

## Good Clinical Practice for the Imaging Technologist: Retrospective Quality Control of FDG-PET in an EORTC Sub-Study

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Quantitative imaging biomarkers such as FDG have the potential to predict very early response to therapy and can be used for treatment modification. However, this requires standardized and reproducible image acquisition and evaluation. The purpose of this project was to review and assess the quality of FDG-PET scans, the compliance with the imaging guidelines parameters directly affecting the quantification of PET results (SUV), and adherence to International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines. The objective of the study was to investigate whether early changes in tumor metabolism, as determined by FDG uptake, were predictive for disease stabilization, response and duration of PFS.

Materials and methods: 44 cancer patients were enrolled in a randomized multicenter (11 sites) sub-study. Scans had to be performed at baseline (within two weeks before treatment start) and at day 10-14 into treatment. A retrospective review and visual quality scoring on a four points system was performed using a four-point scale (good, intermediate, poor, unknown). The image transmittal forms (ITFs) and DICOM headers were exploited and analyzed for compliance with the clinical trial protocol, imaging guidelines and proper de-identification.

Results: 81/88 scans were received. 36/81 scans were properly de-identified. 79/81 serum glucose values submitted, all but one within the imaging guidelines (average: 99 mg/dL, range: 61-200 mg/dL); no information was submitted for one patient and one was reported as diabetic at follow up.

Visual quality assessment for baseline scans was 82% good, intermediate 11%, 0% poor, unknown 7%; respectively follow up scans: 75% / 9% / 14% / 2%. In 35 patients both scans were of sufficient quality to assess uptake time (UT) compliance ( $60 \pm 5$  min).

In 26/70 ITFs the reported UT differed by more than 5 minutes from the DICOM headers (max difference 1hr29 min). According to the DICOM headers, imaging guidelines UT compliance for both scans was 31.4% (11/35 patients). An actual baseline UT  $\pm 10$  min resulted in 60% compliance (21/35).

Liver SUV<sub>mean</sub> measured via VOI (7-8.77 mm<sup>3</sup>) was fairly constant between the 11 patients with UT compliance:  $2.17 \pm 0.13$  at baseline and  $2.23 \pm 0.35$  at follow up and variability substantially increasing for the subjects with unacceptable UT (11 patients):  $2.24 \pm 0.90$  at baseline and  $1.94 \pm 0.63$  at follow up; not assessable in two patients.

Conclusion: The high attrition number of patients due to low compliance with the imaging guidelines and study protocol compromised the assessment of the predictive value for early response monitoring. Liver SUVs could be monitored to assess the quality and compliance of a FDG-PET/CT study. Low compliance with the study protocol and imaging guidelines warrants intense education on ICH-GCP principles. Prospective rapid review and feedback is necessary to improve compliance with study protocol and imaging guidelines.

### References

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