CT. Patient in CR after 6 courses of CT received profylactic cranial irradiation.

Results: 22/27 pts. were evaluable for response. Evaluation after 3 courses; 7 CR, 13 PR, 1 SD, 1 PD, overall response rate RR 20/22 (91%). The main toxicity was bone marrow depression, 6/27 pts. required G-CSF support and 17 pts. received blood transfusions. Infections were seen in 16 pts. of whom 14 were hospitalized. One case of therapy related death occurred.

Conclusion: This chemotherapy regimen seems to be very effective, with considerable but manageable toxicity. In this small study, it seems like that the addition of alternating C/P treatment did not improve the response rate.

1085 PUBLICATION

Interim results of a sequential administration of docetaxel (TAXOTERE®) followed by cisplatin-vindesine in chemotherapy naive patients with locally advanced or metastatic non small cell lung cancer (NSCLC)

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Because of the potential lack of cross-resistance between docetaxel (D) and cisplatin-vindesine (PV) a phase II trial was initiated in order to give them at their optimal dose and scheduling: (Part A) (D) 4 cycles (100 mg/m^2 q3) followed by (Part B) (PV) 4 cycles (120 mg/m^2 d1 q4 weeks-3 mg/m^2 weekly), followed by (Part C) (D) 3 cycles. Main eligibility criteria: histologically proven NSCLC, KPS $\geq$ 60%, no previous chemotherapy, no brain involvement, no neurotoxicity NCI grade $\geq$1.32 patients (pts) have been included. To date 29 pts have been analyzed. Main pts'characteristics: 72% male; median age: 56 years (40–70); median KPS 100% (60–100); adenocarcinoma 41%; squamous cell 35%; large cell 24%; metastatic 83%. Main toxicities for 28 pts (147 cycles): Parts A, B, C: neutropenia G-3 39%, G-4 36%; febrile neutropenia 4%; allergy G-3 7%; severe asthenia 4%; stomatitis G-3 4%; transaminase elevation G-2 4%. Part B: neurosensory G-3 25%; creatinine elevation G-3 4%, G-4 4%; vomiting G-3 4%; neurohearing G-3 4%. No toxic death was observed. To date, 22 pts were off study and received a median number of 6 cycles (1–11). Six pts were withdrawn from study for adverse experience (neurological, hepatic or renal toxicity). Seventeen pts were evaluable for response: 4 PR (23.5%); 8 NC (47%). The response will be reviewed by an independent panel. The main non-hematological toxicity was neurosensory. Its incidence should decrease for the further pts as the dose of PV has been reduced. This sequential administration appears feasible (median number of 6 cycles administered) and seems to achieve a promising activity.

1086 PUBLICATION

The impact of vinorelbine in elderly (aged >70 years) with NSCLC: A preliminary report

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To assess the impact of chemotherapeutic treatment in obtaining better quality of life in elderly aged plus 70 years with inoperable NSCLC, since December 1996 we have submitted 15 patients (pts) to a "palliative" schedule with Vinorelbine 30 mg/mq i.v. days 1 and 8 every 3 weeks for at least 3 cycles.

To date the main features of the treated pts are: M/F ratio = 14/1; median age (years) = 70 (range 65–83); NSCLC stage IIIb = 7, stage IV = 8; all pts had one collateral disease (mainly COPD and diabetes).

All the pts were evaluated according to a MultiDimensional (MD) approach including cognitive state, daily activity functions, comorbidity, nutritional and clinical assessment, psycosocial condition. The MD evaluation was studied before, during and after the treatment.

12/15 pts received 3 cycles of Vinorelbine, 2 pts 2 cycles and are defined as too early to evaluate and 1 pt received only 1 cycle owing to early death (ED).

After 3 cycles, 3 pts have Partial Response and 6 Stable Disease but all the treated pts, excluding the ED, showed, at the MD evaluation, a better "status" of quality of life with less need at supportive care (steroid infusion and antibiotical drugs, mainly) and a good level of autonomous performance status.

The psycosocial examination revealed in 9/6 pts a higher level than before the treatment. The only toxic observed effect owing to Vinorelbine infusion, was phlebitis in the arm where the drug were infused 4/15 pts and hematological G1 in 1/14 pts. No neurological or gastrointestinal toxic effect was observed. Emesis was not recorded and anti-emesis protocol contained Ondansetron.

These preliminary data indicate that even for elderly pts a chemotherapeutic approach is ethic when the aim is good level of quality of life.

Furthermore toxicity related to chemoterapeutic approach in elderly pts isn't so heavy as commonly retained if related not to the age of pts but to comorbidity.

1087 PUBLICATION

Carboplatin (CBDCA), ifosfamide (IFX) and etoposide (VP) in advanced non small cell lung cancer (NSCLC): A phase II trial

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Purpose: Assess efficacy, toxicity and changes of Karnofsky performance status (K) of CBDCA-IFX-VP (CIV) regimen in NSCLC neoadjuvant or palliation therapy.

Methods: Patients (pts) were required to have histologically proven locally advanced or metastatic NSCLC with measurable lesion, no previous chemotherapy and signed informed consent. They were treated in an outpatient setting with CBDCA 300 mg/m^2 on day 1 and IFX 1.5 gr/m^2 + Mesna and VP 60 mg/m^2 both on days 1–2–3 every 4 weeks.

Patients: For a total of 38 pts, 33 were males and 5 females, with a mean age of 59.6 years (33–74) and a median K of 80% (60–100%). 11 pts were stage IV disease, 14 stage IIIB and 13 stage IIIA. Histology were 28 squamous cell, 9 adenocarcinoma and 1 large cell.

Results: All pts were evaluable for response and toxicity. 227 cycles (cyc) were administered (mean 5.9/pts). Clinical complete response was achieved in 1 pts (2.6%) and partial response in 14 pts (36.8%), for an overall response (OR) rate of 39.5% (95% CI: 24%–55%). 16 pts (42%) had stable disease and 7 pts progression disease. K improved in 12 pts, remain unchanged in 13 pts and decreased in 13 pts. The principal toxic effect observed was myelosupression (M), particularly neutropenia. Median time to progression (mtp) was 7 months (mo) (95%CI: 6–13 mo) and median survival (ms) was 10 mo (95%CI: 8–18 mo). 10 cyc (4.4%) were not to be started as scheduled because M. When pts with and without dosage reduction were compared, mtp and ms were not different.

Conclusion: CIV combination is active in advanced NSCLC, with OR comparable to that achieved in other similar trials. Moreover, K improved or remained unchanged in 65.7% of pts. Prospective phase II studies are need to assess the role of dose intensity in advanced NSCLC.

1088 PUBLICATION

Navelbine (NVB), oral etoposide (VP16), in advanced non-small cell lung cancer (NSCLC)

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Methodology: Between 10/94 and 12/96, 25 patients (pts) with advanced/metastatic NSCLC were accrued to the NVB + VP16 phase II trial: pts with PS/ECOG $\leq$ 2, histologically confirmed and measurable disease were eligible for the treatment: NVB 30 mg/m^2 on D1 and NVB 35 mg/m^2 on D8, oral VP16 100 mg/m^2 over 5 days (D1–5) given on a 28-day schedule (maximum 6 cycles).

Results: Pts characteristics are as follows: 19 males (76%); median age 68y (39–75); PS 0, 1 and 2: 40%, 36% and 24% respectively; histology: adenocarcinoma – 11 pts (44%); squamous cell – 10 (40%); large cell carcinoma – 4 (16%). Stage: IIIb – 18 (72%); IV – 7 (28%). The incidence of Grade (G) 3 neutropenia was 12% and G2 neutropenic fever was seen in 2 pts.; non-haematological toxicity: G 2 nausea/vomiting 24%; G1 local phlebitis 4%; G3 alopecia 8%; G1–2 peripheral neuropathy 20%; G1–2 constipation 24%; 65% of pts experienced reversible and mild fatigue.

Response: Overall Response Rate: 72%; CRs: 4 pts (16%); PR: 14 pts (56%); the median TTP was 10 months. Moreover cancer related symtoms were improved as dyspnoea in 80% of pts; haemoptisis in 90%; cough in 60% and pain in 50%. At 1 year follow up 9/12 patients are alive.

Conclusions: This regimen produces encouraging response rates and an excellent tolerance profile in the management of inoperable NSCLC. This regimen should be assessed in the neoadjuvant setting in earlier stage disease.