

Predictive role of [¹⁸F]PSMA-1007 PET parameters in biochemical recurrence-free survival in high-risk prostate cancer patients receiving neoadjuvant hormonal treatment

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Aim

To investigate the **relationship** between [¹⁸F]PSMA-1007 PET parameters and biochemical recurrence-free survival (**BCR-FS**) in high-risk primary prostate cancer patients receiving **neoadjuvant hormonal treatment**.

Methods

This **prospective randomized, double-blind, placebo-controlled phase II trial** included **89** high-risk primary prostate cancer patients who received a pelvic [¹⁸F]PSMA-1007 PET/MRI prior to and following neoadjuvant hormonal treatment. Patients were randomly assigned to neoadjuvant hormonal treatment with degarelix + apalutamide (n=45) or degarelix + matching placebo (n=44) for 3 months followed by radical prostatectomy and extended pelvic lymph node dissection. The following [¹⁸F]PSMA-1007 parameters were determined on the pre- and posttreatment [¹⁸F]PSMA-1007 PET: (i) **semi-quantitative [¹⁸F]PSMA-1007 PET parameters** such as SUV_{max}, SUV_{mean}, PSMA-expressing volume and total lesion activity, and their absolute and relative differences; (ii) **number of pelvic lymph node, distant and extraprostatic metastases** determined on [¹⁸F]PSMA-1007 PET; (iii) [¹⁸F]PSMA-1007 PET-based **response criteria** (aPERCIST and RECIP 1.0); (iv) **molecular imaging TNM-stage** as determined by PROMISE version 2.

Results

Thirty-five percent of included patients developed BCR within a median follow-up time of 38 months. **Multivariate regression analyses** revealed that PSMA-expressing volume posttreatment, the number of distant metastases pretreatment and miN1+miN2 vs. miN0 pretreatment were significant predictors of BCR-FS with hazard ratios of 1.184 (95% CI 1.070-1.309, p=0.0010), 5.820 (95% CI 2.498-13.561, p<0.0001) and 4.024 (95% CI 1.740-9.307, p=0.0011), respectively.

PSMA PET parameter	Hazard ratio	p-value
PSMA volume posttreatment (ml)	1.184	0.0010
No. distant metastases pretreatment	5.820	<0.0001
miN1+miN2 vs. miN0 pretreatment	4.024	0.0011

Conclusions

Our results indicate that [¹⁸F]PSMA-1007 PET can be a tool to **monitor response to neoadjuvant hormonal treatment** and that [¹⁸F]PSMA-1007 PET can be used to aid in **patient stratification** for determining which patients would benefit from additional (neo)adjuvant treatment.