

**Results:** Operative intervention have been performed in 44 patients. Resection of maxilla with ecenteration 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

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### 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 survival 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, diagnosis 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 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.

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### 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%, performance 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 prognostic factors for OSR duration the following parameters: size of primary tumor (T1-2 versus T3-4:  $p < 6$  months versus  $> 6$  months:  $p = 0.01$ ), performance status ( $\geq 2$  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 ( $p = 0.01$ ), performance status at the relapse ( $p = 0.001$ ) and type of relapse ( $p = 0.007$ ) remained significant prognostic factor for the OSR duration.

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

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### 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 patients (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<sup>2</sup> (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.

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### 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 &