Methods 30 pts were enrolled from June 2002 to March 2003. All had measurable ANPC (WHO), ECOG performance status 0-2, adequate bone marrow, renal and hepatic functions. Prior radiotherapy was permitted. We used: capecitabine 1000 mg/m^2 twice-daily, days 1-14, followed by a 1-week rest plus cisplatin 80 mg/m^2 IV day 1, every 3 weeks. All patients received at least 3 cycles. Patients with PD went off study while patients with a complete response (CR), partial response (PR) or stable disease (SD) continued therapy for a maximum of 6 cycles of treatment.

Results 14 pts are evaluable so far: 9 men and 5 women; median age 54 years (range 32-68); median ECOG performance status 1; measurable lesions: liver 8 (57%), lung 7 (50%), lymph nodes 5 (36%) and skin 2 (14%). Median treatment duration is currently 3 cycles (range 1-6). One pt withdrew prematurely (grade 3 diarrhea). Grade 3 adverse events were few with frequencies below 10%: diarrhea, asthenia, cough, stomatitis, abnormalities of SGPT, SGOT and alkaline phosphatase in 1 pt each (7%). There was no grade 4 toxicity. Most common adverse events (>20% grade 1-2): leukopenia 3 pts (21%), abnormality of SGOT 3 pts (21%), abnormality of alkaline phosphatase 3 pts (21%). Only 1 pt experienced Hand-Foot Syndrome, grade 3 (7%).

	After 3 cycles (n=14)
PR	6 (43%)
SD	7 (50%)
Tumor growth control	13 (93%)

Median progression-free and overall survivals have not yet been reached.

Conclusion Capecitabine combined with cisplatin has proven to be a highly active regimen in Chinese ANPC patients and is very well tolerated, with a convenient 3-weekly administration. Updated results will be presented.

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Prognostic factors of combined modality treatment in patients with laryngeal cancer basing on modified Peters' scale of risk of recurrence

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Background: The evaluation of prognostic factors of combined modality treatment in patients with laryngeal cancer basing on modified Peters' scale of risk of recurrence

Material and methods: Between 1994-96 197 pts were irradiated after surgery. Partial resections (PR) of the larynx were performed in 42(21%) of patients (pts), total resections (TR) in 155 pts (79%). Preoperative analysis revealed advanced laryngeal cancer (T3-4) in 67% of pts and absence of neck nodes metastases (N0) in 63% of pts and respectively 72% and 65% in postoperative analysis. Macroscopic non-radicalism was noted in 15 pts (8%). Microscopic non-radicalism was noted in 44 pts (22%). Emergency tracheostomy was done before surgery in 29 pts (15%). The risk of postoperative recurrence was established according to modified Peters' criteria. In 118 of pts (60%) risk of local recurrence was low (0-2), in 59(30%) moderate (3-5) and in 20(10%) high (>5). In 53 of pts (51%) risk of nodal recurrence was low, in 33(32%) moderate and in 13(13%) high.

Results: 5-year actuarial LC and DFS were 88% and 68%, respectively. Along with increasing clinical stage DFS decreases from 79% in stage I to 62% in stage IV. 5-year DFS was 33% and 25% lower in the case of macroscopic or microscopic non-radicalism, respectively comparing to pts after radical resections. 5-year LC was 83% after PR comparing to 90% after TR. 5-year DFS in pts with pretreatment tracheostomy was 47% comparing to 71% in pts with tracheostomy performed during surgery. The most significant influence on treatment results was observed for particular groups of risk recurrence: 5-year LC and DFS was 93% and 76% respectively for pts with low risk of local recurrence, 86% and 57% for moderate risk and 63% and 42% for high risk. Similar, highly significant correlation was observed for groups of risk of nodal recurrence.

Conclusions: Most important negative prognostic factors influencing combined modality treatment are: macro- or microscopicall surgical non-radicalism, presence of node metastases and emergency tracheostomy. The most important influence on efficacy of combined modality treatment seems to have the degree of risk recurrence established according to modified Peters' scale.

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Prognostic and predictive factors in patients with advanced squamous cell head and neck cancer (HNSCC) treated with induction chemotherapy (CT) and radiotherapy (RT)

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Background: In advanced HNSCC combination of CT and RT seems to improve treatment results. However there has been a lack of predictive factors which may help to select patients (pts) for this combined treatment. Aim of this study is to assess clinical, histological and molecular factors influencing prognosis and predictive for response in pts with advanced HNSCC treated with induction CT and RT.

Material and Methods: Between Jan 1988 to Dec 1997 pts with advanced HNSCC received induction CT: cisplatin with 5FU. There were 184 male and 14 female with median age of 57 years (range 36-80 years). Seven pts had stage II, 45 stage III and 146 stage IV disease. 18 pts were given one course of CT only. In 180 pts 2-4 courses were given. Subsequent RT was applied in 158 pts. Treatment results were analyzed in relation to clinical, therapeutic, histological and molecular factors. The archival histological materials were available in 77 pts in whom retrospective assesment of histological grade of tumors was done. Immunohistochemical assays for EGFr, p53, MIB1 was performed. Main endpoint of the analysis has been probability of response to CT (CR+PR), survival without locoreginal recurrence (LRRFS) and overall survival (OS).

Results: Median follow-up time is 16 months. Response to CT was achieved in 46% of pts. LRRFS and OS in relation to clinical, therapeutic, histological and molecular factors are shown in table. Highest response rates to CT were found in pts with laryngeal and hypopharyngeal cancer, with grade III and without EGFr expression.

Factor		No of pts	Response to CT (%) (PR+CR)	LRRFS %	OS %
Localisation	Oropharynx	66	45	24	18
	Larynx	96	61	34	29
	Hypopharynx	12	67	25	9
	Oral cavity	24	37	9	5
Stage	II	7	57	36	38
	III	45	60	34	30
	IV	146	51	24	15
No of CT courses	1	180	59	28	20
	2-4	180	59	28	20
Grade	I	12	33	8	0
	II	37	51	20	14
	III	28	71	36	28
EGFr	–	38	68	31	23
	+	35	40	12	3
MIB1	<54	37	49	23	16
	>54	38	61	23	15
p53	–	34	53	12	7
	+	41	59	30	23

Conclusions: Predictive factors for response to CT are: grade III and lack of EGFr expression. Prognostic significance for survival have: response to CT and localisation of primary tumor.

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Neoadjuvant Docetaxel /Cisplatin /Fluorouracil (TPF) before concurrent chemo-radiotherapy (CT-RT) versus concomitant CT-RT alone in locally advanced Squamous Cell Carcinoma (SCC) of Head and Neck. A phase II feasibility study.

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Purpose: To determine the feasibility of neoadjuvant TPF followed by concurrent CT-RT in comparison to the same CT/RT alone in locally advanced SCC of the Head and neck.

Eligibility Criteria: SCC of the oral cavity, oropharynx, rinopharynx and ipopharynx. Stage III-IVM0; PS 0-1; no prior CT or RT.

Material and Methods: In the original designed of the study, the treatment options were: (Group A) 3 cycles of CT (Carboplatin 70 mg/mq days 1-4 and Fluorouracil 600 mg/mq/d c.i. for 96 hours) starting on days 1, 22, 43 during RT (66-70 Gy/ 33-35 fr) or (Group B) 3 cycles of neoadjuvant TPF combination (T 75 mg/mq; P 80 mg/mq, F 800 mg/mq c.i. 96h) followed by the same CT/RT.

Results: A total of 24 pts were treated. Median age was 59 (range 41-73). Sex M/F: 19/5. Stage II/III/IV: 1/6/17. PS 0/1: 17/7. After the first 16 pts, 8 in Group A and 8 in Group B, the concomitant CT/RT schedule was modified. The limiting toxicity was observed during concomitant CT/RT and was similar in group A and B, independently from neoadjuvant TPF administration. Based on the data showing an excess of G3-4 mucositis not allowing to complete CT/RT without interruption, the following 8 pts (Group C) received 3 cycles of neoadjuvant TPF followed by 2 cycles only of CT with Cisplatin 20 mg/mq days 1-4 + F 800 mg/mq c.i. 96h (PF) during week 1 and 6 of RT.

In the 16 pts receiving 3 cycles of CT during RT, WHO G3-4 hematological toxicity were neutropenia 22% and thrombocitopenia 20%. Non hematological G3-4 toxicity was mucositis 60% and weight loss G2 69%. Toxicities were not increased in the neoadjuvant TPF group. In the last 8 pts receiving 2 cycles only of CT during RT, WHO non hematological G3-4 toxicity were mucositis 28.5% and weight loss G2 28.5%. No WHO hematological G3-4 toxicity was seen.

Toxicities in the 16 pts receiving neoadjuvant TPF were manageable: neutropenia G3-4 37.5% was the principal hematological toxicity while mucositis G2 (44%) was the most important non hematological toxicity. The complete Response Rate for the 24 pts was 77%.

Conclusion: Three cycles of neoadjuvant TPF followed by 2 cycles of PF combination during RT are feasible without limiting toxicities. Three cycles of TPF combination are well tolerated and don't compromise subsequent concomitant CT-RT. A randomized multicentric phase III Italian study has started with the aim of comparing 2 cycles of PF during RT as standard treatment vs the experimental arm with 3 cycles of neoadjuvant TPF followed by 2 cycles of PF during RT.

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Small cell carcinoma of the head and neck: experience of a single comprehensive cancer centre

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Background: To review the experience of a single comprehensive cancer centre with small cell carcinoma originating in the head and neck.

Materials and Methods: Patient records were reviewed for demographics, presenting site and symptoms, disease stage, pathology, treatment and outcome.

Results: Between 1971 and 2002, 11 patients had a pathologic diagnosis of extra-pulmonary small cell carcinoma. Median age was 63 years (range: 20 - 93). The primary sites were: 5 salivary gland (4 parotid; 1 submandibular); 2 larynx; 1 oral cavity; 1 nasopharynx; 1 sphenoid sinus; and 1 unknown primary. There were 2 AJCC(6th ed)/UICC stage 3, 6 stage 4A, and 2 stage 4B tumors. One patient (sphenoid sinus primary) tumour could not be staged. Five of 11 presented with pain and 1/11 with a paraneoplastic syndrome (SIADH). Nine patients had nodal metastases at diagnosis. Definitive surgical resection of primary and regional disease was performed on 6/11. Radical or adjuvant radiotherapy was delivered in 6/11 cases with a median dose of 50 Gy (range 35 to 70). Radiotherapy was not delivered in 3 patients due to post-operative death (1), development of metastases (1) or patient preference (1). Two patients were treated with palliative intent. Five patients received chemotherapy as part of their initial management. Failure was documented locally in 5/11, in regional lymph nodes in 2/11 and distantly in 5/11. For all patients, the median survival was 1 year with a 28% 5 year overall survival. Two patients received both chemotherapy and radiation, each achieved locoregional control; one patient is alive and disease free at 8 years of follow-up.

Conclusion: Extra-thoracic small cell carcinoma of the head and neck often presents in advanced stage and has a poor prognosis. A propensity for rapid local growth and distant metastatic spread, suggests a need for aggressive local and effective systemic treatment.

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Long-term outcome of complications after thyroid cancer surgery

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Vocal cords paresis and hypoparathyroidism are most relevant complications following radical thyroidectomy in differentiated thyroid cancer (DTC). Their frequency in overall population is higher than in published results of specialized centers and according to Hoelzer *et al.* may reach even 15% of cases. Only a few reports consider the impact of these complications on the quality of life and their long-term outcome, both extremely important for the evaluation of benefit/risk ratio of radical surgery in DTC.

Aim of the study was to analyze the persistence of vocal cord paresis and hypoparathyroidism in DTC patients after >2 years since thyroid surgery and assess their impact on the quality of life.

Material and methods. 110 patients, 86% women and 14% men, mean age 50.9, among them 52% patients with vocal cord paresis and 48% with post-operative hypocalcaemia were subjected to re-analysis of parathyroid function (Ca^{2+}, PTH, diurnal calcium excretion, all analyzed after calcium or 25-OH-cholecalciferol withdrawal) and laryngological examination. Health-related quality of life was measured using City of Hope Quality of Life Thyroid version questionnaire (Ferrell, Dow *et al.*). Complication-related clinical symptoms were recorded on own questionnaire with 24 items, each coded on 10-point continuous scale.

Results. Normal parathyroid function was found in 51% of patients, who were claimed persistently hypoparathyroid 6 months after operation. Among patients diagnosed with vocal cord paresis, 33% of cases showed no abnormalities in laryngological examination. Quality-of-Life questionnaire was performed in 41 patients. In the group of patients with vocal cord paresis we revealed a strong impact of nerve palsy on the overall quality-of-life score (correlation coefficient $r=0.826$, $p<0.005$), mainly the physical and psychological well-being. Mean overall QOL score in this group was 5.66 ± 0.50. Hypoparathyroidism exhibited relatively weaker impact on overall QOL score ($r=0.552$, $p<0.05$), affecting mainly the psychological and social subscores (overall QOL 6.17 ± 0.35).

Conclusion. Diagnosis of persistent complications of thyroid cancer surgery made 6 months post-operation should be re-verified after more than 2 years. Persistent complications affect significantly quality of life of patients, vocal cord paresis being more prominent in comparison to hypoparathyroidism, when substituted properly.

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Efficacy of I-131 ablation therapy using different doses based on postoperatine thyroid scan uptake in patients with differentiated thyroid cancer

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Background: The optimal dose of I131 for ablation of functioning residual thyroid tissue after surgery is controversial. The current study was conducted to determine optimal dose of I131 for remnant postoperative ablation including a review of the literature.

Methods and Materials: Two hundred thirty eight patients wiyh papillary and follicular carcinoma were treated with I131 for ablation of postoperative thyroid remnant. I131 dose was based on the 24h percentage neck-uptake in postoperative thyroid scans. Patients with <5% uptake received a median of 85 millicuries (mCi); with 6-10% uptake, 80 mCi; with 11-15%, 60 mCi; with 16-20% uptake, 50 mCi and with 21% uptake, 30 mCi. Ablation results were compared with prognostic factors.

Results: Complete ablation was observed in 40/43 (92%) patients receiving 85 mCi, in 31/33 (94%) who received 80 mCi, in 39/41 (95%) who received 60 mCi, in 51/55 (93%) who received 50 mCi, in 37/39 (94%) who received 30 mCi and in 18/19 (96%) of all others who received 30 mCi. Overall successful ablation rate was 94%, (95% CI, 89%-100%).

Conclusion: Our findings suggest that patients with differentiated thyroid cancer can be treated with doses of I131 according to percentage neck uptake of postoperative TBS, with high complete ablation rates, without exposing patients to higher dose levels of I131.