Podium Session 4: Oncology – Prostate
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POD 4.1

^{18}F-PSMA-1007 PET/CT vs. multiparametric MRI for the locoregional staging of prostate cancer: A phase 2, prospective, validating, paired-cohort trial

Nikhile Mookerji[1], Tyler Pfanner[2], Amaris Hui[2], Guocheng Huang[1], Patrick Albers[1], Rohan Mittal[3], Stacey Broomfield[1], Lucas Dean[1,4], Blair St. Martin[1,4], Niels-Erik Jacobsen[1,4], Howard Evans[1,4], Yuan Gao[3], Ryan Hung[3], Jonathan Abele[2], Peter Dromparis[3], Joema Felipe Lima[5], Tarek Bismar[5,6], Evangelos Michelakis[7], Gopinath Sutendra[7,8], Frank Wuest[8,9], Wendy Tu[2], Benjamin Adam[3], Christopher Fung[2], Alexander Tamm[2,6], Adam Kinnaird[1,4,6,8,9]

[1]Department of Surgery, Division of Urology, University of Alberta, Edmonton, Canada; [2]Radiology and Diagnostic Imaging, University of Alberta, Edmonton, Canada; [3]Laboratory Medicine and Pathology, University of Alberta, Edmonton, Canada; [4]Alberta Centre for Urologic Research and Excellence (ACURE), University of Alberta, Edmonton, Canada; [5]Pathology and Laboratory Medicine, University of Calgary, Calgary, Canada; [6]Alberta Prostate Cancer Research Initiative (APCaRI), University of Alberta, Edmonton, Canada; [7]Department of Medicine, University of Alberta, Edmonton, Canada; [8]Cancer Research Institute of Northern Alberta (CRINA), University of Alberta, Edmonton, Canada; [9]Oncology, University of Alberta , Edmonton, Canada

Introduction: Prostate-specific membrane antigen (PSMA) demonstrates overexpression in prostate cancer and correlates with tumor aggressiveness. PSMA positron emission tomography (PET) has been shown to be superior to conventional imaging for the metastatic staging of prostate cancer. The objective of this study was to determine the accuracy of ^{18}F-PSMA-1007 PET/CT compared to multiparametric magnetic resonance imaging (MRI, the current gold standard) in the primary locoregional staging of intermediate- and high-risk prostate cancers.

Methods: The Next Generation Trial (NCT05141760) was a phase 2, prospective, validating, paired-cohort trial assessing ^{18}F-PSMA-1007 PET/CT and MRI for locoregional staging of prostate cancer, with final histopathology as the gold-standard comparator in 134 patients undergoing prostatectomy. Radiologists, nuclear medicine physicians, and pathologists were blinded to preoperative clinical, pathology and imaging data. The primary outcome was correct identification of the prostate cancer tumor ('T') stage. The secondary outcomes were correct identification of the dominant nodule, laterality, extracapsular extension, and seminal vesical invasion.

Results: PSMA PET was superior to MRI for the accurate identification of the final pathologic T stage (45% vs. 28%, p=0.003). PSMA PET was also superior to MRI for the correct identification of the dominant nodule (94% vs. 83%, p=0.007), laterality (64% vs. 44%, p=0.001), and extracapsular extension (75% vs. 63%, p=0.014), but not for seminal vesicle invasion (91% vs. 85%, p=0.065).

Conclusions: In this trial, ^{18}F-PSMA-1007 PET/CT was superior to MRI for the locoregional staging of prostate cancer. These findings support the use of PSMA PET in the preoperative workflow of intermediate- and high-risk tumors.

Acknowledgements: Financial support provided by CUA and University Hospital Foundation.

POD 4.1. Table 1. Clinical and pathologic characteristics at time of radical prostatectomy

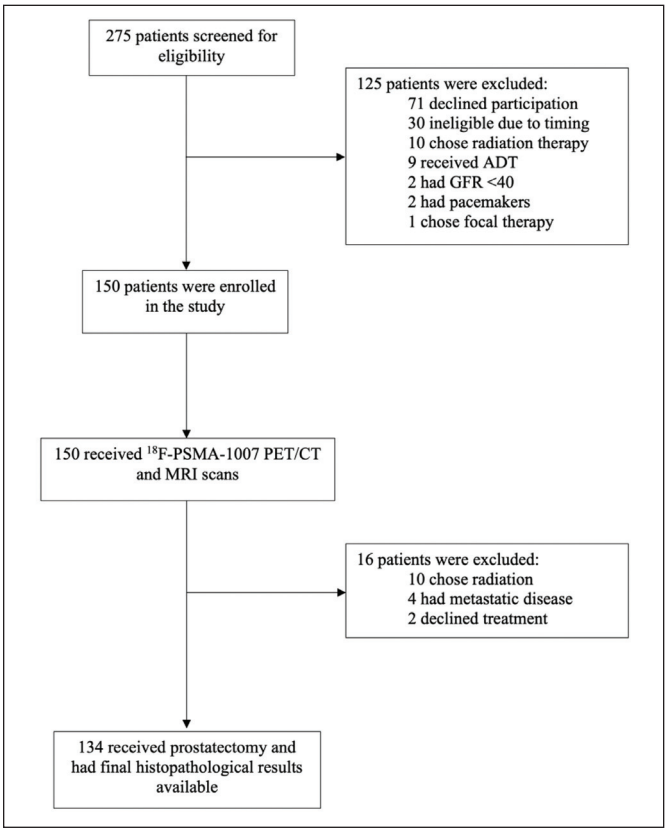
Characteristic	N=134
Mean age at prostatectomy, years (standard deviation)	62 (5.7)
Median preoperative PSA, ng/mL (IQR)	7.8 (6.7–10.9)
Final pathology Gleason group, n (%)	Benign–1 (1) GG 1–0 (0) GG 2–94 (70) GG 3–33 (25) GG 4–1 (1) GG 5–5 (4)
Final pathologic T stage, n (%)	pT0–1 (1) pT2a–5 (4) pT2b–4 (3) pT2c–59 (44) pT3a–44 (33) pT3b–21 (16) pT4–0 (0)
Final pathologic N stage, n (%)	N0–130 (97) N1–4 (3)
Median pathologic prostate volume, cc (IQR)	39 (31–47)
MRI PI-RADS score, n (%)	≤2–16 (12) 3–0 (0) 4–45 (34) 5–73 (54)
PSMA PET modified PROMISE scores, n (%)	0–0 1–54 (40) 2–42 (31) 3–38 (28)
Median dominant nodule pathologic volume, cc (IQR)	6.2 (3–13)
Median dominant nodule SUVmax on PSMA PET (IQR)	16.9 (10–27)

POD 4.1. Table 2. Correct identification of pathologic parameters by preoperative ^{18}F-PSMA-1007 PET/CT and MRI

Pathologic variable	MRI (n=134)	PSMA PET/CT (n=134)	p
Final pathologic T stage, n (%)	38 (28)	61 (45)	**0.003**
Dominant nodule, n (%)	112 (83)	126 (94)	**0.007**
Laterality, n (%)	60 (44)	86 (64)	**0.001**
Extracapsular extension, n (%)	84 (63)	100 (75)	**0.014**
Seminal vesical invasion, n (%)	115 (85)	122 (91)	0.065

POD 4.1. Table 3. Diagnostic accuracy of ^{18}F-PSMA-1007 PET/CT and MRI for laterality of disease, extracapsular extension, and seminal veside invasion

Parameter	MRI (95% CI)	PSMA PET/CT (95% CI)
Laterality		
Sensitivity	39% (31–49)	69% (60–77)
Specificity	93% (64–100)	27% (9–55)
PPV	98% (88–100)	88% (79–94)
NPV	15% (9–25)	10% (3–24)
Extracapsular extension		
Sensitivity	33% (22–46)	58% (45–70)
Specificity	90% (80–96)	90% (80–96)
PPV	75% (55–89)	84% (69–93)
NPV	59% (49–69)	70% (59–79)
Seminal vesicle invasion		
Sensitivity	33% (15–57)	57% (34–77)
Specificity	96% (89–98)	97% (92–99)
PPV	58% (29–84)	80% (51–95)
NPV	89% (81–93)	92% (86–96)



POD 4.1. Figure 1. Flow diagram of participants.

POD 4.2

ExactVu transperineal prostate biopsy as an alternative to MRI-fusion transrectal biopsy

Anna J. Black[1], Quentin Michalchuk[1], Martin Gleave[1], Miles Mannas[1]
[1]Department of Urologic Sciences, University of British Columbia, Vancouver, Canada

Introduction: Transperineal prostate biopsy (TPB) has become a popular alternative to transrectal biopsy (TRB), with a lower post-biopsy infection rate and comparable prostate cancer (PCa) detection rate. Ongoing innovation continues to improve TPB accuracy and accessibility. ExactVu, a novel micro-ultrasound system, produces significantly higher-resolution images than traditional ultrasound and has promise as a tool for cognitive fusion prostate biopsies. The aim of this study was to compare PCa detection, upgrade, and complication rates between transperineal and transrectal prostate biopsies.

Methods: A retrospective analysis was performed on all patients who underwent TRB or office-based cognitive TPB under local anesthesia from 2019–2023 at Vancouver General Hospital. ExactVu was used for all TPBs while targeted TRB was done using the UroNav system. Clinical parameters were compared between the groups using Student's T test, Chi-squared, or Fisher's exact test. Putative predictors of PCa on biopsy and upgrading on radical prostatectomy were investigated using logistic regression.

Results: Data was available for 663 patients (277 TPB and 386 TRB). When compared to the TRB group, a higher percentage of the TPB group had PI-RADs 5 lesions (38% vs. 28%, p<0.01) and a PSA >20 (13% vs. 5.6%, p<0.01). Most (89%) TRBs were combined systematic and targeted, while 75% of TPBs were targeted only. This corresponded to a median of 10 biopsy cores (IQR 8–13) in the TPB group compared to 15 cores (IQR 13–17) in the TRB group. Upgrading occurred in 24% of radical prostatectomy specimens, with no differences if a systematic vs. targeted biopsy was performed. Complications did not differ between TPB and TRB groups, although two TRB and zero TPB patients developed sepsis (p=0.5). PCa detection rates stratified by PI-RADs can be seen in Table 1. Biopsy approach was not a risk factor for PCa detection or upgrading on multivariable analysis.

Conclusions: Although the TPB group had fewer cores taken during biopsy, they had a non-significant but slightly higher rate of PCa diagnosis for PI-RADS 3–5 lesions than the TRB group. Additionally, no TPB patients developed sepsis and TPB was not a risk factor for upgrading on radical prostatectomy. This suggests that targeted TPB using ExactVu is an excellent alternative to traditional MRI fusion TRB.

POD 4.3

Impact of the Prostate Cancer-Empowerment Program (PC-PEP) on quality-adjusted life years (QALYs): A secondary analysis of a randomized clinical trial

Martha Ellen Foley[1], Gabriela Ilie[1,2,3], Ross Mason[1], Ricardo A. Rendon[1], Greg Bailly[1], David Bell[1], Cody MacDonald[3], Robert Rutledge[2]
[1]Department of Urology, Dalhousie University, Halifax, Canada; [2]Department of Radiation Oncology, Dalhousie University, Halifax, Canada; [3]Department of Community Health and Epidemiology, Dalhousie University, Halifax, Canada

Introduction: Undergoing curative prostate cancer treatment can have an impact on patients' mental and physical well-being. The Prostate Cancer-Patient Empowerment Program (PC-PEP) program is an intervention focused on improving quality of life throughout treatment. Short-Form Six-Dimension (SF-6D) is a health utility index that can be used as a surrogate marker of mental and physical well-being with direct correlation to quality-adjusted life years (QALYs). SF-6D is comprised of six dimensions of health, including physical functioning, role limitations, social functioning, pain, mental health, and vitality. Our study aimed to examine the impact of PC-PEP intervention on early compared to late intervention.

Methods: In a randomized trial of 128 men receiving prostate cancer treatment, 66 underwent immediate PC-PEP, whereas 62 entered a delayed waitlist control group, initially receiving six months of standard care before starting PC-PEP (Table 1). Participants completed the SF-6D, a preference-based measure designed to calculate QALYs at baseline, six and 12 months. Analyses were adjusted for Charlson index, age, time randomization, treatment modality, relationship status, and prescribed medication for mental distress.

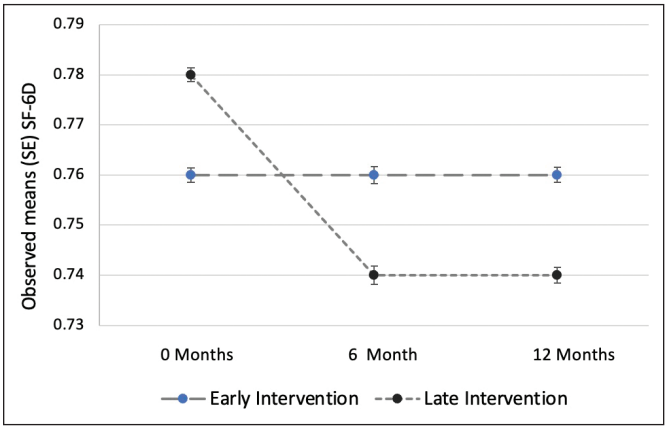
Results: At the start of the trial, QALYs were comparable between the two groups (-0.001, 95% CI -0.034, 0.032, p=0.9). QALYs decreased statistically significantly from baseline to six months among patients in the standard of care

POD 4.2. Table 1. Prostate cancer detection rates stratified by PI-RADs score for transrectal and transperineal prostate biopsies

	PI-RADs				Total
	2	3	4	5	
Prostate cancer present on biopsy					
Transrectal	6 (100%)	36 (40.9%)	132 (71.4%)	89 (84%)	264 (68.4%)
Transperineal	2 (20%)	17 (43.6%)	86 (73.5%)	91 (86.7%)	200 (72.2%)
Clinically significant prostate cancer present on biopsy					
Transrectal	1 (16.7%)	19 (21.6%)	79 (42.7%)	65 (61.3%)	165 (42.7%)
Transperineal	0 (0%)	10 (25.6%)	51 (43.6%)	74 (70.5%)	139 (50.2%)

POD 4.3. Table 1. Baseline characteristics of PC-PEP participants

Baseline characteristics, n (%) (unless stated)	Eligible study cohort (n =128)	Early intervention group (n= 66)	Late intervention group (control) (n= 62)
Demographic characteristics			
Age (years, mean ± SD)	66.2(±7.0)	65.4(±6.8)	67.1 (±7.2)
Race (white)	121	60 (91%)	61 (98%)
BMI (kg/m^2)	28.6 (±5.0)	28.8 (±5.0)	28.5 (±5.0)
Relationship status (yes)	120	59 (89%)	61 (98%)
Household income (>$30K CAD/year)	106	54 (82%)	52 (84%)
Education (university or above)	68	31 (47%)	37 (60%)
Employed (part or full-time)	45	22 (3%)	23 (37%)
Prescribed medication (no)	109	54 (82%)	55 (89%)
Charlson comorbidity index (median ± SD)	2.6 (±1.1)	2.5 (±1.1)	2.6 (±1.0)
Cigarette smoker (yes)	8	5 (8%)	3 (5%)
Study characteristics			
Time from randomization to treatment (days, mean ± SD)	67.3 (±38.5)	64.4 (±36.7)	70.3 (±40.5)
Treatment modality			
RP ± HT	62	29 (44%)	33 (53%)
RT ± HT + Salvage ± HT	66	37 (56%)	29 (47%)
Self-reported questionnaire			
SF-6D Health Utility Index, (mean ± SE)			
Baseline	0.77 (±0.0079)	0.76 (±0.0014)	0.78 (±0.0014)
6 months	0.75 (±0.0094)	0.76 (±0.0017)	0.74 (±0.0018)
12 months	0.75 (±0.0090)	0.76 (±0.0015)	0.74 (±0.0016)



POD 4.3. Figure 1. Observed means of SF-6D Health Utility Index scores among early and late intervention groups at baseline, 6 months, and 12 months.

group (-0.037, 95% CI -0.061 ,-0.013, p=0.003), but not among patients in the PC-PEP intervention (-0.009, 95% CI -0.032, 0.015, p=0.5]. At 12 months, the QALYs of patients in the control group was statistically significantly lower than that of the PC-PEP group (-0.037, 95% CI -0.070, -0.004, p=0.027) (Figure 1).
Conclusions: This study underscores the importance of early and proactive quality-of-life interventions in the management of prostate cancer.

POD 4.4

The association between 5-alpha reductase inhibitors and prostate cancer mortality

Robert J. Hamilton[1], Julian Chavarriaga[1], Najia Khurram[1], Cindy Lau[1], Jin Luo[1], Ning Liu[1], Maria Komisarenko[1], Girish S. Kulkarni[1], Christopher Wallis[1], Neil E. Fleshner[1], Antonio Finelli[1]

[1]Department of Surgical Oncology, Princess Margaret Cancer Centre, Toronto, Canada

Introduction: 5-alpha-reductase inhibitors (5-ARIs) are approved for treating benign prostatic hyperplasia and reduce prostate cancer (PCa) risk by 25%; however, trials also showed 5-ARIs to be associated with high-grade PCa. Whether 5-ARIs may increase mortality among those diagnosed with PCa remains unclear. We studied long-term outcomes of clinically localized PCa arising in men on 5-ARIs compared to non-users in a population-based cohort.
Methods: Men >65 years who developed PCa were studied using Ontario health administrative databases with complete pathologic abstraction. The association between 5-ARI use before PCa diagnosis and all-cause and PCa-specific mortality was examined. Cox proportional hazard models with inverse probability treatment weights (IPTW) were used.
Results: From 2003–2015, we studied 19 938 patients with PCa, available pathology, and complete variables of interest. Of these, 2112 (10.6%) were 5-ARI users and 17 826 (89.4%) were non-users before PCa diagnosis. During a median followup of 8.96 years, 6053 (30.3%) died, including 1047 (5.2%) from

PCa. Pre-diagnostic 5-ARI use appeared associated with increased overall and PCa-specific mortality in crude analyses; however, after IPTW, 5-ARI use was not associated with overall (HR 0.98, 95% CI 0.90–1.07), nor PCa-specific survival (HR 0.79, 95% CI 1.02–1.07).
Conclusions: To date, our study is the largest combined size and followup of a population-based cohort with detailed individual clinicopathologic details. Pre-diagnostic 5-ARI use was not associated with PCa-specific or all-cause mortality. These data offer reassuring safety data for patients using 5-ARIs for both benign and chemopreventive reasons.

POD 4.5

Micro-ultrasound in cancer-active surveillance (MUSIC-AS): A prospective paired diagnostic trial

Patrick Albers[1], Betty Wang[1], Stacey Broomfield[1], Anaïs Medina Martín[2], Wendy Tu[3], Christopher Fung[3], Peter Metcalfe[1], Adam Kinnaird[1,2,4,5,6]
[1]Division of Urology, University of Alberta, Edmonton, Canada; [2]Alberta Prostate Cancer Research Initiative, Universities of Alberta and Calgary, Edmonton, Canada; [3]Department of Radiology & Diagnostic Imaging, University of Alberta, Edmonton, Canada; [4]Cancer Research Institute of Northern Alberta , University of Alberta, Edmonton, Canada; [5]Alberta Centre for Urologic Research and Excellence, University of Alberta, Edmonton, Canada; Department of Oncology, University of Alberta, Edmonton, Canada
Introduction: Accurate assessment of tumor grade is critical for prostate cancer (PCa) active surveillance (AS). Multiple new technologies, including targeted biopsies and advanced imaging techniques (like multiparametric magnetic resonance imaging [MRI] and high-resolution micro-ultrasound [microUS]) may improve tumor risk stratification. Our primary objective was to compare MRI and microUS for the detection of Gleason grade group ≥2 during AS.
Methods: We conducted a prospective, paired diagnostic trial of 210 men with Gleason grade group 1 PCa managed by AS undergoing confirmatory biopsy between December 2022 and December 2023 at an academic tertiary care center. To date, 112 men have consented for the study and 75 have undergone their confirmatory biopsies and have their pathology results available. The primary outcome is the difference in detection of grade group ≥2 found using microUS + systematic biopsy vs. using MRI/US fusion + systematic biopsy. Statistical analyses used are Chi-squared test, Fisher's exact test, and McNemar test.
Results: Of the 75 men biopsied thus far, the average age of the participants was 62.4, with a median PSA of 7.4, and 33 (44%) with a family history of prostate cancer in first-degree relatives. Fifty-four (72%) men had a PRI-MUS score ≥3, and 43 (57%) had a PI-RADS score ≥3. Gleason grade group ≥2 was identified in 33 (44%) men. There was no difference in the detection of Gleason grade group ≥2 between the imaging techniques, with all cancers detected by microUS + systematic biopsy, as well as using MRI/US fusion + systematic biopsy. One limitation of this trial is the single-center nature, although four international sites are currently in the process of being added to the study.
Conclusions: The detection of upgrading to Gleason grade group ≥2 during AS appears similar when using microUS or MRI to inform prostate biopsy.

POD 4.6

Eliminating opioid use in robotic radical prostatectomy patients: A quality improvement and patient safety initiative

Emily Whelan[1,2], John Kell[1,2], Ryan Groll[1,2], Peter Vlaovic[1,2], Rajiv Singal[1,2]
[1]Division of Urology, University of Toronto, Toronto, Canada; [2]Division of Urology, Michael Garron Hospital, Toronto, Canada
Introduction: The opioid epidemic is a serious healthcare concern and is being fuelled, in part, by inappropriate or over-prescription of opioids by physicians. Previous research has shown that patients undergoing robotic radical prostatectomy (RRP) require little, if any opioids postoperatively; however, this has never been validated in the Canadian experience. Given this, we aimed to decrease opioid use in the postoperative period in opioid-naive patients undergoing RRP at Michael Garron Hospital by 75% between August 1, 2022, and June 30, 2023, as part of a quality improvement and patient safety initiative.
Methods: This initiative implemented formalized nursing education, comprehensive preprinted orders, and standardized patient education to reduce opioid use following RRP. The primary outcome observed was opioid requirements after surgery. Balancing and process measures were monitored as well.
Results: Pre-intervention data reported that 86% of patients received opioids during their hospital stay, and only 29% of prescribed hydromorphone tabs were consumed after discharge. After the intervention, no opioids were required after RRP either in hospital or post-discharge. Pain scores, as well as patient satisfaction scores, were unchanged between the pre- and post-intervention groups.
Conclusions: This was the first Canadian intervention of its kind to demonstrate a sustainable, multidisciplinary approach to opioid reduction in RRP. This intervention surpassed the initial goal of simply reducing opioid use; rather, we were able to eliminate opioid use completely. Given the success of this initiative, we would suggest that it be adopted as standard of care in all Canadian robotics programs performing RRP.