Impact of positron emission tomography with ^{18}F-fluciclovine on management of patients with suspected recurrence of prostate cancer: results from the LOCATE trial

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Background

Early and accurate localization of metastases facilitates treatment when tumors are small and most amenable to localized therapy, and may guide clinicians in making management plans regarding salvage therapy. The positron emission tomography/computed tomography (PET/CT) radiotracer, ^{18}F-fluciclovine, is approved for use in Europe and the USA for the localization of metastases in patients with suspected biochemical recurrence of prostate cancer. The prospective, multicenter LOCATE study assessed the impact of ^{18}F-fluciclovine on the planned treatment for patients with recurrence of prostate cancer after curative-intent primary therapy.

Methods

Men who had undergone curative-intent treatment of histologically confirmed prostate cancer, but who were suspected to have recurrence based on rising prostate-specific antigen (PSA) levels were enrolled prospectively. Each had negative or equivocal findings on standard-of-care imaging. ^{18}F-Fluciclovine PET/CT was performed according to standardized protocols. Treating physicians completed a questionnaire regarding the patient's management plan pre- and post-scan, recording changes to treatment modality (e.g., salvage radiotherapy to systemic androgen deprivation therapy) as 'major', and changes within a modality (e.g., modified radiotherapy fields) as 'other'.

Results

Between June 2016 and May 2017, 213 evaluable patients (median age = 67 years; median PSA = 1.00 ng/mL; median time from initial diagnosis = 54 months) were enrolled. ^{18}F-Fluciclovine detected lesions in 122/213 (57%) patients, with a detection rate of 30% in the prostate/bed and 38% in extraprostatic regions (lymph nodes, 29%; soft tissues, 2.3%; and bone, 11%). The detection rate was broadly proportional to the pre-scan PSA level. Subject-level detection was shown to be 31% among those with the lowest PSA (0–0.5ng/mL) and 95% among patients with a PSA > 10 ng/mL, while in the prostate/bed and extra prostatic regions the detection rate ranged from 16–53% and 17–63%, respectively. For patients with PSA > 0.5–1.0 ng/mL, subject-level positivity was 50%, rising to 66% for PSA > 1.0–2.0 ng/mL.

Overall, 126/213 patients (59%) had a change in management post-scan; 98/126 (78%) of these were 'major' and 88/126 (70%) were informed by positive PET/CT findings. The most frequent major

changes were from salvage or non-curative systemic therapy to watchful waiting (32/126, 25%), from non-curative systemic therapy to salvage therapy (30/126, 24%) and from salvage therapy to non-curative systemic therapy (11/126, 9%).

Conclusions

Despite negative/equivocal standard imaging, ^{18}F-fluciclovine PET/CT revealed one or more sites of disease recurrence in the majority of men with prostate cancer who were scanned, and frequently resulted in a change in management post-scan. Over three-quarters of all management changes were considered major. ^{18}F-Fluciclovine PET/CT has the potential to improve management, but further investigation of the impact of such management changes on patient outcomes is warranted.

Conflicts of interest and funding

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