T 45 mgr/m2/iv weekly during the 7 weeks of treatment; Gr-2 received only radiation therapy (60-65 Gys, 200 cGy/day over 6 weeks). 4 p could not be evaluables, 55 p were evaluables for response and 56 p for toxicity.

Results: Upon TCG induction chemotherapy: 1 CR and 37 PR (RR 69.1%;CI95%:56-80), 10 SD (18.1%) and 7 PD (12.8%).7 p went to surgery: 2 pCR, 2 pPR and 3 pSD. 17 p in Gr-1 completed the consolidation treatment with 4 CR, 9 PR, 1 SD and 3 PD (RR 76.5%) and 14 p in Gr-2 with 5 CR, 7 PR and 2 PD (RR 85.7%). At a median follow-up of 9.3 months, the median survival were 16.5 mo (Gr-1 13.7 mo and Gr-2 14.5 mo) and 1-year survival rate of 65% (Gr-1 69% and Gr-2 62%). A total of 168 cycles of TCG were administered (3 per p), with the hematologic toxicity (NCI-CTC) per p Grade 1-2/3-4 (%) as follows: neutropenia 30.3/42.8; anemia 59/12.5; thrombopenia 28.5/25; there was 1 death from toxicity and 10 hospitalisations for complications. The main toxicities (RTOG) in consolidation treatment were: in Gr-1: g1/2 esophagitis in 5/6 p, g 1/2 pneumonitis in 3/3 p, g1/2 neurophathy in 2/5 p; in Gr-2: g1/2 esophagitis in 2/2 p and g1 pneumonitis in 2 p.

Conclusions: The TCG scheme of induction chemotherapy is active against stage III NSCLC with moderate toxicity. A larger number of patients and a longer follow-up will be required to allow final conclusions to be drawn as to the posible difference between the consolidation treatment groups.

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UFT plus cisplatin with concurrent radiotherapy for locally advanced non small-cell lung cancer: a multiinstitutional phase II trial. Cis-UFT-RT Study Group

A. Gemma[1], Y. Ichinose[2], Y. Nakai[3], H. Semba[4], M. Shibuya[1], S. Kudoh[1]. *[1] Nippon Medical School, 4th Dept of Internal Med, Tokyo, Japan; [2] National Kyushu Cancer Center, Dept. of Chest Surgery, Fukuoka, Japan; [3] Sendai Kohsei Hospital, Dept. of Internal Medicine, Sendai, Japan; [4] Kumamoto Regional Medical Center, Respiratory Disease Unit, Kumamoto, Japan*

Purpose: A multiinstitutional phase II study of combined-modality treatment consisting of uraciland tegafur (in a molar ratio of 4:1 [UFT]) plus cisplatin (Platinol) and concurrent radiotherapy was conducted to conclude the high activity of this regimen in patients with locally advanced non small-cell lung cancer.

Methods: Eligible patients with cytologically or histologically confirmed, unresectable stage III non-small-cell lung cancer received UFT (400 mg/m2 orally on days 1 - 14, 29- 42) and cisplatin (80 mg/m2 intravenously on days 8, and 29). Radiotherapy, with a total dose of 60 Gy, was delivered in 30 fractions on days through 40.

Results: Among the 58 patients entered(Stage IIIA 12; Stage IIIB 46), 46 experienced good responses (CR 1; PR 45)(79.3%; 95% confidence interval, 67.2% to 87.7%). Hematologic toxicity was moderate. Grade 3 leukopenia occurred in 11 patients (19%), but grade 4 hematologic toxicity was observed in 1 patient. Grades 3 or 4 nonhematologic toxicities were reported in 1 patient with esophagitis.

Conclusion: These observations suggest that oral UFT plus cisplatin with concurrent radiotherapy can be safely administered to patients with locally advanced non-small-cell lung cancer with mild toxities. The demonstrated antitumor activity is high, making this combined-modality treatment worthy of further investigation in comparison with other cisplatin-based regimens in a prospective randomized trial.

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Preventive epoetin a (EPO) use in the treatment of advanced nsclc: an AIPO oncology study group multicenter trial

L. Portalone[1], A.M. Altieri[1], A. Antilli[1], S. Barbera[2], R. Bernardini[3], A. Lombardi[1], L.G. Monaco[4], C. Seebacher[5], M. Signora[1]. *[1] C. Forlanini H., 6 Pneumo Oncology, Rome, Italy; [2] M. Santo H., 2 Pneumology Unit, Cosenza, Italy; [3] A. & C. Cartoni H., Pneumology Unit, Rocca Priora (Rome), Italy; [4] S. Giovanni H., Pneumology Unit, Rome, Italy; [5] Bolzano H., Pneumology Unit, Bolzano, Italy*

Purpose: Anemy is an important problem which we meet in the treatment of neoplasms. Meanly it reduces drug dose intensity and influences patient quality of life. Epoetin a can improve hemoglobin level but its use, until now, is reserved to correct anemy. Now we try to use Epoetin a to prevent anemy and improve drugs tolerance and quality of life in patients in chemotherapy for advanced NSCLC.

Methods: We have randomised, until now, 64 patients in chemotherapy for advanced NSCLC in two arms when hemoglobin level is 12 g/dl. or less: the group in arm A was treated with Epo a 150 u.i./kg. every other day for three months. Arm B is the control group without Epo a: but, if the hemoglobin level becomes less than 10 g/dl. patient comes out from the trial and will be treated with Epo a. We have evaluated hemoglobin levels, chemotherapy dose intensity and quality of life at 0 time, after one and three months. QoL was measured by patient completion of two scale, FACT-G and FACT-An, which was translated and adapted by us to Italian people.

Results: At this moment only 36 patients, 18 for arm, are evaluable. In arm A the differences between the hemoglobin level of baseline and third month control show an increasing of values ($P<0,093$); the same control in arm B shows a decrease in hemoglobin level, statistically significant ($P<0,0004$). Dose intensity in arm A reaches 95%, in arm B 65%. Scores of the evaluation scale in arm A are uniform in the time; in arm B scores show statistically significant increasing between first and following evaluations.

Conclusions: At this moment our findings show that preventive use of Epoetin a is able to improve tolerance of NSCLC patients to chemotherapy, measured by hemoglobin levels and dose intensity. QoL appeares to be better during the time of treatment too.

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Phase i/ii study of docetaxel(DOC) and carboplatin(CBDCA) with concurrent radiotherapy in patients with stage III unresectable non-small cell lung cancer(NSCLC), preliminary results

S. Kato[1], M. Sakura[1], T. Kazumoto[1], H. Sakai[2], S. Yoneda[2], Y. Noguchi[2], K. Kobayashi[2], S. Honda[2], S. Kosaihira[2]. *[1] Saitama Cancer Center, Radiation Oncology, Saitama, Japan; [2] Saitama Cancer Center, Respiratory Disease, Saitama, Japan*

Purpose: Concurrent chemoradiotherapy plays an important role in the treatment of stage III NSCLC. Both DOC and CBDCA have demonstrated activity as radiation sensitizers in preclinical studies. We conducted a phase I/II study to determine the maximum tolerated dose (MTD) and recommended dose (RD) of DOC and CBDCA when administered with concurrent thoracic radiotherapy (Phase I), and subsequently, to evaluate the efficacy and toxicity of the treatment regimen at the RD (Phase II).

Methods: Twenty three patients with stage III unresectable NSCLC were enrolled in the phase I study. DOC and CBDCA were administered bi-weekly (D1, 15, 29, 43, 57, 71) at the following DOC (mg/m2)/CBDCA (AUC) dose levels: 20/2.5, 20/3.0, 30/2.5, 30/3.0, and 40/3.0. Concurrent thoracic radiotherapy was performed in 2Gy daily fractions to a total dose of 60Gy. DLT was defined as grade 4 hematological toxicity, or grade 3 or 4 nonhematological toxicity. Three to six patients were entered at each dose level. Dose escalation continued until greater than one half of patients developed DLT. After determing the MTD and RD, the phase II study was initiated to evaluate the efficacy and toxicity at the RD.

Results: The MTD was DOC 40mg/m2 and CBDCA AUC 3. To date, 19 patients have been treated in the phase II study. An overall response rate of 83%(95% C.I.: 56-96%) was observed in 18 evaluable patients (15 PR, 2 NC, 1 PD).

Conclusions: Combined chemotherapy of bi-weekly DOC and CBDCA with concurrent radiotherapy in stage III NSCLC was well tolerated. The preliminary efficacy data are promising. Updated results will be presented.

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Neoadjuvant chemo-radiation with paclitaxel/carboplatin in stage III non small cell lung [NSCLC] patients

W. Budach[1], G. Friedel[2], T. Hehr[1], S. Sepe[1], D. Hruschka[3], L. Kanz[4], H. Toomes[2], R. Dierkesmann[3], M. Bamberg[1]. *[1] University of Tuebingen, Radiooncology, Tuebingen, Germany; [2] Klinik Schillerhohe, Thoracic Surgery, Gerlingen, Germany; [3] Klinik Schillerhohe, Oncological Pneumology, Gerlingen, Germany; [4] University of Tuebingen, Medical Oncology, Tuebingen, Germany*

Background: Neoadjuvant chemo-radiation has been shown to induce significant down staging and improved resectability in stage III NSCLC. The reported high response rates of paclitaxel/carboplatin were rationale to test the efficacy of these drugs in combination with radiotherapy in the neoadjuvant setting in a phase II trial.

Methods: Patients (>17 to <70 years, KPS >70%) in stage III NSCLC (staging included CT-thorax/abdomen/cranium, PET, and mediastinoscopy) without supraclavicular lymph node involvment qualified for the study. Paclitaxel 100 mg/m* and carboplatin AUC 2 were administered at day 1, 8, 15, and 22 followed by hyperfractionated/accelerated radiotherapy starting at day 43 (2x1.5 Gy/day, 5x/week to 45 Gy) with simultaneous paclitaxel (50 mg/m*) and carboplatin (AUC 2) at day 44, 51, and 58. Erythropoetin (3x 150 I.E./kg/week) was given at a Hb $\leq$10.5 g/100 ml. After complete restag-