treatment time up to 58% of the treatment time without the protocol. Time analysis shows that the largest part of the added time is spent on the readjustment of the patients' position adding a mean of 37% of time to the treatment of one field. This is despite the fact that the readjustment was performed using a remote couch controller. Finally a statistical analysis shows that it is possible to select patients benefiting from the use of such a protocol after a limited number of fractions.

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EORTC GUIDELINES FOR WRITING PROTOCOLS FOR CLINICAL TRIALS OF RADIOTHERAPY

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The concept of a Master Protocol for phase III studies was raised at the Steering Committee of the EORTC Radiotherapy Group, in order to make the work of the study coordinators easier, when writing protocols and to give them more homogeneity. The Master Protocol defines and clarifies in a logical order the different steps which must be taken when designing a randomized trial—from the rationale to the references. It pays particular attention to eligibility criteria, volumes of interest defined in agreement with ICRU Report 50 (grosstumor volume, clinical target volume, planning target volume and organs at risk), simulation procedure, treatment technique, normal tissue sparing, dose computation, equipment, dose specification (also in agreement with ICRU Report 50). Last but not least, the different procedures of quality assurance for protocols and patients are also defined (site visits, dummy run procedure, in vivo dosimetry, individual case review) to allow working plans to be made in advance. We are aware that this work is not exhaustive, but hope that the contents will be of help to those who are writing a protocol.

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ESTIMATION OF OVERALL PULMONARY FUNCTION AFTER IRRADIATION USING DOSE-EFFECT RELATIONS FOR LOCAL FUNCTIONAL INJURY

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Purpose. To predict the pulmonary function 3–4 months after irradiation for malignant lymphoma from the three-dimensional (3-D) dose distribution. Methods. Dose-effect relations for the relative reduction of local perfusion (Q) and local ventilation (V), were calculated in 25 patients, using correlated SPECT (Single Photon Emission Computed Tomography) and CT data. By combining the 3-D distribution of an individual patient with the dose-effect relations, averaged over all patients, the average reduction of local Q and V per cent (i.e., the overall response parameters) in the whole lung was estimated for each patient. Correlation coefficients were calculated between these overall response parameters and the incidence of radiation pneumonitis was determined. Results. The overall response parameter for perfusion was correlated with the change in standard lung function test, with correlation coefficients varying between 0.53 (p = 0.007) and 0.71 (p < 0.001) for the change of Vital Capacity and Forced Expiratory Volume at 1 s, respectively. For the overall response parameter for ventilation similar correlations were observed. Four out of the 25 patients developed radiation pneumonitis; in these four patients the overall response parameter for perfusion was on average somewhat higher (13.2 ± 14% (1 standard error of the mean)) than in patients without radiation pneumonitis (10.5 ± 10%), but this difference was not significant. A higher incidence of radiation pneumonitis was observed for larger values of the overall response parameter for perfusion; in patient groups with an overall response parameter for perfusion of 0–5%, 5–10%, 10–15%, and 15–20%, the incidence of radiation pneumonitis was 0 (0/1), 10 (1/10), 13 (1/8) and 33% (2/6), respectively. Conclusion. By combining the 3-D dose distribution with the average dose-effect relations for local perfusion or ventilation, an overall response parameter can be calculated prior to irradiation, which is predictive for the radiation-induced change in the overall pulmonary function, and possibly for the incidence of radiation pneumonitis, in this group of patients.

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