1193 POSTER

Topical oral GM-CSF to prevent oral mucositis in patients (PTS) receiving high dose chemotherapy (HDCT)

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Prevention or mitigation of mucositis induced by chemotherapy is an important issue for PTS receiving HDCT with peripheral blood stem cell support. In fact, mucositis is among major HDCT complications and it is caused directly by the cytotoxic effect of chemotherapeutic agents and indirectly by sustained neutropenia. In our Department, from 6/12/98 to 12/12/98 we have started a non-randomized prospective pilot study about topical use of GM-CSF for PTS with Breast Cancer (BC), Non Hodgkin's Lymphoma (NHL) and Multiple Myeloma (MM) undergoing HDCT with the following schedule:

TEC (Taxotere, Epirubicine, Cyclophosfamide):	22 pts	38 Cycles
T-ICE (Taxotere, Ifosphamide, CBDCA, VP16):	8 pts	12 Cycles
IDA, ALK (Idarubicine, Alkeran):	4 pts	4 Cycles
HD ALK (Alkeran):	2 pts	2 Cycles

A total of 56 chemotherapy cycles were administered in 36 Patiens (7 M, 29 F), median age 41 years, range (29–70). Mucositis was as following:

Grade	Cycle	Percent	
0	16	28.8%	
1	19	33.9%	
2	17	30.1%	
3	4	7.2%	(3 T-EC, 1 Ida + Alk.)

Oral mucositis was assessed according to the WHO score. GM-CSF was administered as a viscous mouthrinse administered the day of reinfusion, one vial (300 mcg) for 3 days. Every vial was diluted in 300 cc of steril water for breast cancer or in 20 cc glicerol for NHL and MM, administration was repeated 6 times daily, the duration of each viscous mouthrinse was about 10 minutes. When compared to historical controls, topical GM-CSF mouthrinses were beneficial to reduce oral mucositis. Prospective randomized study to evaluate the incidence and severity of mucositis after HDCT with or without GM-CSF mouthrinse has been planned and will soon start in our Department.

1194 PUBLICATION

High-dose chemotherapy and autologous hematopoietic stem cell transplantation for 62 patients with poor prognosis breast cancer

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Purpose: Between April 1986 and January 1996, 62 consecutive women with poor prognosis breast cancer were treated with high-dose chemotherapy (HDC) followed by autologous hematopoietic stem cell transplantation in our institute.

Methods: At the time of transplant, the median age was 41 y. (range 25–60); all patients were pretreated with anthracyclin-containing regimens. Thirty-two patients were in first complete remission (CR), 11 in second CR, 9 in partial remission: 7 in sensitive relapse and 3 had a refractory disease. The median time between diagnosis or relapse and transplantation was 7.6 mo. (range 3–32). The conditioning regimen consisted of Cyclophosphamide (120 mg/kg b.w.), Mitoxantrone (48 mg/m^2) and Melphalan (140 mg/m^2) followed by peripheral stem cell reinfusion (n = 45), or bone marrow support (n = 12) or both (n = 5).

Results: The median of follow-up from transplantation or relapse was 40 mo. (range 3–104). There were no transplanted-related deaths. The actuarial survival rates are summarized in the table:

	All patients (n = 62)	Metastatic (n = 25)	≥6 nodes (n = 19)	Inflammatory (n = 18)
Overall survival 5 y.	57%	52%	67%	55%
Disease-free survival 5 y.	39%	24%	55%	50%
Alive in continuous CR	26 (42%)	6 (24%)	11 (58%)	9 (50%)

Conclusion: HDC is a safe and effective procedure but a prospective multicentric randomized trial is warranted.

1195 PUBLICATION

Results of high-dose chemotherapy with stem cell support in patients with solid tumors in a subtotal outpatient setting

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Purpose: Various studies have shown that the treatment with high dose chemotherapy (HDC) and stem cell support in a subtotal outpatient setting is possible and save. The IBAT treats patients since June 1997

Methods: We treated 29 patients with solid tumors (advanced (9), inflammatory (1) and metastatic (18) breast cancer, testicular cancer (1)) in a subtotal outpatient setting. There was in summary 38 HDC-cycles. All patients were treated in protocols of randomised studies. Peripheral blood stem cells (PBSC) were harvested in a total outpatient regime.

Results: The HDC was well tolerated. The PBSC were collected in the most of cases with one apherese. For mean 3.65 × 10^6 CD34-positve cells were reinfused.

WBC >1 G/l	PLT >30 G/l	T >38.5 °C (d)	RBCT (units)	PC (units)	i.v. antibiotics (d)
d + 9.03 (6–10)	d + 11.59 (8–17)	1.54 (0–8)	1.84 (0–6)	3.73 (0–23)	4.11 (0–12)

d = days, T = temperature, RBCT = red blood cell transfusion, PC = platelet concentrate, means and range

Conclusion: The toxicities were moderate and there was only one patient with acute CNS-toxicity. Fever during neutopenia continued 1.54 days in 26/38 cycles. The overall response rate was 89.7%. Outpatient management of HDC is acceptable for a lot of patients. Our results show the feasibility and the safety of this setting. The therapy is well tolerated and the costs were decrease. Actual data will be present at the meeting.

1196 PUBLICATION

Lenograstim (glycosylated rHuG-CSF) enables mobilization of enough PBPC in breast cancer and NHL patients from dose of 2.5 μg/kg/day

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Purpose: define optimal dose of lenograstim for peripheral blood progenitor cells (PBPC) mobilization.

Methods: stage II–IV breast cancer or high-grade non-Hodgkin lymphoma (NHL). Mobilization with FEC (5FU 600 mg/m^2, epirubicin 75 mg/m^2, cyclophosphamide 600 mg/m^2 D1) or FAC (5FU 600 mg/m^2, doxorubicin 600 mg/m^2, cycloph. 600 mg/m^2 D1) chemotherapy in breast cancer, or CHOP (cycloph. 750 mg/m^2, doxo 50 mg/m^2, vincristin 2 mg D1, prednisone 75 mg/d D1–5) in NHL. Lenograstim 2.5 (group A), 5.0 (B) or 7.5 (C) μg/kg/d was administered from D5 until last leukapheresis (LK), to collect at least 2 × 10^6/kg CD34+.

Results: 18 pts (6/dose), 16 breast cancer (8 stage IV), 2 NHL, diagnosed from a median of 5.3 months, previously treated with a med. 1 CT line. Median age was 45.5 years. Median 7 days of lenograstim were administered for mobilization. Median CD34+ collected were 3.8 in group A, 4.1 in group B and 5.3 × 10^6/kg in group C respectively (NS) with 1 LK only in all pts except 2. In groups B and C, CD34+ in LK were significantly correlated to CD34+ in blood. No toxicity related to mobilization was reported.

Conclusion: in this pilot study, lenograstim at 2.5 to 7.5 μg/kg/d added to chemotherapy was efficient for good CD34+ mobilization even with one leukapheresis, although there was a trend for higher levels of CD34+ with the 7.5 μg/kg/d lenograstim dose.