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Materials and Methods: HNC patient scheduled for radical radiotherapy were included. They were examined with videoflouroscopy (VF) and answered EORTC C30 and H&N35 quality of life questionnaires (QLQ) as well as questions regarding the exercises (diary). The patients were instructed in exercises for the pharyngeal constrictor, tongue, jaw, suprahyoid muscles and oesophageal sphincter and to perform the exercise program 3 times daily or as frequent as possible. VF was performed before RT and two, five and 11 months after RT. Compliance, the swallowing scale of the QLQ, and the usefulness of the diary were the primary endpoints.

Results: 10 males with cancer of the pharynx (5), larynx (3) and oral cavity (2) with a median age of 59 years were included. All patients had some dysphagia at inclusion. Patient- reported tube dependency peaked at 14 days after therapy (38%) and reached 0% at 8 months. Patients stated complete adherence to the exercise protocol at 11% of encounters. At least one exercise a day for all organs was carried out for 100%, 75% and 66% of patients after 1, 3 and 5 weeks of therapy, respectively and 83%, 85%, 50%, 60% and 50% at 14 days, 2, 5, 8 and 11 months after therapy, respectively). Adherence to the instructions and swallowing capability could not be predicted from pre-RT variables. During and shortly after radiotherapy there was a tendency that pain limited the conduction of exercises. Later the tendency was reversed.

Conclusions: The exercises were uncomfortable during radiotherapy and compliance only moderate. Support from the therapists is crucial for an opportunity to build a relation to the patient that promoted the adherence to the protocol. We will continue to a randomized phase II study with VF changes as the primary endpoint.

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8569 POSTER

Neoadjuvant chemotherapy plus concomitant chemoradiotherapy in head and neck cancer: late toxicity and impact on quality of life

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Background: head and neck tumors and their treatment may negatively affect patient's quality of life (QoL). The aim of this study is the evaluation of the impact of neodjuvant chemotherapy (NACT) followed by chemoradiation therapy (CRT) on QoL and psychological functioning of patients with oral and oropharyngeal tumors.

Methods: the population was composed by 36 patients affected by advanced oral cavity and oropharynx tumors, who underwent NACT, followed by concomitant CRT. In order to evaluate the late effects of RT we used the RTOG–EORTC late radiation morbidity score plus the DISCHE morbidity recording scheme; we also applied a visual analogue scale to evaluate dysphonia, dysphagia and dysmorphism. Psycho-oncological assessment included: HADS, MADRS, MINI MAC, EORTC QoL HN 35.

Results: the late toxicity evaluation demonstrates that salivary glands function, subcutaneous fibrosis, dysphagia and dysphonia are the most relevant and severe damages. Low levels of anxiety and depression were observed; the profile underscores the prevalence of active coping styles (fighting spirit, fatalism, respect to negation, anxiety and desperation). Patients with severe dysphagia (Dische 3–4) showed higher levels of depression: dysphagia influences the perceived global health (GH) and QoL, with effects on fatigue, physical and social functioning. It further determines problems in relationship (sexuality, social eating and contacts). Taste impairment was associated to lower perceived GH and QoL, with higher scores of depression. Dryness of mouth determines impairment in some aspects of QoL, such as social eating and contact, although without effects on emotional scores and perceived GH and QoL.

Discussion: NACT followed by CRT could result in a heavy addictive effect, strongly affecting nutrition. Depressive traits seems to be sub evaluated by auto-report instruments. However, late side effects of treatments, such as dysphagia, are clearly associated to impairment in perceived QoL and global health, and to a higher risk of psychological complains.

8570 POSTER

Body mass index (BMI) – simple tool for prediction and prognosis in patients with locoregionally advanced head and neck carcinomas (LA HNSCC)

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Changes in nutritional status are common in patients (pts) with HNSCC. Some data have pointed out that 5% of weight loss in 6 months before initial

treatment for LA HNSCC, was an independent predictor of poor disease specific survival in men. On the other hand obesity because of high energy intake (alcohol) might also negatively influence final outcomes. In our work we evaluate the correlation between initial BMI (weight kg / height m²), therapeutic response to neoadjuvant chemo and overall survival (OS) in pts with LA HNSCC treated with combined chemoradiotherapy.

During the period Jan. 2003–Oct. 2006, a total of 69 pts (N=69, two pts being females) with T3-T4a, b; N1-N2b; M0 tumors (AJCC, 6-th ed. 2002) has been treated this way. Median age was 54 yrs (range 36–71 yrs) with ECOG status 1 (range 0–2). Two pts had primaries in epipharynx, 30 pts in oropharynx, 29 pts in hypopharynx, and 8 pts in larynx. All received PF regimen enhanced with Cytarabine (CAR) as a Platinum potentiator. Pts had been given 500 mg/m² of CAR (D1), 750 mg/m² of 5 FU as a continuous infusion (D1-D5), and CDDP 120 mg/m² (D1) for 3 cycles, and than proceeded to radiotherapy with concomitantly applied CDDP 100 mg/m² (D2, D23, D44). Before radiotherapy, all of them were evaluated for response. Based on BMI, pts were categorized as overweight (BMI \geq 25; 27% pts), normal weight (18.5 \leq BMI < 25; 57% pts), and underweight (BMI < 18.5; 16% pts). Forty seven pts (68%) achieved response rate (CR+PR), 18 pts (26%) had stabilisation (SD) and four of them (6%) had progressed.

Responders had sygnificantly higher values of initial BMI than non responders (Man-Whitney test; p<0.01). In normally weighted, BMI positively correlates with response (OR=15; p>0.0018) and the same is true in overweighted pts (OR=16.9; p<0.00335). Underweighted pts had also significantly poorer OS compared to normally weighted (log rank test: p=0.003) and overweighted (log rang test: p=0.001). Between normally and overweighted pts such difference has not been observed (log rank test: p=0.648).

In conclusion, we propose pretreatment nutritional assessment using BMI in this population pts which might in addition to TNM staging help in better and more sofisticated treatment planning.

8571 POSTER

Correlation of p53 and PCNA expression with the invasion and prognosis of oral squamous cell carcinoma

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Background: Abnormalities in cell cycle-controlling genes are important in the malignant transformation and proliferation of tumors. Among these genes, the tumor suppressor gene p53 is most notable, and its mutations provide an indicator of tumor progression and prognosis. This study examined the expression of p53 and PCNA at the invasive front of oral squamous cell carcinomas by immunohistochemical staining, and investigated the relationship of these proteins to clinicopathological findings. Moreover, the relationships between the expression of these protein at the invasive front and survival rates were examined.

Methods: Fifty-nine biopsy specimens of oral squamous cell carcinoma were examined by immunohistochemical staining. p53 labeling index (p53-LI) and PCNA labeling index (PCNA-LI) were examined at the invasive front of tumors.

Results: None of the indices correlated significantly with the clinical findings. In highly invasive carcinoma, p53-LI and PCNA-LI were increased and co-expression. Patients with p53 and PCNA co-expression had a worse prognosis than other expression combination.

Conclusions: It is significant to detect p53-LI and PCNA-LI at the invasive front of oral squamous cell carcinoma in the examination of tumor cell characteristics.

8572 POSTER

Therapeutic results of TPF chemotherapy prior to definitive radiochemotherapy for advanced nasopharyngeal cancer

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This is a clinical study conducted to evaluate the toxicity and efficacy of TPF chemotherapy of docetaxel, cisplatin, and fluorouracil prior to definitive radiochemotherapy in patients with advanced epithelial carcinoma of the nasopharynx.

Patients and Methods: Eligible patients with good performance status (ECOG 0-2) who had stage III/IV, or unresectable local recurrent diseases and no distant metastases were assigned to receive TPF chemotherapy. Intravenous infusion of 75 mg/m(2) of docetaxel and 75 mg/m² of cisplatin on day 1 followed by continuous intravenous instillation of 1000 mg/m²/day

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of 5-FU for 4 days from day 2. Patients without progression of disease received radiotherapy concurrent with platinum-based chemotherapy within 4 to 7 weeks after completing chemotherapy. Utilizing 6 MV photons, radiotherapy was performed at an exposure of 1.8–2.0 Gy five times per week to a total dose of 66–70 Gy. The primary end points were toxicity and response.

Results: From December 2007 to May 2008, 14 patients with advanced nasopharyngeal cancer were treated with TPF. Forty cycles were administered to 14 patients. One patient lost to follow-up after the first post-treatment blood test. Thirteen patients received concurrent radiochemotherapy after TPF. The median follow-up time was 5.75 months (range: 0.25-12 months). The major acute toxicities to TPF were neutropenia, anemia and mucositis. Grade 3 neutropenia, anemia, and mucositis were 14.3%, 21.4%, and 42.8%, respectively. Grade 4 neutropenia was 28.6%. The overall objective response rate to TPF was 78.6%, with 7.1% CRs and 71.5% PRs. In addition, the definitive radiochemotherapy increased the objective response to 85.7% and increased the CR rate to 42.8%. There were no progression of the disease or treatment-related death in this study.

Conclusion: TPF has an acceptable toxicity profile for patients with advanced epithelial carcinoma of the nasopharynx. Definitive radiochemotherapy enhanced the objective response of this cancer after induction TPF chemotherapy. Longer follow-up are needed to confirm the contribution of neoadjuvant chemotherapy to standard chemoradiotherapy for nasopharyngeal cancer.

8573 POSTER

Effect of different chemotherapy methods on immune and oxidative processes in patients with malignant tumours of maxilla

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Background: To study features of immune changes and oxidative system in treatment of local spread malignant tumours of maxilla.

Materials and Methods: There examined 63 patients with local spread malignant tumours of maxilla, nasal and paranasal sinuses of T_3 and T_4 stages at the department of head and neck tumours of our centre. Patients were divided in 3 groups depending on therapy methods: 1) intraarterial chemotherapy(CT) with local UHF — hyperthermia with the frequency 40 MHz increasing the temperature up to 41–43 $^\circ$ C in the tumour and radiotherapy (RT) (22 patients), 2) intraarterial CT and RT (21 patients), 3) systemic CT and RT (20 patients) (scheme: Cisplatin 100 mg; Fluorouracil 3000 mg and Doxorubicin 60 mg). There identified CD markers of T-and B- lymphocytes and their sub-populations phagocyte activity of neutrophils (FAN), content of malondialdehyde (MDA) and activity of antioxidant difference-superoxide dismutase (SOD) and catalase. Numeric material was processed by variation statistics.

Results: There established decrease CD3, CD4 against a background CD8+cells that indicated of T-cellular immunodeficiency development, disturbance of natural factors of antitumor defense. There noted intensification of POL against a background of inhibition of enzymes AAD. Between MDA level and CD3, CD4, FAN rates were noted moderate negative correlation, CD+8 positive connection. Low activity of SOD and catalase correlated positively with CD3, CD4, FAN levels. Polychemotherapy aggravated immunodeficiency, disbalance in the POL-AAD system and their expressivity depended on CT method. CD3, CD4, FAN and IRI rates decreased in a lesser degree in 1 and 2 groups patients in comparison with 3 group ones. In intraarterial polychemotherapy with UHF- thermia and RT the expressivity of their changes manifested in a lesser degree. This associated with their concentration increase in lesion focus and maximal damage of tumour cells in minimal effect of chemicals on different body organs and systems.

Conclusion: Neoadjuvant therapy in 2 group patients, particularly in 1 group, allows reducing significantly negative response of polychemotherapy and increase direct results than in 3 group.

8574 POSTER

A phase II study of combination chemotherapy with capecitabine and cisplatin in patients with metastatic or recurrent head and neck cancer

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Background: The higher efficacy of capecitabine than 5-fluorouracil (FU) and clinically proven synergistic activity of the cisplatin and 5-FU regimen

support the rationale for a clinical evaluation of the capecitabine and cisplatin (XP) combination. The authors conducted a phase II study in order to assess the efficacy and safety of XP regimen in patients with metastatic or recurrent head and neck cancer.

Materials and Methods: The study design was a prospective, openlabel, single center phase II study. 45 patients with histologically confirmed metastatic or recurrent nasopharyngeal cancer (NPC) (9 patients) and squamous cell carcinoma of head and neck (SCCHN) (36 patients) were enrolled. One chemotherapy cycle consisted of capecitabine 1,250 mg/m² orally twice a day on day 1 to 14 and cisplatin 60 mg/m² intravenously on day 1. Each cycle was repeated every 3 weeks. Maximum cycles of treatment were 6 cycles.

Results: Of the 45 patients, 42 patients were evaluable for tumor response. 25 patients achieved complete response (CR) or partial response, and 5 patients had stable disease. The overall response rate and CR rate were 55.6% and 2.2%, respectively. The median progression free survival was 3.8 months (95% confidence interval (CI), 2.1–5.5 months), with the median response duration of 7.8 months. The median overall survival (OS) and 1-year OS rate were 12.6 months (95% CI, 4.8–20.4 months) and 40.0%. Additionally, the overall response rates of SCCHN and NPC were 50.0% and 77.8%, respectively. A total of 175 cycles were administrated. Common grade 3 or 4 non-hematologic adverse events were anorexia (6.9%), diarrhea (5.1%), stomatitis (4.0%), fatigue (3.4%), hand-foot syndrome (1.7%). The most common grade 3 or 4 hematologic adverse event was neutropenia (15.4%), followed by leucopenia (8.0%) and anemia (1.1%). There was no treatment-related mortality.

Conclusion: The results showed that the XP regimen is an effective and well-tolerable treatment option in patients with metastatic or recurrent head and neck cancer.

Mini intrusive operations at the lymphadenopathy of the antero-upper

Mini intrusive operations at the lymphadenopathy of the antero-uppe mediastinum

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Objective: To apply procedure of performance video assisted lymph dissection in the anterior-upper mediastinum at metastases of a cancer of a thyroid gland, as alternative of a sternotomy. To analyze the complications nearest and long-term results.

Materials and Methods: With 2002 it is executed 66 video assisted surgical interventions. Operation is carried out at the confirmed cancer of a thyroid gland and metastasises in lymph nodes of the anterior-upper mediastinum, and also at a lymphadenopathy taped at inspection. After a surgical intervention on a thyroid gland – the thyroidectomy, a subtotal resection of a thyroid gland, from the same access, through a bulbar cutting, retrosternal is introduced a telescope, by means of endoscopic instruments block excision and paratracheal fats on a neck from both parties and in the anterior-upper mediastinum under the video control of returnable laryngeal nerves, frames of a mediastinum that reduces to a minimum possible intraoperative complications is effected.

Results: At scheduled morphological research at 47 (71.2%) patients are taped metastasises of a cancer of a thyroid gland: the papillary form at 38 patients, the papillary-foliicular form at 3 patients, the medullary form in 5 cases, low graded the follicular form at 1 patient. At 19 (28.2%) patients of metastasises of a cancer of a thyroid gland have not been taped. The quantity of the removed lymph nodes on the average 8–9 is maximal 26. Time of operation in comparison with a sternotomy was reduced twice. According to 5 years observations from 66 patients in 4 cases advance of tumoral process is taped, in 1 case there was a relapse of metastasises of a cancer of a thyroid gland, in 42 cases at complex inspection of relapse of metastasises in a mediastinum has not been taped. Complications bound to performance of the given operation it is noted.

Conclusions: Application of the video assisted procedure of lymph dissection the anterior-upper mediastinum at metastasises of a cancer of a thyroid gland it is possible to consider application of the video assisted procedure adequate and radi-cal. The given kind of a surgical intervention reduces an operational trauma in comparison with a sternotomy, and possesses the best cosmetic effect.

8576 POSTER

Involvement of pars cartilaginea in the vocal fold affects local control in patients with T1 glottic cancer

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Background: To determine the effects of involvement of pars cartilaginea in the vocal fold on local control in patients with T1 glottic cancer.