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POSTOPERATIVE RADIOTHERAPY(PRT),PULMONARY FUNCTION AND GAS EXCHANGE IN PATIENTS WITH NON SMALL CELL LUNG CANCER (NSCLC).

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The tolerance to adjuvant PRT continues to be a major concern as regards pulmonary function. The aim of this study was to assess the changes of pulmonary function as a result of PRT in patients with resected NSCLC. Radiation treatment was made with high energy; a total dose of 50 Gy was delivered in 1.8 Gy daily fractions. Pulmonary function (VC, FEV1, TLC, DLCO) and arterial blood gases (ABG) were measured 1 month after surgery before the onset of PRT, and the end of radiation therapy. Other follow-up measurements were performed within 60 and 90 days. All the patients assumed Dexamethasone 1.5 mg daily since the onset of PRT. Lung volumes and DLCO did not change over time. A significant reduction of PaO2 was detected 60 and 90 days after the end of PRT

(-5.4 mmHg $t=2.7$ $p<0.05$, -5 mmHg $t=4.42$ $p<0.01$ respectively). Alveolar-arterial PO2 gradient increased as well (30 days $=+6$ mmHg $t=2.87$ $p<0.01$, 60 days $=+4$ mmHg $t=2.57$ $p<0.05$). Adverse effects of radiation should be taken into account even when small fields of treatment are used.

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CHEMOTHERAPY AND HYPERFRACTIONATED RADIOTHERAPY IN STAGE III NON-SMALL CELL LUNG CANCER (NSCLC).

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In order to assess the efficacy and tolerance of a treatment scheme with neoadjuvant chemotherapy (NAC) followed by concomitant chemotherapy and hyperfractionated radiotherapy (HRT) in advanced NSCLC, we undertook a phase II study. From January 92 to December 92, twenty patients with histologically proven squamous or adenocarcinoma NSCLC measurable by CT scan, were entered into this study. There were 9 pts in stage III A (45%) and 11 pts in stage III B (55%). Median age was 58 y (range 45-70). All pts had performance status ECOG grade 0-1. NAC consisted in one cycle of: Mitomycin 10 mg/sqm day 1, Vinorelbine 3 mg/sqm days 1,8,15 and 22, and Cisplatin 120 mg/sqm day 1. HRT was administered 4-6 weeks after NAC. Total tumor dose was 6960 cGy, fractionated in doses of 120 cGy twice daily in six weeks. Cisplatin infusion (20 mg/sqm/day x 5 days) was given concomitantly in the first week of HRT. All pts were evaluable for response by CT scan. **Results:** overall response was 95% (19/20), with 30% (6/20) complete response. Toxicity was mainly mucositis (grade 3 in 4 pts and grade 4 in 1 pt) and leucopenia (grade 3 in 3 pts. and grade 4 in 1 pt). No toxic deaths have been observed.

CONCLUSIONS: This treatment scheme has a high activity with moderate toxicity.

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CISPLATIN (CDDP), EPIRUBICIN (EDX) AND VINDESINE (VDS) +/- LONIDAMINE (LND) IN ADVANCED NSCLC. Ianniello G.P., De Cataldis G., Della Vittoria Scarpati G., Comella P., Maiorino A., Brancaccio L., Belli M., Cioffi R. * A Cooperative Group * To value the real role of the Lonidamine in the treatment of advanced NSCLC, we performed a randomized trial. 127 untreated pts, up to day, entered in a multicenter trial and were given CDDP 60 mg/mq i.v., EDX 50 mg/mq i.v., VDS 3 mg/mq i.v. every 4 weeks x 6 cycles. Pts were randomly assigned to receive LND 450mg/die from the start of the chemotherapy until the disease progression. To date, 112 pts are evaluable for response and toxicity. We archived 3 CR, 22 RP, 20 SD, 10 PD in LND+ group and 2 RC, 15 RP, 23 SD, 17 PD in LND- group. The median time to progression was been of 9 m. in the LND+ vs 6 m in the LND- group and the median overall survival time was been of 10 m. vs 8 m. The statistical analysis (T-Test) has showed a significant difference in favour of LND+ group in the response rate and in the time to progression and, up to day, a favorable trend in the overall survival time. These intermediate data confirm the effective role of LND in the treatment of advanced NSCLC.

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CBDCA IN CONTINUOUS INFUSION AND CONCOMITANT RADIOTHERAPY IN PATIENTS WITH LOCALLY ADVANCED NSCLC.

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Since 1990, at the university policlinic "A.GEMELLI" was activated an interdisciplinary study for pulmonary NSCLC. Patients with locally advanced disease were inserted in a study of phase I- II that foresees a treatment of concomitant radio-chemotherapy; 6 courses of chemotherapy are subsequently foreseen. RT was delivered in dose of 50 Gy. The concomitant chemotherapeutic was the carboplatin (CBDCA), that was administered in continuous infusion in the first four days of radiotherapy, at dose of 30mg/mq/day in the first 13 pz, subsequently increased to 50mg/mq/day in 12, up to present 70mg/mq/day in the remaining 5, for a total of 30 patients, belonging to stage II (2pz), IIIA (11pz) and IIIB (17pz). The partial answers $>50\%$ (RP) resulted evenly in 50% (15/30): of the responsive patients, 12 out of 30 (40%) were judged resectable and 10 (33,3%) subjected to radical surgery. Intra or perioperative complications were not revealed. In 4 pz the histological exam has demonstrated negativity to disease. No evident toxicity was observed.

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HIGH-DOSE EPIRUBICIN (HD-EPI) plus CISPLATIN (CDDP) AND rHu-GM-CSF IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC)

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HD-EPI (120mg/6sm) plus CDDP has significant antitumor activity and produces manageable acute toxicity (ASCO 11:1018,92). Between Jan 1990 and Dec 1992, 23 pts. previously untreated were entered, with unresectable histologically proven NSCLC, Stage III-IV; ECOG: PS: 0-2; median age (R: 42-75) was 61; a life expectancy of at least 3 months; adequate renal, hepatic and bone marrow function. Cardiac function was monitored by the determination of left ventricular ejection fraction by radionuclide ventriculography at the beginning of and periodically during the treatment. Histologies included squamous cell carcinoma (14 pts.), adenocarcinoma (6 pts.) and large cell carcinoma (3 pts.). **Treatment:** Pts. received HD-EPI 130mg/sm, iv, bolus and CDDP: 25mg/sm, iv, dl-2 and rHu-GM-CSF: 5ug/kg/d, sc, days 2-11. The treatment was repeated every 28 days; for up to 6 cycles. **Results:** 14/23 (60.8%) pts. achieved a partial remission (PR); 5/23 (21.7%) pts. SD and 4/23 (17.4%) PD. The median duration of response (MDR) was 10.2 months (r: 4-17). The median survival time (MST) for responders was not achieved and for non responders it was 5.8 months. Nausea and vomiting 68%, alopecia 89%. Only 3 pts. had ANC = 500 lasting 7 days. The regimen HD-EPI+CDDP+GM-CSF has significant antitumor activity and well tolerated toxicity.