weekly. Totally 46 patients were studied. The effective combination dose of Gefitinib + Eterocoxib was Gefitinib 500 mg and Eterocoxib 400 mg.
Recurrent and metastatic disease patients who were not candidates for definitive loco regional therapy and had received platinum based chemotherapy.
Results: Out of 46 patients − 40 were accessible patients. There were 18 patients in Methotrexate (Arm A) and 22 patients in the combination Arm of Gefitinib + Eterocoxib (Arm B). The Response rates, Time to Progression, Median Survival time in Arm A and Arm B are as follows:
Arm A − 1 partial response and 2 stable diseases (clinical benefit seen in 16.67%) with a median time of survival around 94 days, and time to progression 36 days.
Arm B − 1 complete response, 4 partial responses and 6 stable diseases (clinical benefit seen in 50%) with median time to progression 60 days, median survival time 165 days.
The treatment was relatively well tolerated with predictable toxicity including skin rash, diarrhea and dyspepsia. Exploratory study of quality of life showed improvement in quality of life in the experimental arm. Exploratory study of pharmaco-economics suggests that it is cost effective.
Conclusions: Gefitinib combined with Eterocoxib shows better response rates, Median Survival time and Quality of Life, than Methotrexate weekly and historical Gefitinib data. It is worthwhile to combine the 2 oral drugs for a disease status which does not have very effective treatment. A randomized Phase III trial can answer this question.

8590 POSTER

Concomitant Radiochemotherapy With Weekly Cisplatin and Daily Capecitabine in Locally Advanced Head and Neck Cancer-Safety and Efficacy

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Loco-regionally advanced head and neck cancer is associated with a poor prognosis despite treatment with surgery or radiation or both. To improve the major end points of treatment we have focused on the used of concomitant radiochemotherapy. Cis and 5FU have been considered the standard for concomitant radiochemotherapy. The oral fluoropyrimidine, capecitabine was design to mimic continuous infusion 5FU. There is proved that oral capecitabine and 5FU continuous infusion have the same efficacy, therefore, our goal is to evaluate the efficacy and safety of concomitant chemoradiotherapy with cap and cis in locally advanced head and neck squamous cell carcinoma.
Method: Jan 2007–Jan 2009; 31 pts. with locally advanced head and neck squamous cell carcinoma, primary tumour sites: oral cavity − 6 pts, oropharynx − 10 pts, hypopharynx − 8 pts, nasopharynx − 6 pts, paranasal sinus − 1 pts, good performance status, good hepatic cardiac, renal and hematologic function.
Treatment: 70 Gy 3D-external beam RT (1.8−2 Gy/fr) concomitant with cap 660 mg/mp daily and cis 20 mg/mp weekly, entire period of RT.
Results: Follow up period − 2 years. CR − 24 pts. PR − 7 pts. PFS and OS rates at 2 years: 56% and 74% respectively. Toxicity grade 3−4 − neutropenia − 3 pts, digestive toxicity (vomiting, nausea) − 3 pts, mucositis − 5 pts. 4 pts needed to discontinuing the treatment due to toxicity. No death, no renal toxicity, no hand-foot sdr. were observed.
Conclusion: This modality of treatment was found to be well tolerated and effective in pts with locally advanced head and neck squamous cell carcinoma. This regimen can be regarded as an important chemoradiotherapy option for advanced head and neck squamous cell carcinoma and easily used in ambulatory patients. Long term follow-up is needed to evaluate (in larger trials) the late treatment failure and side effects.

8591 POSTER

Effects of Human Papillomavirus (HPV) and Other Potential Risk Factors on Survival in Patients With Oropharyngeal Cancer

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Background: Oropharyngeal carcinomas are associated with HPV or with tobacco smoking and alcohol. HPV associated carcinomas arise most frequently in the tonsils and have a more favorable prognosis in contrast to tobacco smoking and alcohol induced carcinomas. Here we report on frequency and outcome of HPV associated oropharyngeal carcinomas (tonsils and base of tongue) in a Berlin cohort with high prevalence of smoking.
Methods: Between 2005 and 2009 114 patients with oropharyngeal squamous cell carcinomas were diagnosed in a city hospital, 60 arising from tonsils and 54 from the base of tongue. Patients received surgery, chemoradiation or radiotherapy according to stage of disease. Complete follow-up information was obtained in fall of 2010. Histologic slides were retrieved and stained for p16 as indicator of HPV associated disease. Proportional-hazard models and log-rank tests were used to compare the risk of progression and death among patient subgroups.
Results: Of all 114 patients, 81% were smokers and 64% tumours stained positive for p16 (tonsils 73%, base of tongue 54%). With a median follow-up of 28 months 31 patients had disease progression and 39 patients had died. 3-year PFS rates were 79% and 52% in patients with p16+ vs. p16- tumours ($p = 0.001$ by log-rank test) and 3-year OS rates were 78% and 39% in patients with p16+ vs. p16- tumours ($p < 0.001$ by log-rank test). In cox regression analysis, only stage and p16 were independant prognostic factors. For PFS p16 had a hazard ratio (HR) of 0.44% (95% CI, 0.25 to 0.78) and also for OS a HR of 0.44% (95% CI, 0.24 to 0.78).
Conclusions: Even in a European population with high prevalence of tobacco smoking, p16 positivity remains a strong favorable and independant risk factor, as has previously been shown in US cohorts with far lower smoking prevalence.

8592 POSTER

Long Term Quality of Life, Physical and Psychological Functioning in Patients Affected by Relapsed Head and Neck Cancer

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Background: Primary head and neck squamous cell carcinomas (HNSCC) and their recurrences can heavily affect patient's quality of life (QoL). Aim of our study was the evaluation of the impact of treatment on QoL, physical and psychological functioning of patients affected by recurrent HNSCC.
Material and Methods: The sample was composed by 34 patients affected by recurrent HNSCC. Primary tumour treatment was as follows: exclusive RT (radiotherapy) 18%, S+RT 55%, RT + chemotherapy (CT) 27%. In order to evaluate the late effects of RT we used the RTOG–EORTC late radiation morbidity score plus the DISCHE morbidity recording scheme.
Psycho-oncological assessment included: HADS, MADRS, MINI MAC, EORTC QoL HN 35.
Results: Among this population, 55% of pts relapsed on T, 15% on N, 21% on T+N and 9% on M. Recurrences were treated with S+CT 6%, RT+CT 21% and CT alone 73%. The late toxicity evaluation demonstrates that skin alterations, salivary glands impairement, subcutaneous fibrosis and mucous membrane alterations are the most relevant and severe damages. After a median follow-up of 60±26 months, analysing RTOG-EORTC scale, high scores of skin and mucous membrane alterations are related ($p < 0.05$) with higher levels of anxiety and depression, negative coping styles (reduction of fighting spirit, anxiety and depression) are increased by salivary and mucous membrane dysfunctions ($p < 0.05$), moreover lower levels of QoL, in particular physical and social functioning, are correlated with higher levels of mucous membrane damages ($p < 0.05$); all the mentioned above symptoms increase negative thoughts ($p < 0.05$). DISCHE findings are superimposeable.
Conclusions- Treatment of relapsed HNSCC added to surgery and or RT and or CHT on the primary tumour could result in a heavy addictive effect on mucous membrane, skin, subcutaneous tissues and salivary glands referred symptoms. Negative coping styles and thoughts, increased anxiety and depression and lower levels of QoL are strongly associated to high scores of such symptoms.

8593 POSTER

VEGF and Oral Cancer − ex Vivo and in Vitro Studies

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Introduction: Scotland has the highest occurrence of oral cancers in both men and women across the UK (CR-UK, 2006) and the incidence is on the rise. The frequency in Scottish males is 18.4 per 100,000 (UK average is 11.9) and in Scottish women is 7.4 per 100,000 (UK average is 5.8). The aim of this study was to investigate the VEGF family as markers of tumour progression and to investigate how VEGF affects cell migration and signalling pathways, in vitro.
Materials and Methods: Tissue was collected from a cohort of 64 patients with oral cancer and 22 patients with dysplastic lesions. The tissue was analysed for expression of VEGF-A and VEGF-C by immunohistochemistry and then semi-quantitatively assessed. A cohort of serum samples was