3. Is it useful to identify more advanced disease in order to be able to restrict invasive / toxic treatments to those patients who can benefit?

We can use stage in clinical practice as a guide to planning the multidisciplinary approach to therapy. The concept of systemic treatment intensification for poorer prognosis patients is unproven, at least in solid tumours, has been discredited in breast cancer and is still under investigation for Ewing's family tumours. This is most likely due to the very narrow therapeutic index of cytotoxic chemotherapy relative to many-fold levels of resistance of cancer cells. However, defining the presence and sites of metastatic disease can be vital to the choice of treatment, e.g. by indicating a need for systemic therapy, lymph node dissection, radiotherapy, etc.

19-FDG-PET and PET-CT are being used increasingly in routine clinical practice. PET can be used to define the treatment volume for radiotherapy and identify which patients are responding or not. PET-CT is becoming an integral part of staging prior to surgery for NSCLC. Although false positives may occur, it is possible to identify occult mediastinal nodal involvement and prevent pneumonectomy from being performed inappropriately. PET is also used to identify residual active disease after systemic treatment of Hodgkin's lymphoma and testicular tumours, requiring local therapy. MRI, including whole body STIR, can be used to identify metastatic bone disease not visible on isotope bone scan, e.g. in Ewing's. MRI may be the only means of detecting bone disease in metastatic myxoid liposarcoma. Cancer may often be a systemic disease, but local therapy is often the only curative modality. To apply it appropriately requires an accurate knowledge of the disease.

Finally, modern imaging tools are capable of telling us about the biology of a cancer and its response to molecularly targeted therapy. This is put to good use in the management of GIST with imatinib and sunitinib, where FDG-PET can be used to define response or progression within a matter of days and is used to plan local therapies such as radiofrequency ablation of liver metastases. In conclusion, improved whole body imaging techniques are capable of helping deliver genuine improvements in cancer control and should be welcomed.

13 INVITED

Whole-body MRI

H. Schlemmer. *University of Tübingen, Radiologische Diagnostik, Tübingen, Germany*

A malignant tumor is in per se a potential systemic disease. Imaging is of fundamental importance for initial and follow-up staging as serum tumor markers cannot provide information about the localization of tumor tissue and secondary complications related to possibly harmed surrounding anatomic structures. Precise staging and accurate therapy monitoring in individual patients are essential for assessing prognosis and achieving best patient outcome in terms of survival and quality of life.

High-resolution whole-body MRI is a novel and promising technique and its medical and economic is of considerable importance. Due to the provided high soft tissue contrast it is the modality of choice for local staging in a variety of tumors. The method plays particularly an important part for evaluating metastatic disease and for estimating the individual total tumor burden. Compared to CT and PET/CT it has been proven as the most accurate method for detecting metastases in the brain, abdominal organs and bone marrow. Regarding bone metastases, it is particularly more sensitive than conventional bone scintigraphy, X-ray, CT and PET/CT for different tumor types. One major drawback of MRI remains the limited accuracy for an early detection of lymph node metastases. Novel contrast media containing lymphotropic paramagnetic nanoparticles (USPIO) may help to increase the specificity. There is a need of more representative studies evaluating teh benefits of whole-body MRI versus whole-body CT end PET/CT with respect to specific tumor types and stages.

Whole-body imaging significantly increases the number of acquired images per patient. One examination comprises up to 1000 images, which all have carefully to be reviewed for the presence or absence of suspicious mass lesions consuming a notable amount of time and concentration. The time required for reading, documentation and discussion of the high number of images vary substantially, and 15−60 minutes are needed, particularly if additional images, e.g. from follow-up and/or multimodal diagnostic approaches with CT, PET or PET/CT have to be evaluated. Finally, a small number of essential images showing all relevant findings have to be sorted out and demonstrated in a fast and comprehensive manner as therapeutic decisions are increasingly based on recommendations by multidisciplinary conferences. The involved Radiologists will accordingly be faced with heavier workload, in particular as referring clinicians are getting more and more aware of a comprehensive whole-body approach probably cutting down the total time demand for imaging. Logistical implications for work flow optimization have therefore increasingly to be considered to minimize the time demand not only of the patient examination but also of the reading and reporting process. Novel ideas for redesigning the department's workflow concepts are challenging but a reasonable prerequisite for utilizing the potential of whole-body imaging technology.

14 INVITED

PET/CT: improved sensitivity and specificity in staging and therapy monitoring

G. von Schulthess. *University Hospital Zürich, Department medical radiology Clinic for nuclear medicine, Zurich, Switzerland*

Since its first worldwide introduction into clinical practice at our institution in March 2001, PET-CT has been the most rapidly growing imaging modality worldwide, developping into an annual market of over 1 billion US$. There are very good reasons for this, which have been amply documented in the last 6 years:

1. PET is well known to be highly sensitive in detecting tumor manifestations.
2. PET as most Nuclear Medicine procedures, lacks sensitivity in many settings.
3. Adding CT to PET improves – above all – examination specificity.
4. PET-CT is a more accurate examination than either PET, CT or PET and CT read side-by-side.

The purpose of this presentation is to familiarize the participant with the key indications for PET-CT in tumor staging (e.g. NSCLC) and therapy monitoring (e.g. lymphoma). As the CT portion of PET-CT can be run mainly for anatomic localization as a low dose CT, but also as full scale, contrast enhanced multi-phase CT, it is critical for the referring physician to understand, that frequently when the diagnosis is clear and staging with a cross-sectional imaging exam is to follow, referral directly to PET-CT can be made with the advantage that the resulting data are comprehensive, integrated and the patient only needs a single appointment. If CT or MR data exist from a very recent examination, a repetition of a full scale CT within PET-CT frequently is unnecessary.

While deeper insights into reading PET scans is beyond the scope of this presentation, it is a second aim to familiarize the referring physician with some important pitfalls in PET imaging. It is well known that inexperienced PET readers and particularly radiologists who have little formal PET training, are too sensitive in PET image interpretation which in turn leads to too many false positive diagnoses.

In summary, PET-CT has proven to be the staging modality of choice in many important tumors and due to its unique feature of depicting molecular processes rather than just anatomy, is rapidly gaining acceptance as excellent imaging procedure to monitor therapy

Special session (Mon, 24 Sep, 13:30−14:30)
Biosimilars in oncology and hematology – what should a physician know

15 INVITED

Open questions about biosimilars – pharmacovigilance, substitution, labelling, naming and economy

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Biosimilars are new, non-innovative biopharmaceutical agents that are "similar", but not identical to reference biopharmaceutical products. Biosimilars should provide cost savings and greater access to biopharmaceuticals; however, they are unique molecules and should not be considered generic versions of reference products. Characteristics of any biopharmaceutical are closely related to its manufacturing processes (eg, cellular expression system, extraction/purification process), many of which are proprietary information. Thus, biosimilar manufacturers cannot duplicate a reference product. Moreover, small differences between biopharmaceutical products may produce clinical differences with respect to efficacy, safety, and immunogenicity. Because of these issues, the approval process required for biosimilars is not as straightforward as that for small molecule generics. The EMEA has developed a general regulatory pathway for the approval of biosimilars. The approval process will vary according to the product category. For example, specific guidelines have been developed for biosimilar epoetins and biosimilar granulocyte colony-stimulating factors (G-CSFs). In general, the approval of biosimilars will be based on the demonstration of comparable efficacy and safety to an innovator reference product in a relevant patient population. Because clinical data for biosimilars will be limited at the time of approval, regulatory guidelines also require post-approval monitoring (ie, pharmacovigilance) to establish