1054 PUBLICATION

Phase I study concomitant gemcitabine (G) with radiotherapy (RT) in stage III NSCLC

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Purpose: Concomitant radio-chemotherapy in stage III NSCLC has produced encouraging results. G has demonstrated a 20% objetive tumor responserate in patients receiving 850–1250 mg/m^2 weekely. Preclinical studies have demonstrated that G has the potential to sensitize tumor cells to radiation.

Methods: A phase I trial was designed combining a irradiation up to 50 Gy combined with a weekly concomitant injection of G according to the dose escalation (see table) in stage III NSCLC patients. 20 patients were enrolled in the study. These patients were obtained PR or EE with the differents chemotherapy schedules. Median age: 64 years, PS: 0–1.

G (mg/m^2)	RT	N patients	G3–4 H.T	G3–4 no HT
200	50	3	0	0
300	50	3	0	0
400	50	6	2	1
500	50	6	0	3
600	50	2	0	2

Results: 20 patients were assessable for toxicity. Grade 3–4 haematological toxicity: 2 patients included in dose level 3. Esophagitis was the main toxicity, 1 patient with dose level 3, 3 patients with dose level 4 and 2 patients with dose level 5, registered toxicity grade 3. With a median follow-up of 19 months, 14 patients was progresed. The median progresion time is 9 months.

Conclusions: The concurrent administration of G and RT is possible but the non haematological toxicity was hight. The dose of RT was low. This study is still on going

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AK-2123 modification of squamous-cell lung carcinoma response to radiotherapy

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Purpose: To evaluate the efficacy of AK-2123 electron-affinity compound administration in radiotherapy (RT) of inoperable squamous-cell lung carcinoma (SCLC).

Materials and Methods: The study included 24 males with SCLC, 92% of them with moderate and high differentiation of tumor cells. In 60% of the patients the primary tumor spontaneously invaded the mediastinum, the heart, large vessels, trachea, carina, esophagus or bodies of vertebrae; stage IIIA was in 39%, IIIB – in 71% of the patients. RT was administered in a split course with treatment step alternation of the regimens (large-fraction and conventional) of dose fractionation, reaching a total target dose isoequivalent to 64–66 Gy. During the whole course of the treatment, AK-2123 hypoxic sensitizer, a derivative of nitrotriazole N-(2-methoxyl)-2-3 (3″ nitro-1″ – triazolyl) acetamide, was administered. The total dose of the agent was 24 g.

Results: In the course of the treatment, 10 (40%) patients demonstrated morbidity corresponding to 1 in WHO scale: 5 patients had fever, 3-vertigo (2 of them with a headache), 2-paresthesia. No other side effects were observed. The short-term effect of the treatment was evaluated 1.5 month after its discontinuation according to radiological, bronchoscopic and pathological findings. Despite the locally advanced disease, tumor regression was registered in all the patients (100%), significant response -in 19 (79%), complete response – in 2 (8%) of them.

Conclusion: Radical regimen radiotherapy employing AK-2123 radiomodifier produces significant tumor resorption even in patients with a great extent of tumor spread, the side effects of it being negligible.

1056 PUBLICATION

Extrapleural pneumonectomy for pleural mesothelioma

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Purpose: The increasing incidence of young mean age of malignant pleura mesothelioma patients associated with an early diagnosis induced surgeons, in absence of a standard therapy, to execute extrapleural pneumonectomy considered, in the past, an high risk intervention not always balanced by favourable impact on the prognosis. The aim of this work is to evaluate the efficacy of this infrequent surgical intervention.

Methods: From 1994 to 1997, 12 patients were submitted to extrapleural pneumonectomy for malignant mesothelioma. The selective parameters for admission to this treatment were good condition of patient, stage I, a predictive postpneumonectomy FEV 1 > 1300 ml. and a decrease of perfusion of resectable lung >= to 50%. We utilized the technique described by Sugarbaker.

Results: We performed 7 right extrapleural pneumonectomy and 5 left Perioperative mortality was nil. Pericardium reconstruction was in 10 cases goretex patch and in 2 by a marlex patch. Diaphragm was reconstructed in 9 cases by a reverse flap of latissimus dorsi muscle, in 2 cases by dura madra and in 1 case by goretex. All patients received adjuvant radiotherapy. The average of disease-free interval was 13.72 ± 11.06 months, median 10 (range: 5–45 months) Mean survival was 19.02 ± 14.78 months, median 17 (range: 5–49 months).

Conclusion: By our data we can affirm that extrapleural pneumonectomy for pleural mesothelioma has a low risk of morbidity with a good quality of life Postoperative respiratory functionality was on average 70% of beginning value.

1057 PUBLICATION

Serum "Vascular Endothelial Growth Factor" (VEGF) levels in patients with non-small cell lung cancer (NSCLC)

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Purpose: Relationship between serum VEGF levels and disease stage in patients (pts) with NSCLC was investigated in this study.

Patients and Methods: Forty-two male pts with NSCLC who were never treated before, were included in this study. Median age of pts was 57 (42–73). There were squamous cell carcinoma in 30 pts (71.5%), adenocarcinoma in 9 pts (21.5%), large cell carcinoma in 1 pt (2.3%) and adenosquamous carcinoma in 2 pts (4.7%). VEGF levels in sera were measured by ELISA using $VEGF_{165}$ (Quantakine, human VEGF immunoassay, R&D systems).

Results: Serum VEGF level (pg/ml) and number of Pts in every stage were shown as in the Table:

Clinical Stage	Number of Pts (%)	VEGF level (mean ± SD)
I	10 (23.8%)	431 ± 295
II	7 (16.7%)	455 ± 284
IIIA	9 (21.5%)	441 ± 210
IIIB	8 (19.0%)	342 ± 169
IV	8 (19.0%)	376 ± 323

There was not statistically significant differentiation between the clinical stages and VEGF levels in sera ($p > 0.05$). In addition, there were not statistically significant associations between VEGF levels and histologic type, primary tumor diameter, lymph node metastasis and distant metastasis ($p > 0.05$).

Conclusion: There is no relationship between tumor load and serum VEGF levels in pts with NSCLC. Although VEGF expression was shown in tumor tissue in the literature, the serum levels of this angiogenetic factor do not seem to correlate with the tumor burden.