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/m² twice-daily, days 1-14, followed by a 1-week rest plus cisplatin 80 mg/m² 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

A. Mucha-Malecka, K. Skladowski, A. Wygoda, W. Sasiadek. Center of Oncology, Radiotherapy Department, Gliwice, Poland

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 the safer 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)

A. Mucha-Malecka¹, S. Korzeniowski², J. Rys³. ¹ Center of Oncology, Radiotherapy Department, Gliwice, Poland; ² Center of Oncology, Radiotherapy Department, Cracow, Poland; ³ Center of Oncology, Pathology Department, Cracow, Poland

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
	111	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		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.

M.G. Ghi¹, A. Paccagnella², P. D'amanzo³, C.A. Mione⁴, S. Fasan⁵, R. Carnuccio⁶, C. Mastromauro⁷, G. Turcato⁸. ¹ Ss Giovanni E Paolo Hospital, Oncology, Venice, Italy; ² S Giovanni E Paolo Hospital, Oncology, Venice, Italy; ⁴ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy; ⁵ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy; ⁶ S Giovanni E Paolo Hospital, Oncology, Venice, Italy; ⁷ S Giovanni E Paolo Hospital, Oncology, Venice, Italy; ⁸ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy; ⁸ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy; ⁸ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy; ⁸ S Giovanni E Paolo Hospital, Radiotherapy, Venice, Italy

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.