AIMS: To evaluate studies on the use of positron emission tomography with the glucose analog (18)F-fluoro-deoxyglucose (FDG-PET) for the preoperative staging of patients with non-small cell lung cancer (NSCLC) according to the criteria of evidence based medicine and to discuss the cost-effectiveness of the technique. METHODS: Clinical studies published between 1995 and 2002 on the preoperative staging of non-small cell lung cancer were used for this analysis. Studies that did not meet the criteria published by the European Agency for the Evaluation of Medicinal Products (EMEA) were excluded. The validity of the studies was evaluated by a standardized rating system developed by the Agency for Health Care Policy and Research (AHCPR). RESULTS: For the detection of mediastinal lymph node metastases the mean sensitivity and specificity of FDG-PET on a patient basis is 85% and 87% (16 studies, 1355 patients). In studies that compared FDG-PET and computed tomography (CT) the mean sensitivity of CT was 66% at a specificity of 71%. In the detection of distant metastases FDG-PET correctly changed the tumor stage in 18% of the patients when compared to CT based staging (10 studies, 1073 patients). Five cost effectiveness analyses from the USA, Japan, and Germany concluded that FDG-PET improves the outcome of treatment at reduced or only slightly increased overall costs. Improvement of patient outcome was also demonstrated in a
randomized trial, which found that the risk of a futile thoracotomy was reduced by 51% (p=0.003) when FDG-PET was added to the preoperative staging. CONCLUSION: According to the criteria of the AHCPR the use of FDG-PET for detection of mediastinal lymph node and distant metastases is documented at a level of evidence Ia and Ib, respectively. Since systematic analyses also indicate a favorable cost-effectiveness ratio FDG-PET has to be considered as "strictly indicated" for the preoperative staging of non-small cell lung cancer.