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Poster Abstracts

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Abstract 001

Descriptive Analysis of Treatment Patterns and Clinical Outcomes in Patients with Metastatic Castration Sensitive Prostate Cancer who initiated Apalutamide or Darolutamide in United States Urology Practices

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Background: Real world studies have shown that apalutamide (APA) achieves better outcomes than enzalutamide and abiraterone acetate in patients with metastatic castration sensitive prostate cancer (mCSPC), including deep and early reductions in prostate specific antigen (PSA90 by 6 months) and improved overall survival by 24 months. Limited real world evidence has been produced for darolutamide (DARO) in combination with chemotherapy (DARO+C) in mCSPC. This study described treatment patterns and outcomes of patients with mCSPC, also known as metastatic hormone sensitive prostate cancer, treated with APA or DARO.

Methods: A retrospective descriptive analysis was conducted using linked EMR and healthcare claims databases (PPS Analytics; Komodo Research Database). The index date was first APA or DARO dispensation or paid pharmacy claim on or after 8/5/2022. Patients with mCSPC and ≥12 months of pre-index claims and clinical activity were followed from index until the end of insurance clinical activity, or data availability (5/3/2024). Patients initiating DARO were stratified by receipt (DARO+C) or absence (DARO-NC) of concurrent chemotherapy. Unweighted Kaplan-Meier analyses were used to assess PSA response, time to PSA response and progression to castration resistance (CR).

Results: Among patients with mCSPC, 753 treated with APA and 210 treated with DARO (65 [31%] DARO+C; 145 [69%] DARO-NC) were identified. Mean age (years) was 74 (APA), 68 (DARO+C), and 72 (DARO-NC) with a median follow-up (months) of 9.0 APA, 8.1 DARO+C and 8.3 DARO-NC. Across cohorts, the majority were White, had Medicare, and used ADT on index date. Some patients had de novo mCSPC diagnosis before ARPI initiation across the cohorts (223 [29.6%] APA; 32 [49.2%] DARO+C; 60 [41.4%] DARO-NC). Descriptive variations in baseline characteristics were observed for patients with ≥9 Gleason score (174 [23.1%] APA; 23 [35.4%] DARO+C; 41 [28.3%] DARO-NC), and metastases: bone (425 [56.4%] APA; 57 [87.7%] DARO+C; 114 [78.6%] DARO-NC), nodal (477 [63.3%] APA; 35 [53.8%] DARO+C; 35 [53.8%] DARO-NC), and visceral (38 [5.0%] APA; 10 [15.4%] DARO+C; 18 [12.4%] DARO-NC). At baseline, PSA levels in ng/mL (mean [SD]) were 23.93 (111.36) APA, 110.09 (270.60) DARO+C and 67.62 (389.05) DARO-NC).
For patients with baseline PSA >0.2ng/ml, the proportion achieving a 90% reduction in PSA (PSA90) by 6 months was 76.4% (APA), 67.3% (DARO+C) and 61.4% (DARO-NC); median time to PSA90 (months) was 2.8 (APA), 3.4 (DARO+C) and 3.7 (DARO-NC). By 1-year post-index, the proportion remaining CR-free was 89.0% (APA), 75.6% (DARO+C), and 84.4% (DARO-NC).

Conclusions: Although darolutamide is approved for concurrent use with chemotherapy to treat mCSPC, chemotherapy use with darolutamide was observed in less than one-third of darolutamide-treated patients in this study. The rapid, deep 90% reduction in PSA observed with apalutamide was consistent with previous studies. While descriptive differences in early PSA reduction and progression to castration resistance were observed, further analyses of balanced cohorts are warranted to better assess treatment effect.

Abstract 002

Overall Survival in Patients with Metastatic Castration Sensitive Prostate Cancer Treated With Apalutamide versus Abiraterone Acetate – A Head-to-Head Analysis of Real-World Patients in the United States

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Introduction: Androgen-receptor pathway inhibitors (ARPIs) are effective treatment options for patients with metastatic castration-sensitive prostate cancer (mCSPC). So far, no head-to-head studies have compared survival (OS) outcomes between different ARPI agents. The primary objective of this study was to compare OS by 24 months of initiating apalutamide or abiraterone acetate in ARPI-naïve patients with mCSPC.

Materials and Methods: Patients with mCSPC were identified in two de-identified linked healthcare databases (PPS Analytics and Komodo). The index date was defined as the first date with a prescription for apalutamide or abiraterone acetate. Patients were excluded if they were castration resistant, had prior use of an ARPI or other advanced treatment, or had another primary cancer. OS was compared between apalutamide and abiraterone acetate patients using a weighted Cox proportional hazards model. For the primary objective, a 24-month observation period was used. As an exploratory analysis, all follow-up was used.

Results and Discussion: Overall, 1,879 patients initiating apalutamide and 2,073 patients initiating abiraterone acetate were identified (3,952 total patients). After applying inverse probability of treatment weighting to balance treatment cohorts, at the index date the mean age was 72 years; ~62% were White, ~18% were Black; ~66% had bone metastasis; 53% had nodal metastasis, ~22% had visceral metastasis and ~77% had prior use of androgen deprivation therapy. By the pre-specified 24-month timepoint, patients initiating apalutamide had a statistically significant reduction of 26% in risk of death compared to abiraterone acetate (hazard ratio [HR]: 0.74; 95% confidence interval [CI]: 0.59, 0.93; P=0.010). When considering all follow up data available, findings were consistent (HR: 0.72; 95% CI: 0.59, 0.88; P<0.001).

Conclusion: In this real-world retrospective head-to-head analysis of more than 3,900 patients initiating apalutamide or abiraterone acetate in the United States, patients initiating apalutamide had a statistically significant reduction of 26% in risk of death in patients with mCSPC at 24 months post-treatment initiation, when compared with abiraterone acetate.

Abstract 003

Real-World Head-to-Head Analysis of Overall Survival in Patients with Metastatic Castration Sensitive Prostate Cancer Initiated on Apalutamide versus Enzalutamide in the United States

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Introduction: Multiple treatment options exist for the management of metastatic castration-sensitive prostate cancer (mCSPC), however no head-to-head studies have compared survival outcomes between different androgen-receptor pathway inhibitors (ARPIs). The primary objective of this study was to compare overall survival (OS) by 24 months of initiating apalutamide or enzalutamide in ARPI-naïve patients with mCSPC.

Materials and Methods: A retrospective analysis was conducted to compare OS in ARPI-naïve patients with mCSPC in two large, de-identified linked healthcare databases (PPS Analytics and Komodo). The index date was defined as the apalutamide or enzalutamide first prescription date. Patients were excluded if they were castration resistant, had prior use of an ARPI or other advanced treatment, or had another primary cancer. OS was compared using weighted Cox proportional hazards models. For the primary objective, the observation period was limited to 24 months; for exploratory analyses, all follow-up was considered.

Results and Discussion: A total of 3,719 ARSI-naïve patients were studied (1,810 initiating apalutamide; 1,909 initiating enzalutamide). Population characteristics were similar in both cohorts after applying inverse-probability of treatment weighting. At treatment initiation, mean age was 73 years; ~60% were White, 23% were Black; ~72% with bone metastasis; ~49% had nodal metastasis, ~20% had visceral metastasis and ~81% use androgen deprivation therapy at the time of index. By the pre-specified 24-month timepoint, a statistically significant reduction of 23% in the risk of death was observed in patients initiating apalutamide as compared to enzalutamide (hazard ratio [HR]: 0.77; 95% confidence interval [CI]: 0.62, 0.96; P=0.019). Results remained consistent when evaluating OS using all follow-up (HR: 0.77; 95% CI: 0.64, 0.93; P=0.008).

Conclusion: This real-world retrospective head-to-head analysis of more than 3,700 ARPI-naïve patients with mCSPC initiating apalutamide or enzalutamide found that at 24 months post-treatment initiation, when compared with enzalutamide, patients initiating apalutamide had a statistically significant reduction of 23% in risk of death.

Abstract 004

First Results Of Peace-III: A Randomized, Multicenter, Open-Label Phase Iii Trial Comparing Enzalutamide Versus A Combination Of Radium-223 and Enzalutamide In Asymptomatic Or Mildly Symptomatic Patients With Bone Metastatic Castration-Resistant Prostate Cancer

Murilo de Almeida Luz*[1] on behalf of Silke Gillessen[2], Anaya Choudhury[3], Fred Saad[4], Enrique Gallardo[5], Andrey Soares[6], Yohann Loriot[7], Ray McDermott[8], Alejo Rodriguez-Vida[9], Pedro Isaacsson Velho[10], Franco Nolè[11], Felipe Jose Silva Melo Cruz[12], Thierry Roumeguere[13], Gedske Daugaard[14], Rosely Yamamura[15], Frédéric Lecouvet[16], Corneel Coens[17], Beatrice Fournier[18], Bertrand Tombal[19]

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Background: TPEACE-III (NCT02194842) is a randomized, multicenter phase III EORTC/CTI/CUOG/LACOG/UNICANCER cooperative study. In this interim analysis, enzalutamide, in combination with radium-223 (Ra223), was studied to see whether it improves cancer progression compared with enzalutamide alone in patients with bone metastatic castration-resistant prostate cancer (mCRPC).

Methods: Patients with mCRPC and bone metastases were randomized 1:1 to enzalutamide or enzalutamide+Ra223. As of March 2018, co-administration of zoledronic acid or denosumab was obligatory. The primary endpoint was radiologic progression-free survival (rPFS). Secondary endpoints included overall survival (OS), time to subsequent systemic anti-neoplastic therapy, time to pain progression, and time to first symptomatic skeletal event.

Results: From November 2015 to March 2023, 446 patients were enrolled. The median (interquartile range) age was 70 (65–76) years. The median follow-up duration was 42.2 months. 87.9% of patients in the enzalutamide+Ra223 arm who started Ra223 completed the scheduled 6 cycles. The hazard ratio (HR) for rPFS was 0.69 (95% confidence interval [CI] 0.54–0.87; p=0.0009), with a median rPFS of 16.4 (95% CI 13.8–19.2) months in the enzalutamide arm and 19.4 (95% CI 17.1–25.3) months in the enzalutamide+Ra223 arm. The HR for OS was 0.69 (95% CI 0.52–0.90; p=0.0031), with median OS in the preplanned interim analysis, performed at 80% of events, of 35.0 (95% CI 28.8–38.9) months in the enzalutamide arm and 42.3 (95% CI 36.8–49.1) months in the enzalutamide+Ra223 arm. The study will proceed to final OS analysis because of non-proportionality. Treatment-emergent adverse events (TEAEs) ≥ grade 1 were reported in 96.4% and 100% of patients in the enzalutamide and enzalutamide+Ra223 arms, respectively. TEAEs ≥ grade 3 were reported in 55.8% and 65.6% of patients, respectively. The most common ≥ grade 3 TEAEs in the enzalutamide+Ra223 arm were hypertension (34%), fatigue (6%), anemia (5%), and neutropenia (5%). No TEAE ≥ grade 3 was increased by more than 5% in the enzalutamide+Ra223 arm versus the enzalutamide arm.

Conclusions: In PEACE-3, 6 cycles of Ra223 in combination with enzalutamide as first-line therapy significantly improved rPFS in patients with mCRPC. This interim analysis demonstrated a statistically significant OS benefit favoring the combination of Ra223 with enzalutamide. A final OS analysis will be performed for further confirmation of these results.

Abstract 005

Predictive Value of PSA Kinetics and Serologic Markers for the Transition from Active Surveillance to Definitive Treatment in Non-metastatic Prostate Cancer: A 12-Month Preliminary Prospective Cohort Study

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Background: Active surveillance (AS) is a management strategy for patients with low-risk or favorable intermediate-risk prostate cancer, aiming to delay or avoid definitive treatment until disease progression occurs. This approach minimizes overtreatment and preserves the patient's quality of life by avoiding unnecessary side effects from interventions such as surgery or radiotherapy. However, determining the optimal timing for transitioning from AS to definitive treatment remains challenging. Prostate-specific antigen (PSA) kinetics, such as PSA doubling time (PSADT) and PSA velocity (PSAV), along with histopathological changes, are commonly used markers for decision-making. This study seeks to explore the predictive role of PSA kinetics and baseline inflammatory markers in guiding these transitions.

Objectives: The primary objective of this research was to assess the 12-month conversion rate from AS to definitive treatment. Secondary objectives included identifying the baseline predictors associated with an increased risk of conversion, with a focus on PSA kinetics (PSADT, PSAV) and serologic markers such as the neutrophil-to-lymphocyte ratio (NLR), platelet-to-lymphocyte ratio (PLR), and lymphocyte-to-monocyte ratio (LMR). Additionally, the study aimed to establish optimal PSA kinetics cut-off values for predicting disease progression and determining the need for intervention.

Methods: A prospective cohort study was conducted from January 2020 to June 2023 at two hospitals in North-West Cameroon. The study enrolled 73 men aged 40–75 years diagnosed with localized, low- or favorable intermediate-risk prostate cancer (Gleason score ≤ 7; clinical stage ≤ T2a). Participants underwent baseline assessments, including PSA testing, measurement of NLR, PLR, and LMR, and digital rectal examinations (DRE). Follow-up involved 3-month PSA monitoring, 6-month DREs, and a repeat biopsy at 12 months. PSADT and PSAV were calculated to assess disease dynamics, and Kaplan-Meier survival analysis along with Cox proportional hazards models were used to identify predictors of conversion from AS to definitive treatment.

Results: At the end of 12 months, 47.95% of patients transitioned from AS to definitive treatment based on evidence of disease progression, particularly histopathological changes on biopsy. An increase in Gleason score was a significant predictor of conversion (HR = 1.4583, p = 0.0012). PSA kinetics also emerged as reliable indicators, with PSADT < 3.33 months and PSAV > 1.1 ng/mL/year associated with an increased likelihood of progression. In contrast, inflammatory markers (NLR, PLR, and LMR) were not found to be significant predictors of conversion.

Conclusions: PSA kinetics and Gleason score changes play a critical role in predicting the transition from AS to definitive treatment, highlighting the importance of regular monitoring, particularly during the first year. While inflammatory markers had limited predictive value, they may still offer supplementary insights in future studies. This research underscores the value of individualized follow-up strategies using PSA dynamics to optimize decision-making and improve patient outcomes. Further studies with larger sample sizes and longer follow-up periods are recommended to validate these findings and refine clinical guidelines for AS management.

Abstract 006

Comparative Analysis of PSA Nadir and Time to PSA Nadir on Clinical Outcomes in Patients with De Novo Spine Metastasis of Prostate Cancer Undergoing Androgen Deprivation Treatment (ADT) Only vs. ADT Intensification

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Background: Prostate cancer with de novo spine metastasis represents a severe disease state, often associated with poor prognosis. Androgen deprivation therapy (ADT) is the mainstay treatment, though many patients experience progression to castration-resistant prostate cancer. Recent evidence suggests that intensifying ADT with additional therapies, such as abiraterone or radiotherapy, can improve outcomes. This study investigates the effect of ADT intensification on PSA Nadir, time to PSA Nadir (TTPN), and clinical outcomes, including progression-free survival (PFS) and overall survival (OS).

Objectives: The study aims to compare PSA Nadir levels and TTPN between patients receiving ADT alone and those receiving ADT intensification. Additionally, it explores the relationship between these parameters and clinical outcomes such as PFS and OS.

Methods: This retrospective cohort study, conducted at Nkwen Baptist Hospital in Cameroon, analyzed patients diagnosed with prostate cancer and de novo spine metastasis between November 2019 and November 2021. Patients were divided into two groups: ADT only (n=66) and ADT intensification (n=81). Key parameters measured included PSA Nadir levels, TTPN, PFS, and OS. Kaplan-Meier survival curves and Cox proportional hazards models were used to assess survival outcomes and identify predictors of progression.

Results: Patients in the ADT intensification group achieved significantly lower PSA Nadir levels (mean 0.13 ng/mL) compared to those in the ADT-only group (mean 0.27 ng/mL; $p < 0.0001$). Additionally, TTPN was shorter in the intensification group (median 1 month) than in the ADT-only group (median 6 months; $p < 0.0001$). The ADT intensification group also demonstrated significantly longer PFS (median 22.03 months vs. 16.20 months, $p = 0.019$). Although OS improved with ADT intensification (median 21.78 months vs. 17.44 months), the difference was not statistically significant ($p = 0.052$).

Conclusion: ADT intensification results in better PSA Nadir levels, shorter TTPN, and significantly improved PFS in patients with de novo spine metastasis. These findings underscore the potential of intensifying ADT to achieve more favorable clinical outcomes without a significant increase in adverse events. However, the observed trend in OS improvement suggests that further studies with larger populations and extended follow-up are needed to confirm the long-term survival benefits. This study highlights the importance of personalized treatment strategies and close monitoring in managing advanced prostate cancer, particularly in resource-limited settings.

Abstract 007

Multidisciplinary Approach to Oligometastatic Prostate Cancer, Preserving Sexual and Urinary Function Without Hormone Therapy

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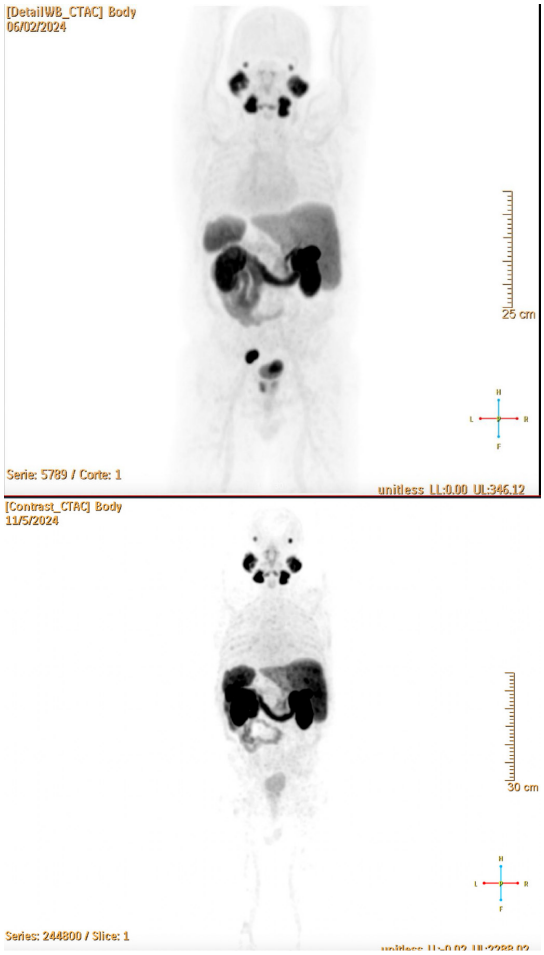
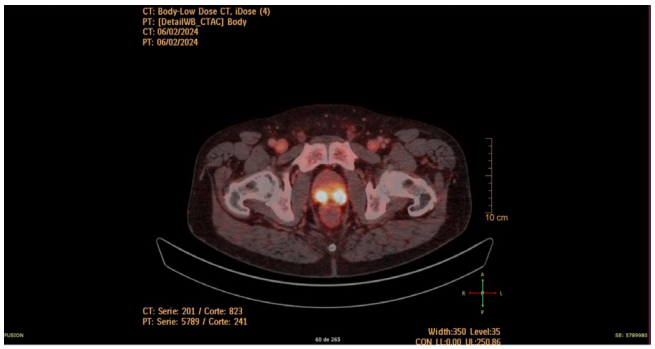
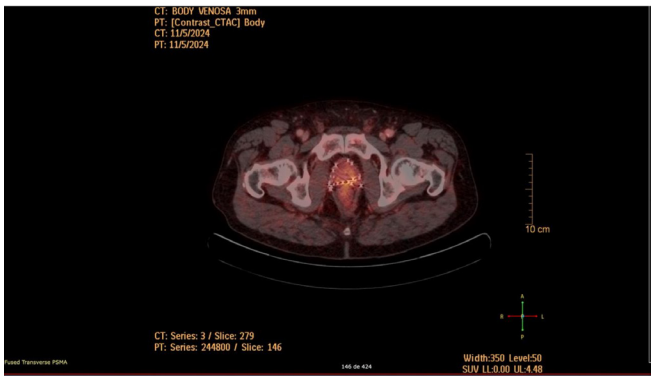
POligometastatic prostate cancer (PCa) presents a complex challenge requiring a multidisciplinary approach to balance disease control and toxicity. This case highlights the management of a 54-year-old male with high-risk, focal advanced prostate cancer. The patient presented with a prostate-specific antigen (PSA) of 48.9 ng/ml and a multiparametric prostate MRI revealed a PIRADS 5 lesion. A biopsy confirmed ISUP Grade 4 PCa in four of six sextants. Prostate-specific membrane antigen (PSMA)-PET detected increased SUV (up to 26) in the prostate, seminal vesicles, and a 3 cm suspicious left iliac lymph node.

A robotic lymphadenectomy was performed, which confirmed metastasis in 1 of 24 lymph nodes (left iliac). The remaining lymph nodes showed no evidence of malignancy. Seventeen days later, the patient underwent low-dose rate (LDR) iodine-125 brachytherapy targeting the prostate and seminal vesicles.

Post-treatment follow-up demonstrated a significant PSA reduction to 1.5 ng/ml at one month and subsequent declines to 1.02 ng/ml at three months and 0.82 ng/ml at six months. Testosterone levels remained stable, ranging from 538 ng/ml to 595 ng/ml during the follow-up period.

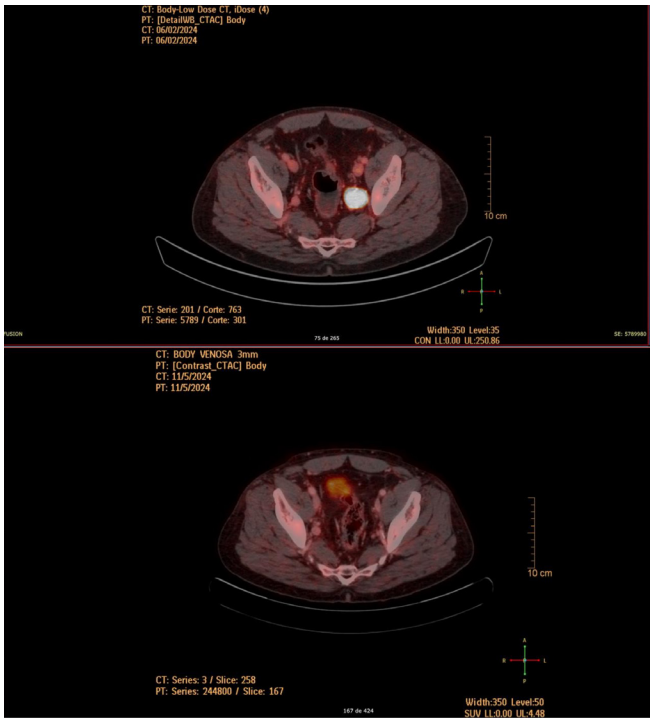


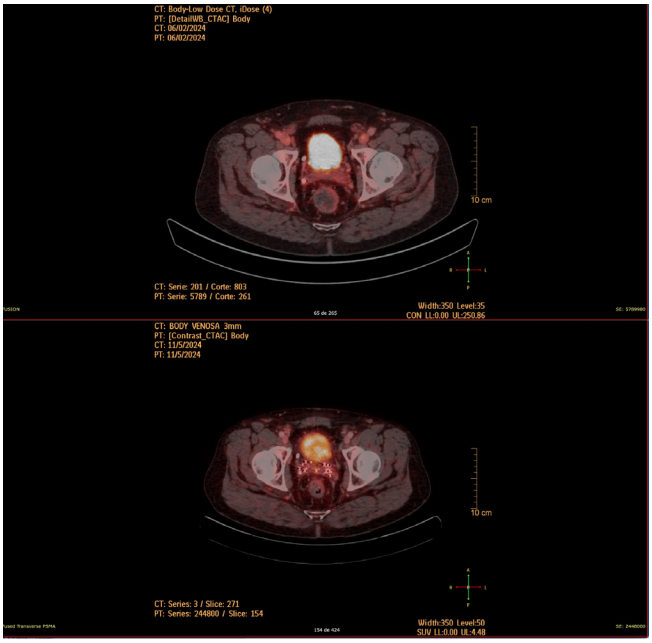




PSMA-PET showed no evidence of active disease at six months, indicating successful local and regional control.

This case underscores the potential of a multidisciplinary treatment strategy in oligometastatic PCa that avoids immediate hormone therapy, preserving sexual and urinary function while achieving effective disease control. This approach emphasizes the importance of precise imaging, histopathological confirmation, and targeted therapy to optimize outcomes. Further studies with more cases and extended follow-up are required to validate this novel approach.





Abstract 008

Low Dose Rate Brachytherapy as Monotherapy in Unfavorable Intermediate and High Risk Prostate Cancer in a Single Center

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Purpose: Low-dose-rate brachytherapy (LDRBr) is a standard treatment for localized low and favorable intermediate risk prostate cancer (PCa). However, its role in localized high and unfavorable intermediate risk PCa remains less well-defined. This study aims to evaluate preliminary oncological outcomes as biochemical recurrence-free survival (BRFS), in patients with localized unfavorable intermediate and high risk PCa treated with LDRBr as monotherapy. PET-PSMA was utilized for staging, and seminal vesicles (SV) were included in the dosimetry planning. A minimum follow-up of one year was required for BRFS analysis.

Materials and Methods: From a cohort of 426 patients, 51 consecutive patients with high risk PCa (T3a, ISUP ≥ 4, or prostate-specific antigen (PSA) ≥ 20 ng/mL) or unfavorable intermediate risk localized PCa (ISUP 3, or 2 of 3 factors: cT2b-c, PSA 10-20 ng/mL, ISUP 2 or 3) were treated with iodine-125 LDRBr as monotherapy. PET-PSMA was used for staging, and dosimetry planning included SV with a prescribed dose of 144 Gy to the prostate and SV planning target volume (PTV). Biochemical recurrence was defined as PSA nadir + 2 ng/mL. We estimated Biochemical Recurrence Free Survival (BRFS) using Kaplan-Meier survival curves.

Results: The mean ± SD age of patients was 66.9±9.7 years. The median follow-up was 12 months, with 30 patients (58.8%) completing one year of follow-up. 13 patients (25.5%) were followed for ≥ 2 years. Patient distribution included 12 (23.5%) with ISUP 2 and PSA ≥ 10 ng/mL, 27 (52.9%) with ISUP 3, 10 (19.6%) with ISUP 4, and 2 (3.9%) with ISUP 5. Mean ± SD pre-treatment PSA was 12.7±9.4 ng/mL.
Only 2 patients (3.9%) experienced biochemical recurrence at 24 and 36 months. In both cases, PET-PSMA detected recurrence in distal bones, which were negative at baseline staging. No local recurrences in the prostate or regional recurrences were observed.
BRFS (95% CI) was 100% at 1 year, 93.2% (78.9–100%) at 2 years, and 79.1% (56.3–100%) at 3 years.

Conclusion: These findings suggest that LDRBr monotherapy is a promising treatment option for selected patients with unfavorable intermediate and high risk localized PCa. Integrating PET-PSMA for accurate staging and SV inclusion in dosimetry planning demonstrates the potential to optimize treatment outcomes. Longer follow-up and larger cohorts are needed to validate and generalize these results.

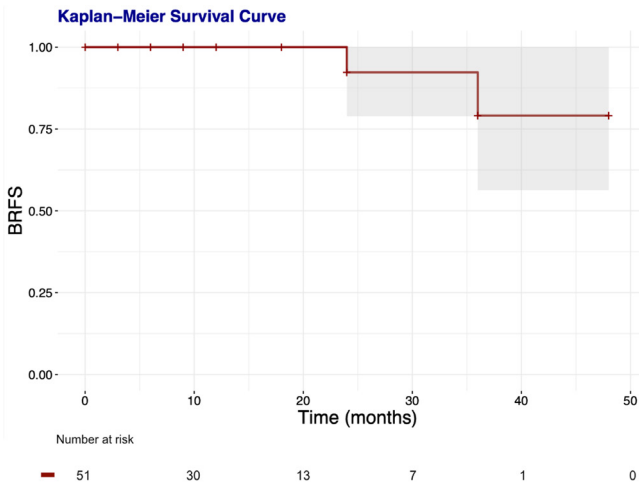

Figure 1. Kaplan–Meier curve for biochemical recurrence free survival (BRFS) in high risk PCa patients treated with LDRBr.

Abstract 009

Elective Pelvic Lymph Node Radiation Therapy in Patients with Localized Prostate Cancer: A Post Randomization Analysis

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Background: The use prophylactic whole-pelvic radiation therapy (WPRT) in patients without pelvic nodal involvement has been debated for decades, with a historical shift from its utilization to exclusion due to evolving results in early studies. Although a contemporary randomized clinical trial (POP-RT) has led to the use of WPRT, long term data evaluating a potential reduction in mortality is lacking. In this study, we perform a post-randomization analysis of a mature randomized controlled trial (median follow-up, 10.2 years) to determine the impact of WPRT on all-cause mortality (ACM) and prostate cancer-specific mortality (PCSM) after adjusting for known prostate cancer (PC) prognostic factors.

Methods: From 2005 to 2015, 350 men with localized, unfavorable risk PC were randomly assigned to receive androgen deprivation therapy (ADT) and radiation therapy (RT) plus docetaxel vs ADT and RT. Treatment of the pelvic lymph nodes was at the discretion of the treating physician. Multivariable Cox and Fine and Grays regression analysis was performed to assess whether a significant association existed between radiation treatment volume and ACM and PCSM respectively, adjusting for known prognostic factors and comorbidity. An interaction term between age (categorized by dichotomized at 65 years to enable clinical interpretation and applicability of the results and which approximates the median [66 years (IQR: 61-70)]) and radiation treatment volume was included in the analysis.

Results: After a median follow-up of 10.20 years (IQR, 7.96-11.41), 89 men died (25.43%); of these, 42 died of PC (47.19%). Of the 350 randomly assigned patients, 88 (25.14%) received WPRT. In men younger than 65 years, WPRT was associated with a significantly lower ACM risk (adjusted hazard ratio [AHR], 0.33 [95% CI, 0.11 to 0.97]; P=0.04) and lower PCSM risk (AHR, 0.17 [95% CI, 0.02 to 1.35]; P=0.09) after adjusting for covariates, whereas this was not the case for men 65 years or older.

Conclusions: The use of WPRT in men younger than 65 years with unfavorable-risk PC was associated with a reduction in mortality. These data should provide reassurance for the continuous adoption of WPRT in patients with advanced disease while waiting for longer-term follow-up and mortality results from the POP-RT trial.

Abstract 010

Comparison Of Real-World Overall Survival In Subgroups Of Patients With Metastatic Castration-Sensitive Prostate Cancer Treated With Apalutamide Or Enzalutamide

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Background: Apalutamide (APA) and enzalutamide (ENZ) are androgen receptor pathway inhibitors (ARPIs) approved to treat metastatic castration-sensitive prostate cancer (mCSPC) in combination with androgen deprivation therapy (ADT). There have been no prior causal head-to-head studies comparing overall survival (OS) between APA and ENZ. This study compared OS at 24 months between APA and ENZ in a nationally representative sample of ARPI-naïve patients with mCSPC and reported treatment effects in important subgroups.

Methods: A causal analysis evaluating OS by 24 months in patients with mCSPC identified in linked US healthcare databases (PPS Analytics and Komodo Research Database; 1/1/2016-12/31/2023) was conducted and sensitivity analyses in subgroups were explored. The index date was the patients' first APA or ENZ dispensation, or pharmacy claim on or after 12/16/2019 (i.e., date of Food and Drug Administration approval of the most recent of both treatments– to ensure both were available). Patients were included if they had a prostate cancer (PC) diagnosis and metastasis in the absence of castration resistance and had ≥12 months of pre-index clinical activity and no other primary cancers. Follow-up spanned from index date until the latter of open insurance claim activity in Komodo or clinical activity in PPS, both no later than 12/31/2023. Patients were not censored if they discontinued the index ARPI, switched to another ARPI, initiated another advanced PC treatment, or progressed to castration resistance. Baseline demographic and clinical characteristics, overall, and in each subgroup were balanced using inverse-probability of treatment weighting. Comparison of OS between cohorts was evaluated with weighted Cox proportional hazards models.

Results: Overall, 1,810 APA and 1,909 ENZ patients were included. Baseline characteristics were similar in both cohorts (median age 73 years, 59% White, 23% Black, 78% Medicare). Of all metastasis types, bone metastasis was the most common in both cohorts (APA: 71.9%, ENZ: 72.8%), followed by nodal metastasis (APA: 49.0%, ENZ: 48.1%) and visceral metastasis (APA: 19.7%, ENZ: 20.8%). Median time between metastasis diagnosis and index date was 2.6 months for APA patients and 2.7 months for ENZ patients. By 24 months, APA treatment resulted in statistically significant 23% reduction in the risk of death as compared to ENZ (hazard ratio: 0.77 [95% confidence interval: 0.62, 0.96]; p=0.019). The treatment effect was robust in subgroups of patients with bone metastases (0.78 [0.62, 0.98]), ≥3 months between metastasis and ARPI initiation (0.59 [0.41, 0.84]), and >6 months between ADT initiation and ARPI initiation (0.55 [0.36, 0.83]) In subgroups of patients with earliest Gleason score <8 (0.81 [0.63, 1.05]), or earliest Gleason score 9-10 (0.67 [0.45, 1.00]), results were trending in favor of treatment with APA.

Conclusions: This study is meaningful in demonstrating survival in a nationally representative group of patients. Furthermore, this study featured patients with more diverse clinical characteristics than in the active treatment arms of registrational clinical trials of either agent. Initiation of APA resulted in statistically significant improved OS by 24 months relative to patients who initiated ENZ. This finding of OS benefit at 24 months was generally consistent in key clinical subgroups.

Abstract 011

Head-To-Head Comparison of Overall Survival In Subgroups of Patients With Metastatic Castration-Sensitive Prostate Cancer Initiating Apalutamide or Abiraterone Acetate – A Real-World Study

Benjamin Lowentritt[1], Mehmet A. Bilen[2], Sabree Burbage[3], Kruti Joshi[3], Ibrahim Khilfeh[3], Carmine Rossi[4], Shawn Du[3], Frederic Kinkead[4], Gordon Wong[4], Dominic Pilon[4], Lorie Ellis[3], Neal Shore[5]

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Background: Apalutamide (APA) and abiraterone acetate (ABI), two androgen receptor pathway inhibitors (ARPIs), used in combination with androgen deprivation therapy (ADT) have been approved to treat patients with metastatic castration-sensitive prostate cancer (mCSPC). Outside of phase 3 clinical trials, there is limited real-world data to assess overall survival (OS) in patients with mCSPC treated with ARPIs, and no head-to-head studies have been performed. This study compared OS by 24 months in ARPI-naïve patients with mCSPC initiating APA or ABI and explored the outcome in patient subgroups.

Methods: A causal analysis to evaluate OS by 24 months in patients with mCSPC using linked US claims data from the Komodo Research Database and clinical data from community urology practices (PPS Analytics; 1/1/2016-12/31/2023) was conducted. Subgroup analyses were explored in patients with key clinical characteristics. The index date was defined as the first APA or ABI dispensation or paid pharmacy claim on or after 9/17/2019 (i.e., date of Food and Drug Administration approval of the most recent of both agents – to ensure both were available). Patients with metastases in the absence of castration resistance and ≥12 months of pre-index clinical activity were included. Follow-up spanned from index date to the latter of insurance claim activity in Komodo or clinical activity in PPS, both no later than 12/31/2023. Patients were not censored if they discontinued the index ARPI, switched to another ARPI, initiated another advanced PC treatment, or progressed to castration resistance. Pre-index characteristics were balanced between cohorts, overall and in each subgroup, using inverse-probability of treatment weighting. Comparison of OS was evaluated with weighted Cox proportional hazards models.

Results: Overall, 1,879 APA and 2,073 ABI patients were identified (median age 72 years, 62% White, 74% Medicare). Most patients were diagnosed with bone metastasis (66% in both cohorts), 53% were diagnosed with nodal metastases, and ~22% were diagnosed with visceral metastases Median time between metastasis and ARPI initiation was similar between APA (2.5 months) and ABI (2.8 months) patients. By 24 months, APA patients overall had a statistically significant 26% reduction in their risk of death relative to ABI patients (hazard ratio: 0.74 [95% confidence interval: 0.59, 0.93]; p = 0.010). Subgroup analysis of OS in patients with ≥3 months between metastasis and ARPI initiation (0.57 [0.39, 0.83]), > 6 months between ADT initiation and ARPI initiation (0.62 [0.40, 0.97]), and earliest Gleason score <8 (0.75 [0.58, 0.98]) demonstrated a robust treatment effect. In subgroups with bone metastases (0.78 [0.61, 1.00]) and earliest Gleason score 9-10 (0.71 [0.47, 1.09]), results were trending in favor of treatment with APA.

Conclusions: This study assessed OS in a nationally representative population that included diverse subgroups of patients not previously represented in randomized clinical trials of APA or ABI. Patients with mCSPC who initiated APA had a significantly greater OS by 24 months relative to patients who initiated ABI. Exploratory analyses of OS by 24 months in clinical subgroups consistently favored APA over ABI. These findings can help inform treatment decisions in specific subgroups of patients with mCSPC.

Abstract 012

Precision and Target Tissue Acquisition in Prostate Biopsy: An In-Vitro Comparison of the Forsvall Needle Design versus Standard Tru-Cut Needle

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Introduction & Objectives: Accurate target biopsy is essential for effective prostate cancer diagnosis and treatment planning, especially due to tumour heterogeneity and current small targets found by MRI. The standard Tru-Cut needle, developed in 1969 and still used today, has an angled tip to enhance tissue collection but also causes deviation due to its asymmetrical design. This study compares target tissue collection between the Forsvall needle, a smooth streamlined 18G needle designed with a closed, balanced tip for enhanced precision in an MRI-first setting, and a standard Tru-Cut (Histocore 18G) needle in an in-vitro prostate biopsy study.

Materials & Methods: Ballistic gelatin blocks (8x8 cm) prepared per NATO standards simulated prostate tissue, with an 8 mm diameter central target representing an anterior or basal PI-RADS 4 lesion. The 25 cm long Tru-Cut and Forsvall needles were alternated across 15 unsupported and 10 supported punctures, simulating transperineal (TP) freehand and transrectal (TR) guided biopsies respectively. Supported conditions used a stabilizing fixed metal tube, mimicking transrectal ultrasound guidance. Laser alignment ensured precise pre-biopsy positioning. Needles were advanced 30 mm and fired. Primary outcome: target tissue length in the biopsy chamber. Secondary outcomes: needle tip deviation and biopsy length. Paired t-tests were used for statistical analysis.

Results: In unsupported (TP) scenarios, the Forsvall needle's mean deviation was 2.2 mm (95% CI: 1.96–2.44 mm) versus Tru-Cut's 6.0 mm (95% CI: 5.24–6.76 mm); ($p < 0.001$). In supported (TR) scenarios, Forsvall needle deviation averaged 2.3 mm (95% CI: 1.92–2.68 mm) versus Tru-Cut's 4.7 mm (95% CI: 4.05–5.35 mm); ($p < 0.001$). The Forsvall needle collected mean target tissue lengths of 4.8 mm (unsupported) and 4.0 mm (supported), compared to Tru-Cut's 0.0 mm and 0.2 mm, respectively ($p < 0.001$ for both). Mean biopsy lengths were longer for the Forsvall needle: 17.07 mm (unsupported) and 19.3 mm (supported) with a 20 mm chamber, versus 15.53 mm and 17.5 mm for Tru-Cut with a 19 mm chamber ($p < 0.05$).

Conclusions: Angled biopsy needles may miss distal targets due to deviation, potentially leaving cancer undetected. The Forsvall needle design demonstrates significantly increased precision in both simulated MRI first TP and TR prostate biopsy scenarios. These findings suggest potential benefits for more accurate modern prostate cancer diagnosis and improved patient care. A clinical trial is planned.

Abstract 013

The Impact of The Smartbx™ System on Prostate Cancer Detection

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Introduction and Objective: The gold standard for Prostate cancer (PCa) diagnosis is the Transrectal Ultrasonography-guided prostate biopsy (TRUS). The quality of biopsy tissue, crucial for accurate diagnosis, depends on factors like core length and preservation. Standard tissue collection methods drop each core directly into a formalin vial, which often fails to maintain the tissue's location and orientation. SmartBx™ is a novel device designed to maintain maximal length and integrity of prostate biopsy tissue, preserving the in-needle configuration and orientation. This study compared the PCa detection rate using the SmartBx™ system versus the standard method and examined the concordance between biopsy Gleason scores and those from radical prostatectomy (RP) specimens for both cohorts.

Methods: The experimental group included 171 patients who underwent SmartBx™ biopsies at University Hospital from 2022 to 2024. The control group comprised patients whose biopsies underwent traditional handling practices from 2019 to 2021. Data were retrospectively collected using Cerner Powerchart. Detection rates and Gleason score concordance were analyzed using T-tests, Chi-Square tests, and the κ-coefficient.

Results: OWhile biopsy lengths were similar between groups, the SmartBx™ group showed a higher rate of positive cores (25.21% vs. 22.53%, p = 0.01), which translated into a significantly higher detection rate for Gleason 7b cancers (31.90% vs. 18.92%, p < 0.001) and a lower rate for Gleason 6 and 9-10 cancers. According to figure 1, the SmartBx™ cohort had a significantly higher match rate of Gleason score at biopsy to Gleason score at radical prostatectomy, with 65.8% (25/38) compared to 44.2% (34/77) in the control cohort (p = 0.014). Gleason score concordance was higher in the SmartBx™ group (65.8% vs. 44.2%, p = 0.014, κ = 0.441).

Discussion and Conclusion: The SmartBx™ system improved cancer detection per core and shows promise in reducing over-diagnosis of low-risk prostate cancer while enhancing detection of intermediate-risk cancers. It also demonstrated greater Gleason score matching at RP, suggesting more precise biopsies. Although the κ-coefficient showed no significant difference in overall agreement, SmartBx™ has the potential to enhance PCa diagnosis, warranting further study.

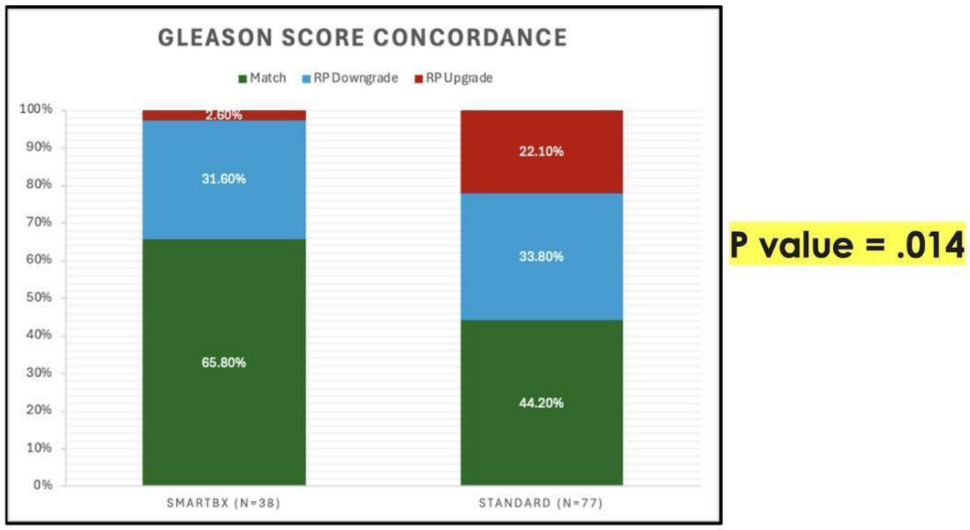

Figure 1. Gleason score assignment between both study cohorts. Gleason assignment: percentages in the graph present Gleason assignment per category (correct, upgraded on RP, downgraded on RP. *P* value was obtained through comparison of overall Gleason assignment between both cohorts with a $\chi 2$ test.

Abstract 014

Predictive Value of IsoPSA and ExoDx Biomarker Tests for Prostate Cancer: A Retrospective Cohort Analysis

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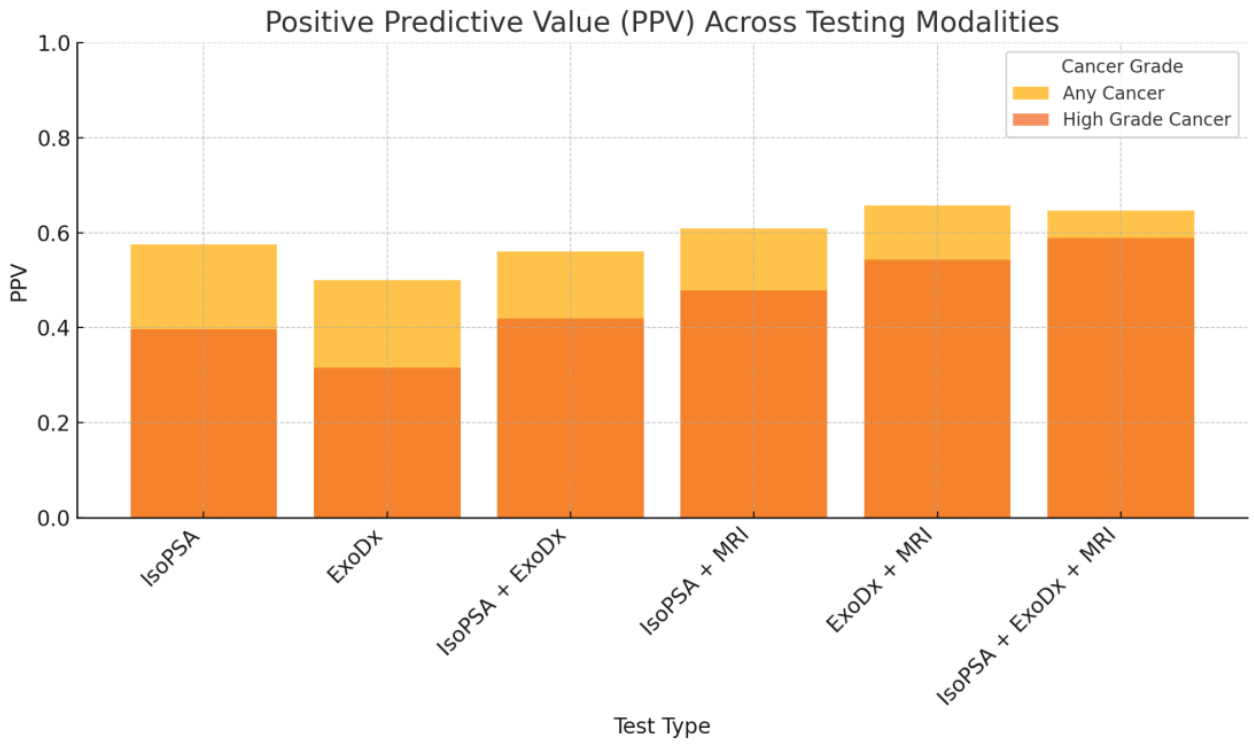
Background: Prostate-specific antigen (PSA) is a widely used biomarker for prostate cancer screening but lacks specificity for high-grade prostate cancer (HGPCa), leading to unnecessary biopsies. IsoPSA and ExoDx are newer biomarker tests as adjuncts to PSA for the prostate cancer workup decision making process. IsoPSA evaluates PSA isoforms associated with HGPCa, while ExoDx assesses genomic biomarkers in urine. This study assesses the results of IsoPSA and ExoDx testing in a cohort of patients who underwent subsequent prostate biopsy, including subgroup analyses by PSA levels and age, to assess if there is a cohort of patients for which the predictive value of these tests is improved.

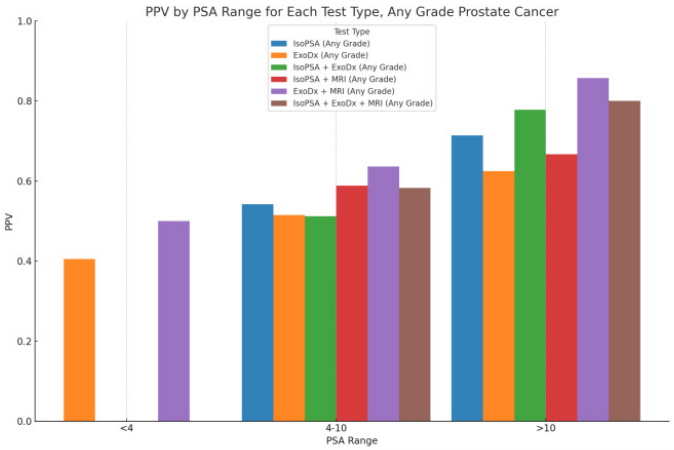
Methods: A retrospective review was conducted on patients from a private group practice who underwent IsoPSA and/or ExoDx testing, with subsequent biopsy results available. Patients were included if they had IsoPSA and/or ExoDx testing done within 6 months prior to the biopsy. Patients were excluded if they had a prior diagnosis of prostate cancer, or if incidental pathology from benign prostate surgery revealed prostate cancer. Data were analyzed for PPV and NPV for any grade of prostate cancer and HGPCa, with subgroup analyses for PSA levels (<4, 4–10, >10 ng/mL) and age (<65, ≥65 years). Combinations of IsoPSA, ExoDx, and MRI were also assessed.

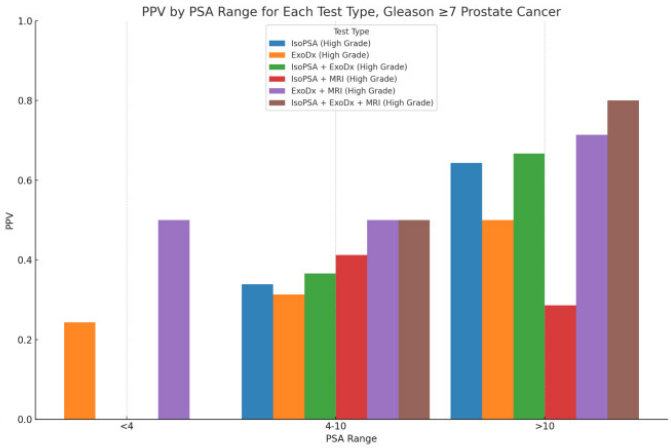
Results: Results from a total of 230 patients were included in the final analysis. For any grade of prostate cancer, IsoPSA alone demonstrated its highest PPV of 0.714 in patients with PSA >10 ng/mL, while ExoDx alone showed a PPV of 0.625 in the same subgroup. Combined ExoDx and MRI testing achieved the highest overall PPV of 0.857 for any grade of prostate cancer in the PSA >10 ng/mL subgroup (n=7). For HGPCa, IsoPSA alone achieved a PPV of 0.643 in patients with PSA >10 ng/mL; ExoDx alone



achieved a PPV of 0.5 for the same cohort. Among combination tests, IsoPSA and MRI yielded a PPV of 0.478 for HGPCa, while ExoDx and MRI yielded a PPV for HGPCa of 0.543. Combined IsoPSA, ExoDx, and MRI had the highest PPV for HGPca at 0.583. Subgroup analyses consistently showed improved PPVs in older patients (≥65 years) and those with higher PSA levels (>10 ng/mL).

Conclusions: IsoPSA and ExoDx offer incremental predictive value for prostate cancer diagnosis, particularly in specific subgroups. Combining these biomarkers with MRI further improves PPV for HGPCa. Further studies, with larger sample sizes to improve the power of subgroup analyses, are warranted.





subgroup	Testing Modality	Number of Patients	subgroup	Testing Modality	Number of Patients
	IsoPSA	92		**IsoPSA + MRI**	24
subgroup by PSA	PSA <4	6	subgroup by PSA	PSA <4	0
	PSA 4-10	71		PSA 4-10	18
	PSA >10	15		PSA >10	6
subgroup by Age	<65 years old	32	subgroup by Age	<65 years old	7
	≥65 years old	60		≥65 years old	17
	ExoDx	170		**ExoDx + MRI**	36
subgroup by PSA	PSA <4	37	subgroup by PSA	PSA <4	6
	PSA 4-10	116		PSA 4-10	23
	PSA >10	17		PSA >10	7
subgroup by Age	<65 years old	64	subgroup by Age	<65 years old	10
	≥65 years old	106		≥65 years old	26
	IsoPSA + ExoDx	51		**IsoPSA + ExoDx + MRI**	17
subgroup by PSA	PSA <4	0	subgroup by PSA	PSA <4	0
	PSA 4-10	42		PSA 4-10	12
	PSA >10	9		PSA >10	5
subgroup by Age	<65 years old	18	subgroup by Age	<65 years old	5
	≥65 years old	33		≥65 years old	12

Abstract 015

The Prostatype Genomic Classifier (PGC) Outperforms Clinical Models in Predicting Prostate Cancer-Specific Mortality (PCSM): A Multi-Cohort International Analysis

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Prostatype Genomics, Irvine, CA

The Prostatype Genomic Classifier (PGC) is a prognostic biomarker designed to improve risk stratification in prostate cancer patients. Developed and validated using biopsy samples from conservatively managed patients, PGC integrates a three-gene expression signature (IGFBP3, F3, and VGLL3) with clinical parameters such as prostate-specific antigen (PSA), Gleason score, and tumor stage at diagnosis. This study assesses the predictive accuracy of PGC for prostate cancer-specific mortality (PCSM) in three international cohorts and compares its performance to established clinical risk models, including D'Amico, NCCN, CAPRA, and EAU classifications.
This study included three independent cohorts from Sweden, Spain, and Taiwan (Table 1). Patients were selected based on the availability of the diagnostic biopsy and long-term follow-up, including prostate cancer-specific mortality (PCSM). PGC's predictive performance was compared to widely used clinical risk stratification models.
PGC demonstrated superior accuracy in predicting 10-year PCSM compared to clinical models (Table 2 and Figure 1)

Conclusion: The Prostatype Genomic Classifier (PGC) consistently outperforms traditional clinical risk models in predicting prostate cancer-specific mortality (PCSM) across multiple international cohorts. Kaplan-Meier survival analysis demonstrates significant stratification of patients into distinct risk groups, with PGC high-risk patients showing markedly higher PCSM over time. These findings support PGC's role as a superior prognostic tool for identifying patients at increased risk of prostate cancer progression and hence, to guide treatment decisions for men considering active surveilllance. Additional data from a US cohort, including African-American patients, is forthcoming.

Table 1. Baseline characteristics of prostate cancer patients in the Swedish, Spanish, and Taiwanese cohorts

COHORT	N	Age (Median, IQR)	PSA (Median, IQR)	ISUP 1	ISUP 2	ISUP 3	ISUP 4	ISUP 5	Rish Classification (Low/Int?High)
Sweden	316	67 (63-75)	9.1 (5.7-20)	17 (5%)	90 (29%)	95 (30%)	44 (14%)	70 (22%)	CAPRA: 30(10%) / 132(42%) / 154(49%)
Spain	93	67 (61-71)	8.1 (5.8-13.6)	26 (28%)	36 (39%)	21 (23%)	10 (11%)	-	NCCN: 17(18%) / 54(58%) / 22(24%)
Taiwan	98	72 (64-77)	16.7 (9.0-45.4)	14	19	22	14	29	NCCN: 6(6%) / 27(27%) / 65(65%)

Table 2. Comparison of the area under the curve (AUC) values for predicting 10-year prostate cancer-specific mortality (PCSM) using the Prostatype Genomic Classifier (PGC) versus established clinical models (D'Amico, NCCN, CAPRA, and EAU).

COHORT	PGC (AUC, 95% CI)	D'Amico	NCCN	CAPRA	EAU
Sweden	0.93 (0.89-0.98)	0.81 (0.72-0.90	-	8.88 (0.80-0.96)	90 (29%)
Spain	0.81 (0.61-1.00)	0.70 (0.53-0.88)	0.77 (0.56-0.97	-	0.70 (0.53-0.88)
Taiwan	0.90 (0.88-0.94)	-	16.7 (9.0-45.4)	-	1

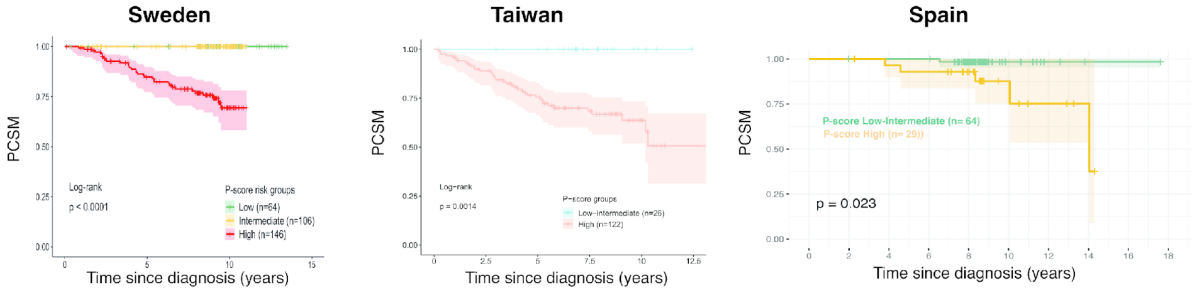

Figure 1. Survival Analysis: Kaplan-Meier curves for risk-stratified groups, with log-rank tests assessing survival differences. Virtually all PCSM occurred in men classified as high risk by PGC.