116 POSTER

Phase II analysis of Taxol and Capecitabine in the treatment of recurrent or disseminated, squamous cell carcinoma of the head and neck region.

J.D. Bentzen, H.S. Hansen. *Rigshospitalet, University Hospital, Dept. of Oncology, Copenhagen, Denmark*

Background: No standard chemotherapy has yet been agreed upon for recurrent or disseminated head and neck cancer, but most regimes tested so far contains Cisplatin; a drug that demands hospitalisation and have a high toxicity profile in this group of patients. We wanted to find a drug regime that could be administered on an outpatient basis and with a more tolerable toxicity. This is the preliminary results from a phase II study with Taxol and Xeloda.

Material: The study started to include patients 3 years ago. 50 patients have been included in the study of which 40 are evaluable. Patients with recurrent or disseminated squamous cell carcinoma are eligible. 42 males and 8 females entered the study: The median age was 55 years (32-73 years). 53% had pharyngeal, 29% oral, 12% laryngeal tumours and a few nose, maxillary and unknown primary tumours. Most patients had inoperable locoregional tumours but 15 patients had distant metastases in lung, lever or bone.

Methods: The treatment consisted of Pacilitaxel (Taxol) 75 mg/m^2, once every third week and Capecitabine (Xeloda) 825 mg/m^2 p.o. b.i.d. for 2 weeks.

Results: Patients who have had at least 3 series were evaluable for response. All patients were evaluable for toxicity, one patient died before treatment. 5 patients had 12 series, 5 had 9 series, 13 had 6 series and 17 patients had 3 series. The overall response shows 1 CR, 14 PR; 12 NC, 9 PD; 4 patients are still in treatment. The patient with complete response had 6 series chemotherapy, and has so far been free of symptoms and disease for more than 1* year. *Toxicity* was moderate. Hair loss after 2 to 3 series was observed in all patients. Hand-and-foot syndrom grade 2-4 were observed in 90%, but reversible even under continous treatment. Three patients had GI toxicity of grade 3+4, of which one had to have his treatment stopped. No heart toxicity was recognized. Blood toxicity was a minor problem. 3 patients had WBC toxicity grade 4 and 6 patients had a neutrophile count grade 4.

Conclusion: Toxicity was tolerable, hair loss and hand-and-foot syndrome were common, but expected. One patient had gastrointestinal toxicity grade 4 and treatment was terminated. The overall response was better than in most series.

117 POSTER

Oxaliplatin plus capecitabine in advanced neuroendocrine tumours (NETs): Is the new WHO classification applicable to daily practice?

L. Catena[1], E. Bajetta[1], G. Procopio[1], L. Ferrari[1], S. Della Torre[1], E. Verzoni[1], E. Bichisao[2], R. Buzzoni[1], S. Iacobelli[3], A. Falcone[4]. *[1] Ist. Nazionale per lo Studio e la Cura dei Tumori, Medical Oncology Unit B, Milano, Italy; [2] I.T.M.O. Group, Milano, Italy; [3] Università "G. D'Annunzio", Chieti, Italy; [4] Spedali Riuniti ASL 6, Livorno, Italy*

Background: WHO has recently suggested diagnostic criteria for classifying NETs, based on histological evaluation. Consequently *poorly-differentiated* and *well-differentiated* NETs are treated by chemotherapy and biotherapy respectively. We have applied the suggested diagnostic criteria in order to choose an adequate treatment and to check its consistency in efficacy and prognosis.

Methods: Twenty-seven patients (pts) with advanced NETs were treated with oxaliplatin and capecitabine. 15 pts had *well-differentiated* NETs progressing after biotherapy (octreotide or lanreotide), 10 pts had untreated *poorly-differentiated* NETs and two pts had Merkel carcinoma.

The plan of treatment was oxaliplatin e.v. 130 mg/mq day 1 and capecitabine 2000 mg/mq per os day 2-15 every 28 days, for a maximum of 6 cycles.

The median age was 60 years (range 28-71). The primary site of disease was lungs 8, pancreas 7, bowel 3, kidney 2, skin 2, unknown 2 and others 3. Eighteen percent of pts had more than two metastatic sites. At baseline, serum cromogranin A levels were increased in 20 (74%) pts and NSE in 7(26%) pts. Six (40%) pts, with well-differentiated NETs, had carcinoid syndrome consistent in diarrhoea (4) and flushing (5).

Results: In 15 pts with *well-differentiated* NETs the objective responses were 3 PR, 6 SD, 3 PD. Two pts are still in treatment and one patient was lost to follow-up. Biochemical responses were 20% and symptomatic responses were about 50%.In 10 pts with *poorly-differentiated* NETs the objective responses were: 2 PR, 1 SD, 6 PD. One patient was not evaluable because is still in treatment. Biochemical responses were 20%. No responses were observed in Merkel cells carcinoma. The adverse events were mild: nausea and vomiting grade 1-2 in 25% of patients, asthenia grade 3 in 5% of pts and thrombocytopenia grade 1-2 in 20% of pts.

Conclusion: The WHO classification simplifies the identification of high risk pts and they are therefore treated accordingly. Oxaliplatine and capecitabine appears less effective in *poorly-differentiated* NETs than in *well-differentiated* NETs that have previously been given biotherapy. Thusthis chemotherapy regimen is well tolerated and feasible in advanced NETs especially in pts rapidly progressing after biotherapy.

Data management by scientific service I.T.M.O. - Italian Trials in Medical Oncology.

118 POSTER

Conformal radiotherapy for carcinoma of the nasopharynx: pattern of acute and late toxicities

J. Domont[1], P. Giraud[1], C. Jaulerry[1], F. Brunin[1], M. Jouve[2], D. Point[3], T. Jouffroy[3], V. Mosseri[4], S. Zefkili[1], J. Rodriguez[3]. *[1] Institut Curie, Department of Oncology Radiotherapy, Paris, France; [2] Institut Curie, Department of Oncology, Paris, France; [3] Institut Curie, Department of Surgery, Paris, France; [4] Institut Curie, Department of Biostatitics, Paris, France*

Purpose: to evaluate the toxicity of conformal radiotherapy (RT3D) alone or associated with chemotherapy in carcinoma of the nasopharynx (NPC).

Patients and Methods: Between 01/89 and 7/01, 51 patients aged from 18 to 86 years (median 47) were treated with curative intent for NPC. All patients received RT3D to a median total dose of 65 Gy with 2 Gy/d. Twenty patients received RT3D alone, 26 received RT3D preceded by chemotherapy (5FU: 600mg/m^2/d D1-5, CDDP: 40mg/m^2/d D2-4, Cyclophosphamide: 500mg/m^2/d D1 and D5, Doxorubicin: 50mg/m^2 D1), 5 received concurrent chemoradiotherapy (Carboplatin: 20mg/m^2 each day). Twenty-six patients were T1T2, 13 T3, 12 T4, 19 N0N1, 13 N2, 17 N3 and 2 Nx; 3 patients were M1. UCNT was present in 40 patients and SCC in 21 patients. The median follow-up was 48 months (range: 19-77). Acute toxicities and chronic toxicities were analyzed according to RTOG and LENT SOMA grades, respectively.

Results: All patients completed RT3D. Grade 2 and 3 acute skin reactions occurred in 14 and 5 patients, respectively. There was no Grade 4. Grade 2, 3 and 4 mucositis were observed respectively in 11, 18 and 7 patients. Acute Grade 3 and 4 dysphagia occurred in 7 and 8 patients, respectively. Weight loss (> 10%) was observed in 13 patients. Only 1 patient experimented Grade 2 fever and 1 Grade 4 thrombopenia. Chronic toxicity included Grade 2 (n=10), Grade 3 (n=13) and Grade 4 (n=2) xerostomia. At 24 months, there were 54.1% patients with Grade>2 xerostomia. There was one Grade 2 trismus. More questionable, Grade 2, 3 and 4 hear loss were observed in 5, 3 and 1 patients, respectively (12.6% at 24 months). Chemotherapy (neoadjuvant or concurrent) didn't increase acute or late toxicities.

Conclusion: Although retrospective, the results suggest that RT3D has acceptable toxicity. Grade 3, 4 acute and late toxicities were equivalent with addition of chemotherapy. IMRT could have the potential to decrease toxicities allowing concurrent chemotherapy addition and/or total dose escalation.

119 POSTER

Re-irradiation for locally recurrent nasopharyngeal carcinoma: treatment results and prognostic factors

D.C. Oksuz[1], G. Meral[1], O. Uzel[1], S. Turkan[1], P. Cagatay[2]. *[1] Istanbul University, Cerrahpasa Medical Faculty, Radiation Oncology, Istanbul, Turkey; [2] Istanbul University, Cerrahpasa Medical Faculty, Biostatistics, Istanbul, Turkey*

Purpose: To analyze the results and evaluate the prognostic factors in the retreatment of locally recurrent nasopharyngeal carcinoma.

Methods and Materials: Forty-one patients with locally recurrent nasopharyngeal carcinoma were re-irradiated at the University of Istanbul, Cerrahpa&sogon;a Medical Faculty, Department of Radiation Oncology, between 1979 and 2000. There were 32 males and 9 females with median age of 46 years (range: 15 to 67 years). Histologically, 9 tumors (22%) were WHO I (squamous cell carcinoma), 17 (41.5%) WHO II (nonkeratinizing carcinoma), 15 (36.6%) WHO III (undifferentiated carcinoma). According to the 1997 TNM staging system of the American Joint Committee on Cancer (AJCC), the recurrent disease was stage I in 5 (12.2%), stage II in 11 (26.8%), stage III in 6 (14.6%), and stage IV in 19 (46.3%) patients.