echelon lymph node drainage) and CTV2 (residual lymph node regions). A total of 60 Gy/30 fractions was delivered to the periphery of CTV1 and 50–54 Gy/25–30 fractions to the CTV2. Treatments were delivered over six weeks, 5 days/week.
There were 23 stage III/IV, seven stage II and three stage I patients. Nine patients received concomitant, weekly platinum based chemotherapy.
Results: At the time of this analysis, Mar/2005, and a median follow-up of 33.3 months, there were seven locoregional and one distant failures. Three patients died of disease and two of other causes.
The 3-year OS was 90%. The 2 and 3-year DFS was 84 and 73%, respectively. The locoregional control (LRC) was 84 and 78% at two and three years, respectively.
Treatments were well tolerated. Seventeen patients had grade III acute toxicity, 11 patients with mucositis/pharyngitis, and 6 with dermatitis. Grade IV acute toxicity occurred in three patients. Late toxicity was limited to grade I/II in 12 patients. One patient had grade IV laryngeal edema requiring a temporary tracheostomy.
Conclusion: Dose escalation by means of dose painting of the H/N SCCa can safely and effectively be delivered using IMRT. Our preliminary results are encouraging and comparable, if not better, to most randomized dose escalation trials. We believe that, dose painting to escalate the dose needs further evaluation in a randomized fashion.

1019 POSTER

Radiotherapy alone versus radiotherapy with amifostine 3 times a week versus radiotherapy with amifostine 5 times a week: a prospective randomised study in squamous cell head and neck cancer

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Background: Xerostomia is an important side effect of radiotherapy in the head and neck region. To increase the therapeutic index of radiotherapy, it could be worthwhile to enhance selectively the radioresistance of normal tissues. The aim of this study was to investigate whether non-daily (3 times/week) intravenous administration of amifostine, a selective radioprotector, is as effective as daily intravenous administration in reducing the incidence of grade II or higher xerostomia.
Material and methods: 91 patients treated with bilateral irradiation for squamous cell head and neck cancer were randomly assigned to receive radiotherapy alone (AMI-0: 30 patients) versus amifostine 200 mg/m^2 intravenously 3 times/week before irradiation (AMI-3: 31 patients) versus amifostine 200 mg/m^2 intravenously 5 times/week before irradiation (AMI-5: 30 patients). Acute and late xerostomia according to RTOG criteria and quality of life (QoL; EORTC QLQ-C30 and QLQ-H&N35) were assessed at baseline, 6 weeks, 6, 12, 18 and 24 months.
Results: Grade $\geqslant$2 late xerostomia according to the RTOG-criteria differed significantly at 6 months, but not after longer time intervals (AMI-0 74% vs. AMI-3 67% vs. AMI-5 52%, ($p = 0.03$)). No significant differences between treatment arms were found for acute xerostomia or acute mucosal toxicity. During follow up, patient-rated xerostomia was significantly worse among the AMI-0 cases (mean difference score (MDS) 52) compared to AMI-3 (MDS 25) and AMI-5 cases (MDS 29)($p = 0.01$). No significant differences were observed for other QoL dimensions. The 2-year locoregional control rate was comparable for all study arms (AMI-0: 79% vs. AMI-3: 67% vs. AMI-5: 83% ($p = 0.31$)) as was the 2-year overall survival (AMI-0: 70%; AMI-3: 58% and AMI-5 84% ($p = 0.26$)). The most frequently reported side effect of amifostine was nausea and vomiting, which was however mild in most cases, i.e. grade 2 or more toxicity was observed in only 4 patients. However, 28% of the patients discontinued amifostine administration before the end of radiotherapy, mostly because of nausea and vomiting.
Conclusions: In this prospective randomised study, patient-rated xerostomia was significantly less among patients that received amifostine. No difference was noted between amifostine 3 times/week as compared to daily administration. For late xerostomia according to the RTOG criteria, a temporary effect was noted at 6 months, which disappeared thereafter.

1020 POSTER

Squamous cell carcinoma of buccal mucosa treated with free-flap based radical surgery and neck dissection

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Background: To analyze the survival and prognostic factors for survival in patients with squamous cell carcinoma of the buccal mucosa (BSCC) treated with free-flap based radical surgery and neck dissection.
Methods: Between February 1996 to July 2002, 161 consecutive untreated BSCC patients who received free-flap based radical surgery were enrolled. In all, 108 (67%) had advanced BSCC (pathologic stage [pS] III and IV). Most patients (154; 96%) had neck dissection (ND), and 41% of these had pathologic neck node metastases. Post-operative radiation therapy (RT) was scheduled for those who had at least one pathologic finding (i.e., pT4 or nodal positive, or margin $\leqslant$4 mm). Adjuvant concomitant chemo-radiotherapy (CCRT) was given in patients with extra-capsular spreading (ECS).
Results: The 5-year local, local regional control, overall, disease–free, and disease-specific survivals were 85%, 76%, 68%, 69%, and 76%, respectively. The 5-year overall survival was 100% in pathologic stage I, 78% in stage II, 69% in stage III, and 56% in stage IV ($p = 0.033$). The 5-year disease specific survival (DSS) was 100%, 86%, 76%, and 64% in pS I, II, III and IV, respectively ($P = 0.01$). By multivariate analyses, the independent risk factors for local regional control and DSS were pathologic nodal status and differentiation. Pathologic nodal status and pathological overall stage were significant prognostic factors of local control.
Conclusions: Good tumor control and survival can be observed in most patients treated with free-flap based radical surgery and neck dissection.

1021 POSTER

Comparison of Cumulative Incidence (CI) and Kaplan-Meier (KM) estimates on late normal tissue outcome in the presence of competing risks: Evidence from CHART (Continuous Hyperfractionated Accelerated Radiotherapy) Head and Neck Study

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Background: Cumulative incidence (CI) and the Kaplan-Meier (KM) estimates are the two estimators used to quantify the late side effects over time in the presence of competing risks. The aim of this study was to estimate and compare the properties of the two estimators for late morbidity over time for different prognostic groups.
Material and Methods: Three late morbidity endpoints were studied, dryness of the mouth, laryngeal oedema and subcutaneous fibrosis. In each patient, the time to first failure was recorded, or, in patients without any of the events, the time of the last follow up was used as input data for the analysis. KM analysis was performed in two ways: (1) KM (1st) estimate: For each patient the type of first event and time to first event were used as input data. (2) KM (any) estimate: For each patient the event of interest whether it was the first event or not was used as input data. KM (1st) and KM (any) and CI estimates were analysed using SPSS. The estimates were compared in early versus advanced T stage disease among 360 node negative (No) patients in the CHART arm where locoregional failure was the competing event.
Results: The CI estimates were lower for advanced T stage group for all three endpoints when compared to early T stage group. The most striking difference was noticed for dryness of mouth. The CI estimate indicated that there was 9% less dryness of mouth in patients with T3–4 disease. KM (any) rates were very close to KM (1st) rates for the dryness of mouth and the laryngeal oedema endpoints. For subcutaneous fibrosis and oedema rates KM (any) estimate was higher than the KM (1st) estimate and this difference was more pronounced in T3–4 disease. The results are shown at the table below.
Conclusion: Without a comprehensive understanding of the assumptions of KM method, the clinical interpretations must be made with caution. The KM and the CI methods should be used as complementary analyses. The natural behaviour of the tumour site and the competing events under study