

in overall survival (15 vs. 37 m.) ( $p > 0.05$ ) and time to progression (8.5 vs. 14.5 m.) ( $p > 0.05$ ) were found between the two groups.

Chemotherapy toxicity was not severe and similar in the two groups, except for febrile neutropenia which was significantly higher in the first group (88.2% vs. 9%).

**Conclusion:** The CDDP-UFT scheme was as effective as the CDDP-5-FU scheme in the treatment of locally advanced head and neck cancer, but produces a lower incidence of febrile neutropenia and avoids hospitalization.

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### Randomized trial of cisplatin (P) plus 5-fluorouracil (F) with or without folic acid in locally advanced head and neck cancer (LAHNC)

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P and F combination has been considered the standard as neoadjuvant treatment in LAHNC. Phase II studies have suggested an improvement in overall response with the addition of Folic Acid.

**Method:** From January 1995 to June 1996, 42 patients (pt) with LAHNC were included in a prospective randomized trial with two different arms. *Group A:* Neoadjuvant chemotherapy with P 25 mg/m<sup>2</sup>/day F 1000 mg/m<sup>2</sup>/day, both in a 96 hour continuous infusion. *Group B:* Identical schedule than group A plus Folic Acid 250 mg/m<sup>2</sup>/day in two hour infusion at the beginning of daily infusion of PF. In both groups 4 courses were administered, every 3 weeks. Both arms were balanced according to age, sex, stage and primary site. Most of pt were in stage IV.

**Results:** 39 pt were evaluable for response and toxicity. (3 pt in group B abandoned the treatment by own decision). Complete treatment (dose and number of courses) were administered in 71% of pt in group A and only in 44% of pt in group B due to toxicity. *Response:* Response Rate was 95% in group A and 94% in group B ( $p = N.S.$ ). Complete Response in group A was 52% and in 39% in group B ( $p = N.S.$ ). *Toxicity:* Main toxicity was grade III/IV neutropenia (29% in group A vs 46% in group B;  $p < 0.1$ ) and grade III-IV mucositis (0% in group A vs 39% in group B;  $p < 0.01$ ). Other grade III-IV toxicity was not observed.

**Conclusion:** In spite of both schedules are effective, addition of Folic Acid increases the toxicity leading to a lower compliance of the treatment without improvement in complete response rate.

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### Postoperative radiotherapy in squamous cell carcinoma of the larynx – Prognostic factors

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**Purpose:** An analysis of the results of postoperative irradiation for squamous cell carcinoma of the larynx and estimation of the influence of selected clinical and physical parameters influencing the efficacy of the treatment.

**Methods:** During the period 1986–1993, 272 patients with squamous cell carcinoma of the larynx were treated with surgery and postoperative radiotherapy. All patients were treated with <sup>60</sup>Co alone. The total tumor doses were in range 54–70 Gy, delivered by conventional fractionation. DFS rates were analysed according to: age, stage of disease, histological type, type of operation, surgical margin, total dose, the time-interval between surgery and irradiation, field size.

**Results:** At 3 years the DFS for the entire group was 53%. DFS was significantly influenced by: age (<40 = 4%, 41–60 = 66%, >60 = 30%), postoperative macroscopic evidence of disease ("–" = 65%, "+" = 40%), field size (<90 cm<sup>2</sup> = 33%, 91–120 cm<sup>2</sup> = 29%, >120 cm<sup>2</sup> = 38%).

**Conclusion:** It was found the age, macroscopic radical surgery and field size could be an important prognostic factors for combined surgery and RT for larynx cancer.

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### Laryngeal cancer T<sub>3</sub>N<sub>0</sub>M<sub>0</sub>: Variations in organ-preservation treatment

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**Purpose:** To study the expediency of organ-preservation treatment of the larynx cancer T<sub>3</sub>N<sub>0</sub>M<sub>0</sub>.

**Methods:** We studied 233 pts with squamous cell carcinoma of the larynx. The average age was 56. The following organ-preservation therapy was applied. 1. Hyperfractionated irradiation (single dose 1.1 Gy 2 times a day with 4 hours interval for 5 days a week, split course, total dose 70 Gy) – 76 pts. 2. Chemoradiotherapy (2 cycles of chemotherapy 5FU, CDDP, leucovorin and hyperfractionated irradiation, split course, total dose 70 Gy) – 67 pts. 3. Conservative surgery (larynx resection) – 90 pts.

**Results:** Alive without relapses and metastases (5 years) with larynx preservation was as follows: 1 group – 56.6%, 2 – 82%, 3 – 60%. Local relapses: 38.2%, 9%, 20%. Regional metastases: 2.6%, 6%, 16%. Distant metastases: 2.6%, 3%, 3.3%. Additional surgery of local relapses and regional metastases helped achieve 79% 5-years survival, which approximated the response of traditional laryngectomy.

**Conclusion:** We confirm the expediency of organ-preservation treatment for T<sub>3</sub>N<sub>0</sub>M<sub>0</sub> larynx cancer.

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### Estimation of the influence of biological modifiers on severity of acute mucosal reaction in patients with head and neck cancer

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**Purpose:** Estimation of the local efficacy of 2%AgNO<sub>3</sub> and dexamethasone-solution on severity of acute mucosal reaction during oral cavity and oropharynx radiotherapy.

**Material and Methods:** 107 patients with head and neck cancer in stage T<sub>2-4</sub>N<sub>0-1</sub> were treated by radiation therapy alone in 2 schedule: accelerated with escalation of fraction dose and conventional continuous irradiation -CAIR (7 × 2Gy per week). The stimulation of buccal mucosal membrane in patients treated by accelerated schedule was performed by 2% AgNO<sub>3</sub> but patients treated in conventional continuous fractionation washed oral cavity by steroid-solution.

**Results:** The difference in acute mucositis intensity between stimulated and unstimulated buccal mucosa was highly significant with regard both to maximum score or duration. Intra oral washing by steroid solution during the radiation treatment diminish the intensity of mucositis chiefly to heal phase and gives better subjective tolerance.

**Conclusion:** Severity of acute radiation mucositis could be diminished by different mechanisms which are discussed. Both 2%AgNO<sub>3</sub> and steroid-solution improve acute radiation reaction tolerance and allow to realize planned accelerated irradiation in majority of patients.

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### Neoadjuvant chemotherapy before radiotherapy of advanced head and neck cancer in Ukraine

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The records of 322 patients with advanced (M0) squamous cell carcinoma of the head and neck treated from 1983 till 1994 at Lviv Regional Hospital (Ukraine) were reviewed and divided in two arms. Arm I – radiotherapy alone (254 patients) 55-70 Gy, 2 Gy per fraction, 5 fractions a week. Arm II – 2 or 3 cycles of chemotherapy d1 -d21 (d28), with CDDP 100 mg/m<sup>2</sup> IVP d1, 5FU 1000 mg/m<sup>2</sup> d1 to d5 in 18 h continuous infusion, followed 15 to 21 days later by the same radiotherapy protocol. The arms were balanced by age, sex, stage, TN-classification, localisation of primary and dose of radiotherapy. Overall response was respectively 77% and 79%, 4-years survival 20% and 25%, but no significant. The results of multivariate analysis of patients from arm I, detected two prognostic groups of patients: group A – all women, men with III stage of disease (all localisations) and IV stage with incidence of primary tumor in nasopharynx and maxillary sinus; group B – only men with IV stage and localisation of primary in oropharynx and oral cavity. Group B has worse survival ( $p = 0.0001$ ).

Use of neoadjuvant CT + RT in analogous group to group B permitted to improve complete response from 11.9% to 21.1% and overall Kaplan Meier survival from 7% to 26% (logrank  $p = 0.02$ ) when compared with only radiotherapy in group B.

**Conclusion:** chemotherapy with CDDP-5FU does not improve the benefit of head and neck carcinoma treatment comparatively to radiotherapy alone. The advantage is possible only in men with IV stage and localisation of primary in oropharynx and oral cavity.