Under strict embargo: 01.00 CEST, Monday 04 July

**New imaging technology less accurate than MRI at detecting prostate cancer, trial shows**

A team of researchers in Australia and New Zealand has found that MRI scans can detect prostate cancer more accurately than the newer, prostate-specific - PSMA PET/CT scanning technique.

The findings are being presented today at the European Association of Urology’s Annual Congress (EAU22), in Amsterdam.

Prostate-specific membrane antigen (PSMA) PET/CT scans, approved by the US FDA in 2020, use a radioactive dye to ‘light up’ areas of PSMA, which is found on the surface of prostate cancer cells. They are presently used to manage prostate cancer, as they can accurately measure the progression or recurrence of the disease. So, in this trial the researchers set out to find if they could be used to diagnose prostate cancer as well.

The PEDAL trial recruited 240 patients across five hospital groups who were at risk of prostate cancer. Every patient was given both an MRI scan and a PSMA PET/CT scan. If imaging suggested the presence of prostate cancer, a biopsy was performed by the patient’s urologist.

The MRI scans picked up abnormalities in 141 patients, while the PSMA PET/CT scans picked up abnormalities in 198 patients. A total of 181 patients (75%) underwent a prostate biopsy, and subsequently 82 of those patients were found to have clinically significant prostate cancer.
Since each patient had both types of scans, the researchers could assess which type had more accurately detected those patients who had prostate cancer. The researchers found that MRI scans were significantly more accurate at detecting any grade of prostate cancer than the PSMA PET scans (0.75% for MRI vs 0.62% for PSMA PET).

Associate Professor Lih-Ming Wong, Consultant Uro-oncologist at St Vincent’s Hospital in Melbourne (AU) headed the research team. He said: “Our analysis found that MRI scans were better than PSMA-PET for detecting any grade of prostate cancer. When we looked only at clinically significant prostate cancers, there was no difference in accuracy. As this study is one of the first to explore using PSMA-PET to diagnose cancer within the prostate, we are still learning and adjusting how to improve using PSMA-PET in this setting.

Although detection thresholds will be fine-tuned as diagnostic use develops, Associate Professor Wong believes the trial has important lessons for clinicians.

He says: “This study confirms that the existing ‘gold standard’ of pre-biopsy detection – the MRI – is indeed a high benchmark. Even with fine-tuning, we suspect PSMA PET/CT won’t replace the MRI as the main method of prostate cancer detection. But it will likely have application in the future as an adjunct to the MRI, or for people for whom an MRI is unsuitable, or as a single combined "diagnostic and staging” scan for appropriately selected patients.”

He continues: “This is why these types of robust studies are crucial so we can better understand the part these technologies can play at every stage of the cancer journey, and progress the management of prostate cancer.”

Professor Peter Albers, Düsseldorf (DE) of the European Association of Urology’s Chief Scientific Office, comments: “New diagnostic tools need to be tested as carefully as new drugs, so we welcome the findings of this remarkable Phase III trial, which showed that MRI was superior in the detection of any prostate cancer.
“It also showed that PSMA PET/CT was not inferior to MRI in the detection of clinically significant cancers (ISUP 2 and higher); and since the ultimate goal of primary staging will be to detect only the more aggressive cancers and avoid unnecessary biopsy, this is not the end of the story. More research will be needed to explore the PSMA PET/CT correlation between the standard uptake value (SUV) and cancer aggressiveness, but the first steps down the road in finding the best diagnostic approach to clinically significant prostate cancer have been taken.”

-ENDS-

Notes for Editors

1. The research was carried out by a multi-institutional collaboration across Australia and New Zealand. The primary site was St Vincent’s Health, Melbourne, Australia, and collaborators were Melbourne Health, Epworth Health (Melbourne), Pacific Radiology, Christchurch, New Zealand, and Sydney Adventist Hospital, Australia.

2. The PEDAL acronym stands for the Prospective Evaluation and comparison of multiparametric MRI and PSMA PET/CT to Diagnose and Localise prostate cancer.

3. The trial PET/CT scans used the tracer 18F-DCFPyL PSMA, a newer and more stable agent than the traditional 68Ga-PSMA.

About EAU22

Europe’s biggest urology congress will take place from 1-4 July 2022 in Amsterdam, The Netherlands. With nearly 1,300 abstracts presented and moderated live, the 37th Annual Congress of the European Association of Urology (EAU22) will be amongst Europe’s biggest medical congresses in 2022.

Clinicians, scientists, and patients will meet to discuss topics such as:
• Prostate cancer: new developments to improve treatments of the most common male cancer
• Urinary incontinence: a growing concern for the elderly population
• Practice changing treatments for both bladder and kidney cancer
• Prevention and treatment of urinary stones; 1 in 10 people (55 million adults in Europe) will form a stone at some point
• Special track for representatives of patient advocacy group on Monday 4 July

…and many other conditions related to the male and female urinary tract system and male reproductive organs. Review the full scientific programme on the congress website.

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The abstracts, A multicentre prospective single arm paired comparison of ability to diagnose and locate prostate cancer between multiparametric magnetic resonance imaging and 18F-DCFPyL prostate-specific membrane antigen positron emission tomography (PEDAL trial) is presented to the European Association of Urology Annual Congress (EAU22) in Amsterdam on Monday 04 July, 2022.

Abstract:

A0743: Update from the PEDAL trial: A prospective single arm paired comparison of ability to diagnose and locate prostate cancer between multiparametric MRI and 18F-PSMA-PET/CT

Introduction & Objectives

To investigate the accuracy of 18F-DCFPyl prostate specific membrane antigen (PSMA)-PET/CT to detect and localize prostate lesions compared to multiparametric MRI (mpMRI) prostate in men with suspected prostate cancer.
**Materials & Methods**

This is a prospective single arm paired comparison of ability to diagnose and locate prostate cancer between mpMRI and 18F-DCFPyL-PSMA PET/CT. Detection and localisation of suspicious prostate lesions were compared between mpMRI, PET/CT and fused PET/MR images. Radiological findings were correlated with histological findings following a targeted prostate biopsy.

**Results**

One hundred and thirty-nine men who completed both imaging arms were analysed. The median age was 58 years and median prostate specific antigen (PSA) level 6.3ng/ml. Prostate mpMRI detected 70 index lesions (PIRADS≥3), compared to 72 index lesions on PET/CT (SUVmax ≥7.0). Fifty four index lesions were detected on both mpMRI and PET/CT, with 16 lesions identified by PET/CT alone. Prostate cancer was detected in 59 of 92 men (64.1%) who underwent prostate biopsy. In 43 men with clinically significant prostate cancer (Grade group ≥2), 35 lesions (81.4%) were visualized on both imaging arms (Table 1). PET/CT visualized 4 (9.3%) clinically significant lesions that were undetected by mpMRI, and identified 21 patients with metastatic disease. One clinically significant lesion was detected by mpMRI alone.

**Conclusions**

18F-DCFPyL PSMA-PET/CT appears to detect lesions seen on mpMRI prostate, as well as identify additional clinically significant prostate lesions. The ability of PSMA-PET/CT to diagnose metastatic disease also saves the need for further staging following diagnosis. These early results provide promising evidence for a fully-powered trial to follow.