NOBLE Registry: Dosing of First Patients Shows Encouraging Early Results in the Investigational Use of ^{99m}Tc-iPSMA for prostate cancer screening*

By Dr. Omar Yehia Hussein

PSMA-PET/CT imaging scans have rapidly gained popularity all over the world because of their higher accuracy to detect prostate cancer recurrence and metastases all over the body compared to conventional imaging techniques.

Following the recent incorporation of PSMA-PET in the National Comprehensive Cancer Network (NCCN) guidelines, the expected adoption of this technique and global awareness is likely to increase even more in the near future. Thus, PSMA-PET scans could become in the coming years the reference in terms of prostate cancer detection and assessment.

Challenges for Global Adoption

The main factors affecting the global implementation and use of this technique concern budget and infrastructure. The challenges are:

- Access to a relatively expensive machine which is "PET/CT"
- There are five times more SPECT cameras already installed worldwide, and this gap is particularly present in developing countries.
- Access to PSMA-PET tracers, which currently are:
• ^{68}Ga-PSMA, which will need investment in buying a relatively expensive gallium generator and to have a local radiopharmacy to produce ^{68}Ga-PSMA tracers in-house
• ^{18}F-PSMA which is produced by a cyclotron (other costly investment) which can be inside the hospital or in a close area with the ready-to-inject doses delivered to the imaging site.

The Idea Behind the NOBLE Registry

As previously mentioned PSMA PET is an emerging standard of care in prostate cancer imaging. However, these technologies are scarce in some parts of the world and their implementation may come at a high cost and require adapted infrastructures, creating a need for a more available and accessible alternative.

The NOBLE Registry aims at filling this gap by introducing novel PSMA radioisotopes that can be labeled with Technetium-99m (^{99m}Tc) and can be imaged using SPECT/SPECT-CT scanners, which is particularly of great value in some countries as well as remote and rural locations where SPECT is the predominant imaging modality.

The idea is to generate a data repository, which may inform further development of PSMA-SPECT products in prostate cancer detection for those emerging markets. Seven centers are currently involved in the NOBLE Registry worldwide with the aim of providing real world evidence to deliver useful publications and clinical practice guidelines. Thus, NOBLE is dedicated to developing an efficient and affordable alternative through SPECT-imaging, allowing people living with prostate cancer, regardless of origin, technology availability or financial situation, to access PSMA-SPECT imaging for accurate diagnosis and further treatment planning with the associated therapeutic agent based on the same vector.

NOvember is MOvember!

**The NOBLE Registry is sponsored by the Principal Investigator and participating expert sites around the world. Telix provided funding support and drug to support the study purpose, but is not responsible for the design, output or results which are led and controlled by the independent team running the study. ^{99m}Tc-iPSMA is authorized for investigational use only and has not received a marketing authorization in any jurisdiction.*

Initial Experience

Ga-PSMA-PET/CT **Tc-PSMA fused with CT**

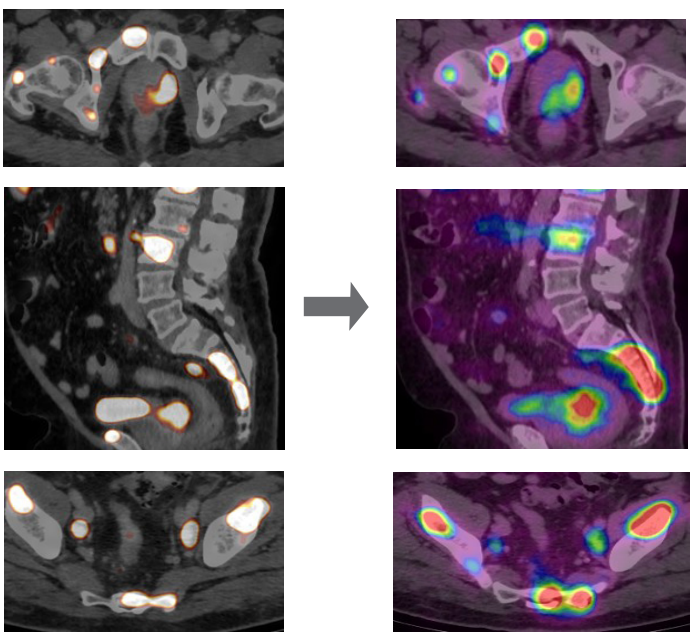

Image courtesy of Dr. Omar Yehia (MISR Radiology Center)
^{99m}Tc-iPSMA is authorised for investigational use only and has not received a marketing authorisation in any jurisdiction

Dr. Omar Yehia is one of the first Investigators enrolled in the NOBLE Registry at the MISR Radiology Center in Egypt.

Early experience indicates that ^{99m}Tc-iPSMA SPECT can potentially identify lesions and important disease characteristics using technology, which is readily available in emerging markets. Most of the lesions of about 8-10mm and larger were detected on the ^{99m}Tc-iPSMA SPECT scan which can be considered promising.

Furthermore, in comparison to bone scan, not only were they able to detect the bony lesions but they could also identify the prostate/prostate bed, lymph nodes and any soft tissue metastasis in one scan.

Overall, this first experience shows promising results using ^{99m}Tc-iPSMA SPECT and could potentially play a role in prostate cancer detection and selection of potential positive responders to PSMA-based radioligand therapy in regions where PSMA-PET is not available.

Future Directions

The first experience from one of the centers involved in the NOBLE Registry is promising. Should the other centers demonstrate the same results, ^{99m}Tc-iPSMA could represent a step in the right direction by facilitating patient access to PSMA-SPECT scans in some regions of the world for an accurate disease staging and accordingly accurate treatment planning for prostate cancer. Thus, enabling hope to achieve NOBLE's objective: NOBody LEft behind.

Moving forward, ^{99m}Tc-iPSMA SPECT imaging could pave the way also for PSMA-radioligand therapy by helping to select the eligible patients with high PSMA uptake that are more likely to respond to radioligand therapy (^{177}Lutetium-PSMA), for which the first drug is expected to get FDA approval soon after the positive results of the VISION Trial.

For more information: **www.nobleregistry.org**

Contact us: **prostatecancer@nobleregistry.org**

Authored by:

Dr. Omar Yehia Hussein
• PI NOBLE Registry (Misr Radiology Centre)
• Ambassador Oncidium foundation (Egypt)

**The NOBLE Registry is sponsored by the Principal Investigator and participating expert sites around the world. Telix provided funding support and drug to support the study purpose, but is not responsible for the design, output or results which are led and controlled by the independent team running the study. ^{99m}Tc-iPSMA is authorized for investigational use only and has not received a marketing authorization in any jurisdiction.*