Prostate Men's Health Update

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Speaker Disclosure Statement

I have no financial relationships with any individuals or companies that influenced the content of this presentation



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Area of Expertise

- Society of Urologic Oncology Fellowship, 2019
 - Kidney, Bladder, Prostate Ca
 - Robotic Surgery
- General Urology Practice
 - Urinary Reconstruction
 - Voiding Dysfunction/Sexual Health
 - Nephrolithiasis
 - Vasectomy

Hospital Privileges at all OU Health Locations, Oklahoma VAMC, Saint Anthony's Downtown, Comanche County Memorial



Objectives

- Prostate Men's Health Update
 - Benign Prostatic Hyperplasia
 - Medical Strategies
 - Surgical Options
 - Prostate Cancer Screening
 - 2023 AUA Guidelines
 - Prostate Cancer Staging
 - Emergence of PSMA PET/CT
 - Prostate Cancer Treatment Update
 - Localized
 - Advanced (2023 ASCO Highlight)



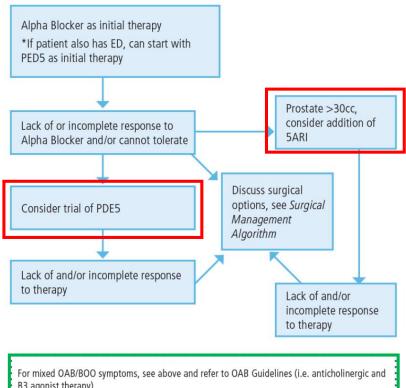
Updates in Benign Prostatic Hyperplasia (BPH)



Updates In BPH

- Three Key Factors Drive Management
 - Predominant Type of LUTS
 - Emptying LUTS
 - Storage LUTS
 - Accurate Assessment of Prostate Size
 - MRI > TRUS > CT > Cystoscopy > DRE
 - Degree of Bother

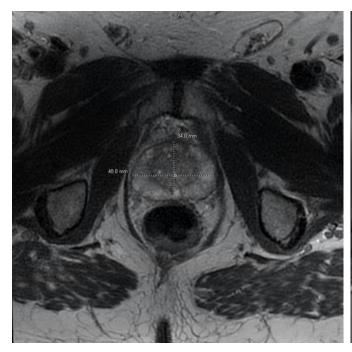
Trial of Medical Therapy Algorithm

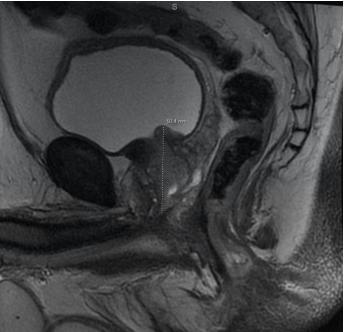


B3 agonist therapy)



Prostate Anatomy Informs Treatment Decisions and Prognosis (3D is best!)







Candidates Who Should Consider Early Surgery

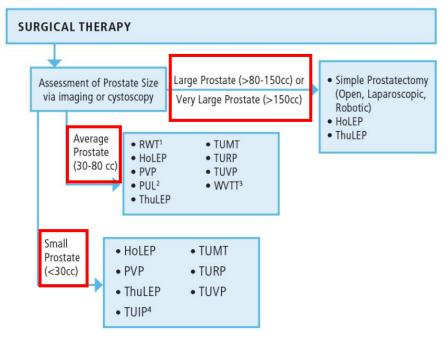
- Acute/Chronic Urinary Retention
- Bladder Stones
- Frequent/Recurrent UTIs
- Intractable Hematuria
- Renal Failure
- Unwilling to Comply with Medication



BPH Surgery Options

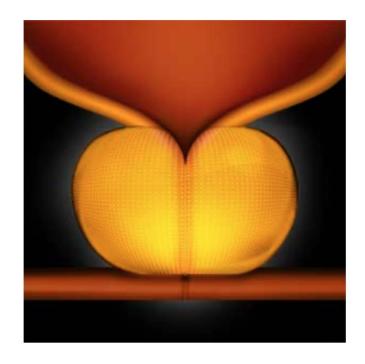
- Prostate Size and Anatomy
- Sexual Function Preservation
- Risk Tolerance for Complications
- Medical Comorbidities
 - Bleeding disorders
 - Anti-platelet/Anti-coagulation requirements

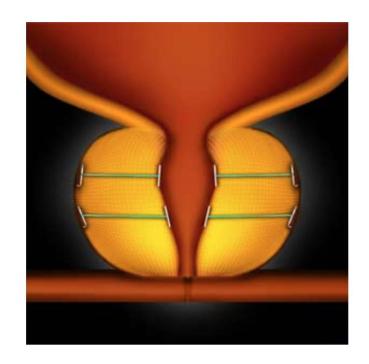
Surgical Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia





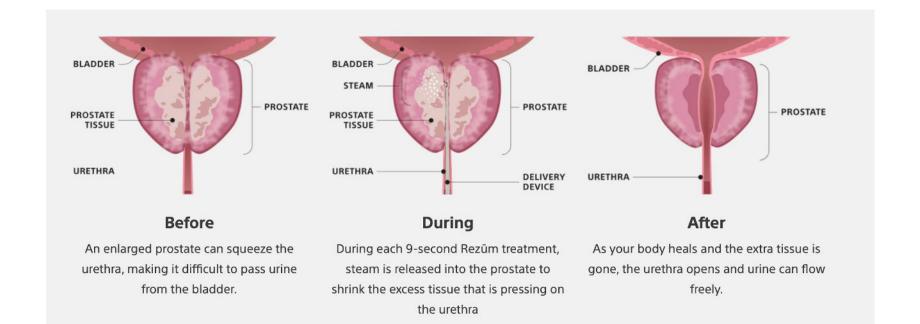
New(ish) Technologies - Urolift



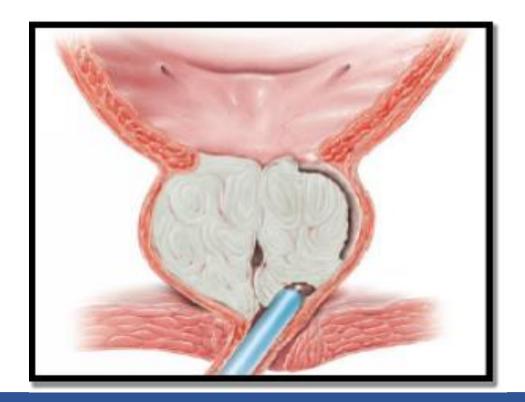




New(ish) Technologies - Rezum

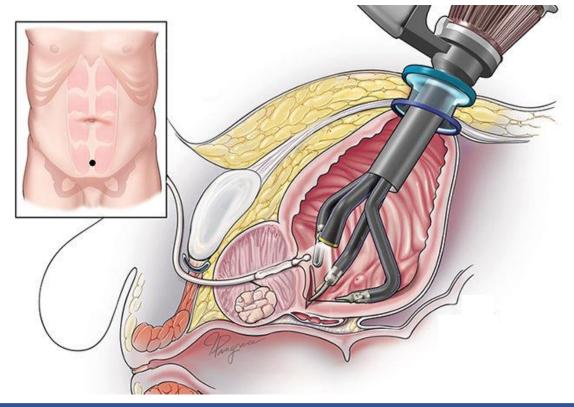


New(ish) Technologies - HoLEP





New(ish) Technologies - Robotics





New_(ish) Technologies - Prostatic Artery Embolization (PAE)



Prostate Artery Embolization (PAE)

41. PAE for the routine treatment of LUTS/BPH is not supported by current data, and benefit over risk remains unclear; therefore, PAE is not recommended outside the context of clinical trials.



BPH Surgery: My Soapbox

- Oklahoma does not have a comprehensive BPH Surgery Center of Excellence
 - No one does it all
- BPH is a hub for mega-Industry R&D (\$\$\$)
- Opportunity for vulnerable patients to be exploited

THE OKLAHOMAN

Doctor offers outpatient prostate procedure

Eddie Roach

Published 12:01 a.m. CT Nov. 26, 2019

However, one Oklahoma City doctor is performing a new, outpatient procedure that has a 90 percent success rate of treating prostate enlargement also known as benign prostatic hyperplasia (BPH).



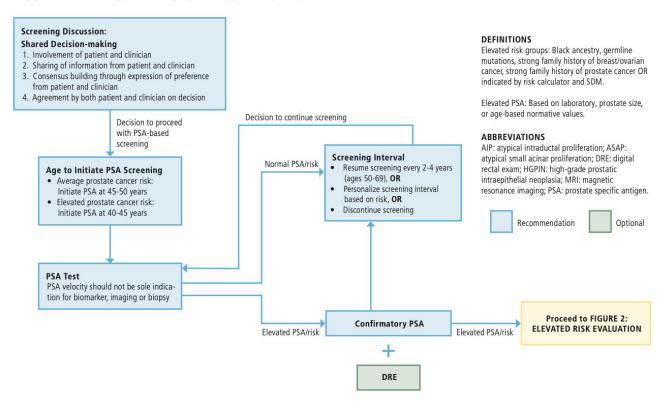
Early Detection of Prostate Cancer: 2023 AUA/SUO Guideline



AUA/SUO

Early Detection of Prostate Cancer Algorithm

FIGURE 1: INITIAL SCREENING FOR PROSTATE CANCER





INITIAL SCREENING FOR PROSTATE CANCER

Screening Discussion:

Shared Decision-making

- 1. Involvement of patient and clinician
- 2. Sharing of information from patient and clinician
- 3. Consensus building through expression of preference from patient and clinician
- 4. Agreement by both patient and clinician on decision



Decision to proceed with PSA-based screening

Elevated risk groups: Black ancestry, germline mutations, strong family history of breast/ovarian cancer, strong family history of prostate cancer OR indicated by risk calculator and SDM.

Age to Initiate PSA Screening

- Average prostate cancer risk: Initiate PSA at 45-50 years
- Elevated prostate cancer risk: Initiate PSA at 40-45 years



Normal PSA/risk

Screening Interval

- Resume screening every 2-4 years (ages 50-69), OR
- Personalize screening interval based on risk, OR
- Discontinue screening



Elevated PSA/risk

Contemporary PSA Thresholds (ng/mL)

$$• 40-49 = 2.5$$



• 70-79 = 6.5

Confirmatory PSA

GUIDELINE STATEMENT 9

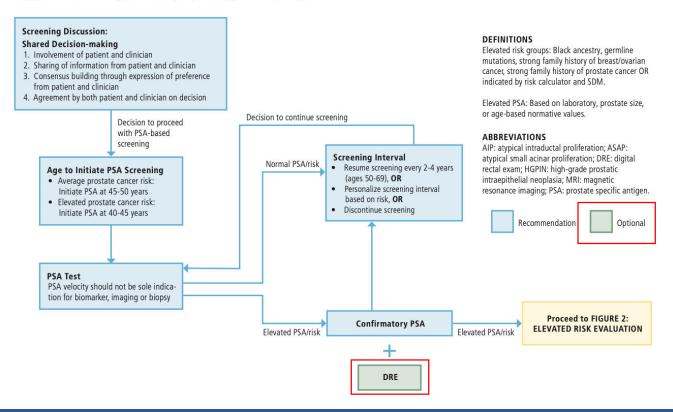
For people undergoing prostate cancer screening, clinicians should not use PSA velocity as the sole indication for a secondary biomarker, imaging, or biopsy. (*Strong Recommendation; Evidence Level: Grade B*)



AUA/SUO

Early Detection of Prostate Cancer Algorithm

FIGURE 1: INITIAL SCREENING FOR PROSTATE CANCER





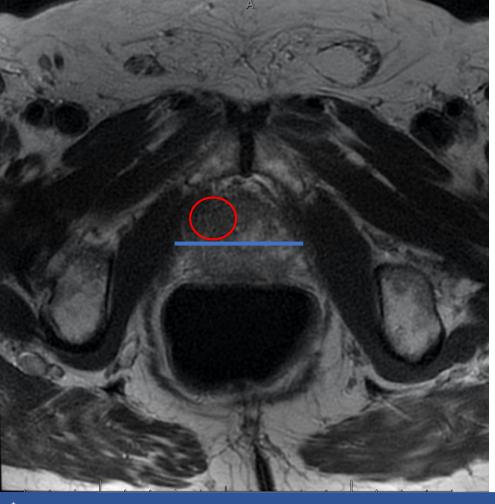
ELEVATED RISK EVALUATION

Patient Presents with Elevated PSA/Risk

Prostate MRI

MRI is optional for initial biopsy; PI-RADS should be used for reporting MRI findings





Lesion Targeting

- Approach Stratification
 - Transrectal
 - Transperineal
- Higher Yield Biopsies
- Fewer Cores
- Safer Procedures



Updates in Prostate Cancer Staging



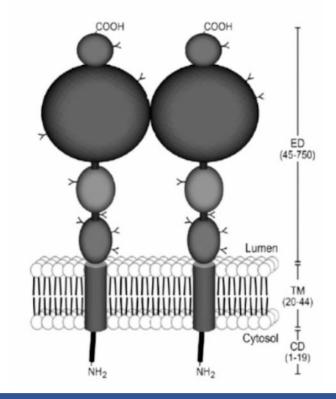
The Problem...

- Conventional prostate imaging (CT/Bone Scan) underestimates the burden of metastatic disease
 - Patients with low PSA
 - Volume (not just presence) of metastatic disease drives management
- Applications for metastatic surveys in prostate cancer
 - Biopsy Guidance
 - Initial Staging
 - Etiology of Biochemical Failure
 - Confirm Extent of Disease
 - Response to Therapy



Prostate Specific Membrane Antigen (PSMA)

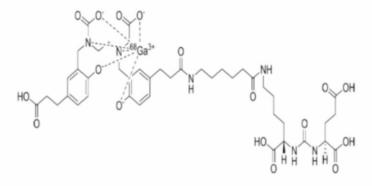
- Dimerized type II transmembrane glycoprotein
- Catalyzes the hydrolysis of N-acetylaspartylglutamate (NAAG) to glutamate
- Overexpressed in prostate cancer epithelial cells





PSMA-Targeted PET Radiotracers Approved in the US

68Ga-PSMA-11

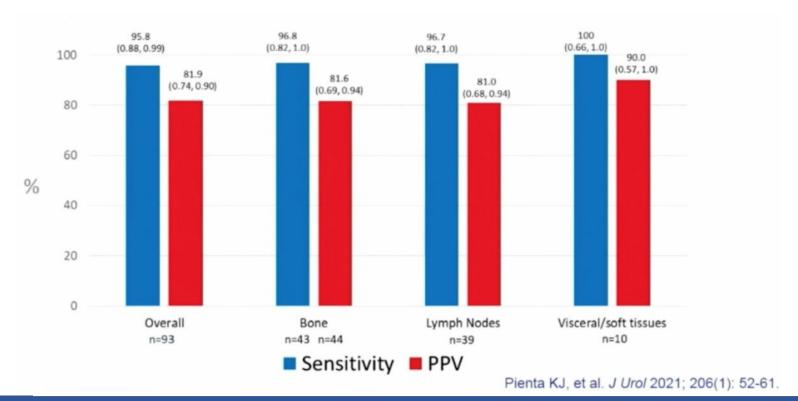




¹⁸F-DCFPyL / PYLARIFY

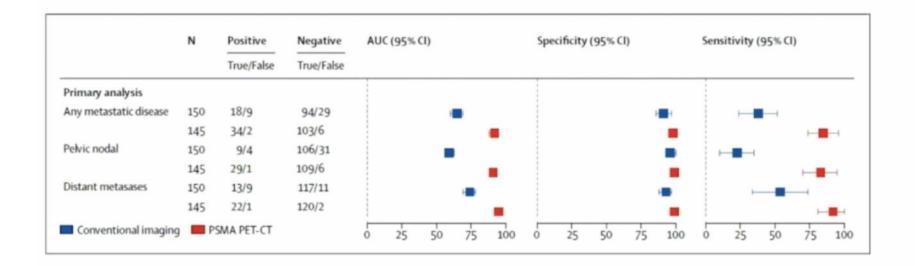


Osprey Trial of ¹⁸F-DCFPyl PSMA PET





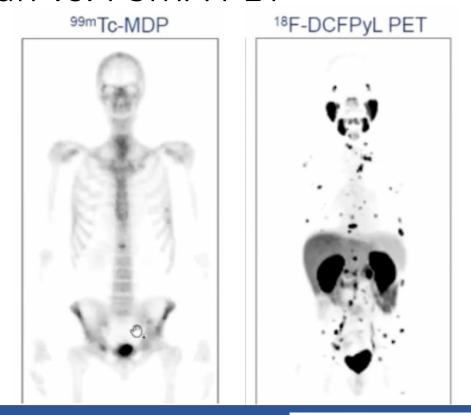
Pro-PSMA Trial (Initial Staging)



Hofman MS, et al. Lancet 2020; 395(10231): 1208-1216.



Bone Scan vs. PSMA PET





NCCN Guidelines Version 2.2023 Prostate Cancer

NCCN Guidelines Index
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Discussion

INITIAL RISK STRATIFICATION AND STAGING WORKUP FOR CLINICALLY LOCALIZED DISEASE

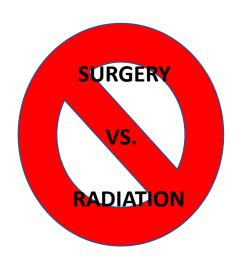
Because of the increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging (CT, MRI) at both initial staging and biochemical recurrence, the panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as an equally effective, if not more effective front-line imaging tool for these patients.



Updates in Localized Prostate Cancer Treatment



Approaching Treatment Discussions in 2023



 Most patients are candidates for surveillance!

- For those who elect treatment, options are many
 - And reasons for choosing an option are nuanced

Beyond "Surgery vs. Radiation"

- Does any part of the prostate require therapy right now?
- Does the whole prostate require treatment?

Monotherapy or multi-modal approach?

Risk tolerance

Baseline LUTS/ED

 What medical baggage does the patient bring to the table?

Quality of life is paramount



My Perspective...

- For low-risk patients, active surveillance is standard
 - This cohort is growing
- For high-risk patients, prostate cancer has largely become a radiohormonal space
 - Early exposure to short durations of ADT are beneficial
 - The guideline-concordant only way to receive ADT is with an XRT regimen
- For the highest-risk patients, we treat as presumed metastatic
 - ADT + XRT + Abiraterone/Prednisone



My Perspective...

- So where does radical prostatectomy fit into this landscape?
 - Fair to say, it should probably be reserved for select circumstances
 - Patient refuses to consider XRT
 - Patient refuses to consider ADT



Updates in Advanced Prostate Cancer (2023 ASCO Highlight)

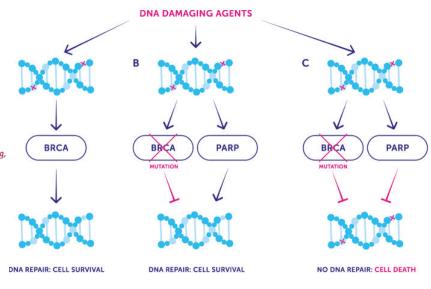


TALAPRO-2

PARP Inhibition now FIRST LINE in mCRPC for patients with HRR gene mutations

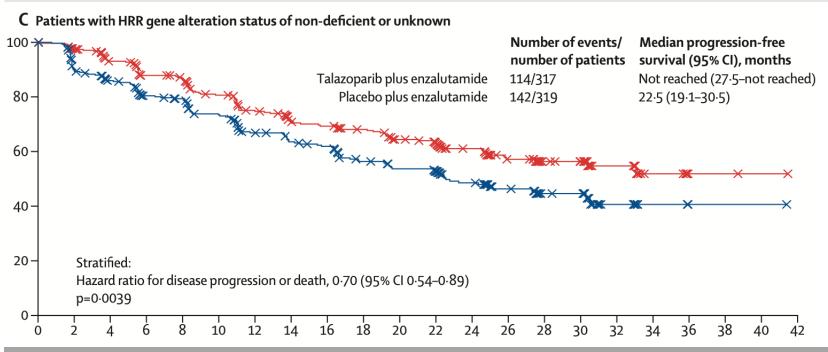
Talazoparib plus enzalutamide in men with first-line metastatic castration-resistant prostate cancer (TALAPRO-2): a randomised, placebo-controlled, phase 3 trial

Neeraj Agarwal*, Arun A Azad, Joan Carles, Andre P Fay, Nobuaki Matsubara, Daniel Heinrich, Cezary Szczylik, Ugo De Giorgi, Jae Young Joung, Peter C C Fong, Eric Voog, Robert J Jones, Neal D Shore, Curtis Dunshee, Stefanie Zschäbitz, Jan Oldenburg, Xun Lin, Cynthia G Healy, Nicola Di Santo, Fabian Zohren, Karim Fizazi*



TALAPRO-2

PARP Inhibition now FIRST LINE in mCRPC for patients with HRR gene mutations



Talazoparib in combination with enzalutamide improves rPFS even in absence of HRR mutations



TALAPRO-2

PARP Inhibition now FIRST LINE in mCRPC for patients with HRR gene mutations

FDA approves talazoparib with enzalutamide for HRR gene-mutated metastatic castrationresistant prostate cancer



On June 20, 2023, the Food and Drug Administration approved talazoparib (Talzenna, Pfizer, Inc.) with enzalutamide for homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, RAD51C



Questions



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