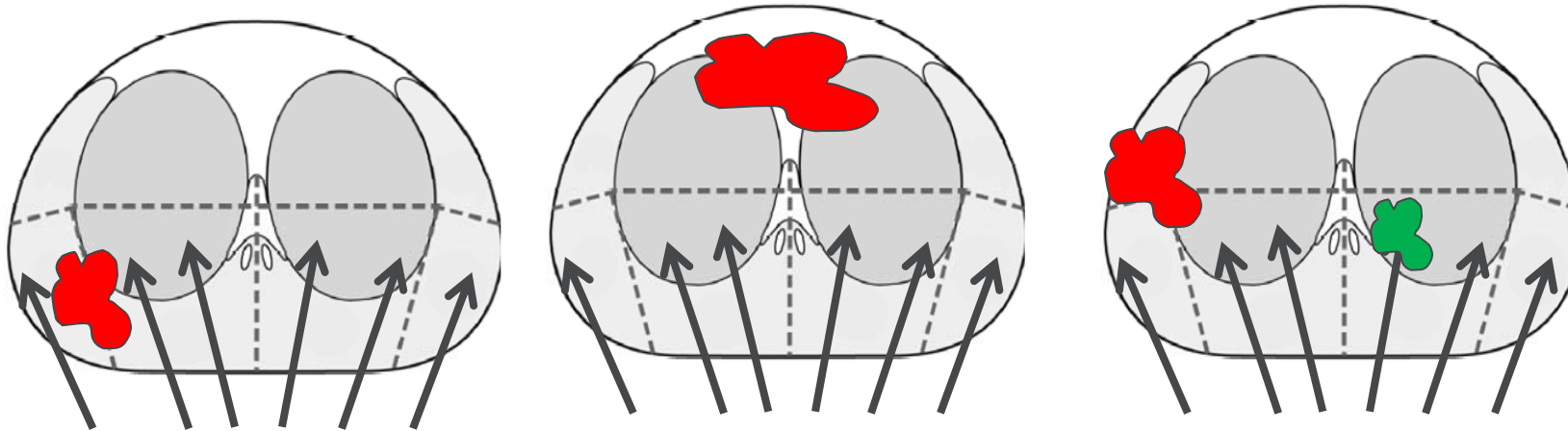
12-core



Saturation

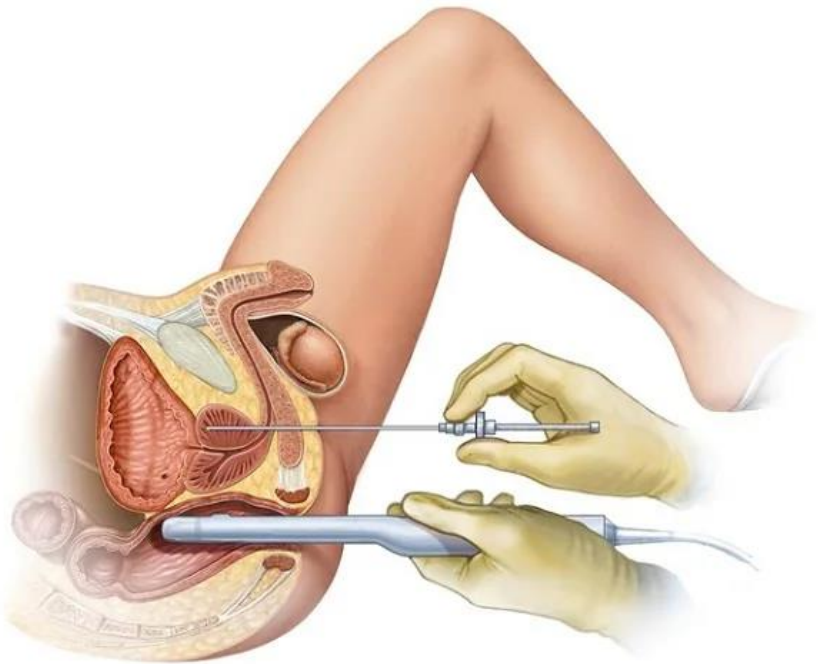
Biopsy techniques have relied on *random* sampling of the prostate gland

Some clinically significant cancers are missed because of sampling error of the biopsy, and many men are diagnosed with clinically insignificant disease.

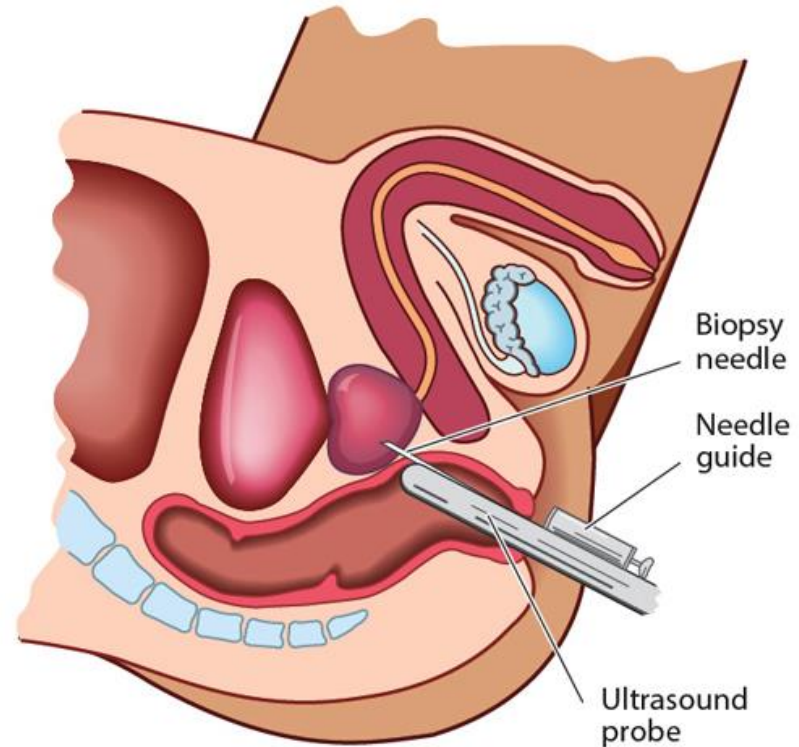


PSA Screening: Accuracy

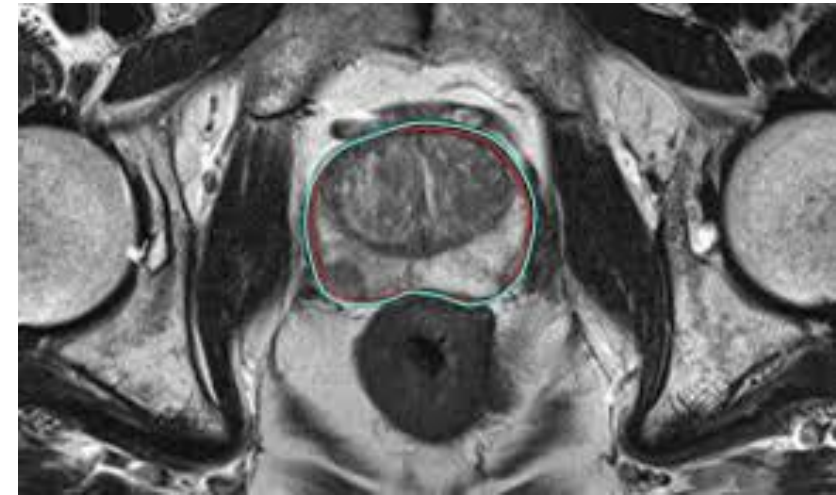
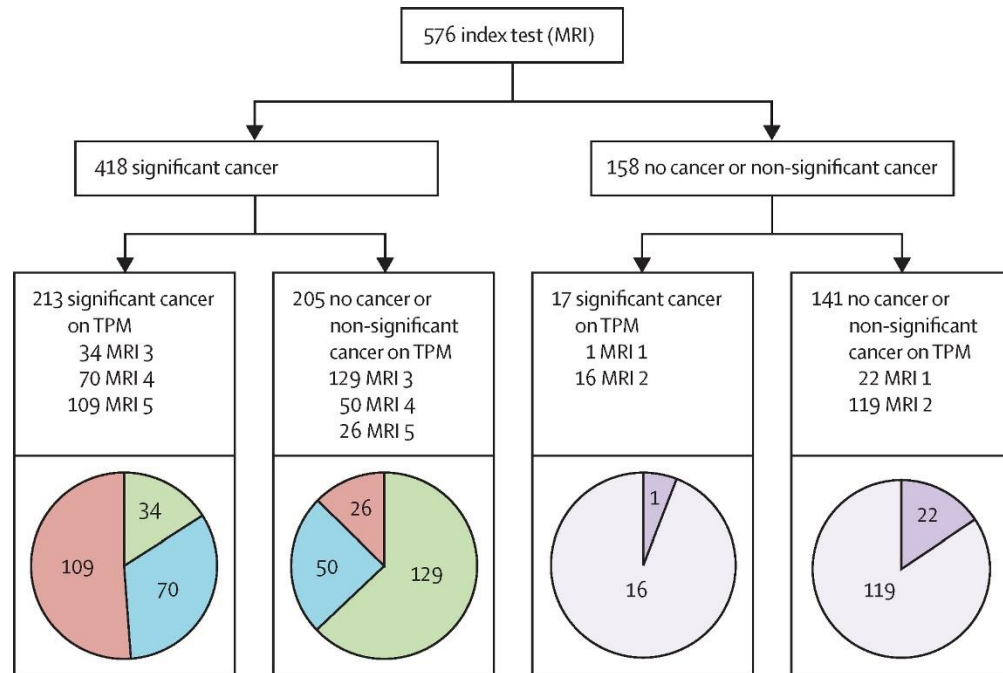
- **Old-Paradigm**
 - Annual PSA check
 - If PSA greater than 3-4 -> repeat -> if persistent -> TRUS Biopsy



© MAYO CLINIC



MRI for prostate cancer screening



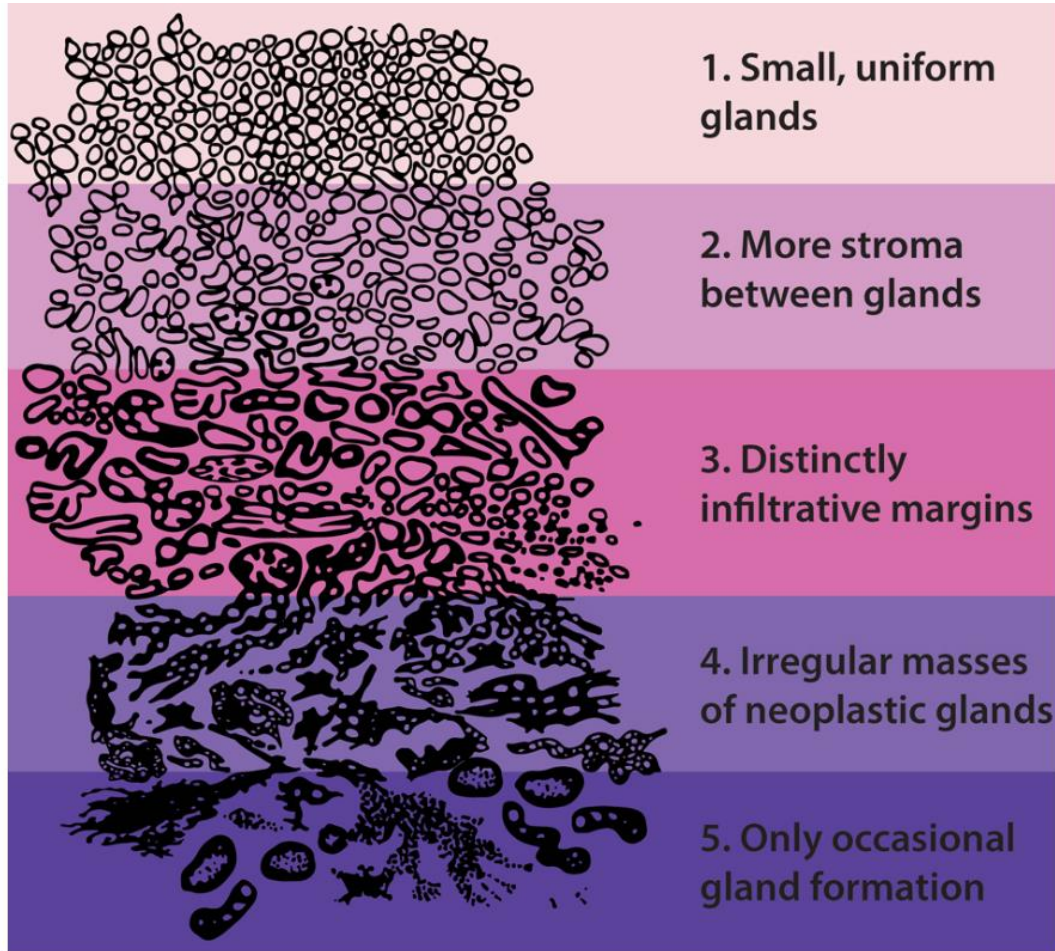
Sensitivity 93% (95% CI 88–96), positive predictive value 51% (46–56), specificity 41% (36–46), negative predictive value 89% (83–94).

Lancet 2017: Diagnostic accuracy of multi-parametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study

UroNav MRI TRUS Fusion



GLEASON PATTERN



Grade 1: Well-differentiated (*not contribute to score*)

Grade 2: Moderately differentiated (*not contribute to score*)

Grade 3: moderate-poorly differentiated

Grade 4: Poorly differentiated, marked anaplasia

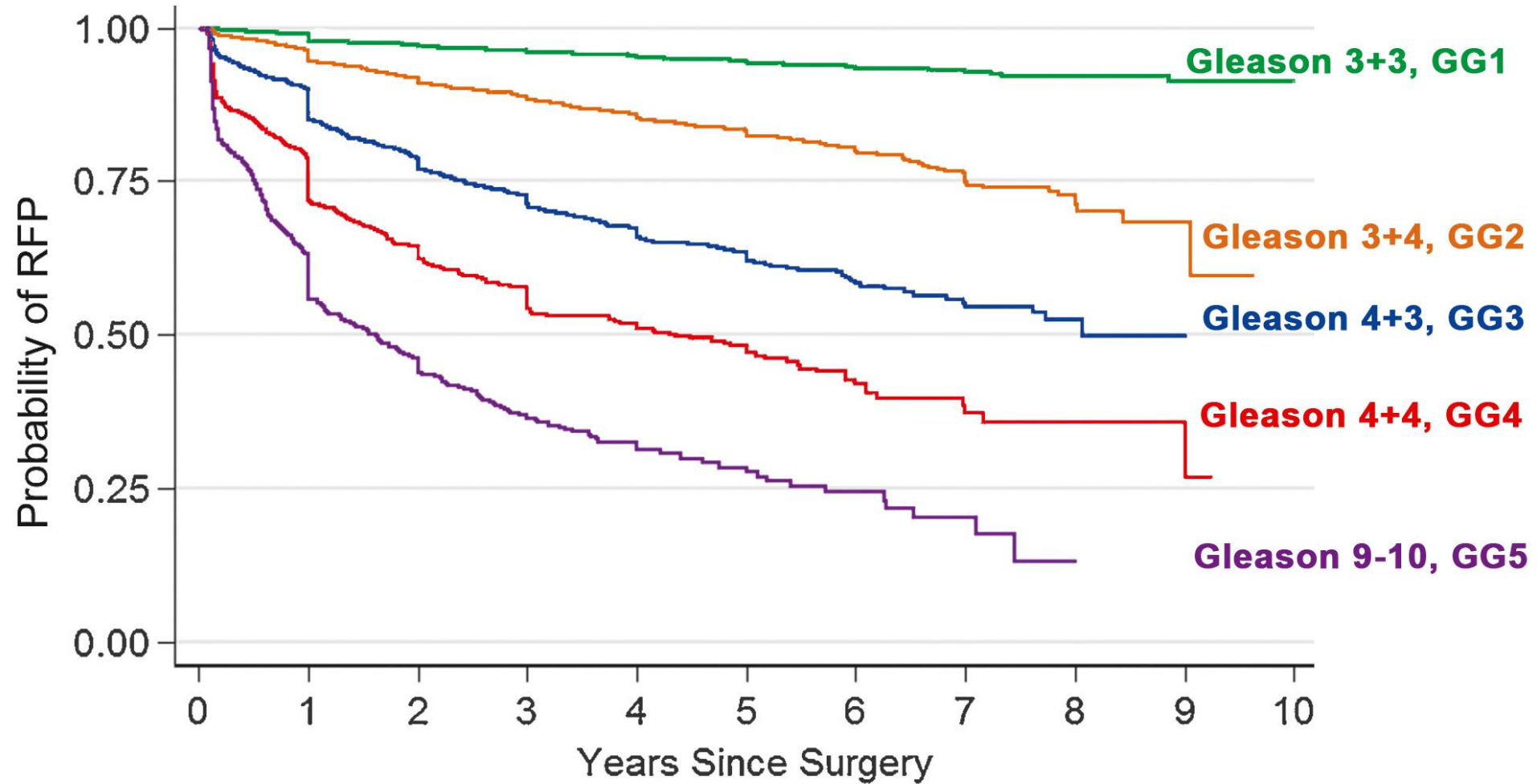
Grade 5: minimal resemblance of normal cells

Primary Grade: dominant tumor pattern

Secondary Grade: next most frequent pattern

GLEASON SCORE = Primary Grade + Secondary Grade (6-10)

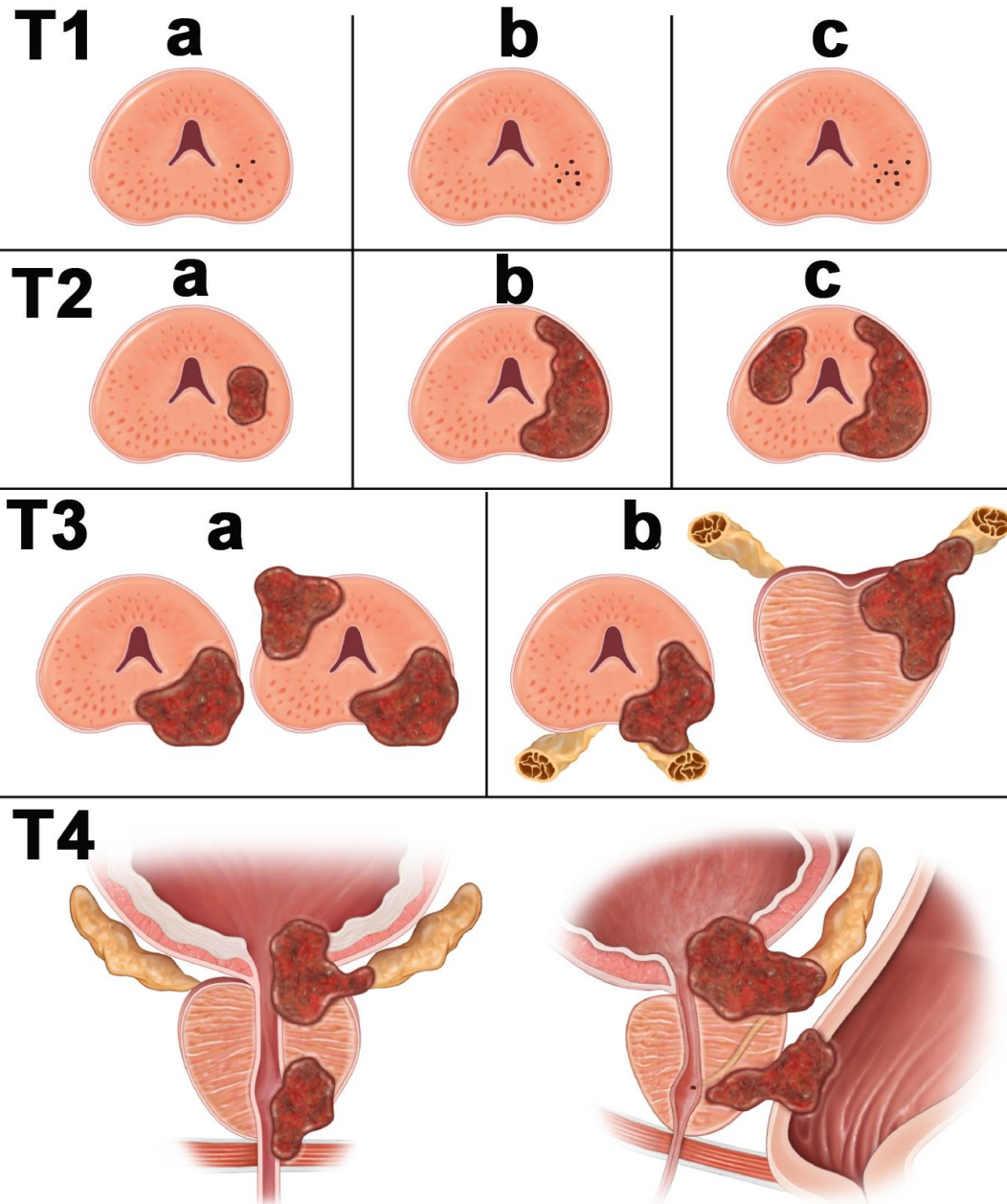
GRADE GROUPS



Epstein et al., European Urology. 2016

Epstein et al., Am J Surg Pathol. 2016

Tumor Staging



T1: <5% histological involvement

T2: confined palpable tumor

T3: extra-prostatic extension

T3b: seminal vesicle involvement

T4: invasion adjacent structures

RISK STRATIFICATION for Localized Disease

Risk Group	Clinical/Pathologic Features		
Very low ^f	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/mL • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core ^g • PSA density <0.15 ng/mL/g		
	Low ^f		
Intermediate ^f	Has all of the following: • No high-risk group features • No very-high-risk group features • Has one or more intermediate risk factors (IRFs): ▶ cT2b–cT2c ▶ Grade Group 2 or 3 ▶ PSA 10–20 ng/mL	Favorable intermediate	Has all of the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (eg, <6 of 12 cores) ^g
		Unfavorable intermediate	Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive (eg, ≥ 6 of 12 cores) ^g
High	Has no very-high-risk features and has exactly one high-risk feature: • cT3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL		
	Very high		
	Has at least one of the following: • cT3b–cT4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • >4 cores with Grade Group 4 or 5		

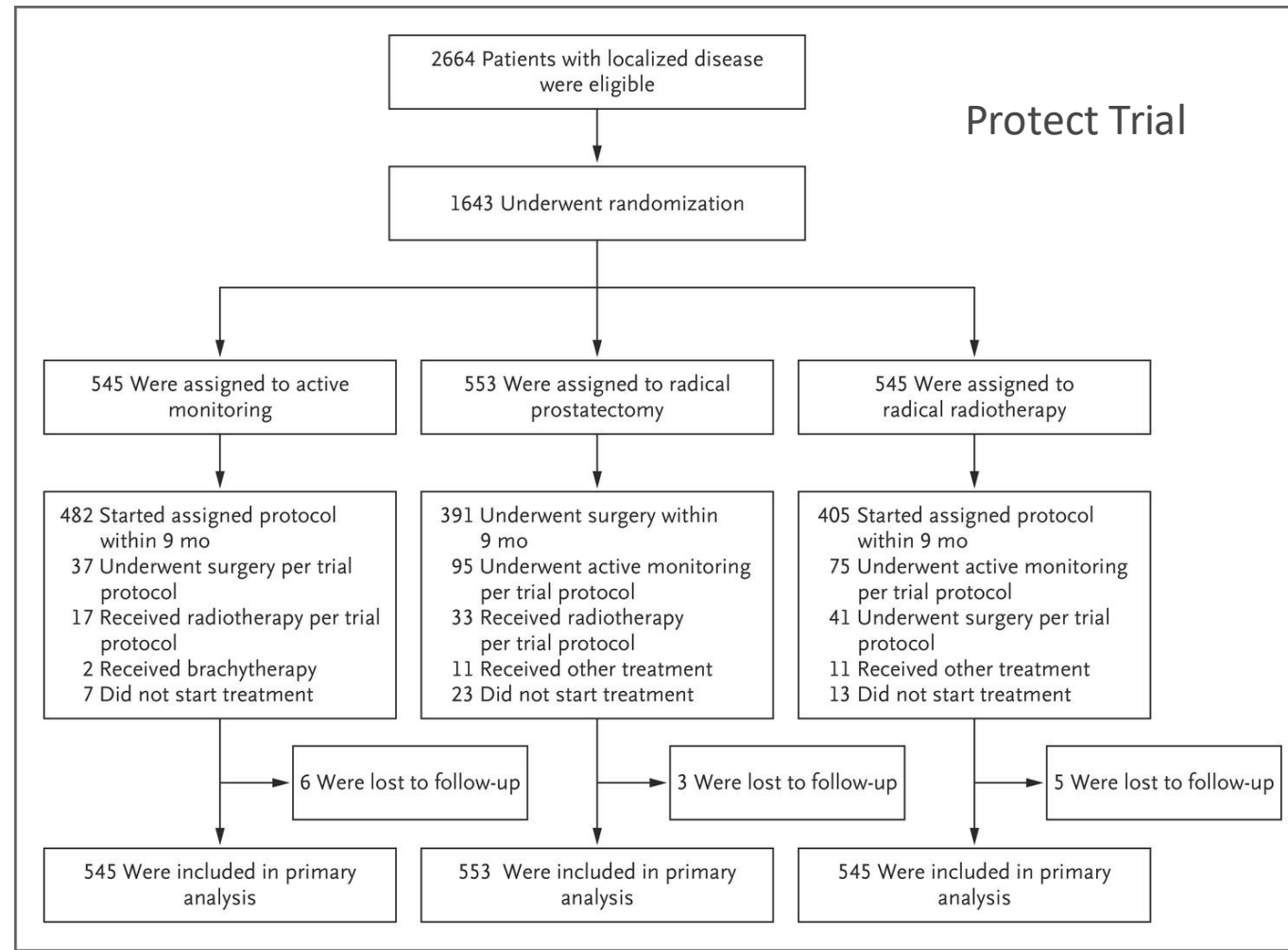
3 Main Factors:

- Clinical tumor stage
- PSA
- Grade Group/Gleason pattern

ORIGINAL ARTICLE

Fifteen-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Prostate Cancer

1999-
2009

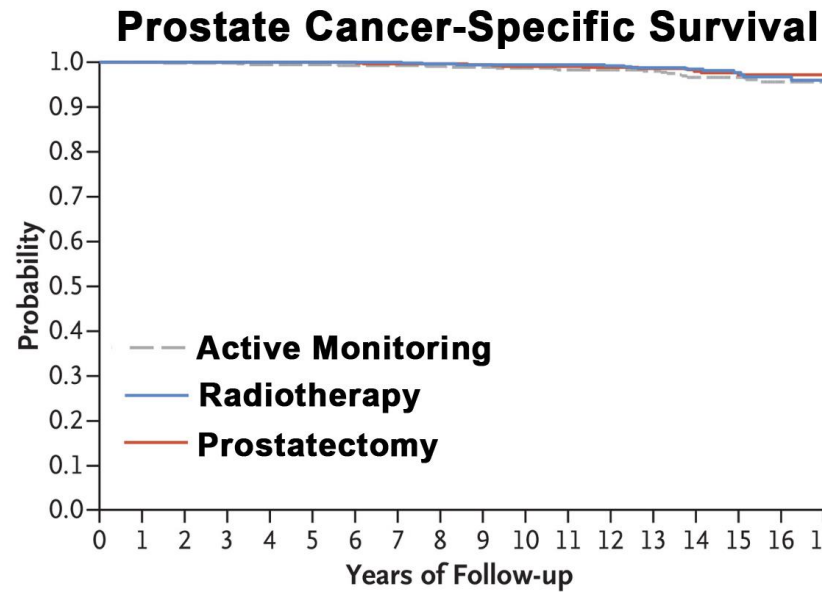


Baseline characteristics stratified by study arm of PROTECT participants

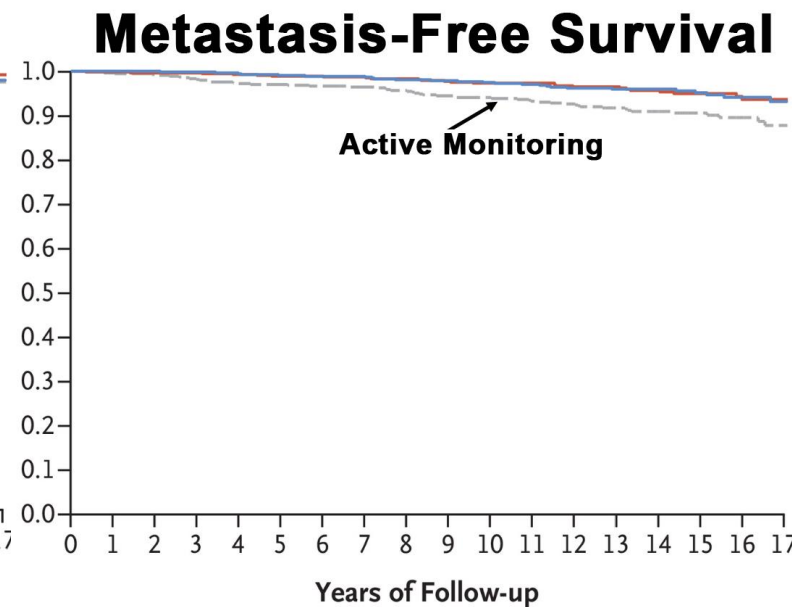
	Active monitoring protocol (n=545)	Surgery (n=553)	Radiotherapy protocol (n=545)
Mean age in years at randomisation (SD ¹)	62 (5)	62 (5)	62 (5)
White ethnic origin (%)	535 (99)	542 (99)	529 (98)
African-Caribbean origin (%)	2 (0.4)	3 (0.5)	5 (0.9)
Married or living with partner (%)	457 (84)	458 (84)	460 (85)
Managerial / professional occupation (%)	229 (43)	229 (42)	226 (42)
Known family history prostate cancer (%)	43 (8)	32 (6)	44 (8)
Median PSA ² in ng/ml (IQR ³)	4.7 (3.7, 6.7)	4.9 (3.7, 6.7)	4.8 (3.7, 6.7)
PSA ² 10+ ng/ml (%)	57 (10)	57 (10)	58 (11)
Gleason score			
6	421 (77)	422 (76)	423 (78)
7	111 (20)	120 (22)	108 (20)
8-10	13 (2)	10 (2)	14 (3)
Missing	0	1	0
Clinical stage			
T1c	410 (75)	410 (74)	429 (79)
T2	135 (25)	143 (26)	116 (21)

ProtecT

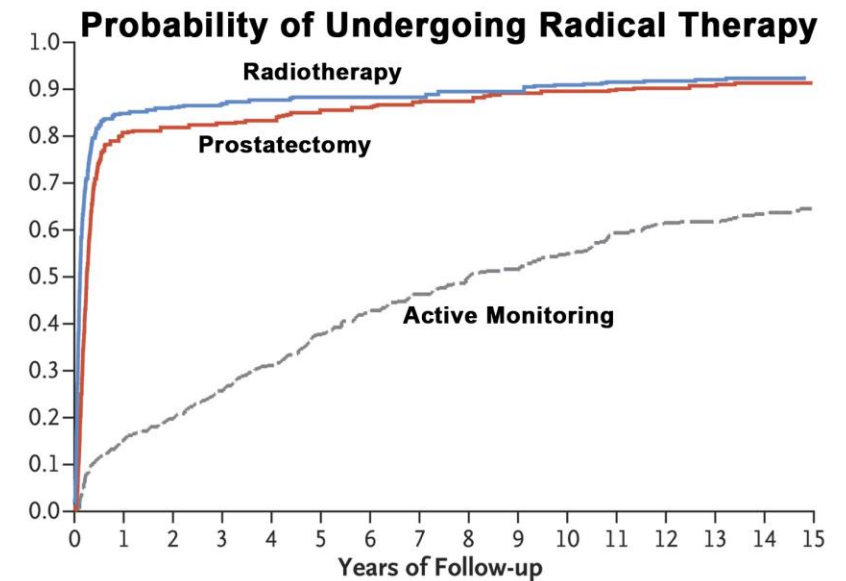
- 1643 men (median age 62) followed for 15 years
- Majority (66%) low risk, 24% intermediate risk, 10% high risk localized PCa
- Equally Randomized to active surveillance vs prostatectomy vs radiation



CSS = 97% for all 3 groups

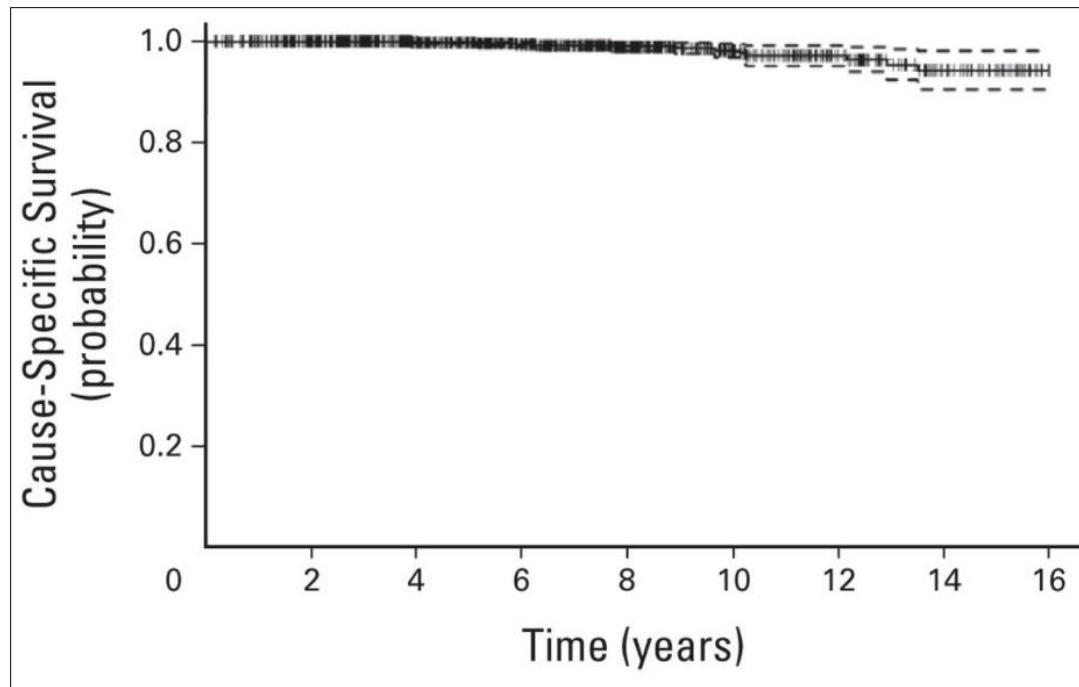


AS arm had ~2X relative risk of distant metastasis



61% of AS patients eventually received radical Tx

CARE OPTIONS– VERY LOW-/LOW RISK



7. Clinicians should recommend **active surveillance as the best available care option** for **very low-risk localized prostate** cancer patients. (Strong Recommendation; Evidence Level: Grade A)
8. Clinicians should recommend **active surveillance** as the preferable care option for most **low-risk localized prostate cancer** patients. (Moderate Recommendation; Evidence Level: Grade B)

RISK STRATIFICATION

The Panel incorporated contemporary Grade Group categorizations to subcategorize intermediate-risk group into “*favorable*” (Gleason 3+4, Grade Group 2) and “*unfavorable*” (Gleason 4+3, Grade Group 3) categories to facilitate decision-making

Gleason Score	Grade Group*
3+3	1
3+4	2
4+3	3
4+4	4
4+5, 5+4, or 5+5	5

*Grade Group = Contemporary Pathology Consensus Based on Gleason Score and Adopted by WHO, 2016

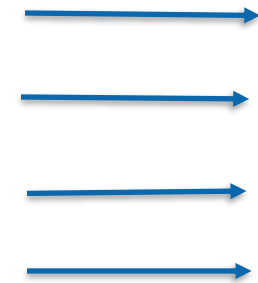
FAVORABLE VS UNFAVORABLE INTERMEDIATE RISK SUB-GROUPS

PCa Intermediate Risk Sub-Group	Pathology Grade Group	PSA (ng/ml)	Clin Stage (DRE)
Favorable	1	10-20	T1-T2a
	2 (3+4=7)	<10	
Unfavorable	2 (3+4=7)	<10	T2b
	2 (3+4=7)	10-20	Any T1-2
	2 (4+3=7)	<20	Any T1-2

(Amount of Pca on biopsy not included in sub-categorization due to lack of such strata in RCT evidence)

Considerable variability in the clinical behavior of intermediate risk prostate cancer

Tumor volume
Percentage Pattern 4
Adverse histology
Genomic Risk Classifier
MRI findings
Patient comorbidity
Patient compliance



- Surgery
- Focal therapy
- Radiation
- +/- ADT

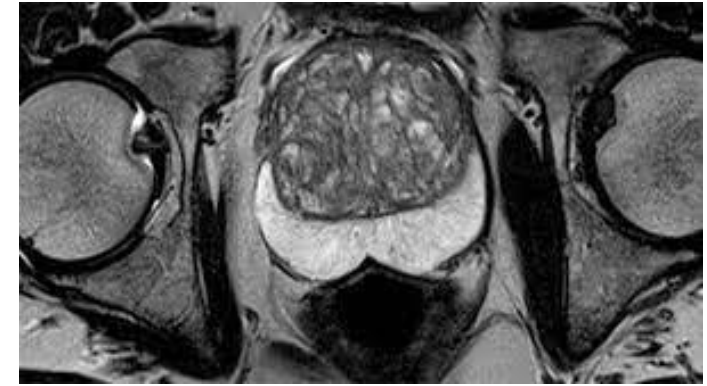
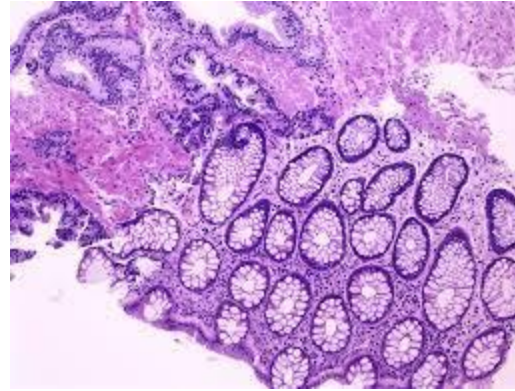
CARE OPTIONS– INTERMEDIATE RISK

16. Clinicians should **discuss active surveillance, radical prostatectomy or radiotherapy** as **standard treatment options** for patients with favorable intermediate-risk localized prostate cancer. (Strong Recommendation; Evidence Level: Grade A)
17. Clinicians should inform patients with **unfavorable intermediate-risk prostate cancer AND > 10 YEAR LIFE EXPECTANCY** that prostatectomy and XRT + 4-6 months of ADT are standard options

PSMA pet staging for uIR and high risk patients

Surveillance: Selection is key!

- Tumor volume
- Percentage Pattern 4
- Adverse histology
- Genomic Risk Classifier
- MRI findings
- Patient comorbidity
- Patient compliance



SelectMDxTM
for Prostate Cancer

Decipher
PROSTATE GENOMIC CLASSIFIER

Adverse Disease Features in Gleason Score 3 + 4 “Favorable Intermediate-Risk” Prostate Cancer: Implications for Active Surveillance



	Gleason upgrade				Gleason downgrade				Non-organ confined				Unfavorable disease			
	OR	95% CI		<i>p</i>	OR	95% CI		<i>p</i>	OR	95% CI		<i>p</i>	OR	95% CI		<i>p</i>
Age	1.06	1.02	1.09	<0.001	0.97	0.94	1.00	0.05	1.03	1.00	1.06	0.04	1.05	1.02	1.08	<0.001
Log ₂ PSA density	1.83	1.17	2.85	0.007	0.67	0.51	0.89	0.006	1.04	0.79	1.35	0.79	1.14	0.90	1.44	0.29
Clinical stage																
cT1	Ref.				Ref.				Ref.							
cT2a	1.13	0.84	1.52	0.43	0.52	0.32	0.84	0.007	1.95	1.32	2.88	<0.001	1.74	1.23	2.46	0.002
Positive cores, % (cont)	0.99	0.99	1.01	0.55	0.98	0.97	0.99	0.007	1.02	1.01	1.03	<0.001	1.02	1.01	1.02	<0.001
Positive cores, %																
<50	ref				Ref.				Ref.				Ref.			
≥50	0.96	0.57	1.62	0.88	0.76	0.45	1.28	0.3	1.87	1.22	2.85	0.004	1.57	1.06	2.31	0.02
Surface area, % (cont)	1.01	1.00	1.02	0.03	0.98	0.97	0.99	<0.001	1.02	1.01	1.03	<0.001	1.02	1.01	1.02	<0.001
Surface area, %																
<50	Ref.				Ref.				Ref.				Ref.			
≥50	0.87	0.29	2.63	0.8	2.62	0.69	9.94	0.16	1.60	0.58	4.44	0.36	1.09	0.47	2.55	0.84
Tumor bilaterality																
No	Ref.				Ref.				Ref.				Ref.			
Yes	0.70	0.43	1.13	0.15	0.86	0.55	1.36	0.52	1.32	0.87	1.99	0.19	1.00	0.69	1.45	0.99
Perineural invasion																
No	Ref.				Ref.				Ref.				Ref.			
Yes	1.37	0.91	2.07	0.13	0.59	0.36	0.96	0.03	2.50	1.75	3.56	<0.001	1.89	1.36	2.62	<0.001

CI = confidence interval; OR = odds ratio; PSA = prostate-specific antigen; Ref = reference.
Boldface shows $p < 0.05$.

- Age
- PSA Density
- Percentage Pattern 4
- Core involvement

Adverse Pathology and germline characteristics

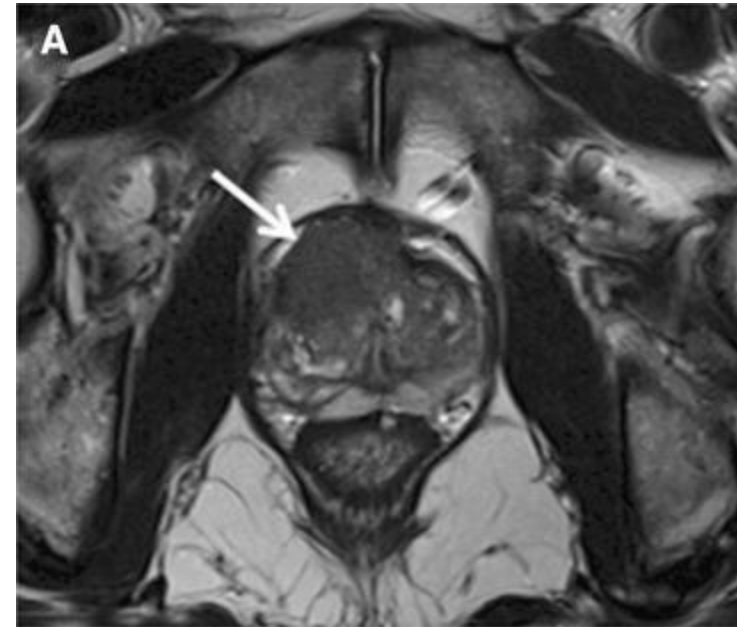
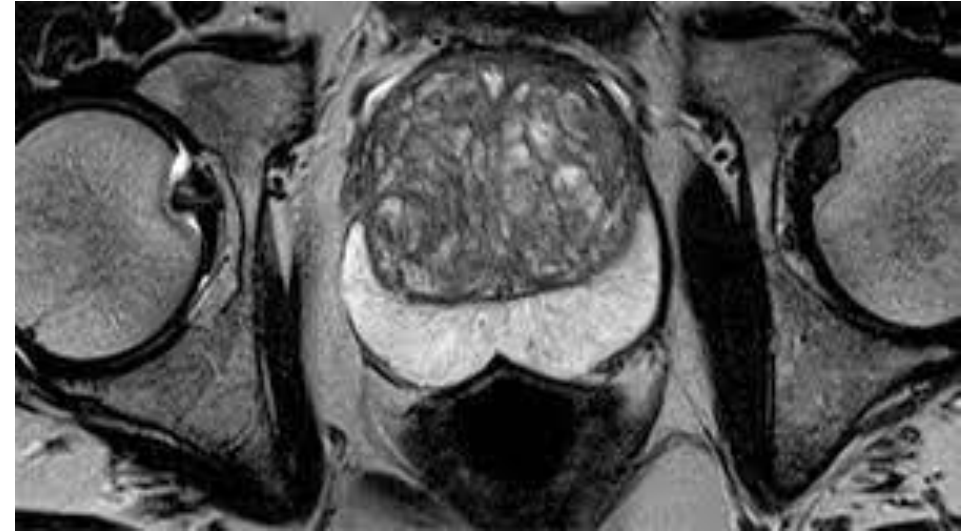
- **Standardized Reporting of cribriform and intraductal histology in Pathology Consensus Statements**

The 2019 Genitourinary Pathology Society (GUPS) White Paper on Contemporary Grading of Prostate Cancer

- **Hereditary GERMLINE considerations**
 - **BRCA1/BRCA2**
 - **Ashkenazi Jewish Ancestry**
 - **DNA Damage Repair Mutations**

MRI features

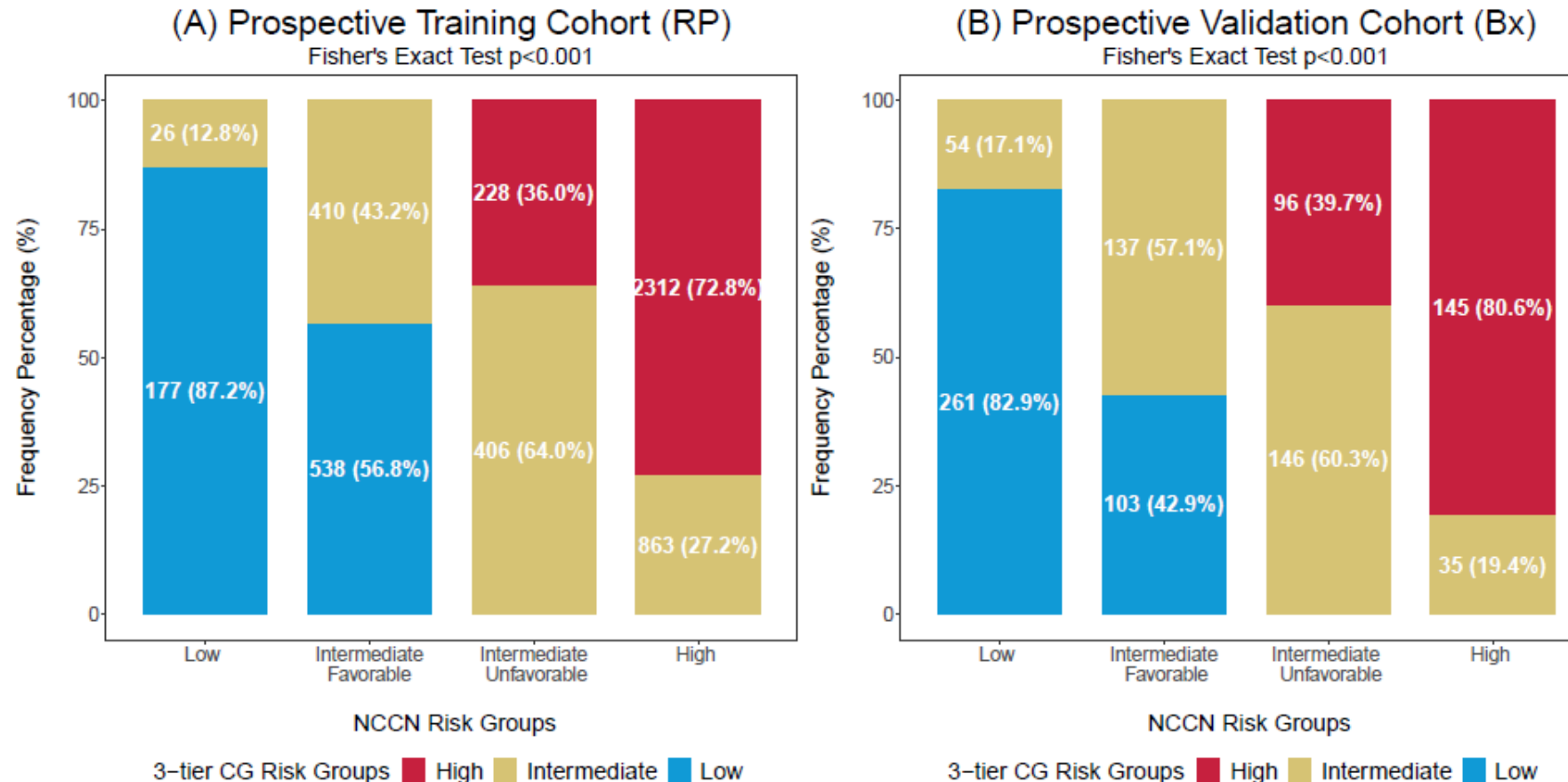
- **Guide confirmatory biopsies**
- **Assess Adverse features**
 - **Extraprostatic Extension**
 - **Large Tumor Volume**
 - **Multifocal Disease**
- **Good Negative Predictive Value**
- **Low rates of undergrading/staging**



PROMIS (NEJM)
PRECISION (LANCET)

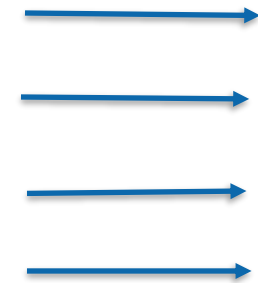
Genomic Risk Classifiers

- Use molecular Characteristics to augment NCCN risk groups



Considerable variability in the clinical behavior of intermediate risk prostate cancer

Tumor volume
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MRI findings
Patient comorbidity
Patient compliance



- Surgery
- Focal therapy
- Radiation
- +/- ADT

Aim of Focal Therapy



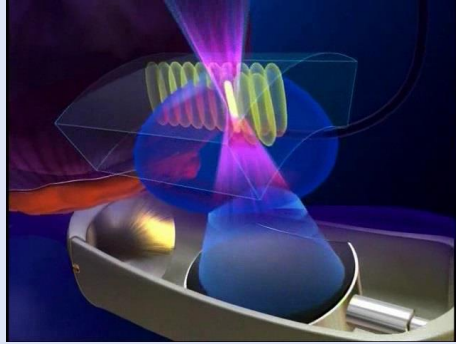
Maintain oncological benefit
of active treatment



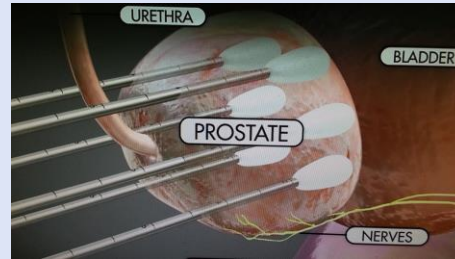
Tissue-preservation to
optimize function

Focal therapy modalities

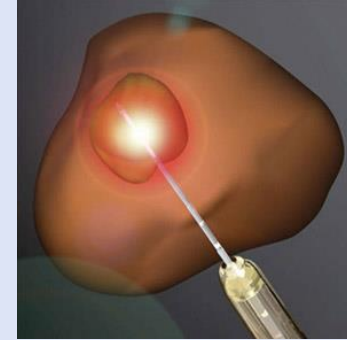
HIFU/TULSA



Cryotherapy



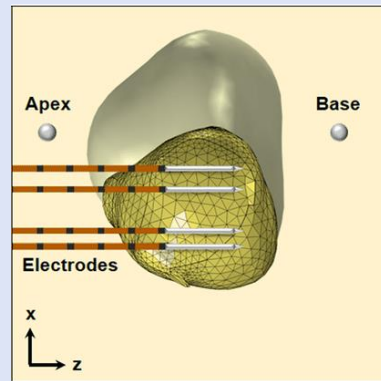
Laser



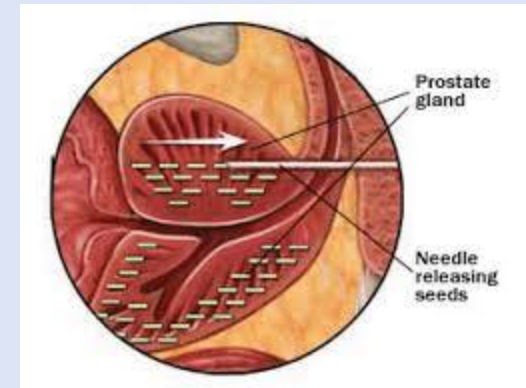
Photodynamic Therapy



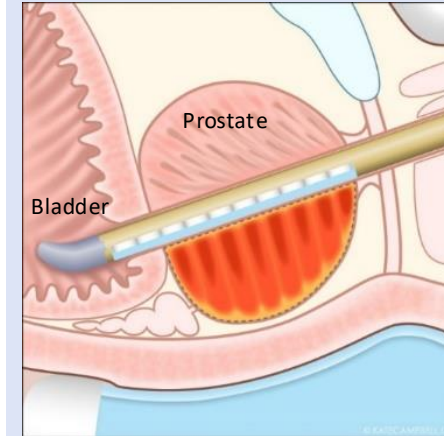
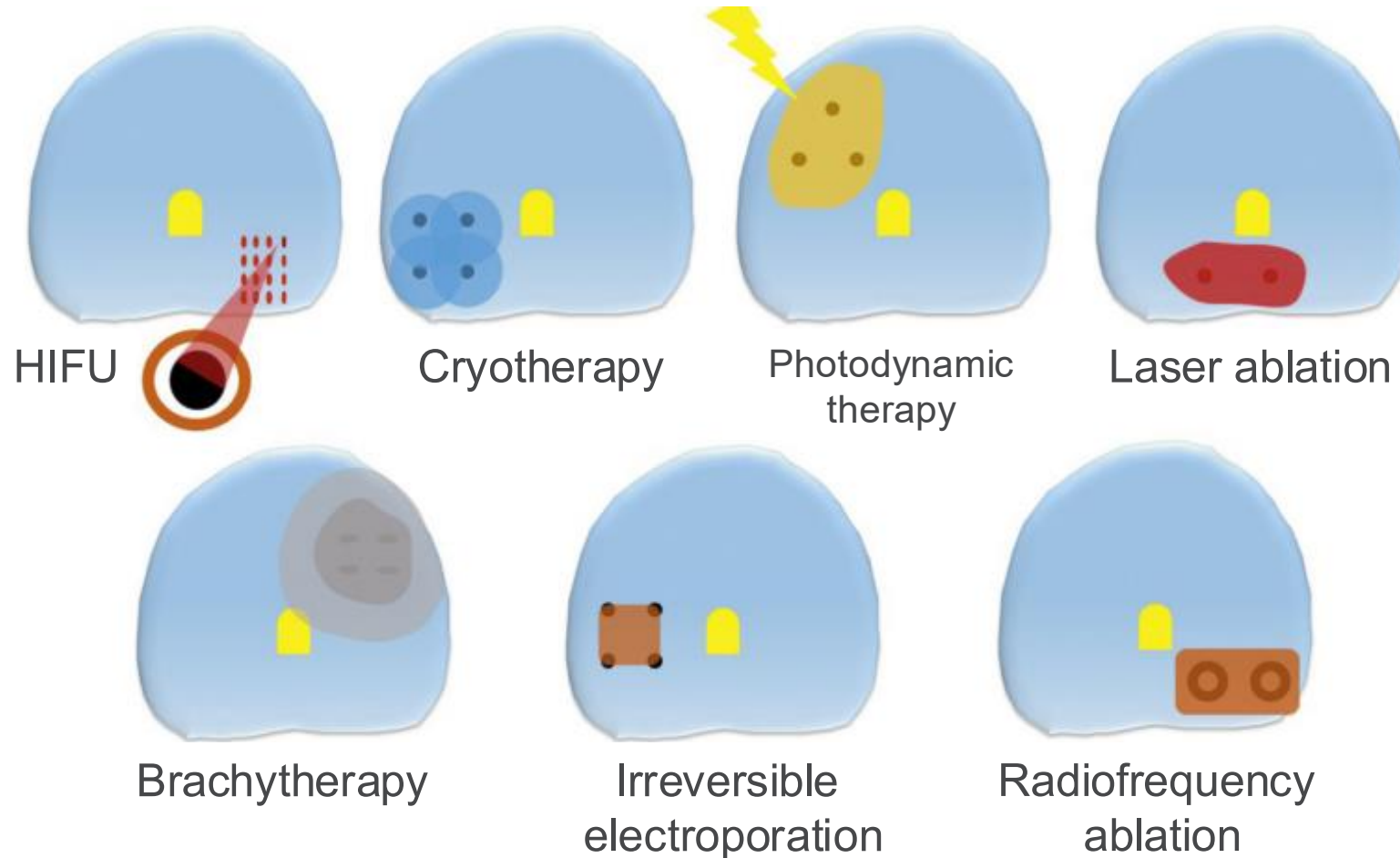
IRE



Radiation



Number of ablation modalities are growing



Transurethral
ultrasound ablation

Rad onc
HDR Brachy
MR-LINAC

Under trials
Vapor ablation – VAPOR2
trial
Aqua-ablation

The Guidelines: AUA/ASTRO/SUO

- **ALL** prostate cancer treatments carry risk
- Provide an **individualized risk estimate of post-treatment prostate cancer recurrence** to patients with prostate cancer. (Clinical Principle)
- For **low-risk prostate cancer**, clinicians should **recommend active surveillance** as the preferred option. (**Strong Recommendation; Evidence Level: Grade A**)
- Clinicians **should not recommend whole gland or focal ablation** for patients with **high-risk prostate cancer** outside of a clinical trial. (Expert Opinion)

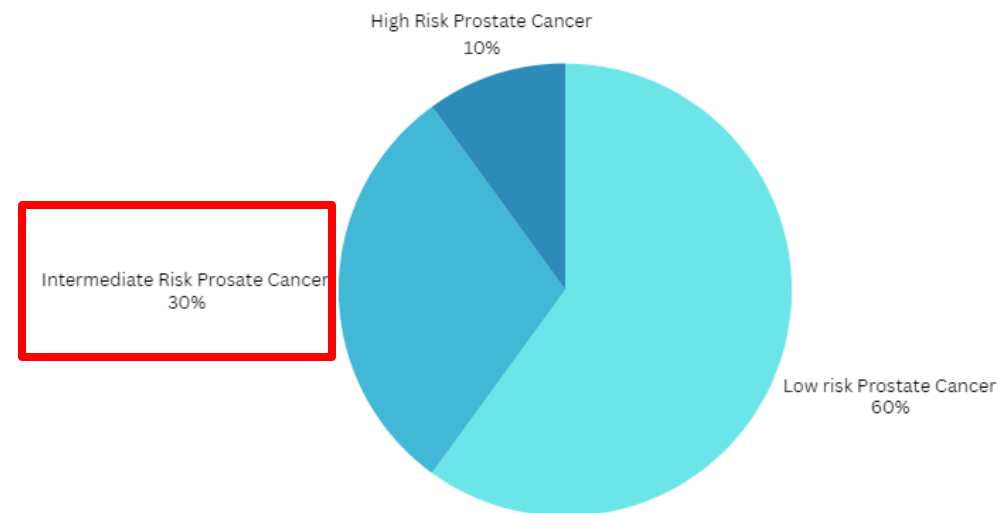
The Guidelines: AUA/ASTRO/SUO

- Clinicians should consider that all treatment options carry risk
- Clinicians should use an **individualized risk estimate** to guide **post-treatment** **prostate cancer** management (Clinical Principle)
- For patients with **low-risk** prostate cancer, **active surveillance** should be recommended. (Strong Recommendation; Evidence Level: I)
- Clinicians should **not recommend whole gland** prostatectomy for patients with **high-risk** prostate cancer (Expert Opinion)

Low and High Risk Prostate Cancer

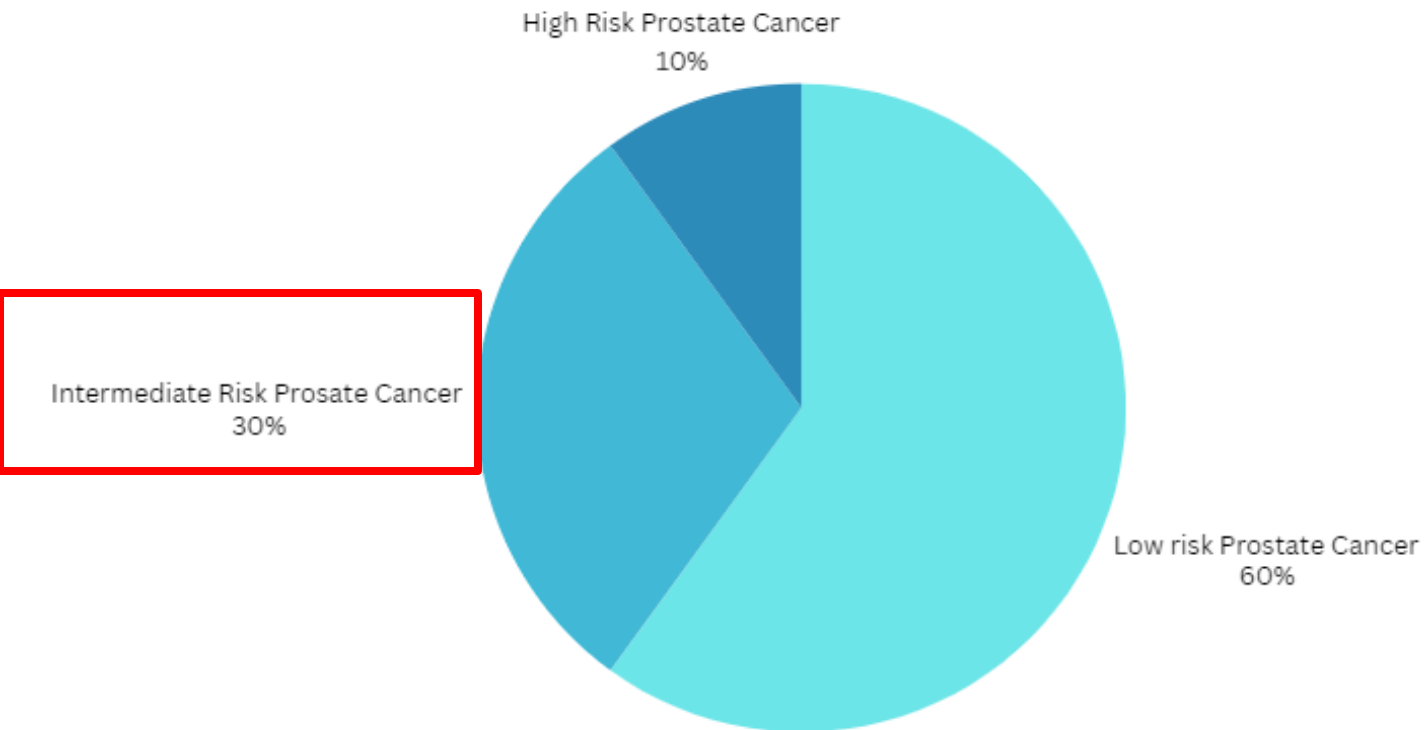
The Guidelines: AUA/ASTRO/SUO

- For patients with **favorable intermediate-risk prostate cancer**, clinicians should discuss:
 - active surveillance
 - radiation therapy
 - radical prostatectomy (**Strong Recommendation; Evidence Level: Grade A**)
- Inform patients with **intermediate-risk prostate cancer considering whole gland or focal ablation** that there are a **lack of high-quality data** comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)



	Active monitoring protocol (n=545)	Surgery (n=553)	Radiotherapy protocol (n=545)
Mean age in years at randomisation (SD ¹)	62 (5)	62 (5)	62 (5)
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Managerial / professional occupation (%)	229 (43)	229 (42)	226 (42)
Known family history prostate cancer (%)	43 (8)	32 (6)	44 (8)
Median PSA ² in ng/ml (IQR ³)	4.7 (3.7, 6.7)	4.9 (3.7, 6.7)	4.8 (3.7, 6.7)
PSA ² 10+ ng/ml (%)	57 (10)	57 (10)	58 (11)
Gleason score			
6	421 (77)	422 (76)	423 (78)
7	111 (20)	120 (22)	108 (20)
8-10	13 (2)	10 (2)	14 (3)
Missing	0	1	0
Clinical stage			
T1c	410 (75)	410 (74)	429 (79)
T2	135 (25)	143 (26)	116 (21)

The Guidelines: AUA/ASTRO/SUO



	Active monitoring protocol (n=545)	Surgery (n=553)	Radiotherapy protocol (n=545)
Mean age in years at randomisation (SD ¹)	62 (5)	62 (5)	62 (5)
White ethnic origin (%)	535 (99)	542 (99)	529 (98)
African-Caribbean origin (%)	2 (0.4)	3 (0.5)	5 (0.9)
Married or living with partner (%)	457 (84)	458 (84)	460 (85)
Managerial / professional occupation (%)	229 (43)	229 (42)	226 (42)
Known family history prostate cancer (%)	43 (8)	32 (6)	44 (8)
Median PSA ² in ng/ml (IQR ³)	4.7 (3.7, 6.7)	4.9 (3.7, 6.7)	4.8 (3.7, 6.7)
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Ideal focal therapy candidates

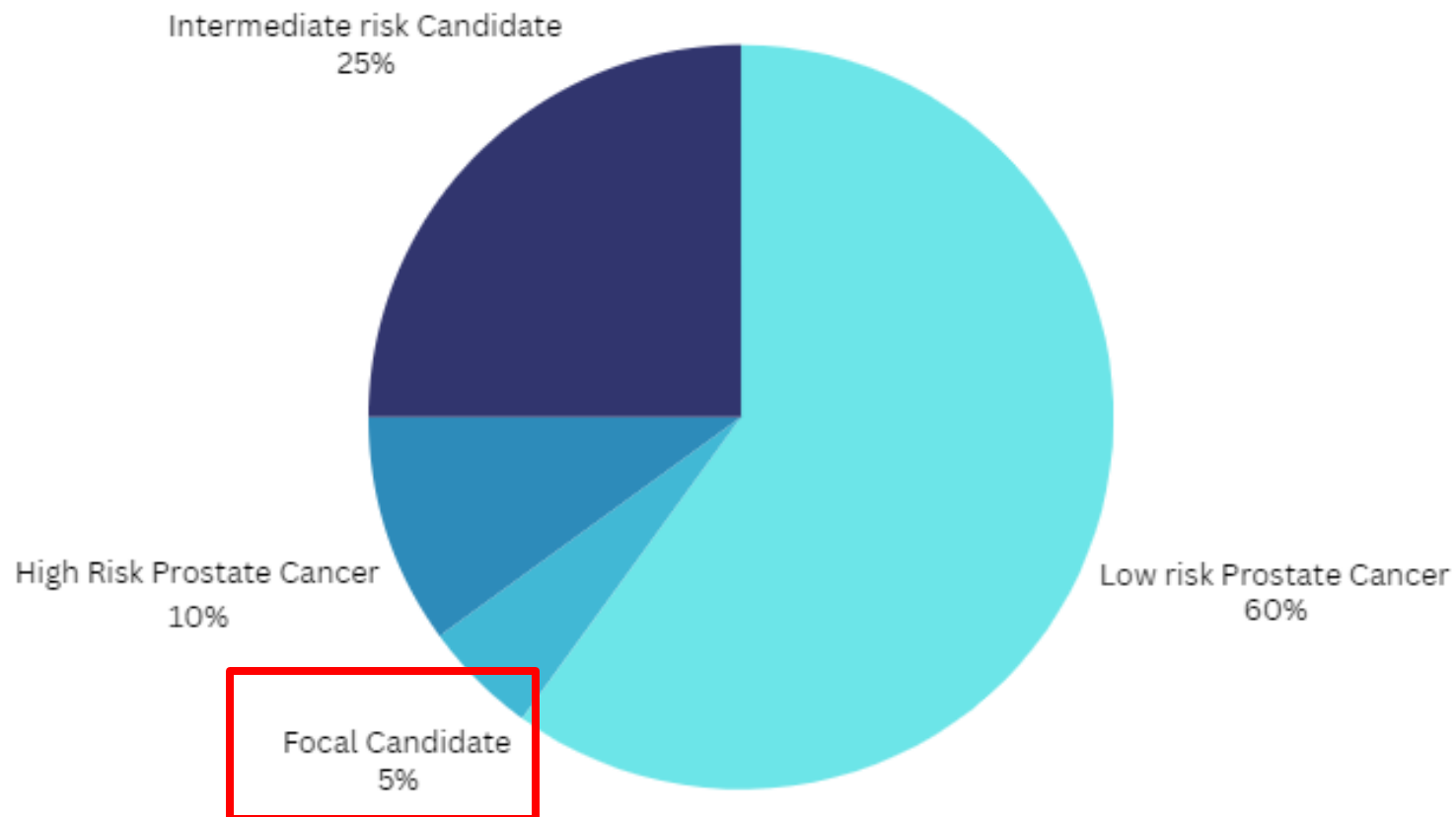
The state of focal therapy in the treatment of prostate cancer: the university of California collaborative (UC-Squared) consensus statement

[Juan Javier-DesLoges](#) , [Marc A. Dall'Era](#), [Wayne Brisbane](#), [Karim Chamie](#), [Samuel L. Washington III](#),
[Thenappan Chandrasekar](#), [Leonard S. Marks](#), [Hao Nguyen](#), [Michael Daneshvar](#), [Gregory Gin](#), [Christopher J.](#)
[Kane](#), [Aditya Bagrodia](#) & [Matthew R. Cooperberg](#) 

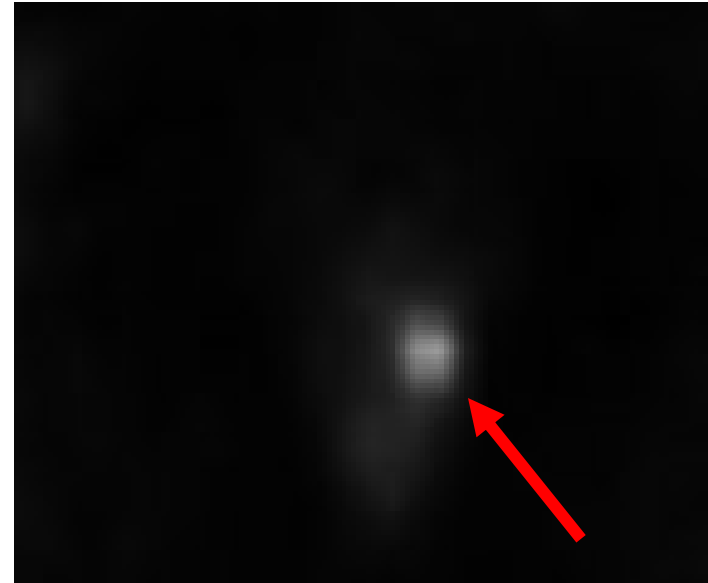
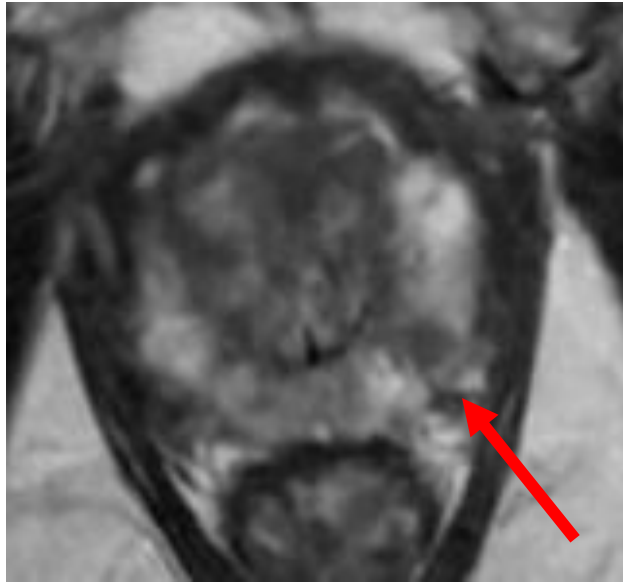
Ideal focal therapy candidates

- Life expectancy >10 years
- Organ- confined, intermediate risk disease
 - Gleason 3 + 4 or low-volume 4 + 3
 - PSA < 10 (or PSA < 20 and PSAD < 0.15)
 - $\leq$ cT2c disease.
 - Additional Gleason 6 outside of the target is not a contraindication
- Patients with unfavorable intermediate risk should receive a PSMA PET scan
- Minimum of 2 biopsies from target lesion
- Consideration of sampling penumbra
- 10–12 core systematic biopsy
- Clinically significant disease (GG2) should be visible on MRI
- All patients offered focal therapy should have a second (confirmatory or planning) biopsy within 12 months prior to treatment.

Ideal focal therapy candidates



Ideal focal therapy candidates

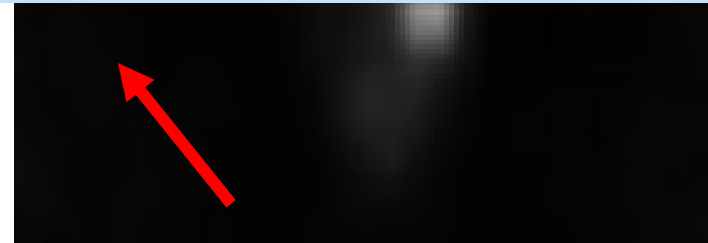


67 year old male T1c Grade Group 2 prostate cancer (60% core involvement, 40% pattern 4, no ID/cribiform), 3/16 cores involved

Ideal focal therapy candidates

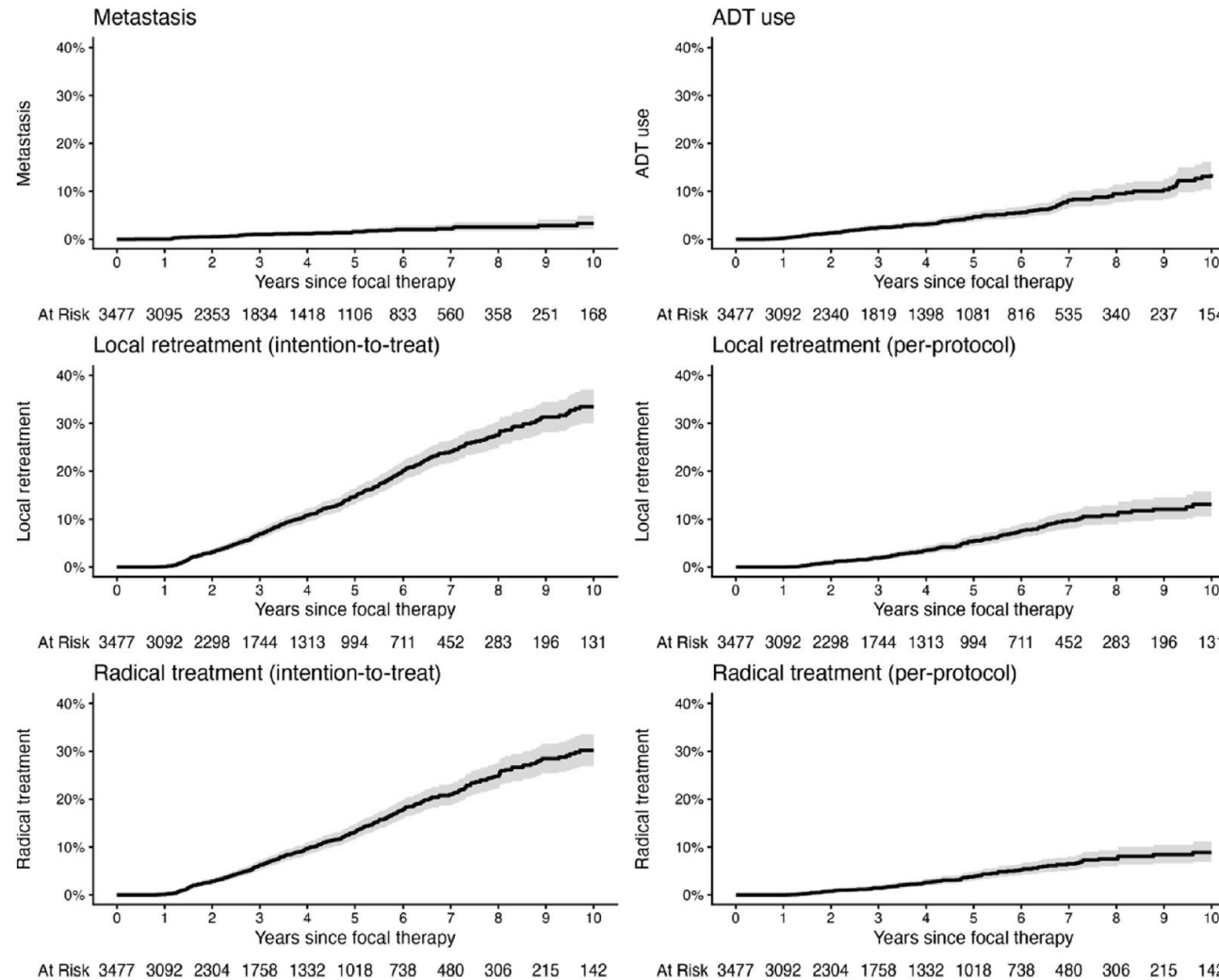


These patients are few and far between!



67 year old male T1c Grade Group 2 prostate cancer (60% core involvement, 40% pattern 4, no ID/cribiform), 3/16 cores involved

Oncological Outcomes Following Focal HIFU and Cryotherapy for Treatment of Nonmetastatic Prostate Cancer in the United Kingdom: An Updated Analysis of 3477 Patients from the Prospective HEAT and ICE Registries



Focal therapy Conclusions

- Focal therapy is a promising option for patients with localized low and intermediate risk prostate cancer.
- Potential for recurrence is likely inherent to most treatments and should be part of counseling
- Complication rate is low and acceptable.
- Long-term oncologic outcomes need to be investigated
- Salvage option also

CARE OPTIONS-HIGH RISK

17. Clinicians should inform patients with **high-risk prostate cancer AND > 10 YEAR LIFE EXPECTANCY** that **prostatectomy and XRT + 18-24 months ADT** are standard options

General Information

Age 59 years

Pretreatment PSA 14 ng/mL

Gleason Pattern

Primary Gleason at biopsy Pattern 4

Secondary Gleason at biopsy Pattern 5

Biopsy Gleason score 9

Clinical Tumor Stages

Clinical Tumor Stage (AJCC Version 7, 2010) T2a

Biopsy Cores

Number of positive biopsy cores 6 cores

Number of negative biopsy cores 6 cores

Percentage of positive biopsy cores 50.00%



15-YEAR PROSTATE CANCER-SPECIFIC SURVIVAL

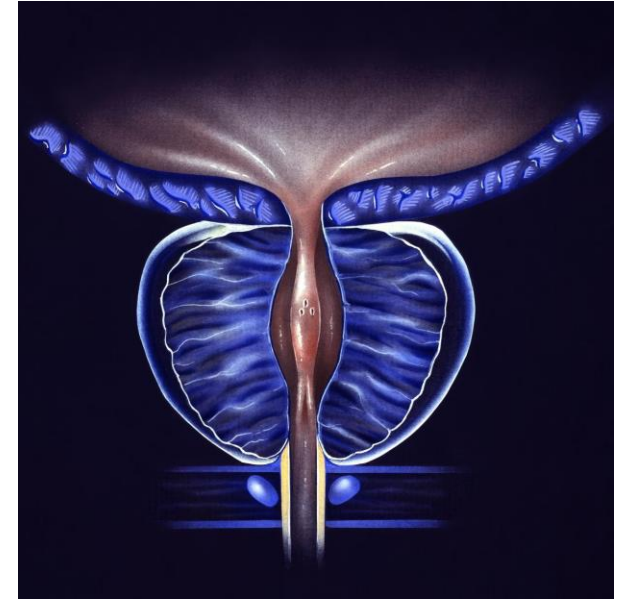
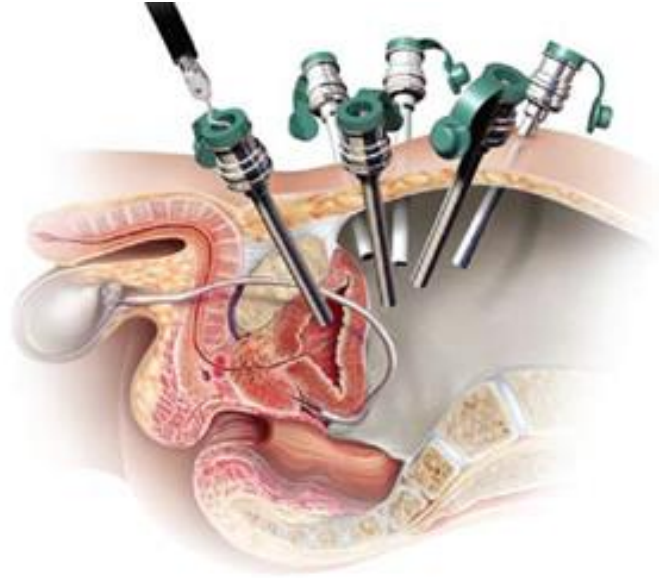
15 YR 66%



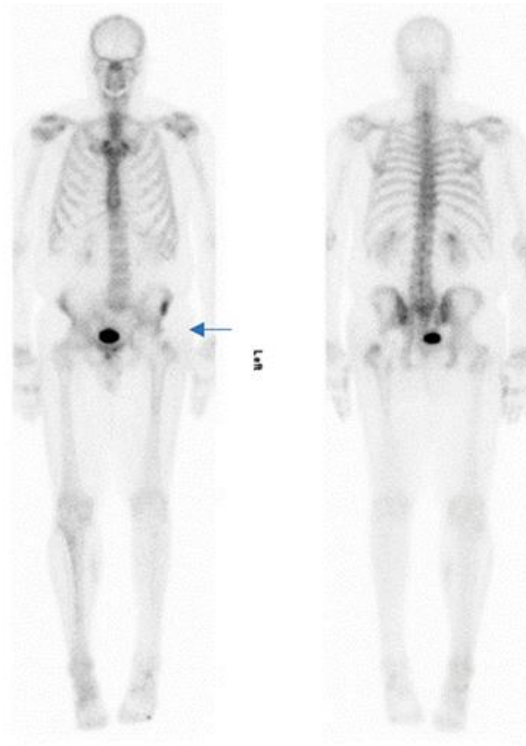
PROGRESSION-FREE PROBABILITY AFTER RADICAL PROSTATECTOMY

5 YR 25% 10 YR 15%

Robotic Prostatectomy



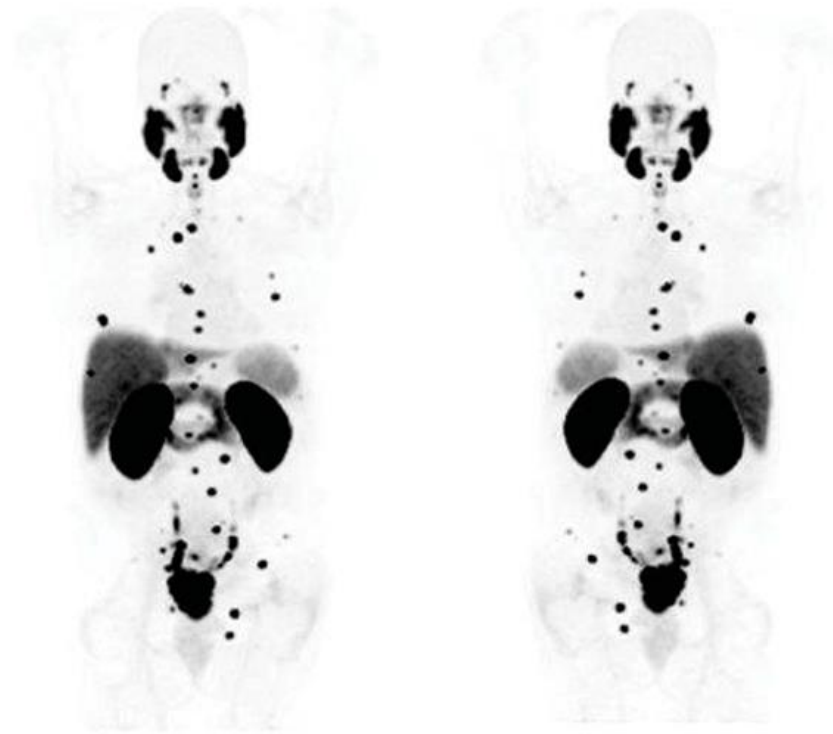
Conventional imaging vs PSMA



Anterior

Posterior

Bone Scintigraphy



Anterior
 ^{18}F -DCFPyL-PET/CT

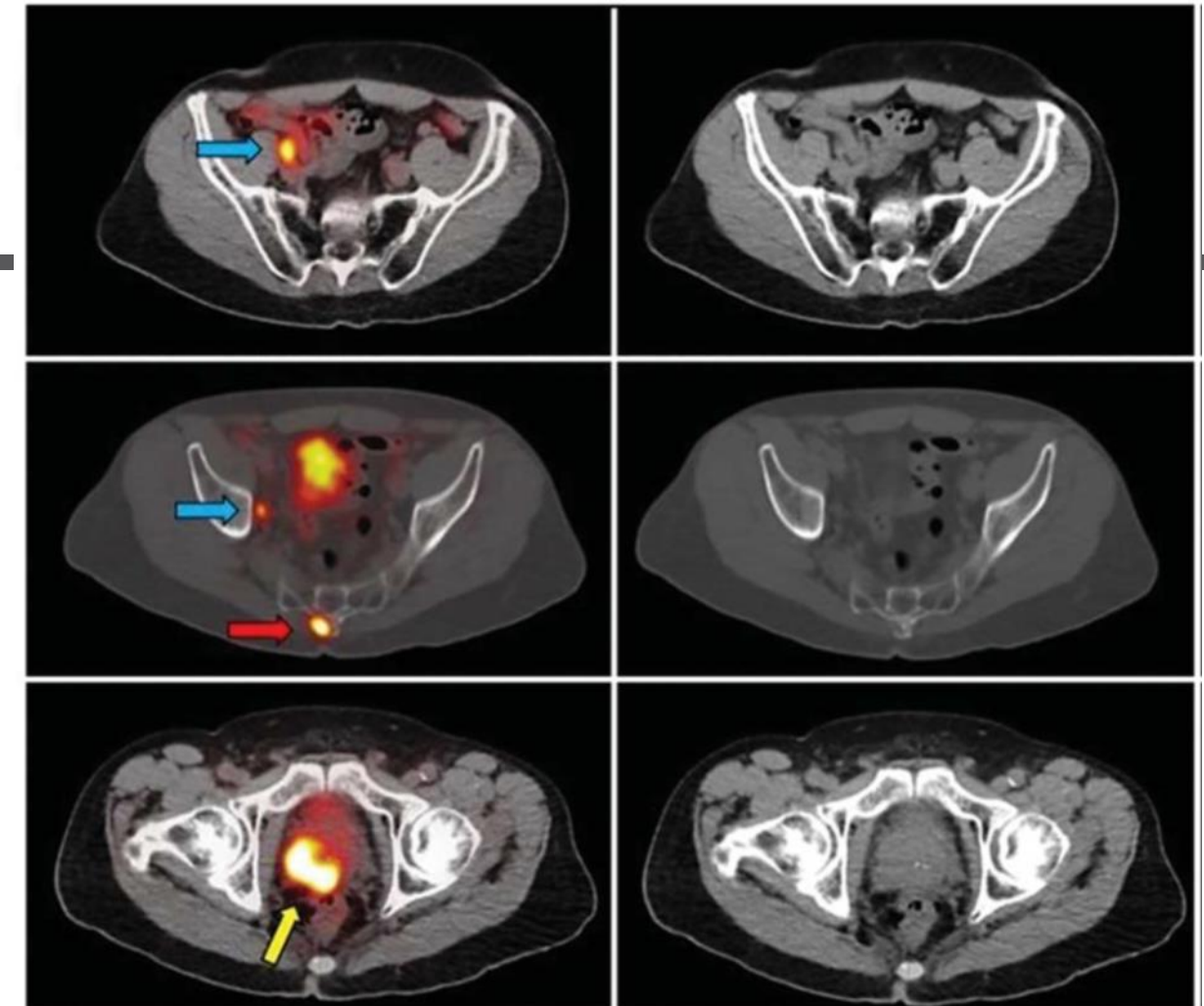
Posterior
 ^{18}F -DCFPyL-PET/CT

Maximum Intensity Projection Images

PSMA PET for Pretreatment Staging

77 yo, PSA 7.1, GG 4+5
Conventional imaging negative

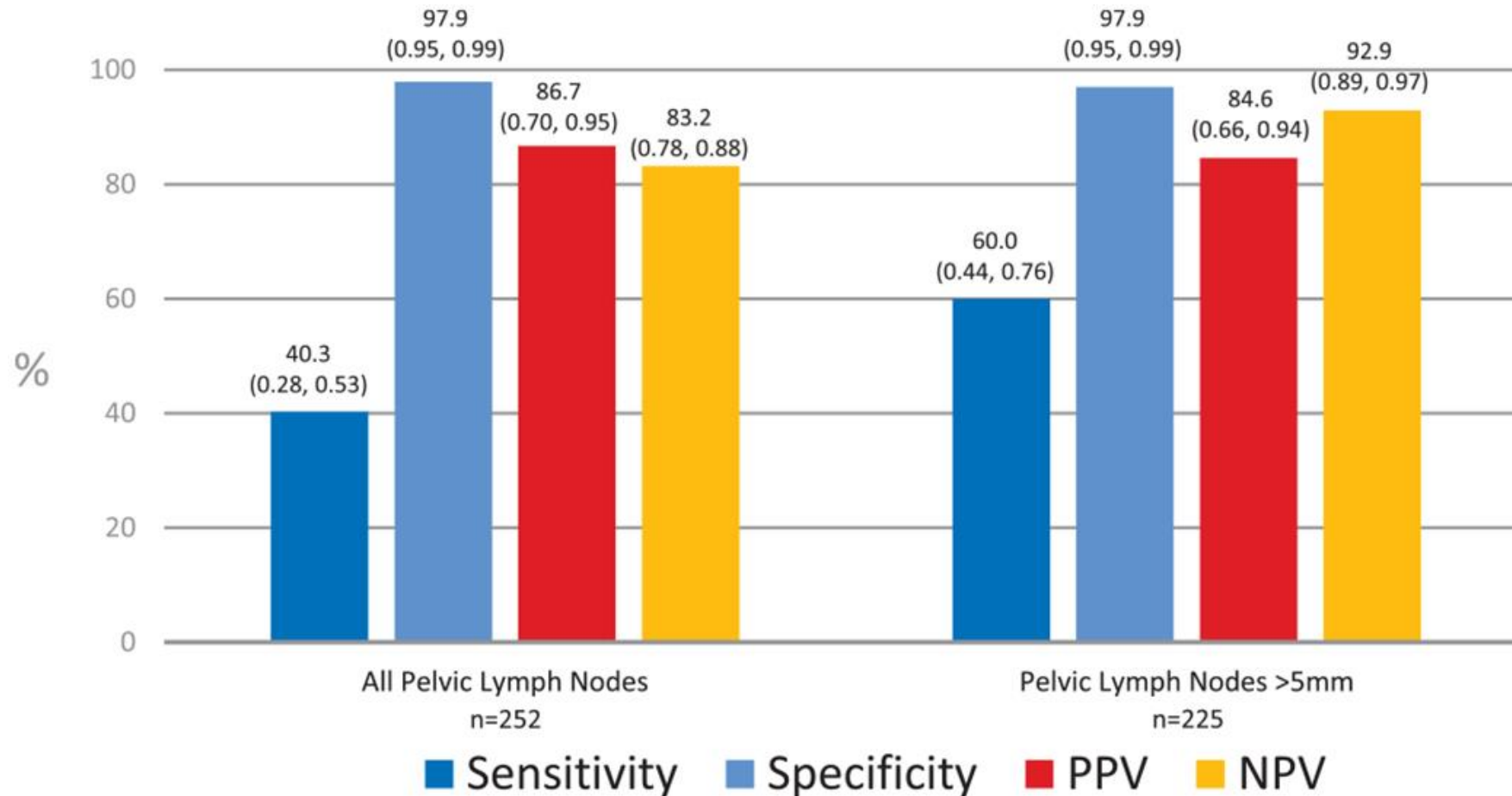
PSMA PET:
2 positive pelvic LNs
1 bone met in sacrum
Lesion in prostate



→ Primary lesion in prostate → Lymph node → Bone

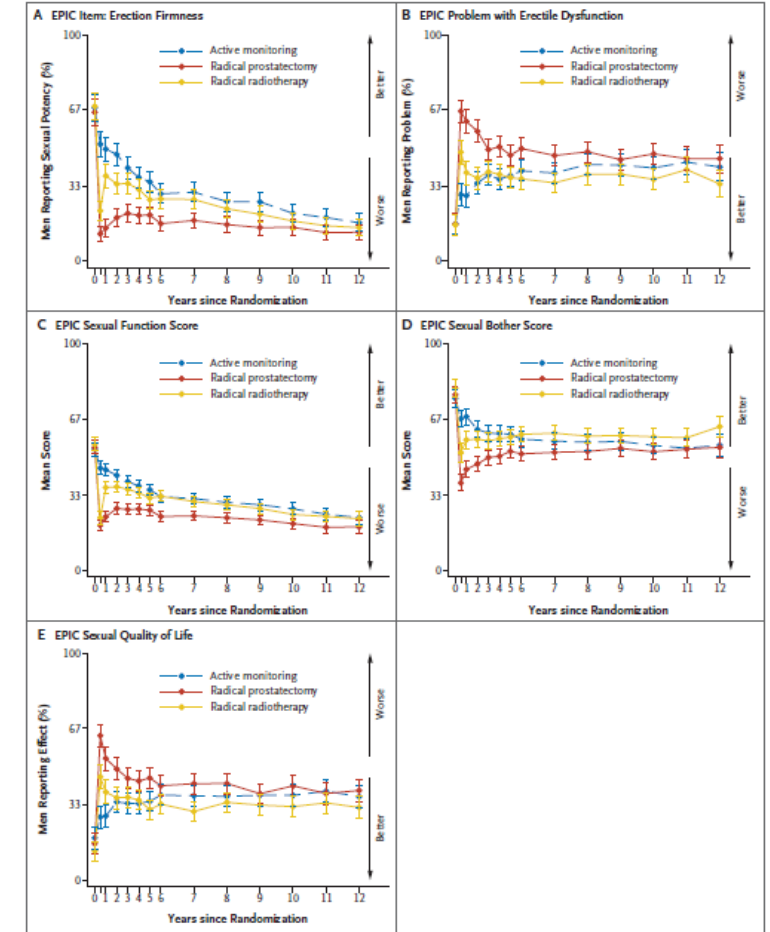
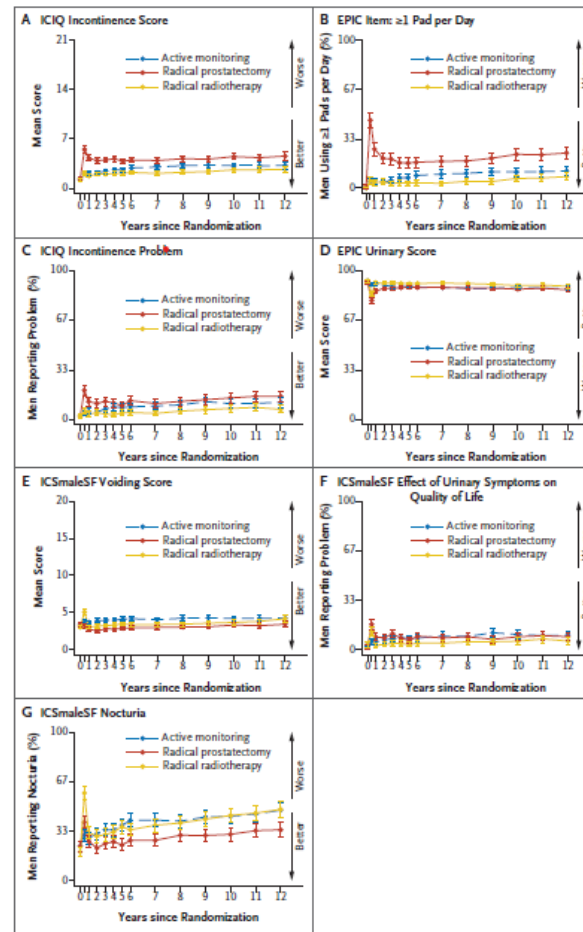
Kuppermann et al. J of Urology 2022

PSMA performance



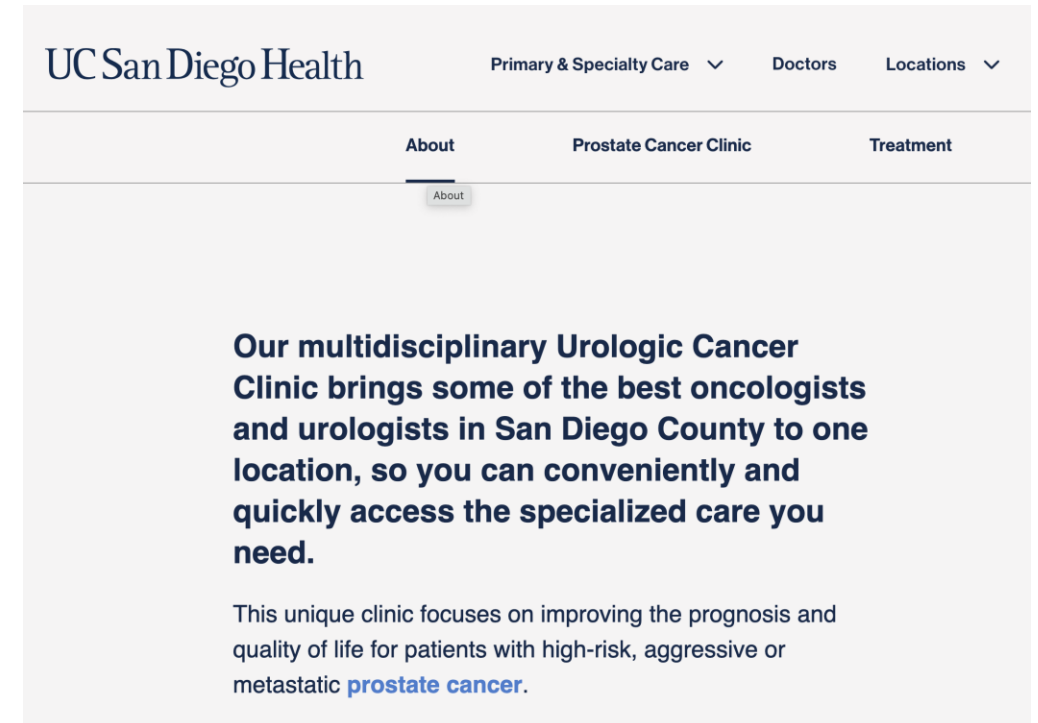
Prostatectomy

- Guideline directed option in men with intermediate/high risk prostate cancer
- Oncologic Outcomes:
 - Canceronomograms.com
- Urinary Function outcomes
- Sexual Health Outcomes



Conclusions

- We are in a very exciting time for prostate cancer management
- Prostate cancer treatment is not "one size fits all"
- Many excellent, guideline-directed options
 - Robotic prostatectomy
 - Radiation Therapy
 - Focal therapy
 - Active Surveillance
- Critical to learn about options and pick the right one for your patients!



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Thank you!



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UC San Diego Health