lates erythropoiesis by the same mechanism as recombinant human EPO (rHuEPO), but has a longer serum t1/2. NESP was shown to be safe and clinically effective in cancer pts when administered every 1, 2, and 3 weeks in phase 1/2 studies. This phase 3 study compared the efficacy of NESP with placebo in lung cancer pts receiving platinum-containing chemotherapy (ctx).

Methods: 320 anemic pts ([Hb] ≤ 11 g/dL) receiving platinum containing ctx (ECOG 0–2, not iron deficient, no rHuEPO therapy within 8 wks or <2 RBC transfusions (tfn) within 4 wks) were randomized to NESP 2.25 μg/kg or placebo (1:1). Study drug was administered SC once weekly (QW) for a maximum of 12 wks (tx phase).

Results: NESP significantly ($p < 0.001$) reduced the Kaplan-Meier proportion (95% CI) of pts transfused during wks 5–12: NESP 21% (15, 28), placebo 51% (43, 60) and during the tx phase (wks 1–12): NESP 26% (20, 33). placebo 60% (52, 68). NESP pts received fewer standard units (mean [SD]) of RBC than placebo pts during wks 5–12: NESP 1.92 (3.27), placebo 0.67 (1.7) and during the tx phase: NESP 2.64 (4.32), placebo 1.14 (2.38). NESP pts were hospitalized fewer mean (SD) days compared with placebo pts (NESP 10.3 [13.5] days, placebo 13.0 [17.7] days). More NESP subjects had a ≥10% increase in the FACT-F scale score than placebo pts ($p = 0.023$) suggesting that NESP decreases fatigue. The safety profile of NESP was similar to placebo and as expected for this population.

Conclusions: NESP 2.25 μg/kg administered QW significantly reduced the proportion of subjects with RBC tfns and was well tolerated. The clinical benefit of NESP was sooner than previously reported for rHuEPO (Abels, 1991) where RBC tfn only reached statistical significance only if the first month of treatment was excluded.

982 POSTER DISCUSSION

Oncologic acute toxicity unit: development of a new tool in the oncologic clinical practice

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Introduction: We have developed an oncologic acute toxicity unit (OATU) in order to attend promptly the specific acute symptoms related to chemotherapy.

Objectives: To analyse the characteristics of patients that contact with the OATU and their outcome.

Patients and methods: Our data set included all the patients receiving chemotherapy in our hospital and the symptoms related to this treatment.

In the first chemotherapy cycle each patient receive an information booklet with the contact phone of the OATU. When patients called, a specialised nurse attended them and she consulted to the medical oncologist if it was necessary. The unit provides access to complementary exams, ambulatory treatment and hospitalisation if it is indicated.

Results: 829 patients established 1465 contacts to the OATU from February 1999 to February 2001. Most common tumours were breast 216 (26%), colorectal 172 (21%) and lung 165 (20%). Most contacts were done by phone (86.5%) and 38.6% were considered inappropriate. From 899 appropriate contacts, the most frequent chemotherapy schedule were 5-FU-Folinic Acid (12.6%) and CMF (11.6%) and the most frequent complaints were fever (35.3%), diarrhoeas (20%), mucositis (15.8%) and emesis (14.5%). 488/899 (54.3%) required attendance to the OATU and 191/488 required hospitalisation (21.2% of the initial appropriated contacts). Grade III/IV neutropenic fever was the most frequent cause of hospital admission (58.1%).

Conclusions: The development of an OATU provides a quick and easy access for patients who suffer acute toxicity related to chemotherapy treatment. In our experience it guaranties a prompt and specialised treatment and avoids unnecessary consults in the Emergency Room. Hospital admission, which was required in 21.2% of appropriate contacts, is therefore optimised.

Paediatric oncology

983 POSTER DISCUSSION

Impact of radiotherapy on survival in supratentorial PNET of childhood: results of the German prospective HIT-trials

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Purpose: To evaluate dose, volume, and sequence of radiotherapy (RX) with respect to progression free survival and pattern of relapse.

Methods: Since 1988 in Germany and Austria children with newly diagnosed malignant brain tumors were enrolled in the multicenter brain tumor trials. In the pilot trial HIT'88/'89 all pts. received immediate postoperative chemotherapy (CX) consisting of 2 cycles of Ifo/VP-16, hdMTX, DDP/Ara-C followed by RX (prescription: 35.2 Gy craniospinal + 20 Gy tumor boost). In the HIT'91 trial pts. were randomized after surgery either to undergo preirradiation CX, or immediate RX followed by maintenance CX (8 x CCNU/VCR/Cis).

Results: 63 children (age 2.9-17.7 months) were eligible. 23 children received maintenance CX, 40 received preirradiation CX. 48 children underwent irradiation according to the guidelines. 7 children were irradiated only locally, in 2 children no RX at all was administered. In 6 children dose was less than 54 Gy to the tumor site, or less than 35 Gy to the neuraxis. Follow-up was 31 months. Overall survival at 3 yrs. was 48.4%. Progression occurred in 38 children with local recurrences in 27 pts. Median time to progression was 10 months. 9 progressions occurred during preirradiation treatment. Dose and volume of RX had significant impact on survival; PFS after 3 years was 49.3% with correct dose and volume of RX as compared to 6.7% for 15 pts. with violations of RX guidelines ($p=0.0001$).

Conclusion: Craniospinal RX is needed to achieve reasonable treatment results in supratentorial PNET in childhood. At least doses of 54 Gy to the tumor, and 35 Gy to the neuraxis are required. The delay of RX seems to increase risk of early progression. Relapses mainly occur at the primary tumor region, but also within the CNS.

984 POSTER DISCUSSION

Dose intensive therapy and myeloablative chemotherapy with haematopoietic stem cell rescue in childhood poor prognosis Ewing's sarcoma

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Purpose: To improve the prognosis of paediatric patients (pts) with high risk Ewing's Sarcoma (HR-ES).

Methods: Previously untreated pts, aged less than 18 years at diagnosis, with newly diagnosed HR-ES of bone because metastatic or localised but with tumour volume more than 100 cm3. Treatment consisted of: induction therapy with two courses of Vincristine (Vcr) 2 mg/m2, Cyclophosphamide (C) 2200 mg/m2 and Adriamicina (Adr) 90 mg/m2 in two days (Hyper-VAdC), alternated to two courses of Etoposide (VP16) 600 mg/m2 in three days plus C 4000 mg/m2 (CE); G-CSF supports each cycle of chemotherapy in order to improve dose intensity and enhance peripheral blood stem cell mobilisation after CE; Surgery and/or Radiotherapy for local control of primary and/or metastatic sites of disease; Maintenance chemotherapy consisting of two courses of Vcr 1,5 mg/m2, C 1200 mg/m2 and Adr 80 mg/m2 in two days (VAdC) alternated with two courses of VP16 500 mg/m2 plus Ifosfamide 9000 mg/m2 in five days (IE). At the end of this phase pts who were not in progression of disease were eligible for consolidation therapy and received Busulfan (Bu) 4 mg/kg/die for 4 days, VP16 800 mg/m2/die for 3 days and Thiotepa (TT) 300 mg/m2 followed by peripheral blood stem cell rescue.

Results: From April 1993 to May 1999, 43 pts 10 with localised and 33 with metastatic disease were enrolled in this protocol. Four pts progressed during the maintenance phase and 34/39 pts eligible were grafted. At time of graft 12 pts were in CR. The median number of CD34+ infused was 6.9 (2.5-40.1)x106/kg. Despite 10 patients received both Bu and total lung irradiation, nor pulmonary toxicity and toxic death related to consolidation procedure were registered. After a median follow up from the diagnosis of 47 (23-89) months, 20/43 patients are in CR, and 2 are alive with disease. The 6 years OS (SE) and PFS (SE) were 48.6% (9.6) and 42.3% (8.3) respectively. Patients with metastasis at diagnosis fared substantially worse than pts with localised disease (6 years PFS 35.8% vs 64.0%, p=.066), moreover pts with bone metastasis (PFS = 14.4%) have a poorer outcome.