Results: Operative intervention have been performed in 44 patients. Resection of maxilla with ecsenteration of orbit have been done in 27(61%) patients. Different volum of resections of maxilla with preserving of eyeball have been performed in 17(39%) patients. Resections of the lower wall of the orbit with simultaneous plastic reconstruction (Kyonig type) using m.temporalis have been done in 7 patients.

Conclusions: Above mentions allows to considers, that study of clinical course and elaborate new approach to combined and complex of treatment patients with malignant tumors of accessory nasal sinuses with defeating orbit are actual problem

139 POSTER

The impact of prognostic factors and treatment on the outcome of anaplastic carcinoma of thyroid.

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Background: To assess the outcome of anaplastic carcinoma of thyroid and analyse the treatment and/or other factors influencing the prognosis.

Materials and Methods: Cases of anaplastic carcinoma of thyroid were identified from the population based Saskatchewan cancer registry.A detailed chart review was conducted.For the cases with a suvival of more than or equal to two years, pathological material was reviewed, where possible.Survival was calculated using Kaplan Meier method and log rank test to compare the groups.

Results: 21 out of 107 cases, initially identified were excluded. The reasons included a coding error, diagnsis at autopsy, based on a pathology review or absence of histological documentation Observed one, two and five year survival was 23%, 12% and 7% respectively. The difference in survival between the sexes was not statistically significant. However after 2 years, females had a slightly better survival trend. Patients with small cell morphology had a better survival versus large cell in 50 evaluable cases (p=0.0271).There was a survival advantage for the patients who underwent a surgical procedure compared to to the group that underwent biopsy alone(p=0.0011). Patients with total thyroidectomy fared better versus lobectomy.An advantage was seen for the patients who received radiation therapy (p=0.0563).A better survival was observed among the patients receiving the higher dose (>4000 cGy) compared to those with the lower dose (<4000 cGy), (p=0.0337). The patients having surgery alone or surgery in combination with radiation therapy fared better than radiation therapy alone (p=0.0051).

Conclusion: Prospective trials of a rare disease entity such as anaplastic thyroid ca. are extremely difficult. Retrospective reviews like this can help in improving the therapeutic approach. It is recommended based on this observational data to combine a higher dose of radiation therapy with total thyroidectomy, where possible, when managing the anaplastic carcinoma of thyroid.

140 POSTER

Prognostic factors of overall survival for patients with recurrent head and neck cancer: a retrospective study.

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Background: The aim of the present study was to determine the clinical prognostic factors for overall survival from recurrence (OSR) in patients with recurrent head and neck squamous cell carcinoma.

Material and methods: Using data recorded in the Doubs Cancer Registry between 1983 and 1998, 309 patients were analysed. The major characteristics were: primary tumor size T1-2 49.8%, primary nodal involvement 63.8%, exposure to radiotherapy during treatment of primary tumor 88.7%, performans status at recurrence date PS0-1 27.8%, local-regional relapse 75.4% and distant recurrence 24.6%. The median disease free survival (DFS) was 10.2 months (range: 1.2 - 157).

Results: The median OSR was 6.6 months (range: 0.1 - 158). The univariate analysis identified as pronostic factors for OSR duration the following parameters: size of primary tumor (T1-2 versus T3-4: $p < 6$ months versus > 6 months: $p = 0,01$), performans status (≥ 2 versus < 2: $p = 0,0001$) at the relapse and type of relapse (loco-regional versus metastatic recurrence: $p = 0,004$). In the multivariate analysis, size of primary tumor ($p = 0.002$), primary lymph nodes involvement ($p = 0.04$), DFS ($p = 0.01$), performans status at the relapse ($p = 0.001$) and type of relapse ($p = 0.007$) remaind significant pronostic factor for the OSR duration.

Conclusion: These prognosis factors are relevant to understand the results of phase II and to encure a fairer comparative evaluation during randomized studies.

141 POSTER

A phase II feasibility study of concurrent radiotherapy and gemcitabine for patients with cancer of the head and neck.

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Background: Gemcitabine (G) has excellent radiosensitizing properties, shown both in preclinical and clinical studies. In addition the drug is active in squamous cell head and neck (HN) cancer. Purpose of the study:1) to study the feasibility of weekly G concomitantly with radiotherapy (RT) in patiens (pts) with tumours in the HN site, 2) to study the safety profile, 3) to assess the antitumour activity of the combination.

Methods: based on previous experiences in phase I studies (Eisbrüch et al. ASCO 1997, 1998) we started in 12.98 with a weekly dose of 100mg/m^2 (given i.v. over 30 min). Eligible were pts with locally advanced tumors of the HN (recurrent (rec) or primary) not amenable to curative surgery (S) with adequate bone marrow, renal and hepatic function and in acceptable condition (Performance status (PS): 0,1,2), who gave consent. Prior use of RT or CT was permitted if discontinued > 4 weeks. Response evaluation (eval) was done according to WHO, toxicity to NCI-CTC.

Results: so far 31 pts entered the study, median age 59 yrs (range 44-80yrs), PS 1 (0-2). Tumor sites: pharynx 21, larynx 4, thyroid 2, oral cavity 1, paranasal sinus 1, primary unknown (TuN3M0)1, melanoma 1. Apart from the Tu and melanoma tumor stages were: 1 stage II (rec), 5 stage III (1 rec), 23 stage IV (3rec). Four pts were not evaluable for resp: 1 was not eval., 2 stopped early (1 unrelated death, 1 refusal), 1 had primary surgery. The median RT dose was 70 Gy (range 50-84.75), the median number of G cycles was 7 (range 2-8). 29 pts were evaluable for toxicity. Five pts were not eval. for pharyngitis, because of preexisting toxicity. Grade (gr.) 3 hematologic toxicity was rare: 2 pts gr. 3 leukopenia and 1 gr. 3 thrombocytopenia. Severe (gr.3/4) mucositis was seen in 83%, dermatitis in 61%, dysphagia in 75%, pain in 18%. Most (77%) pts received tube feeding, prior or during therapy. Response evaluation: 3/3 rec. disease pts responded (1CR) and all of primary disease pts did (10 CR).

Conclusion: RT + G is toxic, but tolerable and highly active.

142 POSTER

Phase II study of imatinib mesylate in salivary gland adenoid cystic carcinoma

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Background: The goal was to assess the antitumor activity of imatinib in adenoid cystic carcinoma of the salivary gland (ACC) expressing *c-kit*. ACC accounts for 22% of malignant salivary gland tumors, arises most commonly from the minor salivary glands & often recurs after local therapy. Pulmonary metastases are present in 40% of pts. The clinical course is often indolent & typical survival is 73% at 5 yrs, 45% at 10 yrs & 35% at 15 yrs. The response rate & duration to conventional cytotoxic agents is sub-optimal. A high level of *c-kit* expression has been identified in 90% of ACCs (Holst 1999). Imatinib specifically inhibits autophosphorylation of the *bcr-abl*, PDGFR-*beta* & *c-kit* tyrosine kinases & inhibits the growth of ACC cell lines *in vitro* (Ward 2002).

Materials and methods: In a single-arm 2-stage phase II clinical trial, adult pts with histologically documented unresectable or metastatic ACC measurable by RECIST criteria & with immunohistochemical expression of *c-kit* were treated with imatinib 400 mg PO bid repeated every 4 weeks. Doses were reduced for gr 3-4 or intolerable gr 2 toxicity. Response was assessed every 8 weeks.

Results: Fourteen pts have received 30 cycles of therapy (9 female & 5 male). Median age is 50 years (range, 31-69). Median ECOG PS 1 (range, 0-2). Twelve pts had lung metastases. Eleven had prior radiotherapy &

6 prior chemotherapy. Toxicities included fatigue, nausea, vomiting &/or diarrhea in at least 50% of patients & anorexia, edema, dyspnea &/or headache in a significant minority, usually gr 1-2. Gr 3-4 toxicities occurred in 1/3 of cycles & included fatigue, nausea, dyspnea, pleural effusion, abdominal pain, blurred vision, neutropenia, hypophosphatemia & elevated ALT. Six pts required dose reductions due to toxicity, & one pt discontinued treatment after 14 days due to intolerable gr 2 rash & is not evaluable for response. No responses have been observed in 13 evaluable pts. Five pts had SD as best response with 2 still on treatment. Nine pts had PD after 2 cycles: 5 radiologic PD, 2 symptomatic progression despite radiologic SD & 2 PD before completing 2 cycles.

Conclusions: Unless one objective response is seen in the 3 pts currently on treatment, the study will be stopped after the first stage & drug declared inactive. Accrual to this study was very rapid for a relatively rare cancer, encouraging further efforts to identify more effective systemic therapy for these pts.

143 POSTER

Stereotactic irradiation for olfactory neuroblastoma of the sinonasal tract

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Background: To review our experiences about Stereotactic Irradiation (STI) in the treatment of olfactory neuroblastoma (ONB), which is a rare tumor of the neural crest origin that arises in the sinonasal tract. There is still no consensus on the optimal treatment for this neoplasm.

Method and Materials: Three patients with ONB of the sinonasal tract who rejected the surgical operation and chemotherapy, or who were inoperable, were treated by only STI between 1999 and 2001 at Fukushima Medical University. A 6MV X-ray was used with a micromultileaf collimator. Two of them (patient#1 #2) were treated with stereotactic radiosurgery (SRS), and one of them (patient#3) was treated with stereotactic radiotherapy (SRT). The prescribed dose to the tumor with SRS and SRT was 20Gy to 25Gy and 3.75Gy to 5Gy, respectively.

Results: After a mean follow-up of 34Months (27-44Months), all patients showed CR and case #1 and #2 were alive with no recurrence, but case #3 died due to a different cause (gastric cancer) at 27Months after treatment. In patient #2, a partial resection of left maxillary sinus cavity was required because of fluid collection in this cavity after SRS. Histological examination revealed that there weren't any viable tumor cells remaining. In Case #3, the ONB was situated beside of the right eye ball and optic nerve, and pushed them to the right side. So, we treated the ONB by SRT to reduce the side effects to the neighboring eye ball and optic nerve. The tumor volume was reduced during SRT, so it was necessary to re-evaluate the treatment area to reduce the exposure risk to the neighbouring organs at the time of 30Gy. Then we increased the dose by 3.75Gy to 5Gy increments to minimize damage to the neighbouring organs. This adjustment was necessary because the tumor pressure was reduced allowing the organs to enter high dose area. There weren't any side effects in any of the patients.

Conclusion: We treated three ONB patients with STI without any complimentary treatments. All patients showed CR with no local recurrence and there weren't any side effects. STI is a successful treatment approach for local control of ONB in the sinonasal tract under appropriate conditions.

144 POSTER

Low clinical value of squamous cell carcinoma antigen in irradiated patients with advanced head and neck cancer

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Aim: Squamous cell cancer (SCC) antigen is widely used as a tumor marker in a broad variety of carcinomas of squamous cell origin. Best described it is in squamous cell carcinomas of uterine cervix and of the pulmonary bronchus. In head and neck cancer the results are contradictory. This study will examine SCC in patients irradiated for advanced cancer of the head and neck.

Methods: In 50 patients (group A) with advanced head and cancer (stage III: 21; stage IV: 29) treated with radiochemotherapy and in 50 patients (group B) (stage III: 25; stage IV: 25) receiving surgery and postoperative irradiation SCC was measured pretreatment and during follow up every 3 months using a commercially available assay. The cut-off level was defined at 2.0 ng/ml.

Results: Pretreatment SCC level in radiochemotherapy group was 1.7 ng/ml (0.2 5.6 ng/ml) in group A and 1.5 ng/ml (0.6 5.4 ng/ml) in group B. In group A only 11 (22%) had elevated serum SCC levels above the cut-off level. In group B there were 9 patients (18%). During follow up (median 20 months) in group A 24 patients (48%) in group A and 21 (42%) in group B suffered from a recurrent or progressing disease. Of these only 6 patients (25%) group A and three in group B (14,9%) had elevated SCC levels.

Conclusions: Our results indicate, that SCC that the sensitivity of SCC for tumor diagnosis and detection of recurrent disease is relatively low. On the other hand the specificity in those cases was a 100%. These results suggest, that in the described patients groups SCC is probably only of low value for tumor diagnosis and follow up.

145 POSTER

Combination docetaxel, cisplatin, and 5-fluorouracil as induction chemotherapy for locally advanced head and neck cancer

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Background: There are few studies on docetaxel (Taxotere®-based combination regimens as induction chemotherapy for head and neck cancer. The aim of this retrospective study was to assess the efficacy and tolerability of the TPF (docetaxel + cisplatin + 5-fluorouracil [5-FU]) regimen as induction chemotherapy for head and neck cancer.

Material and methods: We conducted a review of patients who had received docetaxel-based induction chemotherapy in our hospital between 1999 and 2002. All patients received TPF consisting of docetaxel 75 mg/m^2 iv on d1, cisplatin 20 mg/m^2 iv on d1-3 and 5-FU 300 mg/m^2 on d1-3, given every 3 weeks. Tumour responses were evaluated after induction chemotherapy. Toxicities were graded using World Health Organization criteria.

Results: A total of 25 patients with a median age of 54 (range: 35-75) years were included. Primary tumour sites were: oral cavity (11), tongue base (1), larynx (4), hypopharynx (4) and nasopharynx (5). Nine patients had relapsed after primary treatment. Patients received TPF induction chemotherapy plus surgery (14), radiation (9), or surgery and radiation (2). After induction TPF, 6 patients (24.0%) had a complete response (CR) and 12 patients (48.0%) had a partial response (PR), for an overall response rate of 72%; 7 patients had minimal or no response. Of the relapses, 4 patients (44%) responded after TPF induction chemotherapy (1 CR and 3 PR). Leucopenia occurred in 9/25 (36.0%) patients with the severity being grade 1 in 4/25 (16.0%) patients, grade 2 in 4/25 (16.0%) patients and grade 3 in 1/25 (4.0%) patients. The major nonhaematological toxicities included digestive discomfort and alopecia.

Conclusions: The overall response rate for TPF induction chemotherapy in this retrospective study was slightly lower than previously reported for this regimen. This may be due to the number of patients with locally advanced or relapsed disease. Toxicity of this regimen was manageable.

146 POSTER

Capecitabine combined with cisplatin in patients with advanced nasopharyngeal carcinoma (ANPC)

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Background The incidence of nasopharyngeal carcinoma (NPC) is highest in Southern China and Southern Asia with age-adjusted incidence rates of approximately 29/100,000. Cisplatin-based chemotherapeutic regimens are widely used in NPC. Capecitabine (Xeloda®, a highly active, thymidine phosphorylase (TP)-activated oral fluoropyrimidine carbamate, mimics continuous infusion 5-FU and delivers 5-FU preferentially to the tumour site by exploiting high intratumoral TP concentrations. As 5-FU combined with cisplatin is commonly used in NPC, capecitabine is potentially a more active and more convenient substitute. This study evaluates the activity and safety of capecitabine combined with cisplatin in Chinese ANPC patients (pts).