PET/CT in Clinical Trials, the Need for Standardisation

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Quantification of FDG PET/CT studies using SUVs is affected by many factors related to technical factors, such as scanner calibration, imaging physics related factors and patient related factors [1]. As a consequence, quantitative FDG PET/CT studies in multicentre studies are hampered by large variability in applied PET methodology [2,3], resulting in an up to 2 fold differences in results between centres. Therefore, in 2010 the European Association of Nuclear Medicine (EANM) published the European procedure guideline for PET tumour imaging with FDG [4]. In this guideline recommendations are given to handle various factors affecting SUV. The guideline addresses (1) patient preparation, (2) FDG dosage as function of scanner type, patient weight and scan duration, (3) data acquisition, (4) image reconstruction, (5) data analysis and (6) quality control (QC) procedures. The guideline specifically aims at harmonisation rather than standardisation of quantification in multi-center studies. As SUVs are lesion size dependent, QC experiments measuring SUV as function of lesion size are defined along with harmonising criteria. To support harmonisation of FDG PET/CT quantification in multicentre studies, an accreditation program was launched by EARL (EANM Research Ltd) and endorsed by the European Organisation for Research and Treatment of Cancer (EORTC).

Accreditation include: (1) verification of PET/CT system calibration and uniformity using a uniform cylinder and (2) harmonisation of SUV recovery and image quality using a modified NEMA NU2 2007 phantom. So far, more than 35 sites across Europe have successfully completed the EARL accreditation. Retrospective analysis of clinical data collected in a Dutch trial demonstrated good correspondence in baseline SUV between sites that were performing PET studies in accordance with the guideline, while SUV differed substantially (2 fold) for an imaging site that did not comply with the harmonizing standards. To our best knowledge the European guideline is the first guideline with harmonising performance standards and the EARL accreditation program is the first initiative for implementation into practice.

References