HARVARD MEDICAL SCHOOL

Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

BRIGHAM AND WOMEN'S HOSPITAL

MASSACHUSETTS GENERAL HOSPITAL

Dana-Farber Cancer Institute

Prostate Cancer
Perspectives on Recent Advances

Marc B Garnick MD for the faculty

Harvard Combined Medical Grand Rounds

A re-cap for the LPCSG

8 September 2025

Harvard Combined Medical Grand Rounds- demystified

- Medical Grand Rounds- general term for an educational medical meeting; grand implying that it has the widest appeal, medical for medical disciplines as opposed to specialty/surgical rounds

- A result of Covid Pandemic in 2020- unified approach for all of the Harvard teaching hospitals to work together and share knowledge as opposed to competing with one another; occurred weekly

- Success led to it becoming an enduring event – now monthly with competition for specific (general) topics to be covered

- Nine such meetings per year

A prostate cancer primer

- **Clinically localized prostate cancer- cancer localized to the prostate gland**
  - **Biochemical recurrence – treated clinically localized prostate cancer but PSA is now elevated**
  - **Non-metastatic Prostate Cancer**
  - **Oligometastatic – cancer in a few places outside the gland (usually LN)**
- **Regionally advanced- cancer in the gland and around the gland**
  - **Oligometastatic – cancer in a few places outside the gland (usually LN)**
- **Metastatic – cancer in more than a few places (bones and lymph nodes)**
  - **Hormone sensitive (mCSPC)**
  - **Not hormone sensitive (mCRPC) castration resistant)**

Dr. Alicia Morgans - DFCI

- **Prostate Cancer Screening**
- MRI, Biopsy, Active Surveillance and Surgical Options
- Radiation Therapy (1) for Localized/Regional Prostate Cancer
- Oligometastatic Prostate Cancer- Diagnostic and Treatment Advances
- Radiation Therapy (2) 5for Advanced/Metastatic Prostate Cancer
- Initial Systemic Therapies for Metastatic Prostate Cancer
- Subsequent Systemic Therapies for Metastatic Prostate Cancer
- Survivorship
- Summary of Key Points

Dr. Aria Olumi - BIDMC

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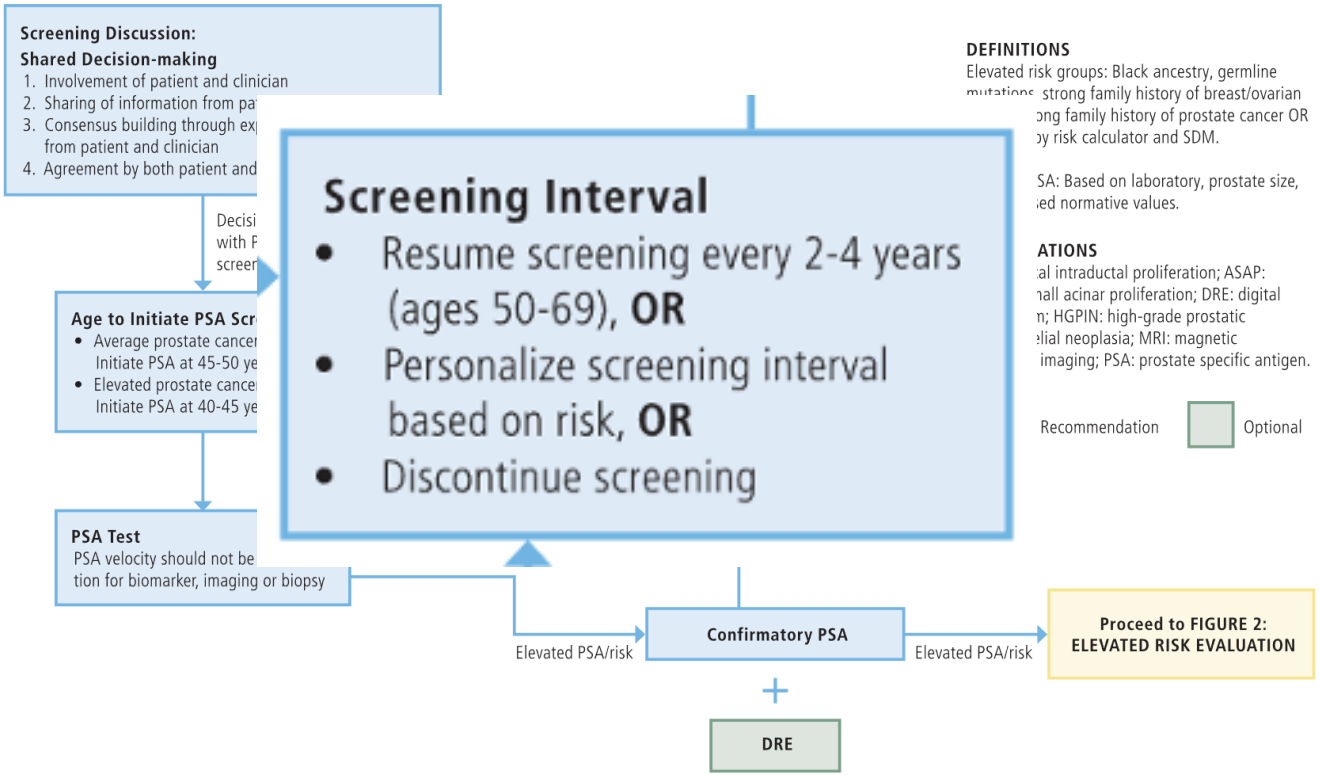
What is a normal PSA level?

- PSA is expected to rise with age
  - Age adjusted PSA levels can be considered as follows:
    - 40 to 49 years: 0 to 2.5 ng/mL
    - 50 to 59 years: 0 to 3.5 ng/mL
    - 60 to 69 years: 0 to 4.5 ng/mL
    - 70 to 79 years: 0 to 6.5 ng/mL
  - Repeat abnormal PSA to confirm elevation

- Post-prostatectomy PSA should be undetectable (< lowest level detected by the lab) **– please send ANY detectable PSA back to urology as soon as possible (lower better)**

Wei JT, et al. J Urol. 2023.
Partin AW, et al. J Urol. 1996

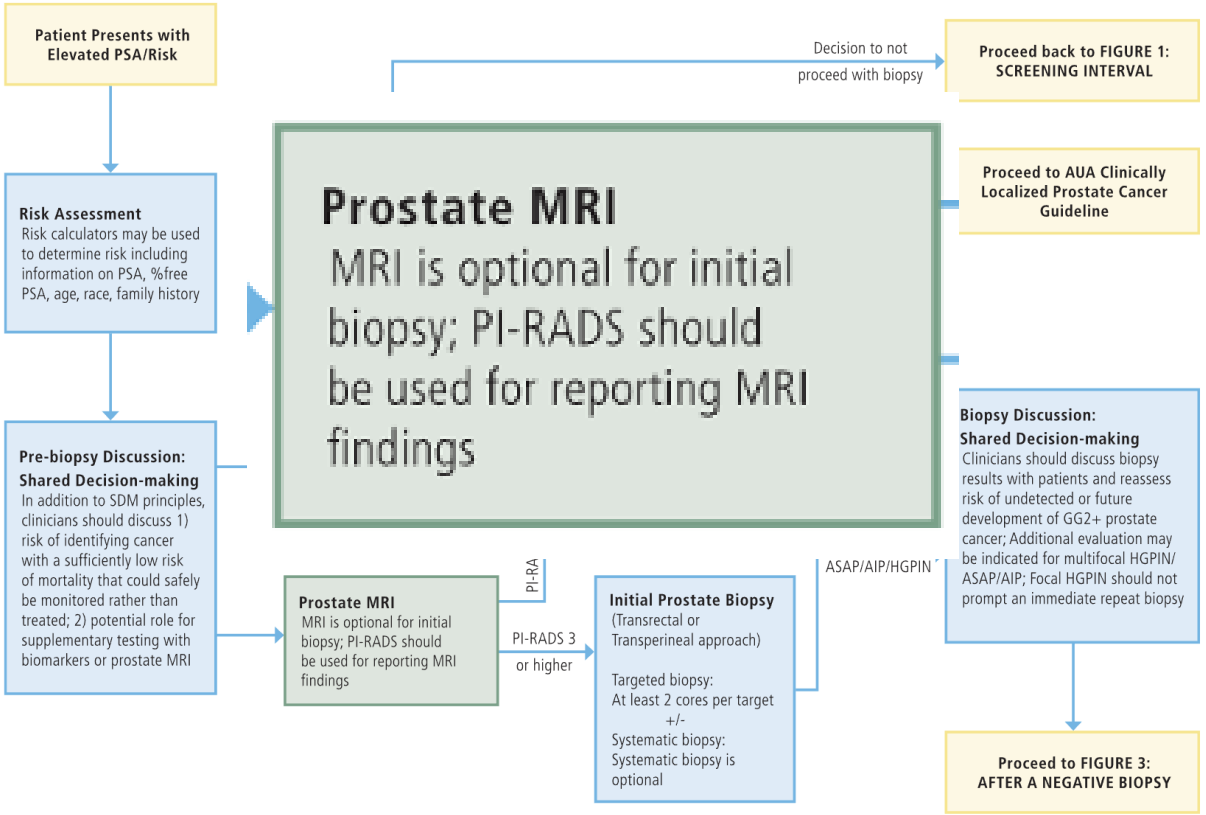
AUA Prostate Cancer Screening Guidelines: Risk stratified and stepwise approach



Wei JT, et al. J Urol. 2023.

AUA Prostate Cancer Screening Guidelines: Risk stratified and stepwise approach (Part II – in the hands of the urologist)

Prostate MRI is usually ordered by the urologist



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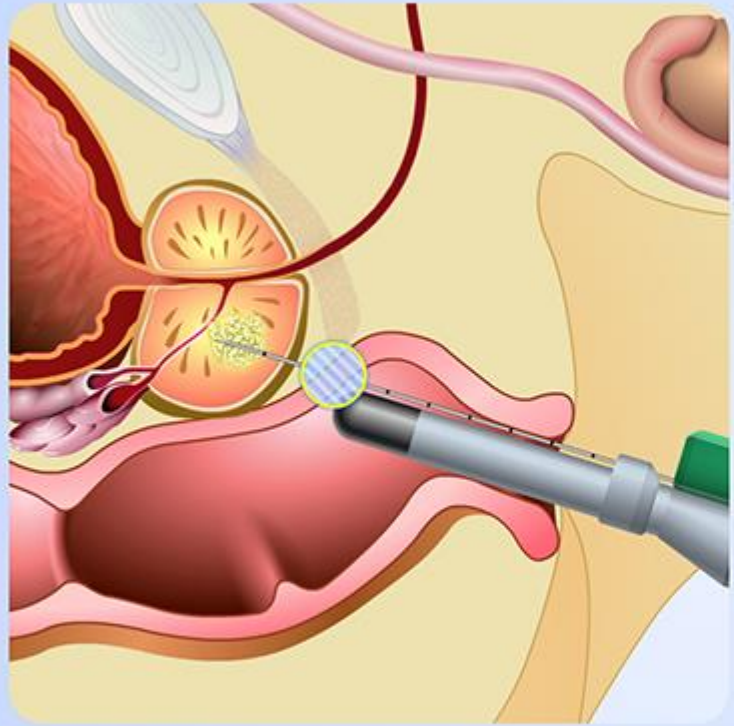
Biomarkers for Early Detection of Prostate Cancer

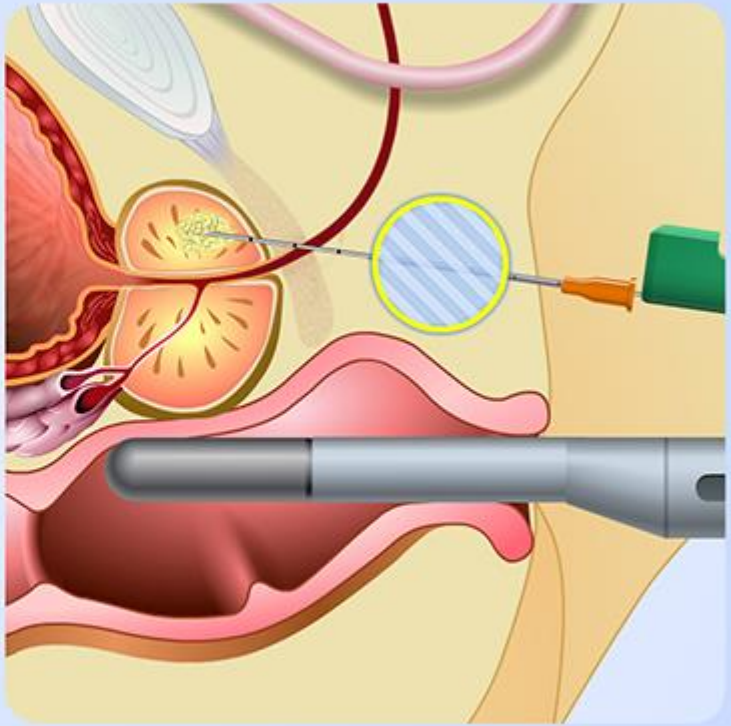
Biomarker	Source	Description
%fPSA	Blood	Ratio between fPSA and tPSA
Prostate Health Index	Blood	Combines 3 PSA subforms (tPSA, %fPSA, and p2PSA) into a single mathematical score
4K score	Blood	Combines 4 kallikrein markers (tPSA, %fPSA, intact PSA, and hK2) with age and prostate examination findings
SelectMDx (MDxHealth)	Urine + clinical risk factors	Measures post-DRE mRNA levels of a 2-gene panel (*DLX1* and *HOXC6*)
Michigan Prostate Score	Urine + blood	Combines findings of fusion gene *TMPRSS2* and *ERG* (*TMPRSS2:ERG*) along with PCA3 and the PCPT risk calculator†
PCA3	Urine	Measures PCA3 mRNA in first-void urine after DRE with prostatic massage
ExoDx (Exosome Diagnostics)	Urine	Exosomes are small membranous vesicles secreted from cells and assessed in urine collected during routine evaluation; urine sample does not have to be obtained after DRE prostate examination
ConfirmMDx (MDxHealth)	Prostate biopsy	Evaluates epigenetic alterations (methylation status) of *GSTP1*, *APC*, and *RASSF1* to look for a field defect
mpMRI	Prostate imaging	MRI can be programmed for several different pulse sequences, or parameters, that highlight specific diffusion of contrast differences based on vascularity of healthy and unhealthy tissue; MRI using ≥2 parameters is called mpMRI

Burns R, et al, Ann Intern Med.170:770-778; 2019

Prostate biopsy methods



Transrectal prostate biopsy
(through the rectum)



Transperineal prostate biopsy
(through the perineum)

Transrectal vs. Transperineal Prostate Biopsies

	Transrectal Biopsy	Transperineal Biopsy
Procedure Time	15 min	30 min
Anesthesia	Local	Local or General
Infection Risk	Higher +/-	Lower
Cancer Detection	Similar to TP	Similar to TR
Anterior Tumor Access	Poor	Better
Cost	Lower	Higher (sedation, general anesthesia)

J Urol. 211(2):205; 2024
JAMA Oncol, 10(11):1590; 2024

D'Amico Risk Stratification for Prostate Cancer

Risk Group	PSA Level (ng/mL)	Gleason Score/Grade Group		Clinical Stage
Low Risk	≤10	≤6	GG 1	T1-T2a
Intermediate Risk	10-20	7	GG 2,3	T2b
High Risk	>20	8-10	GG 4,5	T2c-T3a

Functional outcomes after localized prostate cancer treatment

- **Surgery:**
  - ↑ erectile dysfunction
  - ↑ urinary leakage
- **Radiation:**
  - ↑ urinary frequency
  - ↑ bowel urgency

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Part I: RT in Localized Prostate Cancer

Can we shorten the duration of RT (Short course RT) in the management localized prostate cancer?

Part II: RT in Advanced Prostate Cancer

Is there a role for Prostate RT in the management of

- **newly diagnosed oligo metastatic disease and**
- **Metastasis Directed Radiation Therapy?**

CONCLUSION
Take home points

Short Course RT with photons or protons (1.5 – 5.6 weeks) is non-inferior to Long Course RT (7.8 weeks) with respect to PSA recurrence

CONCLUSION
Take Home Points

Prostate RT may extend survival in patients with oligo-metastatic prostate cancer and may improve urinary symptoms

Radiation Therapy to metastatic lesions is associated with delays in time to PSA and may delay radiographic progression and time to castrate resistant disease

CONCLUSION
Take Home Points

Prostate RT may extend survival in patients with oligo-metastatic prostate cancer and will ~ ½ the occurrence of urinary retention requiring TURP irrespective of metastatic burden

Radiation Therapy to metastatic lesions is associated with delays in time to PSA progressin and may delay radiographic progression and time to castrate resistant disease

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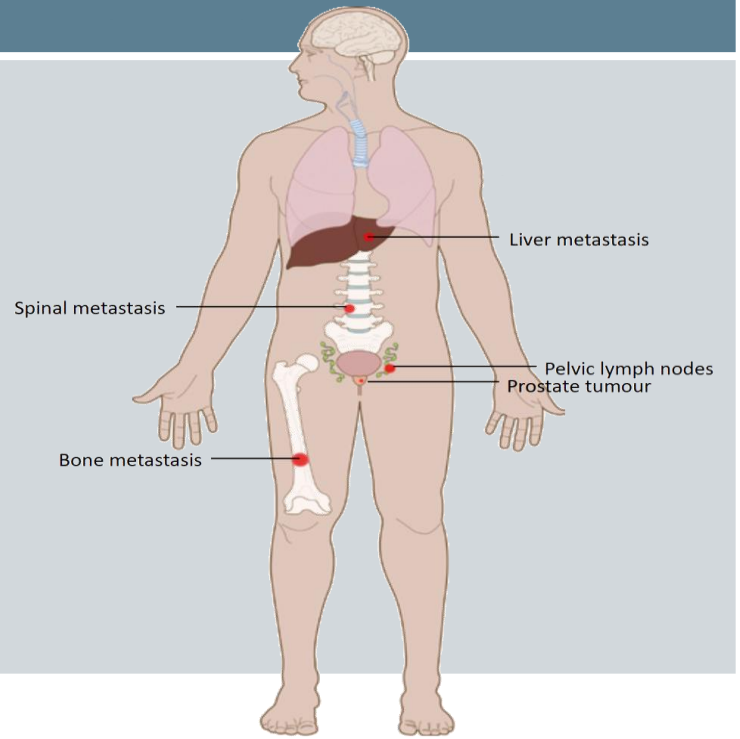
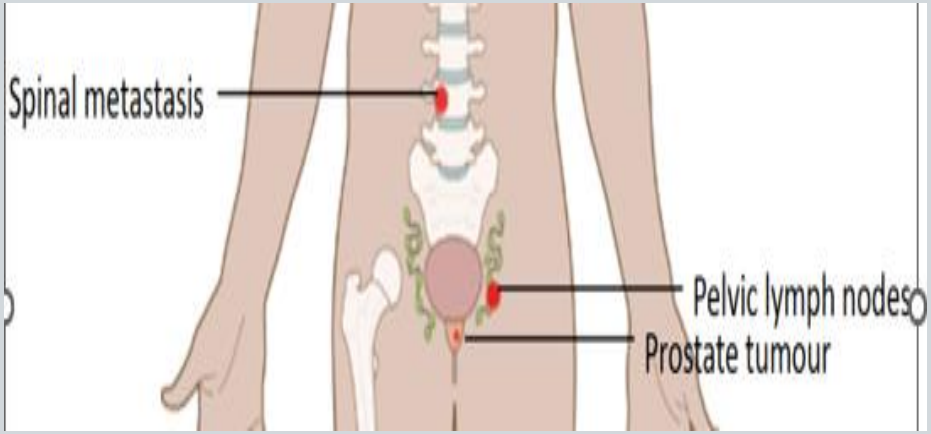
Changing nomenclature for advanced prostate cancer

State / Stage
Localized and **regionally advanced**
Metastatic prostate cancer
Oligometastatic disease
▸*The continuum between local/regional and metastatic*



Changing nomenclature for advanced prostate cancer

State / Stage
Localized and **regionally advanced**
Metastatic prostate cancer
Oligometastatic disease ***(Weichselbaum and Hellman)***

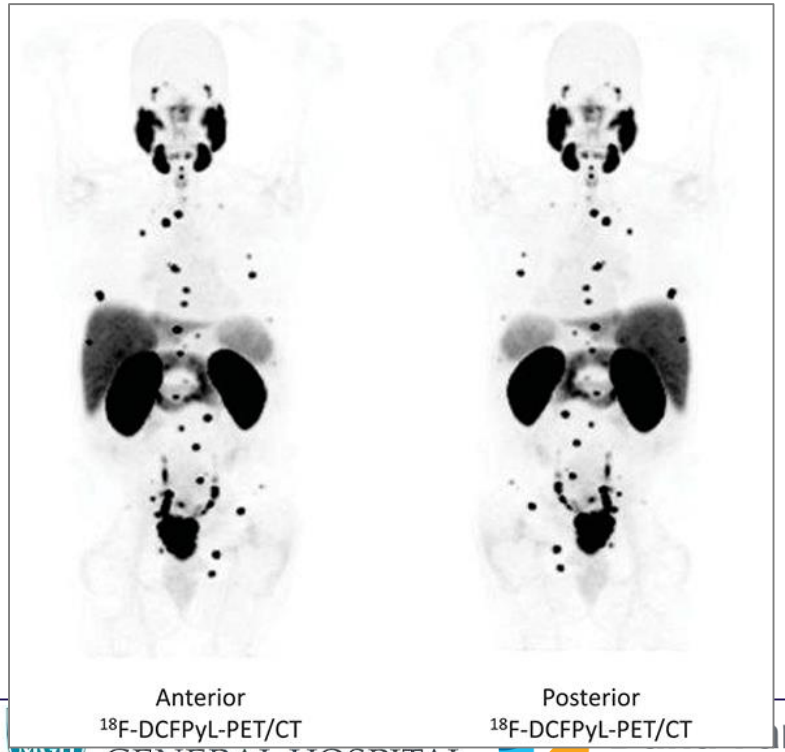


- ***The continuum between local/regional and metastatic***

Traditional vs. Leading-Edge Imaging Scans

Traditional Bone Scan

PSMA scan (approved May 2021)



Why is Oligometastatic Prostate Cancer Important?

Enabled by newer diagnostic PSMA scans (F18, Ga68, Cu64 and others)

Conventional diagnostic scans understage many patients (small deposits of metastases are not picked up) leading to misaligned treatments ---

Now, accurate staging of oligometastatic disease enables treatment to begin before traditional scans become positive

We now use multimodality treatments (Metastasis directed (MDT)+/- systemic therapies)

>>PSMA + scan authorizes use of Lutetium 177 in advanced disease

Your patient with rising PSA values (biochemical recurrence after prostatectomy or radiation therapy) is likely to have a PSMA scan done

- **PSA ≤1 ng/mL after prostatectomy**
  - **59% Positive PSMA Lesion(s)**
- **PSA >1 ng/mL (prostatectomy or radiation)**
  - **89% Positive PSMA Lesion(s)**
- **Nonmetastatic cancer >>>oligometastatic cancer**

Metastasis directed therapy (MDT - surgery or radiation) for oligometastatic disease

▸▸Key Findings and Take Aways

- **Multiple Phase II studies have resulted in long-term disease-free remissions with MDT**
- **The use of androgen deprivation therapies (ADT) can be shortened, delayed or even eliminated**

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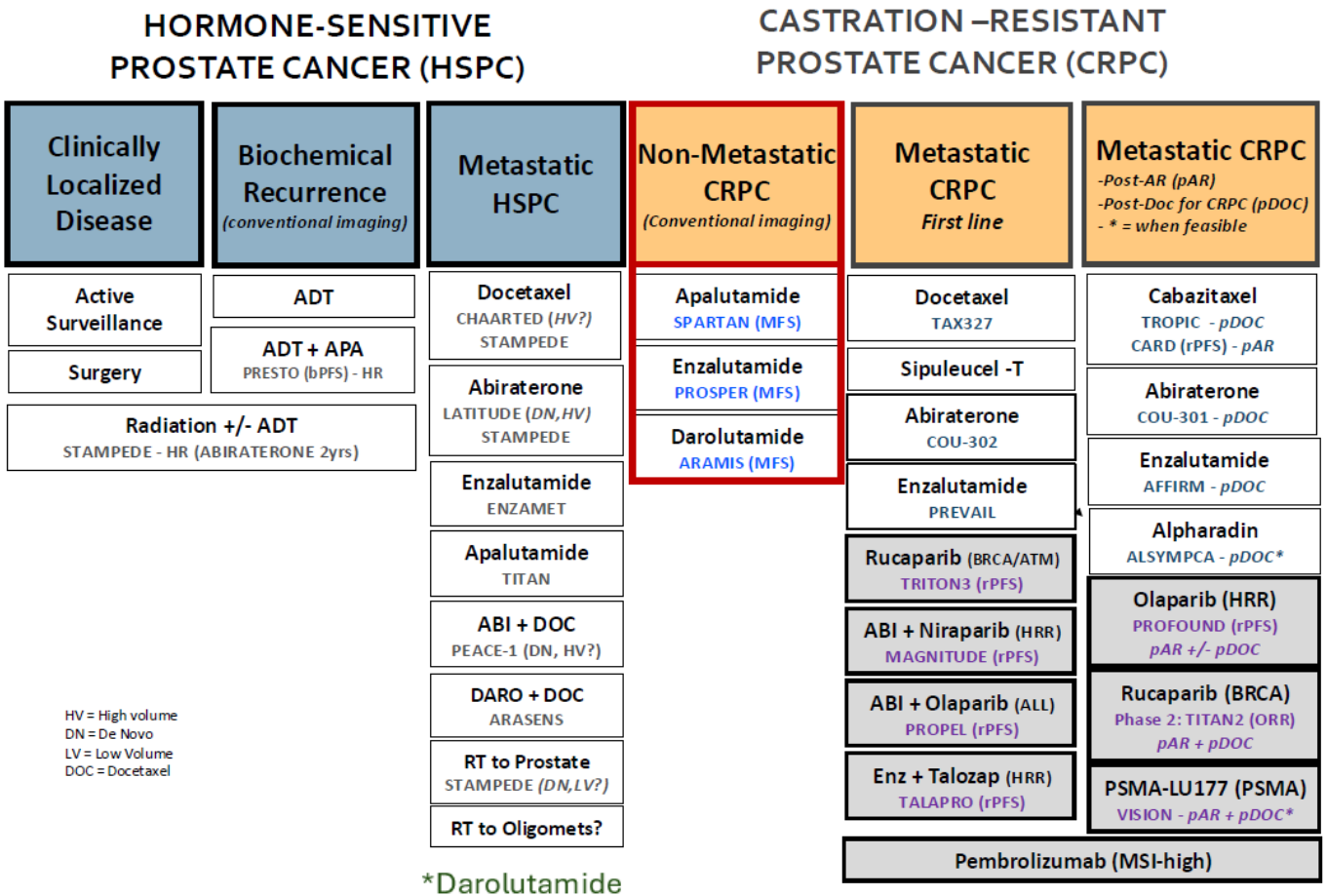
Overview of prostate cancer disease states



Treatment Side Effects

Androgen Deprivation Therapy

Low testosterone = menopause

CYP17 Inhibition: Abiraterone

- Mineralocorticoid excess ⊣ Prednisone
  - Hypertension
  - Hypokalemia
  - Edema
- Hepatotoxicity

AR Antagonists: -lutamides

- Fatigue
- Gynecomastia (especially as monotherapy)
- Falls, cognitive effects
- Drug-drug interactions
- *Rash, hypothyroidism (apalutamide)*

What is the Role of the Internist?

Cardiovascular Supportive Care

Take-home clinical approach:

- **BP:** most associated with abiraterone, but also needs to be monitored with AR antagonists
  - *Increasing* prednisone may help counteract mineralocorticoid excess
- **Cholesterol:** note interaction between darolutamide and rosuvastatin
- **Anticoagulants:** DOACs (Xa inhibitors) are a contraindication to enzalutamide/apalutamide
- **Diabetes:** ADT +/- prednisone may increase insulin resistance
- Use cancer as an opportunity to talk about alcohol and smoking

What is the Role of the Internist?

Exercise as Supportive Care

Fatigue is the #1 complaint on hormonal therapy; exercise is the #1 treatment!

Types of exercise

- Aerobic: may help with fatigue and reduce weight gain
- Resistance/weight training: may help prevent sarcopenia, osteopenia
- Balance training: may help prevent falls

"Prescriptions"

- Livestrong at the YMCA
- Academic exercise programs (Dr. Dieli-Conwright, DFCI)
- Enlist patient's partner or other support system
- Make it "doctor's orders," part of the treatment plan

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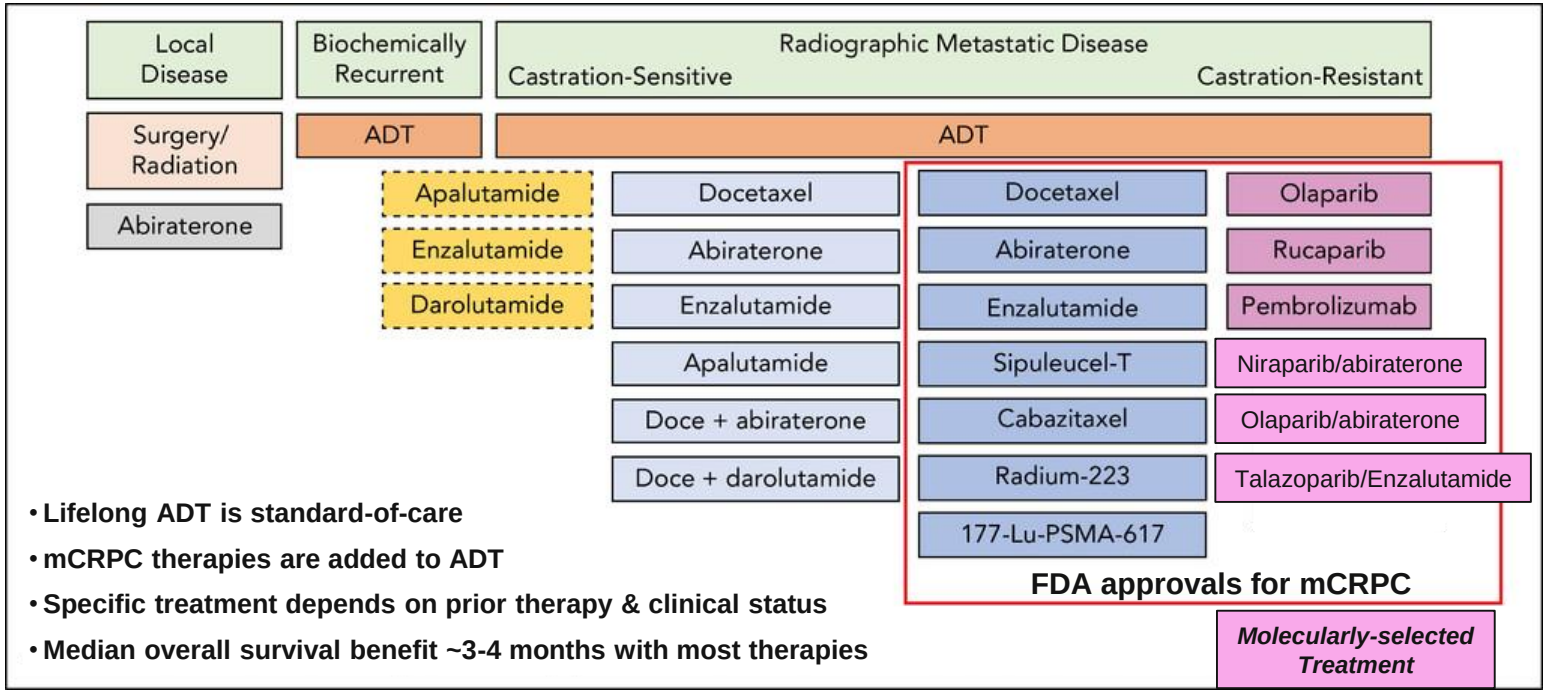
Metastatic Castration-Resistant Prostate Cancer (mCRPC) Cancer-Directed Therapy

Systemic therapy is the primary cancer-directed treatment



Palliative RT
Palliative Surgery

Adapted from Ajmera et al., *JNCCN* 2023.

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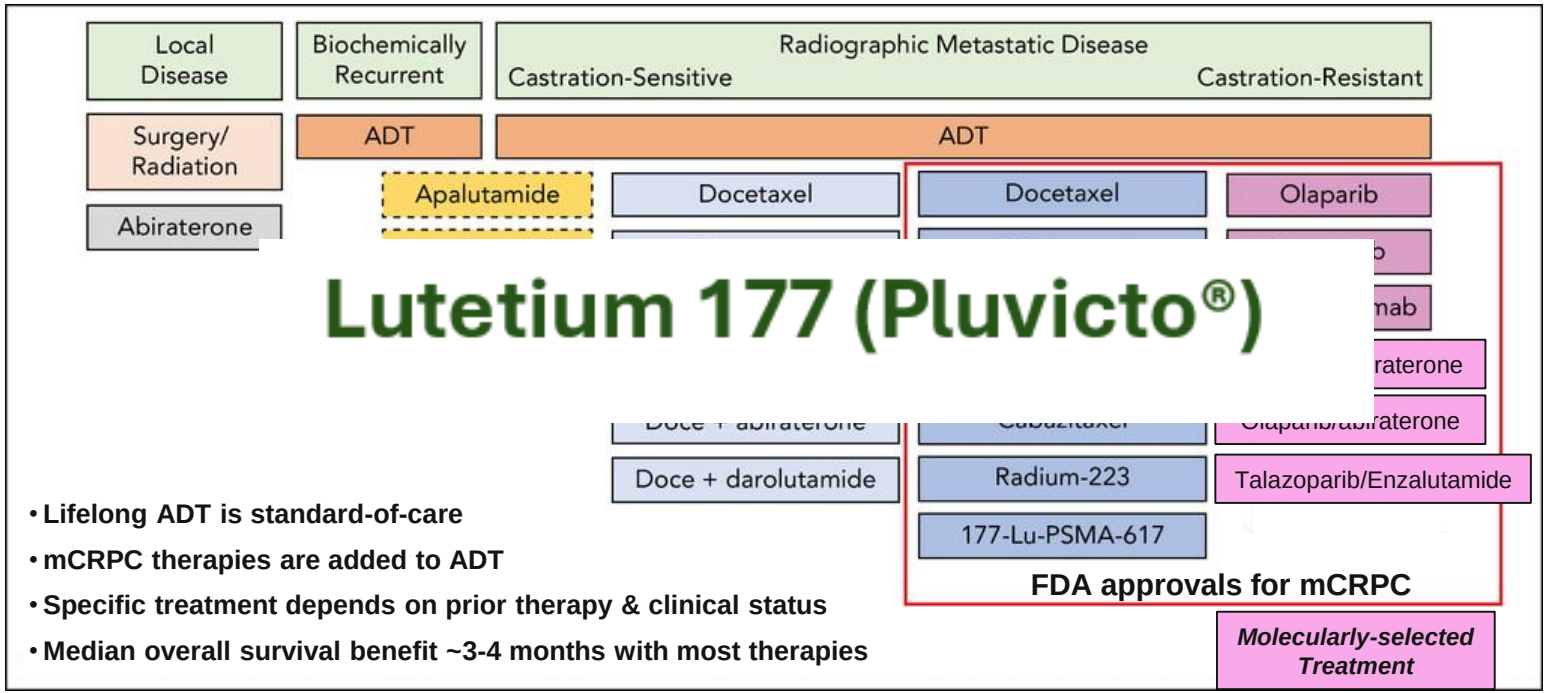


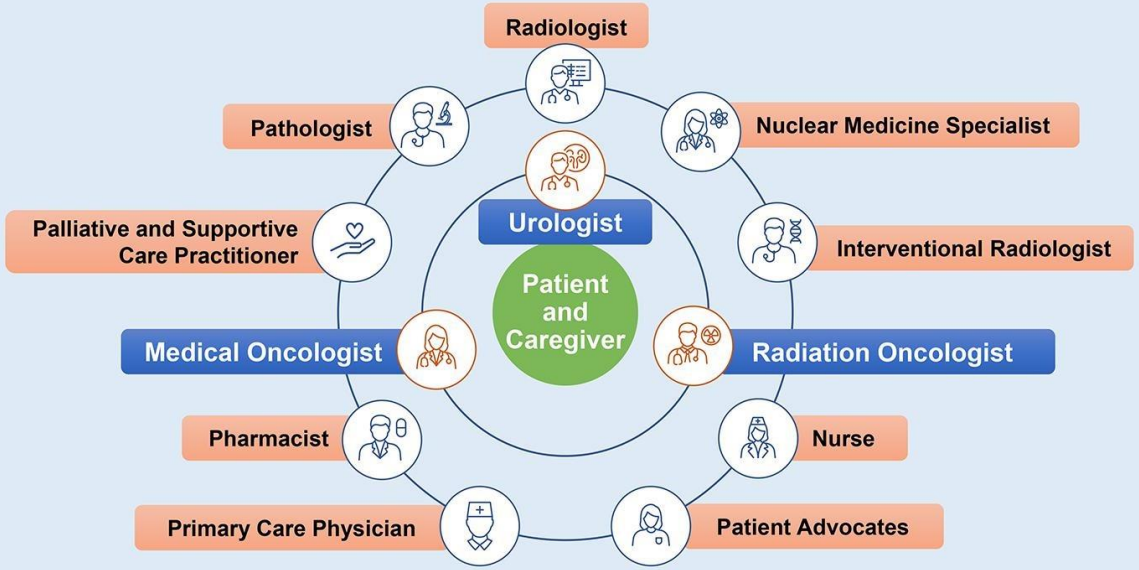
- **Lifelong ADT is standard-of-care**
- **mCRPC therapies are added to ADT**
- **Specific treatment depends on prior therapy & clinical status**
- **Median overall survival benefit ~3-4 months with most therapies**

Palliative RT
Palliative Surgery

Adapted from Ajmera et al., *JNCCN* 2023.

Metastatic Castration-Resistant Prostate Cancer (mCRPC) Multidisciplinary Team

Multidisciplinary Care in Prostate Cancer



Multidisciplinary Care Data are Limited for Biochemical Recurrence and Oligometastatic Disease

Observed Benefits of Multidisciplinary Care Clinics in Localized and Advanced Prostate Cancer

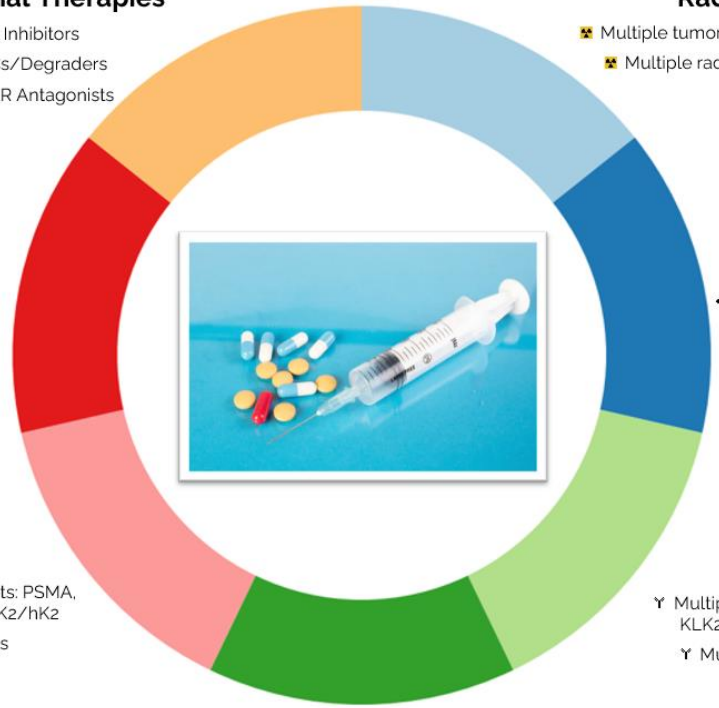
↑ Overall Survival[1,2]
Revised Disease Stage and/or Updated Management Plans[3–6]
↑ Adherence to Practice Guidelines[5,7]
↓ Time to Diagnosis and Treatment Initiation[8,9]
↑ Collaborative Research[6,10]
↓ Physician Bias and Racial Care Disparity[6,8,11]
↑ Patient Engagement in Shared Decision-Making[10,12–14]
↑ Patient Satisfaction and Retention[2,12–15]
↑ Provider Satisfaction [16,17]

1. Reichard, CA et al. *BJU Int.* 2019;124:811-19. 2. Gomella, LG et al. *J Oncol Pract.* 2010;6:e5-e10. 3. Rao, K et al. *BJU Int.* 2014;114 Suppl 1:50-4. 4. De Luca, S et al. *Minerva Urol Nefrol.* 2019;71:576-82. 5. Korman, H et al. *Am J Clin Oncol.* 2013;36:121-5. 6. Aizer, AA et al. *J Clin Oncol.* 2012;30:3071-6. 7. Aizer, AA et al. *J Natl Compr Canc Netw.* 2013;11:1364-72. 8. Tang, C et al. *Cancer.* 2020;126:506-14. 9. Sciarra, A et al. *Am J Clin Exp Urol.* 2013;25;1:12-17. 10. Aizer, AA et al. *Semin Radiat Oncol.* 2013;23:157-64. 11. Hurwitz, LM et al. *Urol Oncol.* 2016;34:233.e17-25. 12. Betschart, P et al. *Oncol Res Treat.* 2019;42:366-74. 13. Patrikidou, A et al. *Clin Transl Radiat Oncol.* 2018;12:28-33. 14. Magnani, T et al. *BJU Int.* 2012;110:998-1003. 15. Colasante, A et al. *Oncol Let.* 2018;15:1823-28. 16. Litton G et al. *J Oncol Pract.* 2010;6:e35-7. 17. Hudak, JL et al. *Urol Nurs.* 2007;27:491-8.

Medical writing support for this summary was provided by Roham Sadeghimakki of Onyx (a division of Prime, London, UK) and funded by Pfizer Inc. and Astellas Pharma Inc.

Efstathiou et al., *Cancer Treat Rev* 2024.

Metastatic Castration-Resistant Prostate Cancer (mCRPC)
Novel Therapies in Clinical Trials (Not FDA-approved)



Novel Hormonal Therapies
- CYP11A1 Inhibitors
- AR PROTACs/Degraders
- N-terminal AR Antagonists

Radioligand Therapies
- Multiple tumor antigen targets: PSMA, STEAP, KLK2/hK2
- Multiple radioisotopes: Actinium-225, Lutetium-177

Targeted Therapies
- AKT inhibitors
- EZH2 inhibitors
- BET inhibitors
- Selective PARP1 inhibitors

Antibody Drug Conjugates
- Multiple tumor antigen targets: PSMA, STEAP1, B7-H3, TROP2, Nectin-4
- Multiple chemotherapy payloads: Topoisomerase I inhibitors, tubulin inhibitors

CAR-T
- Multiple tumor antigen targets: PSMA, PSCA, STEAP1, STEAP2, KLK2/hK2
- Multiple CAR designs

Bispecific Engagers
- Multiple tumor antigen targets: PSMA, STEAP1, KLK2/hK2, DLL3 (neuroendocrine/small cell)
- Multiple immune cell targets: CD3, CD28

Novel Immune Checkpoint Inhibitors
- ✓ PD-1 x CTLA-4 bispecifics

We continue to strive to improve outcomes for prostate cancer patients through research and innovation

In mCRPC, many novel therapies with different mechanisms of action are in clinical development

Many of the recently approved mCRPC therapies are in clinical trials for mHSPC and earlier forms of disease

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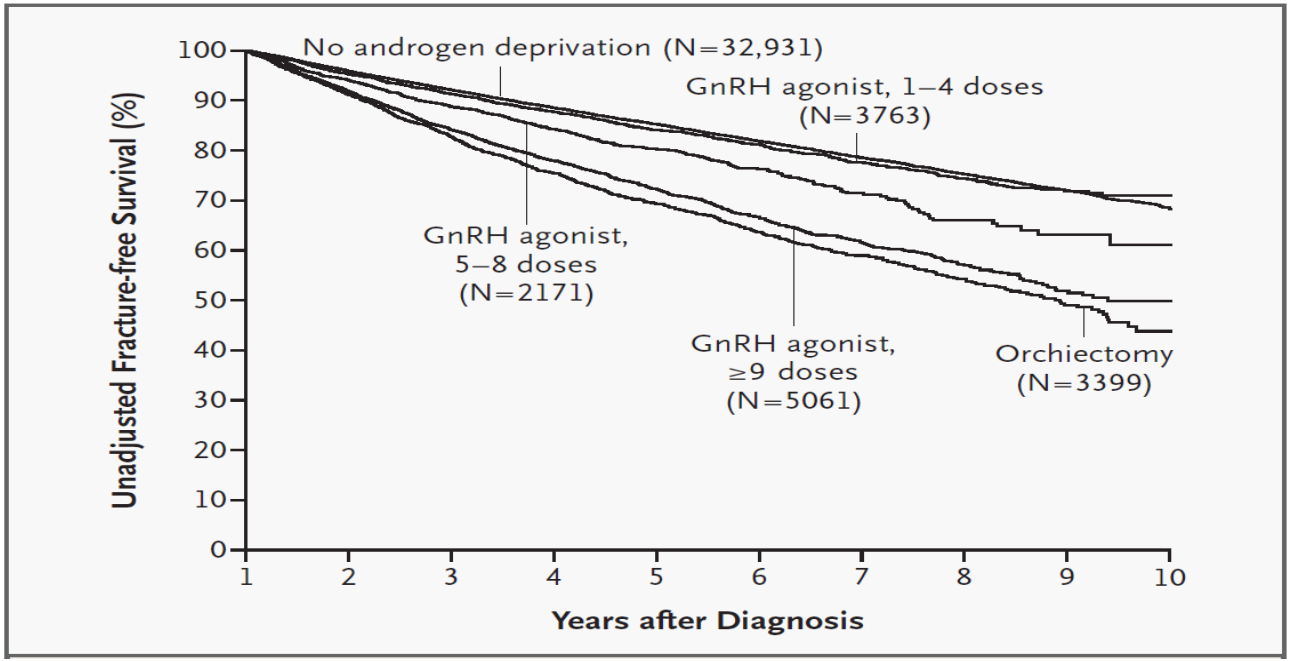
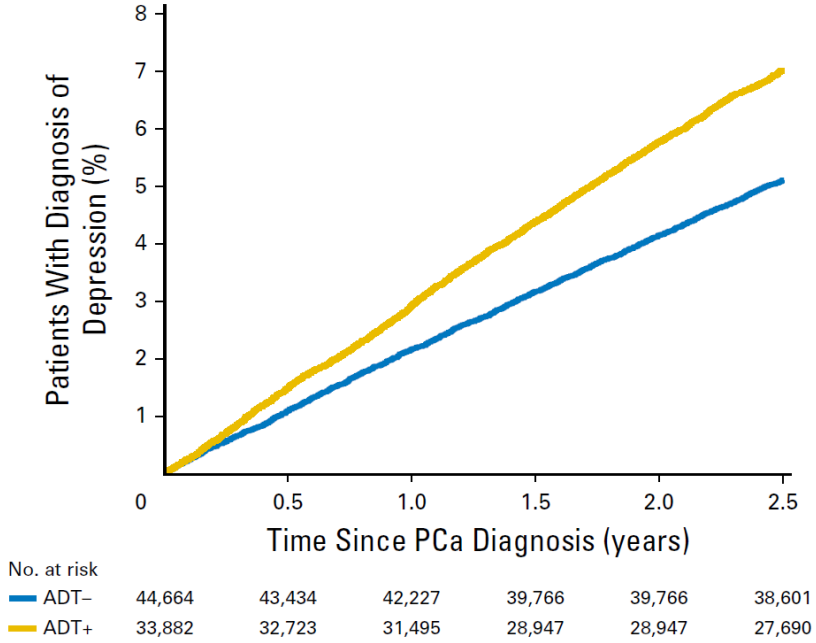
ADT and Fracture
More ADT >> More Fractures



Shahinian VB et al. *N Engl J Med*. 2005;352(2):154-164.

ADT Increases Risk of Depression higher rates with ADT (yellow)



Dinh KT et al. *J Clin Oncol*. 2016;34(16):1905-1912.

Complications of ADT

1. Loss of muscle mass (sarcopenia)
2. Fatigue
3. Osteoporosis
4. Increased risk of falls
5. Inactivity

Complications of ADT

1. Loss of muscle mass (sarcopenia)
2. Fatigue
3. Osteoporosis
4. Increased risk of falls
5. Inactivity

Frailty

1. Loss of lean weight (sarcopenia)
2. Fatigue/exhaustion
3. Osteoporosis
4. Increased risk of falls
5. Decreased activity

Complications of ADT

1. Loss of muscle mass (sarcopenia)
2. Fatigue
3. Osteoporosis
4. Increased risk of falls
5. Inactivity
6. Increased risk of comorbid CVD, DM
7. Depressed mood

Frailty

1. Loss of lean weight (sarcopenia)
2. Fatigue/exhaustion
3. Osteoporosis
4. Increased risk of falls
5. Decreased activity
6. Complicated by comorbidity
7. Often associated with depressed mood

Dr. Marc Garnick - BIDMC

- Prostate Cancer Screening
- MRI Biopsy, Active Surveillance and Surgical Options
- Radiation Therapy (1) for Localized/Regional Prostate Cancer
- Oligometastatic Prostate Cancer- Diagnostic and Treatment Advances
- Radiation Therapy (2) for Advanced/Metastatic Prostate Cancer
- Initial Systemic Therapies for Metastatic Prostate Cancer
- Subsequent Systemic Therapies for Metastatic Prostate Cancer
- Survivorship
- **Summary of Key Points**

SUMMARY AND TAKE HOME POINTS 1

- **PSA screening guidelines are undergoing refinements**

- Multi-parametric Prostate MRI has assumed an important role in the initial screening and follow-up and management following PSA screening

- We can lessen the burden from surgical and radiation management of primary prostate cancer. Active Surveillance is an important option in a substantial percentage of newly diagnosed patients

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SUMMARY AND TAKE HOME POINTS 2

- **Molecularly targeted diagnostic imaging scans detect oligometastatic cancer, which optimize metastasis directed therapies (MDT) and earlier treatment interventions**

- Improvements in survival have resulted from advances in imaging, genomics, radiopharmaceuticals and more precision in delivering radiation and management of co-morbidities

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SUMMARY AND TAKE HOME POINTS 3

- **The addition of new drugs has markedly improved outcomes in patients with metastatic disease**

- It takes a village to provide optimal lifelong care of the prostate cancer patient

SUMMARY AND TAKE HOME POINTS 3

- The addition of novel androgen receptor modulators, radiopharmaceuticals, and mutation directed therapies to androgen deprivation therapy has markedly improved outcomes in patients with metastatic disease

- **It takes a village**

Special shout out to Drs Bubley, Einstein and Dr Garnick's Donor

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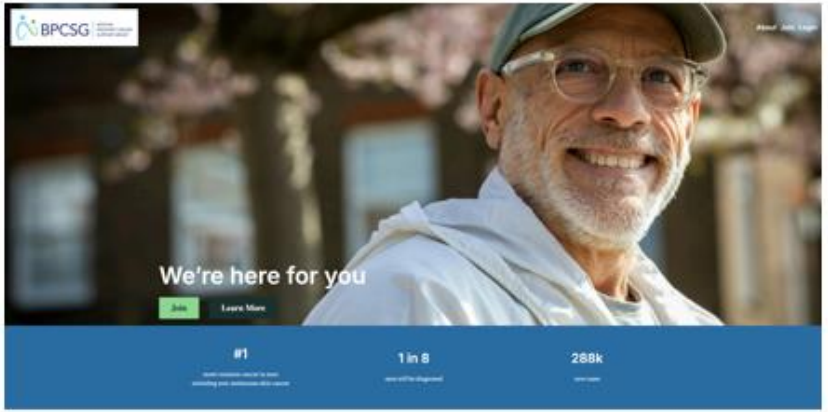

Longwood Prostate Cancer Support Group