

Initial Report of a Randomized Trial Comparing Conventional- vs Conventional plus Fluciclovine (¹⁸F) PET/CT Imaging-Guided Post-Prostatectomy Radiotherapy for Prostate Cancer

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Disclosures



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- Dr. Ashesh B. Jani:
 - Employee: Emory University / The Emory Clinic
 - Advisory Board: Blue Earth Diagnostics, Ltd. (last in 3/2018)
- Dr. Mark Goodman:
 - Royalties: Nihon MediPhysics Co, Ltd.
- Dr. David Schuster:
 - Consultant: Syncona; AIM Specialty Health; Global Medical Solutions Taiwan; Progenics Pharmaceuticals, Inc.
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- Emory University:
 - Blue Earth Diagnostics, Ltd. (Cassette Arrangement)

Background

- The decision to offer radiation after prostatectomy for patients with recurrent prostate cancer is complex
 - High failure rates
 - More accurate radiation therapy decisions and treatment planning needed
 - Limitations of conventional imaging

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2020 AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ASTRO) ANNUAL MEETING



EMPIRE-1 Trial

EMORY

<u>Emory Molecular</u> Prostate Imaging for <u>Radiotherapy</u> Enhancement

NIH RO1 CA169188

ClinicalTrials.gov: NCT01666808

Jani & Schuster

Patient consent / enrollment / eligibility: Adenocarcinoma of prostate, post RRP Detectable PSA **Negative Bone Scan** CT or MR of abd/pelvis showing no extra-pelvic metastases Radiotherapy Decision Attestation Sheet completed by provider

Stratify:

Pathologic Risk Factors [(one or more of: ECE, SV invasion, +margins, or node+) vs none] Pre-radiotherapy PSA level (≤2.0 ng/mL vs > 2.0 ng/mL) Androgen deprivation therapy intent (yes vs no)



FACBC scan done

Radiotherapy decisions and planning based on FACBC scan.

Fluciclovine (¹⁸F) Findings/ Treatment decision:

1. Extra-pelvic uptake: Abort XRT 2. Pelvic nodal uptake: Prostate bed (64.8-70.2/1.8Gy) Pelvis

(40.5-50.4/1.8Gy)

3.

Prostate-bed only uptake: Prostate bed (64.8-70.2/1.8Gy)

4.

No uptake: Prostate bed (64.8-70.2/1.8Gy)

Failure-Free Survival

- Three years after treatment, failure-free survival rates were higher in the PET arm
- FFS benefit remained four years after treatment
- Median follow-up
 - Overall: 2.48 Y
 - Failure-free pts: 3.06 Y



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Provider-Reported Toxicity (CTCAE v.5.0)

No significant differences in maximum:

- Acute GU
- Acute Gl
- Late GU
- Late Gl

Suggests treatment to PET-directed volumes was tolerable.

Patient-reported toxicity (AUA & EPIC-CP) analysis pending

Acute GU (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	7 (8.64%)	53 (65.43%)	18 (22.22%)	3 (3.70%)	0.255
Arm B/2 (PET)	3 (3.95%)	55 (72.37%)	18 (23.68%)	0 (0.00%)	
Acute GI (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Arm A/1 (no PET)	23 (28.40%)	47 (58.02%)	11 (13.58%)	0 (0.00%)	0.436
Arm B/2 (PET)	18 (23.68%)	42 (55.26%)	16 (21.05%)	0 (0.00%)	
Late GU (max)	Grade 0	Grade 1	Grade 2	Grade 3	P-value
Late GU (max) Arm A/1 (no PET)	Grade 0 6 (7.50%)	Grade 1 32 (40.00%)	Grade 2 37 (46.25%)	Grade 3 5 (6.25%)	P-value 0.678
Late GU (max)Arm A/1 (no PET)Arm B/2 (PET)	Grade 0 6 (7.50%) 10 (13.33%)	Grade 1 32 (40.00%) 29 (38.67%)	Grade 2 37 (46.25%) 31 (41.33%)	Grade 3 5 (6.25%) 5 (6.67%)	P-value 0.678
Late GU (max) Arm A/1 (no PET) Arm B/2 (PET) Late GI (max)	Grade 0 6 (7.50%) 10 (13.33%) Grade 0	Grade 1 32 (40.00%) 29 (38.67%) Grade 1	Grade 2 37 (46.25%) 31 (41.33%) Grade 2	Grade 3 5 (6.25%) 5 (6.67%) Grade 3	P-value 0.678 P-value
Late GU (max)Arm A/1 (no PET)Arm B/2 (PET)Late GI (max)Arm A/1 (no PET)	Grade 0 6 (7.50%) 10 (13.33%) Grade 0 47 (58.75%)	Grade 132 (40.00%)29 (38.67%)Grade 123 (28.75%)	Grade 237 (46.25%)31 (41.33%)Grade 210 (12.50%)	Grade 3 5 (6.25%) 5 (6.67%) Grade 3 0 (0.00%)	P-value 0.678 P-value 0.580

Conclusions/Summary

- Randomized trial of imaging tests with primary cancer control endpoint are important but uncommon
- First trial of PET over conventional imaging alone for post-prostatectomy radiation therapy (Note: single institution study where radiotracer was invented)
- Inclusion of fluciclovine (¹⁸F) resulted in significant improvement in failure rate at 3Y

 Integration of novel PET radiotracers into XRT decisions and planning warrant further study



EMPIRE-2 Trial Emory Molecular Prostate Imaging for Radiotherapy Enhancement NIH RO1 CA226992 Jani & Schuster

Aims 2 & 3

ClinicalTrials.gov: NCT03762759 2019-2024 n=140 (enrolled ~50)



PET Findings / **Treatment decision:** 1. Extra-pelvic uptake: Abort XRT 2. Pelvic nodal uptake: Prostate bed + Pelvis XRT (Boost sites of uptake) 3. Prostate-bed only uptake: Prostate bed XRT (Boost sites of uptake) 4. No uptake: Prostate bed XRT (no boost)

Boost:

Pelvic nodes: 54-56 Gy Prostate bed: 70-76 Gy