MRI/PET: Clinician Applications & Challenges in the USA

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1. Overview of the technology

In 2014, there are multiple major manufacturers who are committed to MRI/PET technology. Siemens installed the first commercial systems in the United States in 2011, in Boston and then at the National Institutes of Health in Bethesda MD. The Siemens approach was based on the large bore 3T Verio scanner. A PET insert is installed inside the MRI scanner bore, reducing the bore size from 70 cm (Verio) to 60 cm (Siemens Biograph). The device uses a Dixon sequences to identify four tissue types, including fat, soft tissue, lung and background air. These tissue types are used for attenuation correction for the PET scanner. The Philips approach also uses a 3T scanner (Achieva TX) but does not change the basic scanner configuration. Instead, a sliding bed links the separate PET and MRI scanners. While this is a very limited step towards integration, other advantages are possible. For example, a standard coil set is available for the MRI scanner. The PET scanner uses state of the art technology without any compromises due to the MRI field. In 2013, General Electric announced a fully integrated MRI-PET scanner. The approach is similar to the Siemens concept of a 70 cm 3T scanner with a PET insert. However, the PET detectors are a more advanced generation of silicon photomultipliers (e.g., fully digital). 510K approval is expected in 2014.

2. Radiation issues

The motivation for an integrated MRI-PET scanner will vary from site to site. In the United States, academic centers are the primary early adopters. Typically these are driven by individual lead investigators, rather than standard clinical applications. Nevertheless, an early potential advantage of MRI-PET was to eliminate the need for additional radiation from the CT scanner. Radiation doses for FDG PET scanning averages about 12 mSv. The CT scanner may be diagnostic (5-30 or more mSv) or may be only used for attenuation correction (1-2 mSv). Thus, the savings in radiation exposure to the patient depends more on the adoption of MRI and CT scanning by referring physicians. For example, at the NIH, a strict radiation monitoring policy for CT radiation has been in place since 2008. This, and a tremendous amount of attention in the scientific and lay press, has led to lack of growth of CT volumes, with continued growth of MRI and perhaps MRI-PET.

3. Technologist/ operation/ certification

A major impediment to the integrated MRI-PET unit is the need for technologists certified both in MRI and nuclear medicine/ PET. At our site, none of the MRI technologists have nuclear medicine certification; some of the PET technologists do have dual certification in computed tomography. Additional training is taking place for MRI. Nevertheless, each MRI-PET study requires the full ensemble of PET staff (technologist, PET physicist, PET radiopharmacist) in addition to the MRI

technologist. On average, no operating staff operating efficiency has been gained when using the MRI-PET scanner.

4. Technical challenges and locating the MRI-PET scanner

It is likely that site complexities for MRI-PET are similar both in the U.S and non-U.S. sites. For the MRI staff, the unique requirements of PET siting are unfamiliar. The main constraints are a) location of the cyclotron (if available), b) location of the radiopharmacy and c) location of the uptake room. The uptake room is a quite, dark room where the patient reclines for about 1 hour after the FDG injection. In addition, our site located a dedicated restroom for PET patients in MRI (due to low level excretion of radioactivity). In MRI suites, it is uncommon to have a dark, quite room for patients, and dedicated space for additional restrooms are unlikely. In many hospitals, the nuclear medicine sections and MRI suites are physically distant. In these circumstances, location of the MRI-PET scanner in nuclear medicine has several advantages. Note that short lived radiotracers (C-11, half life ~20 minutes) may be very difficult to use when the MRI-PET scanner is located in the MRI section.

5. USA applications/ reimbursement status

The major applications of MRI-PET may be those that take advantage of the soft tissue resolution of MRI, compared to CT. Unique applications where MRI is preferred over CT scanning include evaluation of the prostate, female pelvis, some liver and kidney applications, endocrine tumor evaluation, head and neck imaging and brain imaging. Of these, several applications also coincide with unique PET applications. The most common radiotracer for PET (FDG) is primarily used for cancer staging, so has wide spread applications for MRI PET. In addition, two new FDA approved agents are now available for Alzheimer's imaging. It is likely that the MRI-PET may have significant advantages for comprehensive evaluation of patients for this disease. In other areas of the body, unique radiotracers are also able that have tremendous potential (although narrow current use) for MRI-PET imaging.

Reimbursement for MRI-PET scanning for clinical studies is a major issue. The units have high cost, between 1.5 and 2x that of an MRI scanner. As a result, the maintenance contracts scale along with the price of the devices. In the current environment of attention to healthcare expense, the MRI-PET investment is a contradiction.

Some encouraging news was delivered by CMS in 2013 for MRI-PET. On June 11, 2013, CMS delivered a statement that primarily addressed PET scanning. This announcement removed the reporting requirement for PET to the National Oncologic PET registry. In addition, instead of 1 follow up scan that was reimbursed, CMS authorized reimbursement for up to 3 PET scans. In addition, they include the language that "integrated FDG PET/CT and the integrated FDG PET/ MRI" are to be treated in the same manner, for their purposes of reporting and follow-up to qualify for

reimbursement. Nevertheless, reimbursement remains a state by state issue, and is often controlled by the insurance carriers. In one example, Aetna has released a position statement indicating that MRI-PET is considered to be 'experimental' despite FDA 510k approval (http://www.aetna.com/cpb/medical/data/1_99/0071.html). Thus, additional evidence and outcome based research will be necessary to determine the eventual status of insurance payments in the United States.