

Imaging in Clinical Trials: Concept and Use of Surrogate Markers

A. Chiti, Milano (IT)

Personalized medicine in oncology means management of a patient's disease using therapeutic strategies that are best suited for an individual patient and for the particular type of tumour that the therapy is aiming to target. Molecular diagnostics influences cancer management in several ways that aid personalisation and this is why research has now focused on individualizing treatment strategies by incorporating a combination of physiological variables, genetic characteristics and environmental factors together with the traditional tumour characteristics that currently drives clinical decision making.

Imaging is playing a major role in individualizing treatment strategies and PET-CT using different radiopharmaceuticals has been demonstrated useful in many diseases to optimize the treatment. In particular, fluorine-18-fluoro-deoxy-glucose as a molecular probe of glucose metabolism in cancer cells has been demonstrated to have high accuracy for detection of many tumour types. Along with diagnosis, staging, detection of relapse, restaging and follow-up, one of the main applications of PET-CT is the assessment of therapy response and treatment planning. In routine practice, structural and tumour volume changes are used to guide therapeutic strategies and to measure the disease-free and overall survival. However, tissue metabolism changes more rapidly than morphology, and changes in tumour FDG uptake may therefore predict alterations in volume.

The use of FDG-PET as a surrogate tool for monitoring therapy response offers better patient care by individualising treatment and avoiding ineffective treatments: surgery, radiation therapy or chemotherapy.

Imaging biomarkers are of paramount importance, not only for patient's evaluation but also for drug development.

References

1. Haberkorn U, Markert A, Eisenhut M, Mier W, Altmann A. Development of molecular techniques for imaging and treatment of tumors. *Q J Nucl Med Mol Imaging*. 2011 Dec;55(6):655-70. Review. PubMed PMID: 22231585.
2. Waterton JC, Pylkkänen L. Qualification of imaging biomarkers for oncology drug development. *Eur J Cancer*. 2012 Mar;48(4):409-15. Epub 2012 Jan 5. Review. PubMed PMID: 22226478.
3. Bayouth JE, Casavant TL, Graham MM, Sonka M, Muruganandham M, Buatti JM. Image-based biomarkers in clinical practice. *Semin Radiat Oncol*. 2011 Apr;21(2):157-66. Review. PubMed PMID: 21356483.
4. Sharma R, Aboagye E. Development of radiotracers for oncology--the interface with pharmacology. *Br J Pharmacol*. 2011 Aug;163(8):1565-85. doi: 10.1111/j.1476-5381.2010.01160.x. Review. PubMed PMID: 21175573; PubMed Central PMCID: PMC3166688.
5. Bayele HK, Chiti A, Colina R, Fernandes O, Khan B, Krishnamoorthy R, Ozdafi H, Padua RA. Isotopic biomarker discovery and application in translational medicine. *Drug Discov Today*. 2010 Feb;15(3-4):127-36. Epub 2009 Dec 28. Review. PubMed PMID: 20038454.

Oct.30