

Changes in planned disease management after piflufolastat F 18 PET/CT in men with biochemically recurrent prostate cancer and low PSA levels: a secondary analysis of results from the CONDOR study

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Introduction and Overall Goal: Piflufolastat F 18 is a PSMA-targeted radiopharmaceutical approved in the US for imaging prostate cancer (PCa) patients both at the time of initial staging and at disease recurrence. The overall goal of the CONDOR study was to demonstrate the utility of piflufolastat F 18 PET/CT in patients with biochemically recurrent (BCR) PCa and negative/equivocal baseline standard imaging.

Specific Aims: Here we report the changes in intended management in the subset of patients with very low/low PSA levels (<0.5 ng/mL).

Rationale and Background: The clinical utility of piflufolastat F 18 scanning in men with very low/low PSA levels (<0.5 ng/mL) and a detection rate of ~36% has not been previously described. In a phase 3 study of patients with BCR PCa, we reported that nearly two-thirds (63.9%; 131/205) of participants had a change in their intended disease management plan based on pre- and post-piflufolastat F 18 PET/CT management questionnaires (MMQs) completed by the treating physicians.

Methods: Men ≥ 18 years of age with a rising PSA after definitive PCa therapy and negative or equivocal imaging were enrolled. A single ~9 mCi (333 MBq) dose of piflufolastat F 18 was administered followed by PET/CT from mid-thigh through skull vertex 1-2 hours later. Prior to scanning, the treating physicians completed a pre-PET MMQ to document the initial intended management plan for their patients based on available clinical information including baseline conventional imaging results. After PET, they completed a post-PET MMQ and recorded the management plan in light of PET findings. Treatment recommendations that differed from the pre-scan recommendations were reported as changes in the intended management plan.

Results: 208 men (median PSA 0.8 ng/mL [range 0.17-98.45], n=202) underwent piflufolastat F 18-PET/CT. 200 evaluable patients had both a baseline PSA value and completed MMQs. Of 131 patients with a recorded change in intended management, 127 had an evaluable baseline PSA level. Of the 69 patients with baseline PSA levels ≤ 0.5 ng/mL, 27 (39.1%) recorded a change in intended disease management based on positive (n=20) or negative (n=7) PET, including salvage local to systemic therapy (n=15); systemic to local therapy (n=3); observation to treatment (n=5); and treatment to observation (n=4). An additional 15 patients (21.7%) had recommended bidirectional change in management (e.g. salvage RT+ADT) and are excluded in this report. Specific treatment intensification/de-intensification plans are under investigation.

Discussion and Conclusions: The frequency of changes in intended disease management observed in BCR PCa patients with low baseline PSA levels (≤ 0.5 ng/mL) was 39.1%. Both negative and positive PET/CT results impacted treatment recommendations and can provide useful and actionable information. NCT02981368