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Phase II trial of gemcitabine and paclitaxel (GEMTAX) combination in recurrent or advanced squamous cell carcinoma of the head and neck

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In preclinical and clinical studies, gemcitabine and paclitaxel have shown activity against squamous cell carcinoma of the head and neck (SCCHN). We have initiated a phase II study in patients with recurrent and/or advanced SCCHN to investigate the efficacy and toxicity of gemcitabine 3000 mg/m2 iv in 30 min and paclitaxel 150 mg/m2 iv in 180 min (GEMTAX) administered biweekly (on days 1 and 15 of each 28-day cycle) as described by Rothenberg et al. (Ann Oncol 9:733-738, 1998). 27 patients on the study had received 1-2 previous chemotherapy regimens, 34 patients had previous radiation therapy and 31 had previous surgery. Ten patients had received previous cisplatin and 5-fluorouracil and 17 had concurrent radiation and cisplatin chemotherapy given as postoperative adjuvant therapy. 218 cycles of chemotherapy was administered to 41 patients. Patients received 0-20 cycles (median 5) of the study treatment. Survival ranged from 1 to 28+ months (median 15). Twelve patients had grade 3 toxicities (9 anemia, 2 neutropenia and 7 infection). There was no grade 4-5 toxicity. Among the 31 response-evaluable patients, 3 had complete response (10%), 15 had partial response (48%), with an overall objective response rate of 58%. Eight patients had stable disease (26%) and 5 had progressive disease (16%) after 4 cycles of treatment. Ten patients were unevaluable for response because they received less than 4 cycles of therapy (required for response evaluability) or were lost to follow-up or had no repeat CT scan to evaluate response. The biweekly administration of gemcitabine and paclitaxel at the prescribed doses was extremely well tolerated with little or no toxicity even though relatively large doses of the two drugs were administered. This regimen appears to have remarkable activity in advanced and/or recurrent SCCHN. Current studies are investigating the pharmacokinetics, pharmacodynamics and possible bone marrow protection when the drugs are administered on days 1 and 15, instead of days 1 and 8, which is customary for most regimens employing gemcitabine.

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Long term results of radiotherapy for T1 glottic carcinoma

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A review was undertaken of all, 726 patients with stage T1 glottic squamous cell carcinoma treated between 1961 to 1996. The 5 year results are:

Overall survival (death any cause)	77%
Overall survival (cause specific)	92%
Relapse free survival	87%
Local control (freedom from local relapse)	89%

The 10 year local control results were similar.

The main factor affecting outcome was year of presentation with patients in the latest decade having a significantly better outcome than in the earlier period. Other factors examined included substage, age, sex, histological grade, radiation dose and field size.

Of those who relapsed locally, salvage was successful in 69%.

Severe complications occurred in five cases, 4 necrosis and one carotid stenosis.

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Merkel's cell carcinoma: our experience

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Merkel's cell carcinoma is a very uncommon cancer, located in the basal layer of the epidermis and in the hair follicules, occurring mostly in white, elderly people. It usually grows rapidly and is able to give distant metastases and regional lymph node involvement, and often local recurrences occur. Because of these charachteristics the prognosis is often poor even when a medical treatment is feasible according to the age and the conditions of the patient. We are able to give data about twelve patients, followed by the Divisions of Medical Oncology (since 1998) and Dermatology (since 1991) of Molinette Hospital. Seven of them are women, five are men, according to the literature that describes the same incidence between men and women; the age at the diagnosis was comprised between 63 and 94. In six of them the primary lesion was on the thight, in three on the cheek; in the other three the site was respectively shoulder, neck, sculp. After the excision of the primary lesion, six of them had to undergo the dissection of the regional lymph node because of secondary localizations. The two who underwent a profilactic dissection of them, followed by radiotherapy, have never had recurrence, and are nowadays with no evidence of disease at 3 and 7 years from the diagnosis. Five of them were also submitted to chemotherapy with Platinum compounds, Etoposide and Doxorubicin, two women with adjuvant intent, and three men in order to control a rapidly progressing illness; all of the men have died but for two of them it is difficult to give conclusions about the causes of death, because they also had a NHL; we don't know if the concomitance in two patients of a NHL is of any relevance; surely these tumor cells often present different histological patterns, one of which is "lymphoma-like diffuse type of growth". Seven patients are alive, disease free, after a follow up ranging from 9 years to 1; five of them underwent regional lymph node dissection. This seems to confirm that surgical approach must be extended to the lymph-glands, and that radiotherapy must follow surgery. Chemotherapy can slow the evolution of a recurrent disease, but, because of the small number of patients, we are not able to say if it can modify disease free survival and overall survival.

Endocrine tumours

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Prospective randomized multicenter trial on adjuvant percutaneous radiotherapy in locally advanced differentiated thyroid cell carcinoma

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Purpose: In locally advanced differentiated thyroid cancer (DTC), the role of adjuvant radiotherapy in addition to best standard care (surgery, ablative I-131 therapy, and TSH suppressive therapy) has not yet been sufficiently defined. Some retrospective analyses demonstrated improved local control while others documented similarly good treatment results without adjuvant percutaneous irradiation. We have initiated the first prospective randomized trial addressing this question.

Methods: Patients with differentiated papillary or follicular thyroid cancer in stages pT4 pN0/1/x M0 R0/1 between 18 and 70 yrs. are included in the study. All patients undergo thyroidectomy, central cervical lymph node dissection, and ablative radioiodine therapy. Patients are randomized to receive adjuvant percutaneous irradiation or not. Radiotherapy doses are chosen depending on stage and resection status with an application of 50,4 - 54 Gy to the lymph node areas of the neck and the upper anterior mediastinum and 59,4 - 66,6 Gy to the thyoid bed. Toxicity is evaluated with the RTOG/EORTC score. Quality of life is evaluated with QLQ C-30 of the EORTC. A central review of pathology slides, surgical reports, and radiotherapy plans is performed.

Results: The trial was started in October 2000. So far 49 centers in Germany and Austria are participating, and 63 patients have been included until April 2001. No unexpected toxicity or adverse events have occurred so far.

Discussion: A prospective randomized trial has been initiated to define the role of adjuvant percutaneous irradiation in locally advanced DTC. Assuming continued good recruitment, the study will for the first time allow a definite answer on the clinical utility of this treatment modality.

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Pediatric thyroid cancer

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Purpose: The biological behaviour – and so the extent of surgery – of childhood and adult thyroid carcinomas is controversial. The authors give