NEOADJUVANT CHEMOTHERAPY WITH 4 CYCLES OF CISPLATIN (P) AND 5 FLUOROURACIL (F) IN ADVANCED HEAD AND NECK CANCER (AHNC)

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21 patients (pts) with AHNC, were treated with P 100 mg/m2. IV day (d) 1 and F 1000 mg/m2 IV dl-5 in continuos infusion, every 21 days, four times. All pts were males and ECOG 1-2. Mean age were 57.1 years (range 40-77). 18 squamous cell and 3 undifferentiated carcinoma. Stages: III (4pts), IV (17 pts). Primaries: 8 oral cavity, 5 oro pharynx, 3 nasopharynx, 3 hipopharynx, 1 larynx and 1 sinus maxillary.

RESULTS:19 pts were evaluables (2 abandoned treatment after I cycle). The overall response was 73.6% (95%CI=51.2% 88.1%), with CR 42.1% (95%CI=23.2%-63.6%) and PR 31.5% (95%CI=15.3%-53.9%). Between CR 6/8 were histological responses. According the cycle number: 1º 0% CR and 52.6% PR 2º 10.5% CR and 63.1% PR; 3º 26.3% CR and 47.3%PR#º 42.1% CR and 31.5% PR. Median survival: 18.5 m. The most important Toxicity (WHO), over 73 cycles, was: neutropenia Gl-2: 20.5%: N/V G3-4: 16.5%.

 $\underline{\text{CONCLUSIONS}}$ : This protocolo get an important number of responses with a moderate toxicity. The administration of 49 cycle increase the number of CR.

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## CDDP+5-FU AND REIRRADIATION IN THE TREATMENT OF LOCALLY RECURRENT HEAD AND NECK CANCER.

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Curative treatment of locally recurrent head and neck cancer in radiated areas is very difficoult. The feasibility of combining reirradiation (20-46 Gy) and CDDP+5-FU(CDDP  $100 \text{ mg/m}^2 \text{d}1,5-\text{FU}1000$  $mg/m^2d1-5$ ; q 21 days)(3-6 cycles)was investigated in pts with good prognosis characteristics:disea se-free survival>6 months, ECOG PS<2, MO status, T or N "not bulky". Thirty-one pts(nasopharynx, 13; larynx,6;oropharynx,5;hypopharynx,5;oral cavity, 1; external auditory canal, 1). There were 6 CRs(46%) 6 PRs(46%) and 1 NC(8%) in undiff. nasopharyn.ca.; median duration of CR was 22+ months(9-64+). Two year actuarial overall survival was 28%. In the other sites there were 3 CRs(17%), 9 PRs(50%) and 6 NC(33%); median remission duration was 12+ mon ths and median survival 16+ months for CRs.

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## POLYCHEMOTHERAPY IN THE TREATMENT OF RECURRENT CARCINOMA OF THE PARANASAL SINUSES.

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Eighteen pts(12 m,6 f; median age 55 yrs) with recurrent ca. of the paranasal sinuses(14 maxillary s.,4 ethmoid s.;12 squamous-cell ca.,4 adenoca., 2 undiff.ca.) were treated with polychemotherapy. Eleven pts had been previously treated with surgery+TCT,7 with TCT alone.All pts had lo cally recurrences, 4 had CNS invasion and 2 had lung mts.Pts received the following polychemothe rapeutic regimens:MTX+5-FU(3 pts),5-FU+EPI+CYC (2 pts),CDDP+BLM(4 pts),CDDP+5-FU(9 pts).Pts trea ted without CDDP had 2 PR(40%), 2 NC(40%) and 1 PD (20%).PRs remission duration:5-6 months.Pts treg ted with CDDP-based combinations had 2 CR(15%), 5 PR(38%), 4 NC(31%) and 2 PD(15%). Median remission duration: 9 months (6-28). Median survival duration was 17 months for CRs,14 for PRs and 6 for NC-PD. 795

CONCOMITANT CHEMO-RADIOTHERAPY WITH CARBOPLATIN (CART) IN CONTINUOUS PROLONGED INFUSION IN HEAD AND NECK CANCER (HNC)

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A pilot study on concomitant radio-chemotherapy in inoperable or recurred after surgery HNC began on April 1992 to evaluate toxicity and response to treatment. In 9 months 19 patients (average age 63 y, range 29-85; 13 M, 6 F) underwent the following schedule: Carboplatin (CA) 30 mg/m² in continuous infusion for 14 consecutive days (group A; total dose 420 mg/m²) in 7 pts and for 21 days (group B; total dose 630 mg/m²) in 12 pts; Radiation (RT) was planned on T and N for a maximum dose of 65-70 Gy, 180 cGy/f 5d/w. Side effects were recorded according to WHO scale

RT was interrupted for 7 days if grade 4 toxicity occurred. Eleven pts stage IV are evaluable for local response: we observed 5 CR, 5 PR, 1 NC. Two more pts one in stage I and one in stage II, inoperable for site of the tumor, obtained a CR. We conclude that CART treatment is well tollerated (expecially with 14 d infusion of CA) and effective in advanced HNC.

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PRELIMINARY RESULTS OF STANDARD USE OF INDUCTION 5FU+CISPLATINUM FOLLOWED BY RADIOTHERAPY (RT) IN ADVANCED LARYNGEAL CANCER

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Instituto Português de Oncologia de Francisco Gentil, Lisboa, Portugal In 1991, we adopted sequential chemotherapy (CT) and RT as standard treatment for stage (st) III/IV resectable laryngeal cancer, trying to reproduce published results (NEJM 1991;324:1885) which suggested induction CT and definitive RT to be effective in preserving the larynx whithout compromising survival. From 11/1991 to 8/1992, 22 patients (pts) were treated. All male; median age 61. Nine well differentiated (diff), 9 moderately diff and 3 poorly diff epidermoid carcinomas (cc) and 1 basaloid-squamous cc. Eleven pts had at III and 11 had at IV disease. Treatment (tt) consisted in 5-FU, 1 g/m2/day, continuous infusion, days 1 to 5 and Cisplatinum, 100 mg/m², IY, day 1. After two 3-weekly cycles (cy), pts were reevaluated by clinical exam and CAT scan and, if objective response greater than 50% had been achieved, a third CT cycle was performed, followed by RT on the primary tumor and neck, to a total of 70 Gy in 7 weeks. Non-responders (NR) to CT and pts with relapsed or persistent tumor after RT were surgically rescued. Mucositis during CT and RT and vomiting during CT were the most frequent toxicities (tox). There were no treatment related deaths. With a median follow-up of 12 months (m), median overall survival is 9+ m. Thirteen pts (59%) responded and completed CT and RT; 12 of them (55%) are alive without operation and without disease at 8+ to 12+ m. Two pts received RT after just 1 cy of CT (1 tox, 1 refusal) and are alive with disease at 8+ and 5+ m. Higher accrual and longer follow-up are needed, but data seem to confirm the possibility of conservative tt of advanced laryngeal cc with 5FU+CDDP and RT.

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SURGERY VERSUS PRIMARY CHEMOTHERAPY PLUS SURGERY IN SQUAMOUS CELL CARCINOMA OF THE ORAL CAVITY: PRELIMINARY REPORT OF A RANDOMIZED STUDY. C Grandi, R Molinari, G Bonadonna, L Licitra, R Cavina, M Guzzo, S Podrecca, G Gelosa, A Negri, E Colombo, F Zibordi, R Demicheli, G Gardani. Istituto Naz. Tumori and Osp. Niguarda, Milano; Osp. Civile, Melegnano, Italy. A prospective randomized trial comparing primary chemotherapy (CT) followed by surgery (arm A) with surgical standard treatment (arm B) in pts with oral cavity cancer was activated in April 1989 in three Italian institutions. Pts with operable oral squamous cancer staged T2-4 N0-2 M0 were eligible, being stratified by institution and nodal stage. CT consisted of cisplatin 100 mg/mq day 1 and fluorouracil 1000 mg/mq, as a 120 h infusion, for 3 cycles. Postoperative radiotherapy was scheduled in the case of positive surgical margins and/or more than 3 nodal metastases and/or extracapsular spread. As of today, 92 patients were included (262 pts are required), 48 in arm A and 44 in arm B. In the CT group treatment had to be stopped early in 8 pts, due to lack of response (6), refusal (1) or toxicity (1). One death was recorded due to neutropenia after the first cycle. In the other pts toxicity was generally mild: grade 3-4 neutropenia was assessed in 4 cases; nausea and vomiting was grade 1-2; no renal or hepatic toxicity higher than grade 1 was recorded. No surgical death occurred, while surgical morbidity was similar in both arms. PR rate to primary chemotherapy was 47% and CR rate was 30%. Histologically positive surgical margins were observed in 8 pts in arm B vs no pt in arm A. Median follow-up is now 24 mos. Overall survival is 69% (95% CI: 54-83%). The study will be concluded in 2 years.