Abstract
CT225

Quantitative assessment of PSMA imaging before and after ^{177}Lu-PSMA-617 treatment in a Ph I/II trial

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Background

Prostate Specific Membrane Antigen targeted radiotherapy (**PSMA-TRT**) allows exquisite delivery of ionizing radiation

A single dose-intense cycle of **^{177}Lu-PSMA-617** is effective in pretreated mCRPC w/o requiring PSMA+ PET to enroll[1]

Quantitative analyses of pre-treatment PSMA PET may allow for better patient selection and prediction of toxicities.

Analyses of sequential PET images may also provide insights that may be associated with longer term outcomes.

Our previous analysis demonstrated association of PSMA PET signal with overall survival (OS) and PSA responses, as well as trends with adverse events (Nauseef GU ASCO 2022).

Here we present long-term follow up data and expanded imaging correlatives from our completed phase I/II study.

Methods

Entry criteria: progressive mCRPC after at least one prior potent AR pathway inhibitor and prior chemotherapy (excepting men ineligible for or refusing of chemotherapy) with allowance for prior radionuclides.

Treatment was fractionated-dose (D1 and D15) of 177Lu-PSMA-617.

TRAQinform IQ (AIQ Solutions) was used to identify, track, and quantify regions of interest suspicious of cancer (lesion-ROI) on PSMA PET/CT.

Measurements included SUVmean across all lesion-ROI, volume of lesion-ROI, and SUVtotal (sum of SUV in all lesion-ROI), as well as changes after treatment, including in PSMA-expressing healthy tissues.

Associations with survival were tested via Cox proportional hazard models in univariate analyses and associations with adverse events (AEs) and PSA responses were via assessed via Wilcoxon rank sum tests.

Results

32 pts (of 50 total in the study between 1/2017-2/2021) had pre- and post-treatment imaging suitable TRAQinform IQ analysis and associated survival analyses.

PSA response of 50% was observed in 21/32 (66%) of which 16 were confirmed.

No imaging variable predicted PSA30 or PSA50, although an association was observed in pretreatment SUVmean and lesion-ROI volume reduction.

No imaging variable was significantly associated with OS.

Pretx SUVmean was associated with mPFS (HR 0.85, 95% CI 0.74, 0.98, p=0.023).

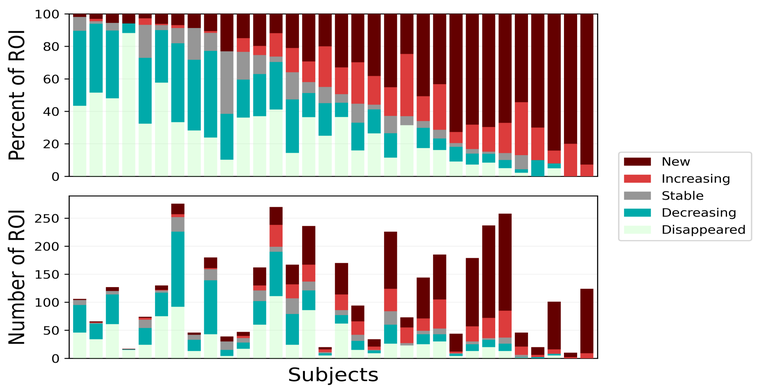
Adverse effects

Anemia was associated with non-lesion-ROI skeleton SUVtotal in pre- (p=0.027) and post treatment (p=0.007).

Higher pre-treatment salivary gland uptake (SUVmean) was associated with more xerostomia (p=0.11).

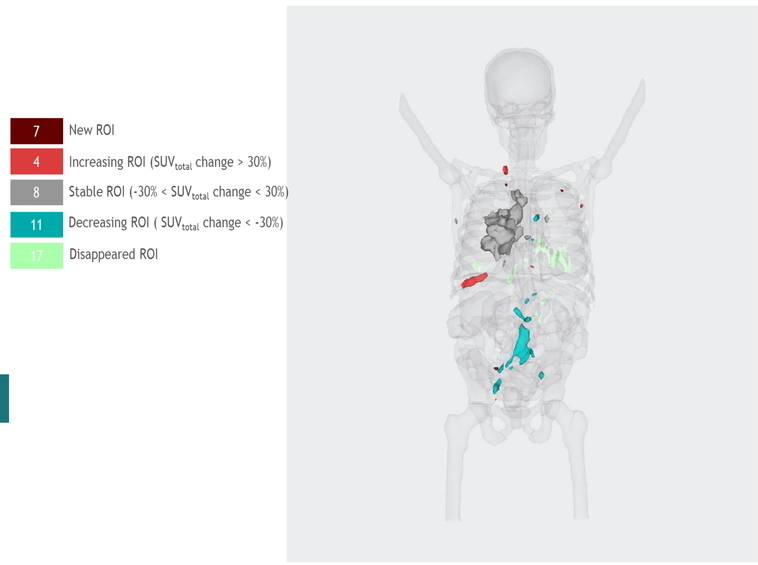
Fatigue was associated with a variety of and post-treatment bowel SUVmax (p=0.030). variables including salivary SUVs (mean, max, and total).

Heterogeneity plot – 32 patients



TRAQinform IQ Representative Image

Automatically detects and matches lesions across time points



Conclusions

Pre-treatment and pre- to post-treatment 68Ga-PSMA11-PET data analyzed may be associated with outcome.

While a strength of this study is the prospective nature of patient enrollment and fixed imaging timepoints, our associations are limited by small sample size.

Expansion of this analysis to larger datasets may improve our ability to predict treatment response and toxicity by body-wide PSMA detection.

ClinicalTrials.gov Identifier: **NCT03042468**.

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