adriamycin- ($P = 0.03$) had a positive impact on survival in both series of pts suggesting a potential benefit of a prolonged treatment when adjusting for the intensity of the first regimen.

92 POSTER

CPT 11 (IRINOTECAN) IN PRETREATED SMALL CELL LUNG CANCER (SCLC): A PHASE II STUDY IN PATIENTS PROGRESSING AFTER A FIRST RESPONSE (PRELIMINARY RESULTS)

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The standard combination chemotherapy of SCLC is an etoposide based regimen. After failure of this regimen the prognosis is very poor although the use of a rescue regimen still displays clinical activity.

It has been already suggested that investigational new drugs should to be assessed in second line therapy in SCLC and that a RR $\geqslant$ 10% among 29 patients would be relevant for the screening of active new compounds.

CPT11 is a new DNA topoisomerase I inhibitor active in colorectal cancer and other solid adult tumors.

22 patients with progressive extensive SCLC after a prior response on a VP16-based chemotherapy have been so far entered onto the study. Sex ratio M/F =19/3; median age = 57.2 (43–72). Performance Status 0 = 14%; 1 = 45%; 2 = 41%. Median number of involved organ 4 (1–6) with liver (27%), lung (22%), lymph nodes (16%) and brain (11% of patients).

57 cycles at the planned dose of 350 mg/m^2 every 3 weeks have been delivered with a median Relative Dose Intensity of 0.95 (0.78–1.03).

Efficacy: One CR and three PR have been observed among the 15 evaluable patients.

Safety: The incidence of grade 3 and 4 toxicity per cycle has been: neutropenia: 49% (with febrile neutropenia sepsis in 14%), delayed diarrhea: 18%, nausea vomiting: 14%.

Conclusion: The activity of CPT 11 in SCLC is likely to be attractive on the basis of these preliminary data. Neutropenia is clearly the dose limiting toxicity in this population of pretreated patients with frequent occult bone marrow involvement.

93 POSTER

A NEW STAGING SYSTEM FOR SMALL CELL LUNG CANCER (SCLC): A PROPOSAL

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The staging system should aim at four goals: (1) to define more accurate prognosis for individual pts; (2) to help in treatment planning in clinical practice; (3) to better compare therapeutic results in clinical trials; and (4) to define optimal risk groups for pt stratification in prospective studies.

From 2/85 to 6/93, 173 consecutive pts with SCLC received treatment tailored to disease extent. Fourteen out of 16 pts with stage I and II, 25/62 with stage IIIA and 5/37 with stage IIIB were subjected to surgery plus chemotherapy (CT) and RT (chest and brain). Pts with inoperable stage I–II (2/16) and III (IIIA 37/62, IIIB 32/37) received CT followed by RT while CT +/− symptomatic RT was administered in pts with stage IV disease. In all pts CT consisted of CAV-like regimens and/or cisplatin + VP16. The 5-year results (%) are as follows:

		Extent		Stage				
	Total	Limited	Extended	I	II	IIIA	IIIB	IV
FFP	16	24	0	54	50	22	15	0
Survival	16	26	0	67	65	19	27	0

Our data confirm the prognostic value of limited vs extended SCLC. However, analyzing our data according to a different stage grouping we obtained the following results:

New stage grouping	Stage (TNM)	% FFP (5-yrs)	% Survival (5-yrs)
Limited (L)	I–II–IIIA (T3N0)	48*	49**
Locally-extended (LE)	IIIA (T3N1–2)-IIIB	19*	22**
Extended (E)	IV	0*	0**

*L vs LE $P = 0.007$ *L vs E $P = 0.0001$ *LE vs E $P = 0.0001$ **L vs LE $P = 0.0025$ **L vs E $P = 0.0001$ **LE vs E $P = 0.0001$

This 3-stage grouping seems to better correlate with long-term results and may represent a more reliable staging model for SCLC.

94 PUBLICATION

SMALL CELL LUNG CANCER (SCLC) AND LONG-SURVIVORS. A REVIEW OF 276 PATIENTS (P)

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We reviewed 276 patients (pt) with histologically confirmed SCLC in a single institution from January 1981 to May 1992. They were treated with three different combination chemotherapy regimens. Among 251 evaluable patients only 18 (7.17%) were alive after two years (y). All these patients were men with a median age of 59 y. All but four had Limited Disease (LD). Four patients were treated with ECCP regimen (VP-16, CYC, CcNU, prednisolone), 4 with ECCA (VP-16, CYC, CcNU, ADM) and 10 with ECAP (VP-16, CYC, ADM, PCB). Among the 18 pt, 5 pt underwent chest radiotherapy and also 5 underwent prophylactic brain irradiation. Fifteen pt got a complete response (CR) and the time diagnosis-treatment was brief with a median time of 3.3 days. All the 18 pt had 0–1 ECOG performance status (PS) and most of them (15/18) a PS = 0. The 4 pt with Extensive Disease (ED) had disease in contralateral axila (1), bone and liver (1) and 2 pt were classified as ED because of exclusively having mediastinal syndrome. The median survival was 51 months (26–89 m) and, in May 1994, 9 pt were alive, 8 had died and 1 had disappeared on follow-up. Seven pt lived more than 5 y (2.78%). This results confirm that stage (LD), high PS and getting a CR are the main prognostic factors and, although relapses may exist after 2 y of survival, two-thirds of the patients being then free of disease will not relapse in the future. To find new drugs with more cytotoxic power is mandatory.

95 PUBLICATION

FOUR VERSUS 6 COURSES CISPLATIN ETOPOSIDE (E.P.) WITH EARLY CHEST RADIOTHERAPY. A RANDOMIZED STUDY IN SMALL CELL LUNG CANCER (SCLC)

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Despite several trials testing increased dose intensity, alternating drug administration etc. the survival of patients (pts) with SCLC has not improved. Early chest radiotherapy in pts with Limited Disease (LD) has been shown to improve patients' survival. In an effort to reduce toxicity we have compared the efficacy and toxicity of 4 courses (Group A) versus 6 courses (Group B) of EP chemotherapy combined with early chest radiotherapy. In a randomized study 52 evaluable pts have been treated with E.P. (Etoposide 120 mg/m^2 days 1–3, Cisplatin 80 mg/m^2 day I). All responders have been irradiated after the 4th course. Objective Response (O.R.) for Group A was 16/24 = 66%, with 5 CRS 20% and 11 PRS 46%, Group B OR: 21/28 = 75% with 7 CRS 25% and 14 PRS 50%. Median Time to progression group A: 8 mo group B: 13 mo ($P = 0.050$) Median Survival group A: 9 mo (5–28+) group B: 12.5 mo (6–43+) ($P = 0.033$). Median Survival LD pts group A: 15.6 mo, Group B: 20.5 mo (N.S.). Extensive Disease (E.D.) Group A: 7.5 mo, Group B: 11.5 mo ($P = 0.027$). Myelotoxicity and renal toxicity were not significantly different. We consider 4 courses inferior to 6 courses even with early radiotherapy. E.D. patients seem to benefit more from the two extra courses.

96 PUBLICATION

NONESOPHAGICAL EXTRAPULMONARY SMALL CELL CARCINOMA

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Extrapulmonary small cell carcinoma (ESCC) is a well known but uncommon neoplasm of uncertain origin. In spite of its rarity, the appearance of this type of tumor has been described in various organs of the economy. Of these, the esophagus has usually been reported as the most common location.

Eight patients with nonesophagical small cell carcinomas have been evaluated in our service between 1988–1995, constituting 2.2% of all small cell carcinoma (SCCs) that we have seen in the same lapse of time.