Initial Report of a Randomized Trial Comparing Conventional- vs Conventional plus Fluciclovine (\(^{18}\text{F}\)) 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.

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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
Background

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

*PRIMARY ENDPOINT

3Y-FFS: 63.0% vs 75.5%
P=0.003 (Z test)

4Y-FFS: 51.2% vs 75.5%
P < 0.001 (Z test)
Provider-Reported Toxicity (CTCAE v.5.0)

No significant differences in maximum:
- Acute GU
- Acute GI
- Late GU
- Late GI

Suggests treatment to PET-directed volumes was tolerable.

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

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<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>P-value</th>
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<td><strong>Acute GU (max)</strong></td>
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<td>Arm A/1 (no PET)</td>
<td>7 (8.64%)</td>
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<td>Arm B/2 (PET)</td>
<td>3 (3.95%)</td>
<td>55 (72.37%)</td>
<td>18 (23.68%)</td>
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<td><strong>Acute GI (max)</strong></td>
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<td>Arm A/1 (no PET)</td>
<td>23 (28.40%)</td>
<td>47 (58.02%)</td>
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<td>Arm B/2 (PET)</td>
<td>18 (23.68%)</td>
<td>42 (55.26%)</td>
<td>16 (21.05%)</td>
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<td><strong>Late GU (max)</strong></td>
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<td>Arm A/1 (no PET)</td>
<td>6 (7.50%)</td>
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<td>5 (6.67%)</td>
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<td><strong>Late GI (max)</strong></td>
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<td>Arm A/1 (no PET)</td>
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<td>Arm B/2 (PET)</td>
<td>49 (65.33%)</td>
<td>20 (26.67%)</td>
<td>6 (8.00%)</td>
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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 \(^{18}F\) resulted in significant improvement in failure rate at 3Y**

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