

1 pt, leiomyosarcoma 1 pt, unknown primary site 1 pt. IL3 was given at a dose of 10 mcg/kg/die s.c. from the onset of G1–G4 thrombocytopenia and continued until recovery. IL3 was given for a mean of 5.7 days (range 2–10) and a median of 5 days. So far 17 out of 21 cycles of chemotherapy with thrombocytopenia are evaluable. At present our results are as follows:

- thrombocytopenia G1 (4 cycles): mean increase of platelet counts = 32% within a period of 4.75 days (range 2–10);
- thrombocytopenia G2 (8 cycles): mean increase of platelet counts = 31% within a period of 5.75 days (range 2–10);
- thrombocytopenia G3–4 (5 cycles): mean increase of platelet counts = 157% within a period of 7 days (range 4–10).

The main toxicities were: fever G1–2 8 pts; tremor 3 pts; erythema 1 pts; flu-like symptoms 4 pts; nausea/vomiting G2 1 pts; myalgia G2 6 pts; mental derangement 1 pt.

1 pt, after first administration, has developed acute hypersensitivity with lipothymia.

These data seem to show that IL3 is an active drug in the treatment of thrombocytopenia following a standard dose of chemotherapy. The study is still ongoing and definitive results will be discussed.

255

PUBLICATION

COMPARISON BETWEEN RHGM-CSF AND RHG-CSF ADMINISTERED DURING RADIOTHERAPY AND AFTER PROLONGED CARBOPLATIN INFUSION IN PREVENTING LEUKOPENIA AND MUCOSYTES PRODUCED BY CHEMORADIOTHERAPY IN ADVANCED HEAD AND NECK CANCER

G. Ausili-Cefaro, L. Marmioli, G. Fincato¹, L. Nardone, A.M. Scapati, A.D. Andrucci, D. Genovesi, G. Salvi

Div. Radioterapia, University of Cattolica S. Cuore, Rome, Italy

¹SANDOZ Prod. Farm. S.p.A, Milan, Italy

Concomitant radio-chemotherapy is considered the therapy able to increase the percentage of positive responses in advanced head and neck cancer patients. Nevertheless the related toxicity can become important from the clinical point of view, specially the haematological and mucosa one. In order to reduce the severity of the foreseen haematological

and mucosa toxicity, a pilot study with haematological growth factors (G-CSF and GM-CSF) has been performed. Both growth factors were given at the end of the chemotherapy schedule and throughout the radiotherapy programme prosecution. Patients were exposed to infusional chemotherapy for 14 days on end with Carboplatin 30 mg/m² and concomitant radiotherapy at the dose of 180 cGy/5 d/w on T and N (*Proc ASCO* 1993, 12:902). G and GM were given at the dose of 3 µg/kg starting 24 h since the end of the CBD CA infusion for 14 days. Five patients received G-CSF and 6 patients GM-CSF. All patients gave their informed consent to take part in this pilot study. Results were considered according to the incidence of leukopenia, thrombocytopenia and mucosites severity, in comparison with a previous group of 28 patients treated with radio-chemotherapy (5th International Congress on Anti-cancer Chemotherapy, Paris, 0–536, 1995).

		GM	G	Control
Mean peak value	WBC	11.630 (9.390–14.400)	22.146 (6.150–31.400)	
Mean nadir value	WBC	2.473	3.012	2.010 (median 1.921)
	Neutrophils	1.379	2.254	1.051 (median 943)
	Platelets	76.900	91.460	80.400 (median 74.000)
Mean day to nadir	WBC/Neutr.	45	37	40
	Platelets	35	27	32
Mucosites grade	1	4/6 (67%)	1/5 (20%)	35.7%
	2	2/6 (33%)	2/5 (40%)	50%
	3	0	2/5 (40%)	14.3%

In conclusion these preliminary data show that both GM and G slightly reduce the severity of Leukopenia but GM-CSF delays the nadir mean day. Moreover GM-CSF, given during radiotherapy remarkably reduces the severity of mucosites in comparison both with the G-CSF and the historical group. These data are very encouraging and support the elaboration of a further and larger clinical trial in order to confirm the important clinical role of GM-CSF in preventing patients, subjected to a radiochemotherapy programme, from the arising of mucosites problems.

Nervous system tumours in adults and children

256

ORAL

CHEMOTHERAPY WITHOUT IRRADIATION (RT) IN MEDULLOBLASTOMA PATIENTS YOUNGER THAN THREE. A PROSPECTIVE STUDY BY THE FRENCH SOCIETY OF PEDIATRIC ONCOLOGY (SFOP)

C. Kalifa, M. Raquin, E. Bouffet, J.C. Gentet, F. Doz, P. Chastagner, Y. Perel, H. McDowell

SFOP Brain Tumor Group

The prognosis of medulloblastoma/PNET of the posterior fossa (PF) in very young children is poor. Survival rate is usually lower than in older children and the quality of life is of particular concern because of the damaging effects of RT on the developing brain. Since 1990, we have been using a post-operative chemotherapy (CT) protocol without RT. The CT regimen included 7 cycles of carboplatin, procarbazine, etoposide, cisplatin, vincristin, cyclophosphamide for 16 to 18 months. In case of progressive disease or relapse under or after conventional CT, salvage treatment including busulfan and thiotepa with bone marrow rescue followed by 50 Gy on PF alone was recommended. Thirty-five children <3 yr (median, 16 m) entered this study. Twelve of 35 patients (pts) with no measurable disease after surgery were considered as low risk pts (LR), and 23 with local residue or metastasis as high risk pts (HR). Among the 12 LR pts, 8 are in CR1 with a median follow-up of 30 m (11 to 54 m). Four out of twelve experienced local relapse. Three of them are in CR2 after salvage treatment along with surgery (2 pts), 10 m⁺, 18 m⁺ and 30 m⁺ after relapse. The last pt died without further therapy. Among the 23 HR pts, only 2 achieved CR with conventional CT (17 and 34 m⁺), 10 relapsed 1 to 19 m after surgery, 11 had progressive disease 1 to 17 m under CT. The 3-yr DFS for LR and HR pts was 67% and 6.5%,

respectively (overall DFS, 27%). The 3-yr overall survival for LR and HR pts was 92% and 28% respectively. This protocol appears efficient in LR pts. Another strategy needs to be designed for HR pts. **Supported by ARC, FRANCE.**

257

ORAL

RADIATION THERAPY (RT) IN THE MANAGEMENT OF CRANIOPHARYNGIOMA

J.L. Habrand, L. Kochbati, C. Kalifa, A. Pierre-Kahn, W. Mseddi
Institut Gustave-Roussy (IGR, Villejuif) and Hôpital des Enfants Malades, Paris, France

This is a review of 37 children and adolescents treated by RT at IGR between January 1969 and December 1992. Maximum follow-up is 22 years. Mean age is 6.4 years (range 1–15) and the M/F sex ratio is 0.76. RT was applied in the initial management, alone or following a surgical procedure, in 18 cases (49%). In the remaining 19 patients, surgery was used as initial single modality and repeated in 13 of them. In these cases, external RT was considered at the time of a further relapse only. In 2 patients, an intra cystic radiocolloid administration (Re 106) was also employed. External RT delivered 45 to 55 Gy using Megavoltage equipment (Co 60: 15, 5–25 MV, X-rays: 22) in 3 to 5 daily sessions of 1.8 to 3.3 Gy. At the time of analysis, 8 children (22%) presented with a local failure. All were observed in children in which RT had been initiated at the time of relapse, and none if RT had been applied in the initial course ($P < 0.01$). All failures were located in the target volume. Nine patients died: 7/9 died from tumor progression, 1/9 from second malignancy and 1/9 from brain injury. Five and 10 years survival are 89 and 67%. Two