and emotional well-being – 17.5 vs 23.8. The difference between the two groups concerning emotional well-being will be tested for significance and the remaining items of the scale concerning cervix and gynaecological complaints are also under analysis.
Conclusions: General quality of life in cervix cancer survivors treated with chemoradiation isn't affected. Analysis of the specific part of our scale concerning gynaecological complaints will also be presented.

Head and Neck Cancer

Oral presentations (Mon, 24 Sep, 10.45–12.45)
Head and neck cancer

5500 ORAL

Induction chemotherapy for larynx preservation. Updated results of the GORTEC 2000–01 randomized trial comparing docetaxel + cisplatinum + fluorouracil (TPF) versus cisplatinum + fluorouracil (PF)

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Background: Induction chemotherapy (CT) with PF followed by RT in case of objective response is a standard alternative to total laryngectomy for patients with locally advanced larynx and hypopharynx cancer. Data have suggested that T may add to the efficacy of PF. The objective of this randomized phase III trial was to determine whether the addition of T to PF could increase the larynx preservation rate.
Material and Methods: Patients with larynx and hypopharynx cancer for whom surgical procedure required total laryngectomy were randomized to receive PF or TPF. Other inclusion criteria were: adequate organ function, WHO performance status 0 or 1, age between 18 and 70, signed informed consent. Treatment arms were: Arm 1 (PF): P: 100 mg/m^2/d1 and F: 1000 mg/m^2 continuous infusion (CI) d1 to 5, Arm 2 (TPF), T: 75 mg/m^2/d1, P: 75 mg/m^2/d1 and F: 750 mg/m^2 CI d1 to 5. 3 cycles with 21 days interval were planned. Patients with complete or partial response and who recovered normal larynx mobility received RT to a total dose of 70 Gy(35 f and 7 weeks). Non responders to the induction CT underwent total laryngectomy followed by RT. The primary endpoint was 3-year larynx preservation rate. To detect an absolute difference of 15% the sample size was 210 patients.
Results: 220 patients were randomized (108 to PF, 112 to TPF). Patients and T characteristics (age, sex, PS, primary site, TN) were well balanced. The TPF arm showed greater grade 3–4 alopecia (19% vs 2%) and neutropenia (57% vs 35%) while the PF arm showed greater grade 3–4 mucositis (9% vs 4%). Toxic death rate was not different (2%). Compliance to CT was better in the TPF arm. The specified treatment (according to the protocol) was delivered in 81.2% of patients in the TPF arm vs 67.4%. The overall response rate (T and N) was 82.8% in the TPF arm vs 60.8% ($p = 0.0013$). 60.6% of patients achieved a complete endoscopic response vs 46.7%. Larynx preservation was offered for 80% of patients in the TPF arm vs 57.6% in the PF arm. In a multivariate analysis, a high hemoglobin level (>14 gr/l) and a compliance to treatment >80% are associated with a better response rate. With a median follow up of 45 months the 3-year actuarial larynx preservation rate is 74% following TPF induction chemotherapy versus 51% using the PF regimen.
Conclusion: In advanced larynx and hypopharynx carcinomas, when it is used as induction chemotherapy, TPF regimen demonstrated significantly superior overall response rate compared to the PF regimen. Larynx preservation could be achieved for a higher proportion of patients. Results will be updated for the meeting and functionnal results will be presented.

5501 ORAL

Cetuximab plus platinum-based therapy first-line in recurrent and/or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN): Efficacy and safety results of a randomized phase III trial (EXTREME)

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Background: The epidermal growth factor receptor (EGFR) inhibitor, cetuximab, an IgG1 monoclonal antibody, is effective in the treatment of R/M SCCHN progressing on platinum-based therapy. This phase III trial assessed the efficacy, safety and QoL of cetuximab in combination with a standard platinum-based regimen in the first-line treatment of R/M SCCHN.
Materials and Methods: In this multicenter phase III trial, patients (pts) with stage III/IV R/M SCCHN, not suitable for local therapy, were randomized to receive a maximum of 6 three-weekly cycles of cisplatin (100 mg/m^2 IV on day 1) or carboplatin (AUC 5, day 1) and 5-FU (1000 mg/m^2/day continuous infusion over the first 4 days of each cycle) either in combination with cetuximab (initial dose 400 mg/m^2 then 250 mg/m^2 weekly) (Group A) or alone (Group B). Cetuximab was administered until disease progression or unacceptable toxicity. Randomization was stratified according to previous chemotherapy (CT) and Karnofsky performance status (KPS) <80 and ⩾80. The primary endpoint of the trial was overall survival time (OS). Secondary endpoints included response rate, progression-free survival time, safety and quality of life (QoL).
Results: 442 pts, from 80 sites in 17 European countries were randomized: Group A: 222 and Group B: 220. Pts were mainly male (399M/43F), with a median age of 57 years [range, 33–80], and a median KPS of 80 [range, 50–100]. The pharynx (47%) and the larynx (25%) were the most common primary tumor sites. Prior therapies included surgery, radiotherapy (RT), induction CT or concomitant CT with RT. The combination of platinum-based chemotherapy and cetuximab significantly prolonged OS: 10.1 months in Group A and 7.4 months in Group B ($p = 0.036$). At the date of 10 February 2006, an interim safety analysis on 429 pts revealed no increases in the incidence of grade 3/4 adverse events commonly known to be due to CT in the cetuximab and CT arm as compared to the CT alone arm. Grade 3/4 skin reactions and infusion reactions, present in Group A (3.3% and 2.3%, respectively) were not found in Group B.
Conclusions: The addition of cetuximab to platinum-based CT in the first-line treatment of R/M SCCHN significantly improved survival by over 2.5 months compared with CT alone. The addition of cetuximab did not modify the characteristic adverse event profile of platinum-based CT. Final analyses on efficacy, safety and QoL will be presented at the meeting.

5502 ORAL

Accelerated weekly concomitant boost postoperative radiation therapy combined to concomitantchemotherapy in patients with locally advanced head and neck cancer

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Background: To assess the feasibility and efficacy of accelerated weekly 6 fractionated 66-Gy postoperative radiotherapy (PORT) using a single fraction regimen from Monday to Thursday and a concomitant boost in the Friday afternoon sessions combined with concomitant cisplatin chemotherapy (CT) in patients with locally-advanced head and neck cancer (LAHNC).
Materials and Methods: Between 2001 and 2006, 40 (m/f ratio: 35/5; median age: 60 years) patients with pT1-pT4 and/or pN0-pN3 LAHNC were included in this pilot study. Indications of PORT/CT were positive