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Diagnostic and staging performance of CAIX-targeted [⁶⁸Ga]Ga-DPI-4452 PET/CT in clear cell renal cell carcinoma: A prospective trial

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Background

Conventional imaging lacks accuracy for primary characterization and metastatic staging of clear cell renal cell carcinoma (ccRCC). This study evaluated [⁶⁸Ga]Ga-DPI-4452 PET/CT for ccRCC identification and staging, and directly compared its efficacy with [¹⁸F]FDG.

Methods

Patients were prospectively recruited into two cohorts. Cohort A (n=30, suspected renal masses scheduled for surgery or biopsy) evaluated the initial diagnostic and staging performance. Cohort B (n=30, suspected/confirmed metastatic ccRCC) underwent paired [⁶⁸Ga]Ga-DPI-4452 and [¹⁸F]FDG PET/CT within 14 days to assess comparative staging efficacy. Reference standards included histopathology and/or composite clinicoradiological follow-up (≥3 months).

Results

A total of 60 patients (38 men, 22 women; overall median age, 58 years) were enrolled. In Cohort A (23 ccRCC, 7 non-ccRCC/benign), [⁶⁸Ga]Ga-DPI-4452 PET/CT identified primary ccRCC with 100% sensitivity and 85.7% specificity (AUC for SUVmax: 0.913). For systemic staging, [⁶⁸Ga]Ga-DPI-4452 PET/CT detected 42 metastatic lesions versus 23 on CT/MRI, identifying 19 additional lesions (an 82.6% increase). Tracer uptake correlated strongly with tissue CAIX H-score ($r = 0.84$, $P < 0.001$). In the initial analysis of Cohort B, [⁶⁸Ga]Ga-DPI-4452 significantly outperformed [¹⁸F]FDG by successfully detecting numerous FDG-negative metastases, and it exhibited markedly higher uptake in ccRCC lesions (median SUVmax: 35.4 vs. 8.2 for FDG, $P < 0.01$). Importantly, [⁶⁸Ga]Ga-DPI-4452 PET findings identified previously unknown metastatic regions in 40% of patients and directly altered clinical management in 16.7% (5/30) (e.g., shifting to active surveillance or enabling curative-intent surgery). No tracer-related adverse events occurred across either cohort.

Conclusions

[⁶⁸Ga]Ga-DPI-4452 PET/CT is a safe and highly effective imaging tool for ccRCC. By successfully characterizing primary renal masses and demonstrating preliminary superiority over CT/MRI and [¹⁸F]FDG in detecting hidden metastatic burdens, it refines systemic clinical staging and directly empowers oncologists to optimize personalized treatment decisions.

Clinical trial identification

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Legal entity responsible for the study

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Disclosure

All authors have declared no conflicts of interest.

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