1168 PUBLICATION

A phase II study of biweekly irinotecan plus cisplatin in patients with extensive stage small cell lung cancer

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Background: Superiority of irinotecan/cisplatin (IP) combination over etoposide/cisplatin has recently been suggested in a phase III study in patients with small cell lung cancer (SCLC). But about 70% of patients in the study recieved assigned IP treatment with modified doses or delivery schedule due to the adverse events (N Engl J Med 2002; 346: 85–91).
Aim: This multicenter, phase II trial was designed to confirm these results in chemo-naïve pts with ES SCLC using a modified biweekly regimen of IP to improve tolerability with acceptable response.
Patients and methods: 37 chemotherapy-naïve patients with ED-SCLC received irinotecan (d1, d15: 60 mg/m^2)/cisplatin (d1, d15: 30 mg/m^2)(biweekly IP). Pts were restaged every 2 cycles. Eligibility criteria included: measurable disease, ECOG PS 0–2, adequate organ function, no active brain metastases, and informed consent.
Results: 37 pts were enrolled between 09/03 and 01/05. Baseline characteristics include: median age 66 years (49–78); male/female, 31/6; ECOG PS 0,1,2: 13/18/5. Grade(G) 3 non-hematologic toxicity included: nausea (21%), vomiting (5%) and diarrhea (5%). G3 hematologic toxicity included: neutropenia (10%) and thrombocytopenia (3%). There were no treatment-related deaths. Response data are available for 30 pts. Complete/partial response were observed in 4 pts (13%)/21 pts (70%), respectively, for an overall RR of 83%. One pt (3%) had stable disease, and 4 pts (13%) had progressive disease (7 pts were unevaluable because of intercurrent illness, poor compliance, or treatment toxicity.) Median progression-free (PFS) and overall survival (OS) were: 33 weeks (95% CI, 22–44) and 76 weeks (95% CI, 43–109), respectively.
Conclusions: modified IP is a safe and well-tolerated regimen with acceptable RR in the first-line treatment of extensive-stage SCLC.

1169 PUBLICATION

A pharmacoeconomic feasibility study of three chemotherapy regimens for advanced non small cell lung cancer (NSCLC) in India

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Background: Incidence of lung cancer in Bangalore among men is 495 per 1,000,000 population. Majority of these patients present with stage IIIB/IV disease. Hence palliation of symptoms and prolongation of life are the primary goals of treatment. Newer third generation platinum-based regimens have emerged as the mainstay of chemotherapy for such patients with an absolute increase in survival of 4% at 1yr over second generation platinum based regimens. This study was undertaken to compare the efficacy, toxicity, pharmacoeconomics and feasibility of the newer third generation regimens as against the second generation in our set up.
Materials and methods: The study population included previously untreated stage IIIB/ IV NSCLC patients with an ECOG performance status of $\geqslant$2. The study arms included: 1) Gemcitabine + Cisplatin (G + C), 2) Paclitaxel + Cisplatin (P + C) and 3) Etoposide + Cisplatin (E + C). Twenty patients were recruited into each arm and prospectively studied for response rates (RR), median time to progression (TTP), toxicity profile and cost of therapy.
Dosages of drugs were as follows: Gemcitabine – 1250 mg/m^2 on days 1&8; Paclitaxel – 175 mg/m^2 on day 1; Etoposide – 100 mg/m^2 on days 1, 2, 3 and Cisplatin – 75–100 mg/m^2 on day 1 of three weekly cycle. Chemotherapy was administered for a maximum of six cycles or till progression. Pharmacoeconomics was calculated for the three arms based on cost of drug, hospital stay, loss of wages and management of toxicity.

Results:

	G + C	P + C	E + C
RR (%)	35	30	15
TTP (months)	4.5	4	2.7
GradeIII/IV hematological toxicity (%)	45	30	15
Pharmacoeconomics per patient per cycle in Indian Rupee	30,000	20,000	6,000

Third generation agents (Gemcitabine and Paclitaxel) were associated with better respose rates and time to progression. However cost of therapy in the Gemcitabine arm was 5 times more as compared to Etoposide arm and cost of therapy in Paclitaxel arm was 3.3 times more as compared to Etoposide arm. Cost of the drug and management of toxicity resulted in the higher pharmacoeconomics of third generation agents.
Conclusion: With a percapita income of only Rs. 10000–13000 and with more than 80% being rural poor, third generation agents do not appear to be economically viable for the management of advanced NSCLC in India.

1170 PUBLICATION

Radiochemotherapy in the treatment of small cell lung carcinoma. Results and evaluation of acute toxicity

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Background: The schedules of concurrent chemo-radiation in the treatment of small cell lung carcinoma (SCLC) are leading to improved survival when compared to sequential treatments but also with a considerable increase in acute toxicities. We analized the acute toxicity and the efficacy of concurrent chemotherapy and radiotherapy in the treatment of limited stage of small cell lung carcinoma.
Methods: Since 1999, sixty patients affected of limited small cell lung carcinoma were included. In 98.3% of patients the chemotherapy administrated was Cisplatin (80 mg/m^2), on day 1 and Etoposide (100 mg/m^2), on days 1–3, and in 88.4% of cases the radiotherapy began between the first to third cycles of chemotherapy. All patients were treated with standard technique, administering 45 Gy in 25 fractions to the mediastinum plus a boost of 9–10 Gy to the tumor. The fractionation was 180 cGy/day, five days/ week; in 19 patients (31.7%) accelerated radiotherapy was used administering twice daily 150 cGy fractions separated 6 hours each other. The 78.3% of patients had profilactic cranial irradiation.
Results: The most common toxicity was the esophagitis, followed by dermitis. Three patients presented pneumonitis grade II. In any case the radiochemoterapy was interrupted. A complete response was observed in 62.7% of cases, a partial response in 25.4%, stable disease in 5.1% and 6.8% had local progression. After a mean follow-up of 24 months the overall survival, cause specific survival and local recurrence free survival at two years was 49.5$\pm$7.3%, 55.2$\pm$7.5% and 69.3$\pm$7.6% respectively.
Conclusions: Radiochemotherapy improve the results in patients with SCLC, despite an increased toxicity. The acute side effects seems acceptable and controlled with standard treatments. The twice-daily schedule has worse side effects as compared with concurrent once-daily radiotherapy. Despite of the limited number of patients and the shorter follow-up these data are promissing, beacuse they represent an improve in the response rates.

1171 PUBLICATION

What is the role of radiotherapy in advanced mesothelioma?

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Background: Adjuvant radiotherapy (RT) to prevent biopsy site metastases in patients with mesothelioma is standard practice in the UK based on one randomised trial of 40 patients carried out in the pre-chemotherapy era. In Edinburgh, between 2000 and 2003, patients were offered chemotherapy (CT) within the context of a series of clinical trials and the use of adjuvant RT was not routine.
Aim: To evaluate our use of RT in patients with advanced pleural mesothelioma.
Methods: Between January 2000 and December 2003 116 patients were referred to the Edinburgh Cancer Centre with pathologically confirmed mesothelioma. Nine patients had primary peritoneal disease and were excluded from further analysis. Six patients had an extrapleural pneumonectomy for early mesothelioma and are also excluded, leaving 101 for this review. Data was extracted on age, gender, stage, use of CT and RT (including site) from the data base. The case notes of 95 were available for review and data was extracted on histology, surgical intervention, performance status (PS) and indication for RT.
Results: The median age of the cohort was 68 (range 46–91) years and 95 were male. 27 patients had epithelioid tumours, 10 sarcomatoid, 4 mixed and the remainder were unspecified. PS was not documented in 15 cases. Of the remainder 8 were PS 0, 42 PS 1, 21 PS 2, and 10 PS 3. 67 patients had pleural aspiration, 83 closed pleural biopsy, 39 thoracoscopy and 13 thoracotomy.