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Abstract 118

Treatment trends of a large active surveillance cohort for men with prostate cancer

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Introduction: Active surveillance (AS) is widely accepted as a treatment pathway for low-risk and favorable intermediate-risk localized prostate cancer. We aimed to report the long-term progression of patients on AS to treatment.

Methods: In a retrospective cohort study performed at a single institution center, 2521 men with low or favorable intermediate-risk prostate cancer were managed with an active surveillance protocol from 2000–2023. Main outcomes measured were overall survival and time to treatment.

Results: Of the patients enrolled, 620 (24.6%) entered treatment, 395 (15.7%) patients died, 34 (1.3%) had metastasis, and six (17.6% of those with metastasis) died with metastasis. By race, 2337 (92.7%) were White, 143 (5.7%) African-American, 20 (0.8%) American Indian/Alaskan, 14 (0.6%) Asian, and seven (0.2%) other. Median followup was four years and maximum followup time was 22.2 years. Median age of patients was 73.8 with a range of 43.8 to 98.1 years. At five, 10, and 15 years, 71.3%, 62.7%, and 52% of patients remained untreated and on AS. For patients with Gleason score (GS) 3+3=6 on AS at five and 10 years, 81.4% and 76.3% remained untreated. Similarly, patients with GS 3+4=7 demonstrated 41.5% and 27.4% untreated rates.

Conclusions: To our knowledge, we report the largest AS cohort examining time to treatment. AS for favorable-risk prostate cancer seems safe and effective in the 10-year timespan. In our study, 24.6% of patients progressed to treatment and 1.3% of patient developed metastasis. Additionally, 0.2% of patients on AS died with metastasis.

Funding: N/A

Abstract 119

Oncologic and functional outcomes from 171 consecutive HIFU treatments for localized prostate cancer

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Introduction: The objective of this study was to determine the oncologic and functional outcomes of patients treated with the FocalOne device in a community setting with long-term followup. This study also provides insight into the learning curve for this newer technology.

Methods: We performed a retrospective review of high-intensity focused ultrasound for prostate cancer (HIFU) procedures performed for localized prostate cancer at our institution from 2019–2023. International Prostate Symptom Scores (IPSS), the Sexual Health Inventory for Men (SHIM) questionnaire, and Expanded Prostate Cancer Index Composite (EPIC-26) surveys were tracked to assess changes in preoperative and postoperative functional outcomes. Prostate-specific antigen (PSA), prostate magnetic resonance imaging (MRI), and post-HIFU prostate biopsy or transurethral resection of prostate (TURP) specimens were used to determine biochemical control, radiographic free cancer control, and pathologically confirmed cancer control, respectively. Treatment failure was defined as freedom from residual or recurrent disease based on biochemical data, imaging data, and pathology data.

Results: One hundred seventy-one patients underwent HIFU prostate ablation at our institution from October 2019 to May 2023. Median age was 70 years (interquartile range [IQR] 12), mean prostate volume was 43.9cc±20.8, and median preoperative PSA was 6 (IQR 3.59). One hundred sixty patients (93.6%) were treatment-naïve, with 11 patients (6.4%) being treated with HIFU as salvage therapy. Only six patients (3.5%) underwent a pre-HIFU TURP. With median followup of 22 months, the re-treatment rate was 15.2% (26/171 patients), with 69.2% (18/26) being performed for an in-field recurrence. Half of the in-field treatment failures had disease located anteriorly or in the transition zone (9/18). Of the 26 patients requiring re-treatment, 10 underwent repeat focal therapy, five proceeded with prostatectomy, and 10 underwent radiation therapy. Metastasis-free survival was 100%. There was no statistically significant difference in risk of treatment failure based on Gleason Grade Group ≤2 vs. GG ≥3 (15.45% vs. 15.52%, p=0.99). The re-treatment risk was 22.12% for the first 113 patients treated vs. 1.72% for the subsequent 58 patients treated, reflecting a learning curve with this new technology. There was no statistically significant change in mean IPSS from baseline to 12 months (8.9 vs. 7.7, p=0.42). The continence rate in our series (defined as social continence, ≤1 pad per day) was 93.8%. There was no statistically significant change in mean SHIM score from baseline to 12 months (12.6 vs. 9.1, p=0.19).

Conclusions: HIFU focal ablation of the prostate is safe and effective, allowing for preservation of urinary and sexual function. It carries a low risk of requiring subsequent radical or systemic therapies for prostate cancer that may affect quality of life indices more severely.

Funding: N/A

Abstract 120

The development of luteinizing hormone-releasing hormone (LHRH) agonists: A race to the Nobel prize with a Montreal twist

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Introduction: Here, we describe the search for a messenger that regulates luteinizing hormone (LH) and follicle-stimulating hormone (FSH) production in the hypophysis. The race lasted many years and was the subject of a fierce competition that led to the Nobel Prize for both Schally and Guillemin.

Methods: We searched the literature for articles describing what led to the discovery of the luteinizing hormone-releasing hormone (LH-RH) with a special interest in the time both researchers spent in Montreal.

Results: The Nobel Prize in 1977 jointly went to Roger Guillemin and Andrew V. Schally "for their discoveries concerning peptide hormone production in the brain". Schally spent, as he said, his academically formative years in Canada. In 1952 he joined McGill University and became an endocrinologist, as well as receiving a PhD. He and others had proven the existence of the corticotropin-releasing factor (CRF) in the hypothalamus and anterior hypophysis. This was the first discovery of experimental evidence of hypothalamic hormones regulating hypophysary function. In 1971, his group described the structure of LH-RH and won the race against Guillemin just a few weeks ahead of Guillemin's group. The rivalry is described in the book "The Nobel Duel". Guillemin arrived in Montreal in 1948 in order to do research in a lab at the University of Montreal. In 1953, he obtained a PhD in physiology with specialization in experimental endocrinology. That same year, he left for Baylor College. Schally joined him from 1957 to 1962 in Houston, setting up methods for purification and *in vivo* bioassays of hypothalamic hormones. Contrary to Guillemin, Schally maintained a scientific collaboration with Montreal by conducting the first study of LH-RH agonists in patients with prostate cancer at the Royal Victoria Hospital in Montreal. The study included 10 men treated between six weeks and 12 months with daily injections of an agonistic analog of LH-RH and was published in 1982 (Proc.Natl.Acad.Sci.79). Interestingly, at the same place as the prostate cancer trial was done, the same treatment was also being tested in "four male transsexual subjects" and was published in 1981 (J.Clin.Invest.68).

Conclusions: The discovery of LH-RH forms the basis for the development of LH-RH agonists in prostate and breast cancer. The race was won by Schally with a

lead of only a few weeks. Both main scientists who won the Nobel Prize spent some important early years in Montreal, where the first clinical trial of LH-RH agonists was performed in 1982.
Funding: N/A

Abstract 121

Treatment trends of a large active surveillance cohort for men with prostate cancer

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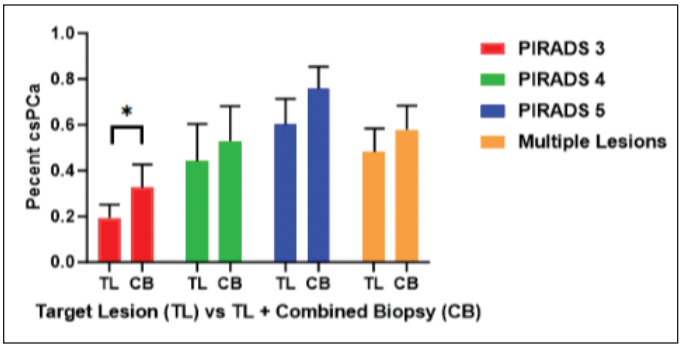
Introduction: Active surveillance (AS) is widely accepted as a treatment pathway for low-risk and favorable intermediate-risk localized prostate cancer. We aimed to report the long-term progression of patients on AS to treatment.
Methods: In a retrospective cohort study performed at a single institution center, 2521 men with low or favorable intermediate-risk prostate cancer were managed with an active surveillance protocol from 2000–2023. Main outcomes measured were overall survival and time to treatment.
Results: Of the patients enrolled, 620 (24.6%) entered treatment, 395 (15.7%) patients died, 34 (1.3%) had metastasis, and six (17.6% of those with metastasis) died with metastasis. By race, 2337 (92.7%) were White, 143 (5.7%) African-American, 20 (0.8%) American Indian/Alaskan, 14 (0.6%) Asian, and seven (0.2%) other. Median followup was four years and maximum followup time was 22.2 years. Median age of patients was 73.8 with a range of 43.8 to 98.1 years. At five, 10, and 15 years, 71.3%, 62.7%, and 52% of patients remained untreated and on AS. For patients with Gleason score (GS) 3+3=6 on AS at five and 10 years, 81.4% and 76.3% remained untreated. Similarly, patients with GS 3+4=7 demonstrated 41.5% and 27.4% untreated rates.
Conclusions: To our knowledge, we report the largest AS cohort examining time to treatment. AS for favorable-risk prostate cancer seems safe and effective in the 10-year timespan. In our study, 24.6% of patients progressed to treatment and 1.3% of patient developed metastasis. Additionally, 0.2% of patients on AS died with metastasis.
Funding: N/A



Abstract 123. Figure 1. Likelihood of csPCa in target lesion vs. combined biopsy. csPCa: clinically significant prostate cancer; MRI: magnetic resonance imaging; PIRADS: Prostate Imaging and Data Reporting System.

Abstract 122 – WITHDRAWN

Abstract 123

Does combined biopsy have equivalent value for all men presenting with a PIRADS lesion?

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Introduction: Prostate magnetic resonance imaging (MRI) has improved the detection of clinically significant prostate cancer (csPCa) (Gleason score 3+4=7 or higher) that determines future treatment and management; however, there is debate about the value of MRI-targeted lesion (TL) only biopsy vs. combined biopsy (TL and systematic biopsy [SB]). Here we present biopsy outcomes in those presenting with solitary or multiple Prostate Imaging and Data Reporting System (PIRADS) lesions from a single institution.
Methods: Data was retrospectively obtained through chart review of patients who underwent MRI between October 2020 and May 2021 performed at the University of Rochester School of Medicine (URMC). All MRIs were performed on a 3-Tesla MRI and read by one of two experienced radiologists at URMC using the PIRADS v2.1 reporting scheme. Patients underwent prostate biopsy within six months of MRI. Chi-square tests were used for comparisons. Statistical analysis was performed using R 4.4.2 and GraphPad Prism 10.1.0.
Results: This study included 308 patients who were eligible based on the above criteria. The mean patient age was 65.8 (range of 45–85) with a mean prostate-specific antigen (PSA) of 8.4 (range of 0.4–74.1). Of the 308 patients, 86 patients had PIRADS 3, 34 had PIRADS 4, and 53 had PIRADS 5 solitary lesions. Eighty-one patients had multiple lesions (two or three lesions) on MRI. Fractional percentage of finding csPCa associated with PIRADS grading for target lesion-only biopsy vs. combined biopsy is shown in Table 1. Comparison of clinical significance of the MRI target lesion vs. combined biopsy is shown in Figure 1. Only patients with a solitary PIRADS 3 lesion had a significant increase in csPCa detection rates by adding SB in both analyses.
Conclusions: When there is a solitary lesion on MRI, the relative additional value of systematic cores for detection of csPCa is greatest when the solitary lesion is PIRADS 3 (vs. 4 or 5). Further, the addition of systematic biopsy to a targeted biopsy may have less value when multiple lesions are detected. More research is needed to determine whether SB can be excluded in some individuals.
Funding: N/A

Abstract 123. Table 1. Detection of clinically significant prostate cancer: Targeted lesion vs. combined biopsy

	PIRADS 3 (n = 86)	PIRADS 4 (n=34)	PIRADS 5 (n=53)	Multiple lesion (n=81)
Targeted lesion	0.163 (0.100–0.255)	0.441 (0.289–0.605)	0.605 (0.469–0.724)	0.481 (0.376–0.589)
Combined biopsy	0.326 (0.430–0.236)	0.529 (0.367–0.685)	0.755 (0.624–0.851)	0.580 (0.472–0.682)
p	0.013	0.467	0.096	0.207

Results are fractional % (95% CI) positive of finding clinically significant prostate cancer, given PIRADS type. Clinically significant prostate cancer was defined as 3+4=7 or greater. CI: confidence interval; PIRADS: Prostate Imaging and Data Reporting System.

Abstract 124

Prostate-specific antigen dynamics from the phase 3 EMBARK trial: A post hoc analysis

Stephen J Freedland[1,2], Ugo De Giorgi[3], Christopher M Pieczonka[4], Jamal Tarazi[5], Yiyun Tang[6], Gabriel P Haas[7], Matt Rosales[8], Fabian Zohren[9], Neal D Shore[10]

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Introduction: In EMBARK, enzalutamide + leuprolide (enzalutamide combination) and enzalutamide monotherapy showed improvements in metastasis-free survival (MFS) vs. placebo and leuprolide (alone) while maintaining quality of life in patients with high-risk biochemically recurrent (BCR) prostate cancer. Importantly, EMBARK included treatment suspension at week 37 if prostate-specific antigen (PSA) was <0.2 ng/mL and reinitiation once PSA rose to predefined thresholds. Here, a post hoc analysis of PSA dynamics is presented to understand the time course to undetectable PSA and likelihood of undetectable PSA after treatment reinitiation.

Methods: EMBARK is a phase 3 study of patients with BCR after local therapy considered high-risk: PSA doubling time ≤9 months and PSA ≥2 ng/mL above nadir post-radiotherapy (RT) or ≥1 ng/mL after radical prostatectomy (RP) ± postoperative RT. Patients were randomized (1:1:1) to enzalutamide combination (160 mg/day; double-blind), leuprolide alone (22.5 mg every 12 weeks; double-blind), or enzalutamide monotherapy (open label). If serum PSA was <0.2 ng/mL at week 36, treatment was suspended at week 37 and restarted when PSA was ≥2 ng/mL for patients with primary RP and ≥5 ng/mL for patients without RP. A post hoc analysis of PSA dynamics in the intent-to-treat population was analyzed descriptively in each treatment cohort.

Results: Of 1068 patients, most patients in all three treatment cohorts reached the first occurrence of undetectable PSA (<0.2 ng/mL) by week 25 (Table 1); percentages were higher for enzalutamide combination and monotherapy vs. leuprolide alone. More patients treated with enzalutamide combination and enzalutamide monotherapy had treatment suspended vs.leuprolide alone. Of patients who suspended treatment at week 37, 89% of patients reinitiated treatment with enzalutamide monotherapy, 85% of patients reinitiated treatment with leuprolide alone, and 75% patients reinitiated treatment with enzalutamide combination. Of patients who reinitiated treatment, ~90% or more of patients treated with enzalutamide combination or monotherapy reached undetectable PSA vs. 73% with leuprolide alone.

Conclusions: In patients with high-risk BCR, a greater proportion of patients treated with enzalutamide combination or enzalutamide monotherapy reached undetectable PSA, reached undetectable PSA sooner, had treatment suspended at week 37, and achieved undetectable PSA following treatment reinitiation vs. leuprolide alone.

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Funding: The study was sponsored by Pfizer Inc. and Astellas Pharma Inc., the co-developers of enzalutamide. Medical writing and editorial support, funded by the sponsors, were provided by Julie B. Stimmel, PhD, CMPP, and Rosie Henderson, MSc, of Onyx (a division of Prime, London, UK).

Abstract 124. Table 1. EMBARK PSA dynamics

n (%)	Enzalutamide combination (n=355)	Leuprolide alone (n=358)	Enzalutamide monotherapy (n=355)
First occurrence of PSA <0.2 ng/mL			
≤week 25	317 (89.3)	224 (62.6)	291 (82.0)
week 36	9 (2.5)	22 (6.1)	13 (3.7)
≥week 37†	20 (5.6)	36 (10.1)	23 (6.5)
Treatment suspension‡	321 (97.0)	240 (71.4)	304 (90.2)
Treatment suspension ongoing at data cutoff	34 (10.6)	14 (5.8)	13 (4.3)
Reinitiation of treatment§	241 (75.1)	203 (84.6)	270 (88.8)
PSA <0.2 ng/mL after treatment reinitiation	231 (95.9)	149 (73.4)	242 (89.6)
PSA ≥0.2 ng/mL after treatment reinitiation	10 (4.1)	54 (26.6)	28 (10.4)

Data cutoff January 31, 2023. †Patients who did not suspend treatment. ‡Percentages calculated based on the number of patients with PSA values at week 36; patients who discontinued following treatment suspension are not included. §Percentages calculated based on the number of patients who suspended treatment. PSA: prostate-specific antigen.

Abstract 125

Enzalutamide combination treatment suspension in men with high-risk biochemically recurrent prostate cancer: Outcomes from EMBARK

Stephen J Freedland[1,2], Paul R Sieber[3], Ugo De Giorgi[4], Christopher M Pieczonka[5], Bryan A Mehlhaff[6], Daniel C Danila[7], Curtis J Dunshee[8], Costas D Lallas[9], Marc J Pliskin[10], Yiyun Tang[11], Gabriel P Haas[12], Matt Rosales[12], Jamal Tarazi[13], Fabian Zohren[13], David Russell[11], Neil D Shore[14]

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Introduction: EMBARK found improvements in metastasis-free survival (MFS) with enzalutamide + leuprolide (enzalutamide combination) and enzalutamide monotherapy vs. placebo + leuprolide (alone) in patients with high-risk biochemically recurrent (BCR) prostate cancer. Treatment was suspended at week 37 in 321 patients (90.9%) treated with enzalutamide combination and 240 (67.8%) treated with leuprolide alone. Outcomes for enzalutamide combination vs. leuprolide alone by suspension status are reported.

Methods: The phase 3 EMBARK study enrolled patients with high-risk BCR (prostate-specific antigen [PSA] doubling time ≤9 months, and PSA ≥2 ng/mL above nadir post radiotherapy (RT) or ≥1 ng/mL after radical prostatectomy [RP]± postoperative RT) randomized (1:1) to enzalutamide 160 mg/day + leuprolide (22.5 mg q12w) or leuprolide alone. Treatment was suspended at week 37 if serum PSA was undetectable (<0.2 ng/mL) at week 36 and restarted at ≥2 ng/mL (primary RP) or ≥5 ng/mL (no primary RP). Proportion of patients with undetectable PSA two years after suspension was a secondary end point. MFS was analyzed descriptively by suspension status. *P*-values were nominal.

Results: The three-year MFS rate (95% CI) was 94.4% (91.2–96.5%) with enzalutamide combination, 90.0% (85.3–93.2%) with leuprolide alone in the suspension

group, and 76.2% (33.2–93.5%) and 66.9% (55.4–76.1%) in the no suspension group, respectively. MFS in the suspension group was improved with enzalutamide combination vs. leuprolide alone (observed HR 0.470, 95% CI 0.308–0.717; *P*=0.0003); no difference was observed in the no suspension group (0.719, 0.225–2.295; *P*=0.5763). More patients in the suspension group received prior RP vs. no suspension and less received prior RT (Table 1). Two years after suspension, more enzalutamide combination patients had undetectable PSA than leuprolide alone (Table 1).

Conclusions: MFS was observed to be improved with enzalutamide combination vs. leuprolide alone for patients who suspended treatment. No difference was observed in the no suspension group, but the patient numbers were limited. Patients who suspended treatment had higher rates of prior RP vs. those who did not. Patients who received enzalutamide combination were more likely to have undetectable PSA two years after suspension vs. leuprolide alone.

Clinicaltrials.gov: NCT02319837.

Funding: The study was sponsored by Pfizer Inc. and Astellas Pharma Inc., the co-developers of enzalutamide. Medical writing and editorial support, funded by the sponsors, were provided by Megan Christian and Rosie Henderson of Onyx (a division of Prime, London, UK).

Abstract 125. Table 1. EMBARK combination treatment suspension

	Suspension at week 37†		No suspension at week 37†	
	Enzalutamide combination n=321	Leuprolide alone n=240	Enzalutamide combination n=9	Leuprolide alone n=92
Prior treatment at baseline, %				
Prior hormonal therapy	30.2	27.1	66.7	43.5
Prior radical prostatectomy	76.6	78.3	33.3	52.2
Prior radiotherapy	73.8	76.7	100	85.9
Undetectable PSA (<0.2 ng/mL) 2 years after suspension, % (95% CI)	16.8 (12.9–21.4)	9.6 (6.2–14.0)	-	-
p	0.0089‡		-	

†Patients who discontinued treatment ≤week 37 were balanced across treatment arms and excluded from the analysis. ‡P-values were nominal. CI: confidence interval; PSA: prostate-specific antigen.

Abstract 126

Overall survival with darolutamide vs. placebo in combination with androgen-deprivation therapy and docetaxel accounting for subsequent therapy: A sensitivity analysis from ARASENS

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Introduction: Darolutamide in combination with androgen-deprivation therapy (ADT) plus docetaxel is approved for metastatic hormone-sensitive prostate cancer (mHSPC) based on the phase 3 ARASENS study (NCT02799602). This *post hoc* sensitivity analysis of overall survival (OS) in censored patients aims to address the impact of informative intercurrent disease-related events.

Methods: Patients with mHSPC were randomized 1:1 to darolutamide 600 mg twice daily+ADT+docetaxel or placebo+ADT+docetaxel. The primary end point was OS using a log-rank test, with hazard ratio (HR 95% confidence interval [CI]) calculated by Cox model, stratified by extent of disease (EoD; nonregional lymph node vs. bone ± lymph node vs. visceral ± lymph node/bone metastases) and alkaline phosphatase (<vs.≥upper limit of normal). Patients without documented death were censored at last known alive or data cut-off date, whichever was earlier. The *post hoc* sensitivity analysis counted initiation of subsequent systemic antineoplastic therapy as an event in censored patients still alive at end of followup. Three planned sensitivity analyses used a log-rank test and Cox model without stratification, with stratification based on electronic case report forms, and with EoD stratification based on central imaging review.

Results: Darolutamide+ADT+docetaxel significantly improved OS (HR 0.68, 95% CI 0.57–0.80, P<0.0001) vs. placebo+ADT+docetaxel, despite 374/495 (76%) patients in the placebo group receiving subsequent life-prolonging systemic therapies. Time to first subsequent systemic antineoplastic therapy was significantly longer in the darolutamide vs. placebo group (HR 0.39, 95% CI 0.33–0.46, P<0.001). Findings from the *post hoc* sensitivity analysis counting initiation of subsequent systemic antineoplastic therapy as an event in censored patients (patients with events: darolutamide 300/651, 46.1%; placebo 476/654, 72.8%) and the planned sensitivity analyses were consistent with and supported the primary OS analysis (Table 1). Treatment-emergent adverse events were similar between groups and led to darolutamide/placebo discontinuation in 13.5% and 10.6% of patients, respectively.

Conclusions: The *post hoc* and planned sensitivity analyses were consistent with and supportive of the ARASENS primary OS analysis. These data reinforce darolutamide in combination with ADT+docetaxel as an effective and well-tolerated standard of care for early treatment intensification in mHSPC.

Funding: Bayer HealthCare Pharmaceuticals, US (NJ, USA)

Abstract 126. Table 1. ARASENS overall survival sensitivity analyses

Analysis	HR (95% CI) darolutamide vs. placebo	One-sided p
Primary OS analysis	0.68 (0.57–0.80)	<0.0001
Sensitivity analyses		
Counting initiation of subsequent systemic antineoplastic therapy as an event in censored patients[a]	0.47 (0.40–0.54)	<0.0001
Unstratified	0.69 (0.58–0.82)	<0.0001
Using stratification factors based on electronic case report forms	0.68 (0.57–0.81)	<0.0001
Using EoD stratification factors from central imaging review	0.68 (0.57–0.81)	<0.0001

[a]Patients with events: darolutamide 300/651, 46.1%; placebo 476/654, 72.8%.
CI: confidence interval; EoD: extent of disease; HR: hazard ratio; OS: overall survival.

Abstract 127

Cardiometabolic predictors of prostate cancer risk: A longitudinal cohort study

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Introduction: Cardiometabolic diseases have been associated with an increased

risk of various cancers. This study hypothesizes that such conditions could predict the development of prostate cancer in individuals aged 50 and older. Through longitudinal analysis, we aim to evaluate the potential of cardiometabolic disorders as indicators for prostate cancer risk, contributing to more effective prevention and early detection strategies in this population.
Methods: We conducted a longitudinal analysis using the Health and Retirement Study data, following participants for 22 years, from 1998 to 2020. Eligible participants were those without prostate cancer at baseline who reported the presence or absence of at least one cardiometabolic condition, including stroke, heart disease, diabetes, obesity, hypertension, or dyslipidemia, at baseline. Cox regression models were utilized to ascertain the hazard risk for developing prostate cancer. Confounding variables such as age, educational attainment, mobility, activities of daily living (ADL), instrumental activities of daily living (IADL), alcohol usage, and smoking habits were statistically controlled to ensure the robustness of the findings.
Results: A total of 1958 participants were included in the current study. Cardiometabolic diseases were confirmed as predictors of prostate cancer in this demographic. Multivariate Cox regression analyses demonstrated that after adjusting for confounders, dyslipidemia (HR=1.29, SE=0.05, z=5.01, p<0.001) and hypertension (HR=1.21, SE=0.05, z=3.75, p<0.001) predicted the incidence of prostate cancer. Patient characteristics, namely, age, years of education, and decreased mobility were further determined to be predictors of prostate cancer incidence within the sample. A moderation effect was identified, indicating that while diabetes and high cholesterol individually increased the risk, their combined effect did not proportionately amplify the hazard, suggesting a non-additive interaction between these factors.
Conclusions: Within our sizable sample, our study demonstrates the prognostic importance of cardiometabolic health in predicting prostate cancer, with substantial implications for clinical risk assessment and public health policy. These findings further challenge conventional notions of risk accumulation, suggesting that individual cardiometabolic conditions may interact in complex, non-linear ways to influence cancer development. These findings advocate for an integrated approach to cardiometabolic and cancer risk management in the geriatric population.
Funding: N/A

Abstract 128

Enhancing prostate cancer diagnostics: Transitioning to transperineal biopsy: Single center experience

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Introduction: In the evolving landscape of prostate cancer diagnostics, we mark the transition from the traditional transrectal ultrasound-guided biopsy to the innovative transperineal biopsy (TP Bx). This study reviews our center's experience with TP Bx, focusing on the associated complications and diagnostic efficacy.
Methods: This retrospective study, spanning from May 2023 to March 2024, analyzed patients who underwent TP Bx at our center. We meticulously tracked post-procedural complications to evaluate the safety profile of TP Bx along with recorded pre-Bx magnetic resonance imaging (MRI) findings, which was performed based on clinical indications and not as a routine standard of care, to correlate with biopsy pathology outcomes.
Results: During the study, 36 men, median age 68, underwent TP Bx without any reported complications. The median prostate-specific antigen (PSA) level pre-biopsy was 8.4 ng/dL. MRI was used in 19 patients (48.7%). Pathological results from TP Bx showed 33.3% (n=12) negative, 36.1% (n=13) with low-grade or favorable intermediate cancer, and 30.5% (n=11) with unfavorable intermediate or high-risk cancer. Among the patients with negative biopsy results, six had MRI, two PIRADS IV, one PIRADS III, three PIRADS II. Notably, 53.8% of the patients with low-grade or favorable intermediate results had MRI scores of PIRADS IV or V. For those classified with unfavorable intermediate or high-risk cancer, only two had corresponding MRIs, with one showing PIRADS III and the other PIRADS V.
Conclusions: Our study's preliminary results affirm the transperineal biopsy as a safe and effective method for prostate cancer diagnosis, despite some variations in MRI and biopsy correlations. The technique's reliability in detecting all cancer grades without complications signals its potential for wider clinical adoption, pending further research with larger sample size and more robust design (larger sample size and long-term followup). (Complete results are pending.)
Funding: N/A

Abstract 129

Referral cancer center 30-day mortality rates after major cancer surgery

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Introduction: In recent years, cancer care has shifted towards a centralized model in which patients who require complex treatment receive it at regional referral centers. One goal of centralization is to improve patient outcomes; however, the impact of cancer treatment centralization at the population level is unknown. To better understand variation among regional referral centers and its impact on patient outcomes, we sought to estimate 30-day mortality following major surgery for cancer patients receiving care at regional referral centers.
Methods: We examined the Pennsylvania Cancer Registry, linked to hospital discharge data, to identify major surgeries for cancer patients at 16 Commission on Cancer/National Cancer Institute designated referral centers from 2013 to 2020. We included adults with surgery for bladder, brain, colorectal, esophageal, liver, lung, and pancreatic cancers. We then estimated the adjusted 30-day mortality for each hospital and stratified by cancer type using a Bayesian logistic regression with random effects for hospitals. We adjusted for age, sex, race, ethnicity, comorbidities, and pathologic T stage or tumor grade. For each hospital, we calculated a risk-adjusted, weighted average 30-day mortality across cancers using inverse-variance weights.
Results: A total of 35 348 patients underwent cancer surgery at the 16 referral centers. For bladder cancer, a total of 2398 patients underwent surgery, with three hospitals performing 62% of all cases. The adjusted, weighted average 30-day mortality rate across all cancer types ranged from 1.48% (95% CI 0.66–2.30) to 3.69% (95% CI 2.08–5.31). For bladder cancer, 30-day mortality ranged from 1.50% (95% CI 0.01, 4.98) to 12.80% (95% CI 0.50, 33.50), with mortality at the highest-volume centers ranging from 1.50% to 2.88%.
Conclusions: Across 16 regional referral centers, there is variation in the adjusted 30-day mortality rates following major cancer surgery. This difference is even greater following bladder cancer surgery. The clinical significance of this range is unclear. However, it shows that centralization of care to regional referral cancer centers does not guarantee standardized and improved quality. Additional work is needed to develop nuanced metrics of quality that includes demonstrated outcomes.
Funding: N/A

Abstract 130

The neutrophil-to-lymphocyte ratio as a biomarker in metastatic castrate-sensitive prostate cancer patients treated with abiraterone acetate

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Introduction: The aim of this study was to investigate the role of neutrophil-lymphocyte ratio (NLR) as a biomarker in metastatic castration-resistant prostate cancer (mCRPC) patients receiving androgen deprivation therapy (ADT), either as monotherapy or in conjunction with abiraterone acetate (AA) and prednisone.
Methods: This retrospective cohort study analyzed the LATITUDE study of men with high-risk mCSPC. Patients were assigned to receive either AA, prednisone, and ADT, or placebo plus ADT. Using a previously established NLR threshold of 2.5, we evaluated whether this could predict clinical response to abiraterone.
Results: At baseline, there were no significant differences in NLR values between the treatment groups. Of the known baseline prognostic factors, NLR was associated with albumin levels and Eastern Cooperative Oncology Group performance

scores. Moreover, the number of bone metastases was higher in patients with NLR ≥2.5. On multivariable analysis, baseline NLR ≥2.5 did not predict overall survival, PSA progression-free, or metastasis-free survival. However, changes in PSA and NLR at six months indicated distinct survival patterns between the placebo and AA groups, suggesting the potential for their combined assessment as a prognostic tool.

Conclusions: Baseline NLR was not an independent predictor factor for response to AA in the LATITUDE study. This may be related to the predominant high-grade cancer population. Further research is required to better understand which populations of patients with advanced prostate cancer NLR changes may be a useful prognostic tool.

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Funding: N/A

Abstract 131

Oncologic outcomes and rates of adverse events following focal therapy for clinically-localized prostate cancer

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Introduction: Focal therapy (FT) is an alternative to radical surgery/radiotherapy for the treatment of clinically localized prostate cancer (PCa) which has been demonstrated to have fewer adverse events compared to radical therapy. However, rates of adverse events and recurrence following FT have been poorly described. We sought to describe complications arising from FT and the rate of recurrence of clinically significant PCa (csPCa) following focal therapy among a cohort of men treated with FT.

Methods: A retrospective review of men undergoing FT for unilateral intermediate-risk PCa from 2021 to 2022 conducted by a single surgeon was performed. FT was performed using high-intensity focused ultrasound (HIFU) or cryotherapy; ablative therapy was administered to half the gland (hemiablation) based on preoperative lesion/biopsy data. All patients received followup prostate magnetic resonance imaging (MRI) and subsequent biopsy at six months. Clinically significant PCa (csPCa) was defined as Grade Group (GG) ≥2.

Results: FT was performed on 63 men (mean age 66.3±6.5 years) for either GG2 (70%) or GG3 (25%) PCa. Median prostate-specific antigen (PSA) was 6.1 (interquartile range [IQR]: 5.0–8.3) ng/dL median prostate volume was 42 (IQR: 34–51) cc. Postoperative new-onset erectile dysfunction occurred in six patients (9.5%), urgency incontinence occurred in seven patients (11.1%), development of urinary retention requiring operative intervention occurred in four (6.4%) patients, and one patient required hospitalization for urosepsis. Upon followup, four (6.4%) patients had csPCa detected upon biopsy and were managed with either active surveillance or referred for salvage radiotherapy.

Conclusions: Focal therapy is a safe, effective treatment for PCa with few adverse effects, of which the most common was urinary urge incontinence; however, 6.4% of patients developed urinary retention following FT. Further studies with larger cohorts are needed to better understand predictive factors and mitigation.

Funding: N/A

Abstract 131. Table 1. Patient features

Patient features	All patients N=63
Mean age, SD	66.3, 6.4
Focal modality, n (%)	
Cryotherapy	30 (47.6)
HIFU	33 (52.4)
Preoperative PSA	6.1 (5.0–8.3)
Preoperative biopsy	
GG1	3 (4.8)
GG2	44 (69.8)
GG3	16 (25.4)
Cribriform pathology	10 (16.1)
PIRADS	
PIRADS-3	17 (27.0)
PIRADS-4	14 (22.2)
PIRADS-5	29 (46.0)
Prostate volume	42 (34–51)
Postoperative ED	6 (9.5)
Postoperative urgency incontinence	7 (11.1)
Complications	8 (15.9)
Retention, managed with TUR	4/8 (50.0)
Retention, resolved conservatively	1/8 (12.5)
Perineal pain	1/8 (12.5)
Catheter dysfunction	1/8 (12.5)
Urosepsis requiring IV antibiotics	1/8 (12.5)
Biopsy at 6 months	
Negative	12 (40.0)
GG1	14 (46.7)
In-field ≥ GG2	3 (10.0)
Out-of-field ≥ GG2	1 (3.3)

ED: erectile dysfunction; GG: Grade Group; HIFU: high-intensity focused ultrasound; IV: intravenous; PIRADS: Prostate Imaging and Data Reporting System; PSA: prostate-specific antigen; SD: standard deviation; TUR: transurethral resection.

Abstract 132

Newer is not always better: A comparison of oncologic and functional outcomes between different HIFU modalities: Ablatherm vs. FocalOne

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Rochester Regional Health System, Rochester, NY

Introduction: High-intensity focused ultrasound for prostate cancer (HIFU) prostate ablation was granted Food and Drug Administration (FDA) approval in 2016 with the Ablatherm device. The FocalOne device was subsequently granted approval in 2019. Our objective was to compare oncologic and functional outcomes of patients treated in our practice with the original Ablatherm device vs. the next generation FocalOne device.

Methods: Retrospective chart review was performed on prospectively collected data for all HIFU procedures performed on the Ablatherm and FocalOne platforms for localized prostate cancer at Rochester Regional Health from 2016 to 2023. International Prostate Symptom Scores (IPSS), Sexual Health Inventory for Men (SHIM), and Expanded Prostate Cancer Index Composite (EPIC-26) surveys were tracked to assess changes in preoperative and postoperative functional outcomes. Post-treatment prostate-specific antigen (PSA), prostate magnetic resonance imaging (MRI), and post-HIFU prostate biopsy or transurethral resection of prostate (TURP) specimens were used to determine oncologic efficacy in terms of biochemical control, radiographic free cancer control, and pathologically confirmed cancer control, respectively. Treatment failure was defined as freedom from known residual/recurrent disease based on biochemical data, imaging data, and pathology data. Freedom from any re-treatment was also assessed. The presence of recurrent/persistent disease was further examined for whether this represented in-field or out-of-field disease following prior focal therapy.

Results: At our institution, 24 patients underwent HIFU ablation using the Ablatherm platform from October 2016 to October 2019, and 171 patients underwent HIFU ablation using FocalOne from October 2019 to May 2023. The failure rate among HIFU salvage cases was higher with Ablatherm, but this was not statistically significant. If we exclude the salvage HIFU cases, the risk of treatment failure in the Ablatherm group for treatment-naïve patients was only 9.1% vs. 14.4% in the FocalOne group (p=0.5), but there was a significantly higher rate of in-field treatment failures in the FocalOne group (69.2% vs. 20%, p=0.04). At one-year followup, there was no difference in social continence rates or SHIM scores. There was a significantly higher rate of re-treatment for obstruction in the Ablatherm group, however.

Abstract 132. Table 1. Baseline demographic information

	Ablatherm (n=24)	FocalOne (n=171)	p
Mean age	71.0	70.3	0.34[a]
Mean prostate volume	25.1±18.5	43.9±20.8	**0.000047[a]**
Median preoperative PSA	5.1 (IQR 2.12)	6 (IQR 3.59)	0.13[c]
Pre-HIFU TURP	18 (75%)	6 (3.5%)	<0.00001[b]
Salvage HIFU	4 (16.7%)	11 (6.4%)	0.08[b]
Grade group ≤2	18 (75%)	109 (64%)	0.28[b]
Grade group ≥3	6 (25%)	62 (36%)	
Mean preoperative IPSS	6.6	8.9	0.22[a]
Mean preoperative SHIM	16.1	12.6	0.10[a]

a = Student's t-test, b = chi square, c = Mann-Whitney U-test. HIFU: high-intensity focused ultrasound; IPSS: International Prostate Symptom Scores; IQR: interquartile range; PSA: prostate-specific antigen; SHIM: Sexual Health Inventory for Men; TURP: transurethral resection of the prostate.

Abstract 132. Table 2. Oncologic and functional HIFU outcomes

	Ablatherm (n=24)	FocalOne (n=171)	p
Re-treatment for obstruction	7 (29.2%)	20 (11.7%)	**0.02[b]**
Re-treatment for prostate cancer	5/24 (20.8%)	26/171 (15.2%)	0.48[b]
In-field CaP recurrence	1/5 (20%)	18/26 (69.2%)	**0.04[b]**
Out-of-field CaP recurrence	4/5 (80%)	8/26 (30.8%)	
Risk of re-treatment for prostate cancer for non-salvage (primary) cases	2/22 (9.1%)	23/160 (14.4%)	0.50[b]
Risk of re-treatment for salvage HIFU cases	2/4 (50%)	3/11 (27.3%)	0.41[b]
Mean 12-month IPSS	3.8	7.7	**0.02[b]**
12-month social continence (≤1 ppd)	90.9%	93.8%	0.70[b]
Mean 12-month SHIM	10.9	9.1	0.38[a]

a = Student's t-test, b = chi square. HIFU: high-intensity focused ultrasound; IPSS: International Prostate Symptom Scores; SHIM: Sexual Health Inventory for Men.

Conclusions: Patients who underwent HIFU with the FocalOne device had a significantly larger prostate size but still had a lower rate of requiring a pre-HIFU TURP or post-HIFU treatments for obstruction; however, there was a significantly higher rate of in-field treatment failures with the FocalOne vs. Ablatherm groups, and ultimately no long-term differences in terms of sexual or urinary control.

Funding: N/A

Abstract 133 (Video)

Case cracked! The uniqueness of tungsten carbide penile ring removal

Aaron Saxton[1], Stephen Hassig[1], Christopher Wanderling[1], Timothy Campbell[1], Austin Lee[1], Lauren Shepard[2], Jonathan Bloom[1]
[1]University of Rochester, Rochester, NY; [2]Johns Hopkins University, Baltimore, MD

Our institution has seen an increase in tungsten carbide rings causing penile strangulation, a urologic emergency. Due to the unique challenges associated with tungsten carbide's hardness and the lack of literature in a urologic context, we would like to share our experience with proper removal.

Funding: N/A

Abstract 134 (Video)

Does latest mean greatest? comparing usability and video quality of single-use ureteroscopes

Raviraj Rege[1], Stephen Hassig[2], Kaela Mali[1], Aaron Saxton[2], Scott Quarrier[2], Rajat Jain[2]
[1]University of Rochester School of Medicine and Dentistry, Rochester, NY; [2]Department of Urology, University of Rochester Medical Center, Rochester, NY

Single-use digital flexible ureteroscopes have emerged as a valuable alternative to standard reusable ureteroscopes. This study aims to compare usability and image quality across nine different single use ureteroscopes and one digital reusable ureteroscope.

Funding: N/A

Abstract 135 (Video)
Removal of eroded ethylene vinyl alcohol urethral bulking agent from a male with spina bifida
George Panagis[1,2], Derek Friedman[1,2], Brian Inouye[1,2]
[1]Department of Urology, Albany Medical College, Albany, NY, [2]Albany Medical Center, Albany, NY
This video submission demonstrates an approach to treating a unique case of prostatic urethral erosion in a CIC dependent male who received an off-label urethral bulking agent that eroded into and obstructed his urethra. The urethral bulking agent used in this patient was Tegress®, an ethylene vinyl alcohol-based urethral bulking agent initially approved for women with stress urinary incontinence; however, this agent was withdrawn from the market in 2007 after being found to cause urethral erosion.
Funding: N/A

Abstract 136 (Video)
Overcoming challenges during anatomical endoscopic enucleation of the prostate (AEEP)
Husain Alaradi, Khaled Alotaibi, Saud Alhelal, Loay Abbas, Ruba Abdul Hadi, Amr Hodhod, Hazem Elmansy
Urology Department, Northern Ontario School of Medicine, Thunder Bay, ON
Anatomical endoscopic enucleation of the prostate (AEEP) is rapidly gaining popularity among urologists worldwide. It is regarded as an effective and size-independent treatment for benign prostatic hyperplasia (BPH) with durable long-term outcomes; however, AEEP is characterized by its steep learning curve. This video aims to identify challenges encountered while performing AEEP and describe steps surgeons can take to overcome them.
Funding: N/A

Abstract 137 (Video)
Thulium fiber laser versus holmium MOSES™ in endoscopic enucleation of the prostate: Which one is "the one"?
Husain Alaradi, Khaled Alotaibi, Saud Alhelal, Loay Abbas, Ruba Abdul Hadi, Amr Hodhod, Hazem Elmansy
Urology Department, Northern Ontario School of Medicine, Thunder Bay, ON
There is limited evidence comparing the holmium laser with MOSES™ technology and thulium fiber laser (TFL) in endoscopic enucleation of the prostate (EEP). Both MOSES™ holmium laser enucleation of the prostate (MoLEP) and thulium fiber laser enucleation of the prostate (ThuFLEP) are effective treatment options for benign prostatic obstruction (BPO). This video aims to describe our experience using MoLEP and ThuFLEP at our institution.
Funding: N/A

Abstract 138 (Video)
Posterior urethroplasty after pelvic fracture urethral injury
Nikolas Moring, Michael Tram, Brian Inouye
Albany Medical Center, Albany, NY
In this video, we show our operative approach and methods for posterior urethroplasty after pelvic fracture urethral injury, highlighting two of the four common steps to gaining length during posterior urethroplasty: bulbar urethral mobilization and corporal splitting. We then demonstrate our approach for anastomotic suture placement using a pass and retrieve method where needles are flattened, and two needle drivers are employed for this difficult to reach area.
Funding: N/A

Abstract 139 (Video)
Robotic artificial urinary sphincter placement after failed pubovaginal sling
Michael Tram, Adrien Bernstein, Brian Inouye
Albany Medical Center, Albany, NY
In this video, we describe the methodology and tips for artificial urinary sphincter (AUS) implantation in a spina bifida female patient with a history of failed pubovaginal sling. The sling can be used as a handle to safely roll the urethra off the vagina when dissecting the urethrovaginal plane to safely place the AUS and treat significant stress urinary incontinence in a difficult patient population.
Funding: N/A

Abstract 140 (Video)
Endourological management of ureteral stump syndrome
Abdulrahman Alharbi, Meshari Owayed, Rawan Al-Yousef, Rehan Khan, Abdullatif Alterki
Division of Urology, Department of Surgery, Al-Amiri Hospital, Kuwait City, Kuwait
Our objective in this video is to highlight the advantages and the feasibility of treating ureteral stump syndrome with minimally invasive approaches.
Funding: N/A

Abstract 141 (Video)
Flexible and Navigable Suction (FANS) ureteral access sheath: A case study
Ashley Li, Jason Fairbourn, Scott Quarrier, Rajat Jain
University of Rochester, Department of Urology, Rochester, NY
The objectives of this video are to demonstrate our use of flexible and navigable suction (FANS) ureteral access sheaths, review current literature, and describe the advantages and disadvantages of this new technology.
Funding: N/A

Abstract 142 (Video)
Female urethroplasty with buccal mucosa with self-retaining retractor
Elizabeth Bearrick[1], Guanqun Li[1], Benjamin Cedars[1], Melissa Estabrook[1], Dmitriy Nikolavsky[2]
[1]SUNY Upstate, Syracuse, NY; [2]SUNY Upstate, Syracuse, NY
Demonstration of self-retaining lighted retractor in female urethroplasty
Funding: N/A

Abstract 143 (Video)
Use of microdebrider for vaginectomy
Elizabeth Bearrick, Benjamin Cedars, Guanqun Li, Conor Policastro, Gustavo De La Rosa, Dmitriy Nikolavsky
SUNY Upstate, Syracuse, NY
Use of microdebrider for vaginectomy.
Funding: N/A

Abstract 144 (Video)
A nerve-sparing approach to bilateral postchemotherapy retroperitoneal lymph node dissection
Pocharapong Jenjitranant[1], Shiva M. Nair[1], Justin Lamont[2], Neel Patel[2], Tyler S. Beveridge[2], Nicholas E. Power[1]
[1]Division of Urology, Department of Surgery, University of Western Ontario, London Health Sciences Centre, London, ON; [2]Department of Anatomy and Cell Biology, Schulich School of Medicine and Dentistry, University of Western Ontario, London, ON
This video has been specially developed for the purpose of surgical education in teaching open nerve-sparing retroperitoneal lymph node dissection and has been used in a research project named, "Teaching advanced surgical technique using peer-reviewed multimedia: An assessment of technical competence in cadaveric-based simulation."
Acknowledgement: The authors thank Patrick Barfoot (Technology Support Specialist, Schulich School of Medicine and Dentistry, University of Western Ontario, London, Canada) for developing the video.
Funding: N/A

Abstract 145 (Video)
Nephron-sparing approach for pediatric Wilms' tumor- robotic assisted laparoscopic partial nephrectomy
Christopher Wanderling, Ashley Li, Kaela Mali, Aaron Saxton, Denzel Zhu, Jimena Cubillos, David Diamond, Guan Wu
University of Rochester Medical Center, Rochester, NY
We present a case of a three-year-old female with the diagnosis of Stage V Wilms' tumor who presented with a tumor rupture after a fall leading to an open radical left nephrectomy. She subsequently proceeded with chemotherapy and radiation and eventually underwent a successful robotic right partial nephrectomy.
Funding: N/A