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.

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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.

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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.

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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.

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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).

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.