

correlated with weight ( $r=0.50$ ,  $p<0.001$ ) and LBM ( $r=0.33$ ,  $p=0.036$ ) and net gain was observed with 1.5-2 cans/d. Similarly, E patients demonstrated positive correlations between increasing total protein intake (meals plus E) and both weight gain ( $r=0.52$ ,  $p<0.001$ ) and increased LBM ( $r=0.46$ ,  $p=0.004$ ). Such correlations were not observed in C patients. Increased plasma EPA levels were associated with LBM gain ( $r=0.51$ ,  $p=0.001$ ).

**Conclusion:** This study demonstrates that energy and protein dense supplements can stabilise weight in cancer cachexia. Furthermore, net gain of body weight and LBM can be achieved with adequate consumption (1.5-2 cans/d) of such a supplement when it is enriched specifically with n-3 fatty acids and antioxidants.

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ORAL

### Does systemic chemotherapy prior to surgery increase the operative risk of a major hepatectomy?

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The efficacy of systemic chemotherapy sometimes allows secondary resection of hepatic metastases. The potential hepatic toxicity of anticancer agents may influence the surgical procedure and the post-operative complications of a major hepatectomy. The objective of this study was to assess the impact of preoperative chemotherapy on liver function, the modalities of hepatic surgery, and on postoperative morbidity.

**Patients and Methods:** Pts without known chronic liver disease, treated by right or left hepatectomy in a curative intent for liver metastasis were analyzed retrospectively. Two groups of pts were compared: 44 non pretreated pts versus 42 pts treated by systemic chemotherapy within 6 months before surgery (median duration of chemotherapy = 6.7 months [extr 1-26]) for the following characteristics using a multivariate analysis: age, gender, body mass index, cancer primary site, number and size of the liver metastasis, existence and duration of preoperative chemotherapy, duration of operative procedure, duration of clamping of the hepatic pedicle, blood loss volume, liver function tests (ASAT, ASAT, ALP, GGT, bilirubine, prothrombin time (PT)) before and just after surgery, existence of postoperative complications and total duration of hospitalization).

**Results:** The 2 groups were well balanced for all the preoperative characteristics except for age which was statistically different (50 vs 58.7 years,  $p=0.0002$ ). Preoperative liver function tests, preoperative PT, duration of hepatectomy, duration of clamping of the hepatic pedicle, blood loss volume, postoperative complications, and total duration of hospitalization were not different between the 2 groups. Only the postoperative PT was significantly lower in the pretreated group: 60% versus 49%,  $p=0.0002$ . The duration of preoperative chemotherapy (< 6 mois versus > 6 mois) did not influence those results.

**Conclusion:** Preoperative systemic chemotherapy, even longer than 6 months, did not seem to have a deleterious effect on the surgical procedure and the post-operative complications of a major hepatectomy for liver metastasis, neither on postoperative morbidity despite macroscopic abnormalities of the liver parenchyma frequently described during surgery. Only the postoperative PT was significantly lower in case of preoperative chemotherapy, but this biologic feature had no impact in terms of post-operative complications.

## Lung cancer I

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ORAL

### Cisplatin/gemcitabine (CG) vs cisplatin/gemcitabine/vinorelbine (CGV) vs sequential doublets of gemcitabine/vinorelbine followed by ifosfamide/vinorelbine (gv/v) in advanced non-small cell lung cancer (NSCLC): final results of a Spanish lung cancer group phase III trial (GEPC/98-02)

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The GEPC/98-02 trial was designed to compare a cisplatin-based 3-drug

combination vs non-cisplatin sequential doublets vs a cisplatin-based reference regimen in NSCLC. The chemotherapy regimens administered were: Arm A: cisplatin 100 mg/m<sup>2</sup> d1 plus gemcitabine 1250 mg/m<sup>2</sup> d1&8; Arm B: cisplatin 100 mg/m<sup>2</sup> d1 plus gemcitabine 1000 mg/m<sup>2</sup> d1&8 plus vinorelbine 25 mg/m<sup>2</sup> d1&8 repeated every three weeks; Arm C: gemcitabine 1000 mg/m<sup>2</sup> plus vinorelbine 30 mg/m<sup>2</sup> d 1&8 for three cycles followed by ifosfamide 3 gr/m<sup>2</sup> d1 plus vinorelbine 30 mg/m<sup>2</sup> d1&8. Eligibility criteria were measurable stage IV (brain metastases eligible if asymptomatic) or stage IIIB (malignant pleural effusion) NSCLC and PS=0-2. 562 patients (pts) were included between September 1998 and August 2000. Median age 58 (32-76); PS 0-1: 84.2%, PS 2: 15.8%; Stage IV: 79%, Stage IIIB: 21%. The three arms were balanced for the main prognostic features. Response rates were: Arm A: 41%; Arm B: 40%; Arm C: 24.1%. With a follow-up of 12 months median survival was: Arm A: 40.8w (95% CI, 24.5-57.2); Arm B: 34.4 w (95% CI, 27.1-41.7); and Arm C: 44.8 w (95% CI, 31.8-57.9). Toxicities include, in Arms A, B, C, respectively: Grade 3-4 neutropenia 26.3%, 30.1%, and 18.5%, with neutropenic fever in 6.3%, 22.4% and 7.4%; Grade 3-4 thrombocytopenia 18.2%, 23.1% and 7.4%. Nausea and vomiting, neuropathy and renal toxicity were similar in the three arms. Final results will be presented in october 2001.

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### Sequential versus concurrent chemo-radiation (RT-CT) in locally advanced non small cell lung cancer (NSCLC): A French randomized phase III trial of GLOT-GFPC (NPC 95-01 study)

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Recent results suggest that concurrent RT-CT is superior to sequential administration in stage III NSCLC. From 10/96 to 05/00, 212 patients (pts) presenting with unresectable locally advanced NSCLC, stage IIAN2/IIIB, treated in 30 french centers, were randomized in a phase III trial between sequential RT-CT (arm A) and concurrent RT-CT (arm B). The mean age was 57 years (18-70), PS 0 in 110 pts, 1 in 95; stage IIAN2: 50, stage IIIB: 156, with normal renal, cardiac, hepatic and hematologic function. In arm A pts received induction treatment: Cisplatin (C) 120 mg/m<sup>2</sup> on D 1, 29, 57 and Vinorelbine (V) 30 mg/m<sup>2</sup>/d once a week from day 1 to 78 followed by a thoracic radiotherapy (TRT) delivering 66 Gy in 33 fractions, 5 days per week for 6.5 weeks. Pts in arm B, received the same TRT starting on D 1 with 2 concurrent cycles of C 20 mg/m<sup>2</sup>/d and Etoposide 50 mg/m<sup>2</sup>/d (d1-5 and d29-33), followed by C 80 mg/m<sup>2</sup>/d, D78 and 106 and V 30 mg/m<sup>2</sup>/d, once a week, D 78 to 127. The total dose of C was equivalent in both arms. Treatment arms were well-matched for baseline characteristics. Survival results are evaluable in 207 pts, toxicity (G3-4 WHO) in 178 pts (Table). Treatment was stopped for toxicity in 18.2% pts (arm A) and 22.3% (arm B). Six toxic deaths occurred in arm A, 10 in arm B.

	Neutropenia	esophagitis	pneumonitis	Median Survival	1-year Survival	2-year Survival
ARM A	88%	1%	1.4%	13.8 mo	56%	23%
ARM B	75%	19%	2.3%	15	56%	35%

This large, randomized study shows an acceptable feasibility, the toxicity of this aggressive regimen reflects the multi-institutional phase III approach; the results, especially in Arm B, compare favorably with other trials, with a clear trend in favor of concurrent RT-CT. An updated analysis will be presented at the meeting.

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ORAL

### Paclitaxel plus carboplatin versus paclitaxel plus gemcitabine in advanced NSCLC. Final results of a randomized phase III study

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**Purpose** of our multicenter trial was to compare the efficacy and toxicity of the non-platinum combination Paclitaxel (P) plus Carboplatin (C) to the commonly used combination Paclitaxel plus Gemcitabine (G) in advanced inoperable NSCLC.

**Patients and Method:** Since February 1998, 509 patients were enrolled in the study. Among them, 201 chemotherapy - naïve patients with his-