the risk to develop catheter-related thrombosis. Heparin prophylaxis protected cancer patients undergoing chemotherapy against the increased risk of catheter-related venous thrombosis in centrally, but not in peripherally inserted ports.

1320 POSTER

Open-label, phase I/II dose escalation study of NESP in patients with chronic anemia of cancer

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Purpose: NESP stimulates erythropoiesis by the same mechanism as recombinant human erythropoietin (rHuEPO), but has a 2- to 3-times longer serum half-life than rHuEPO. A limited number of rHuEPO studies indicate potential benefit in patients with chronic anemia of cancer not on chemotherapy. However, no systematic dose finding studies have been reported.

Method: This study includes anemic patients (Hb ≤ 11.0 g/dL) with non-myeloid malignancies who are not on chemotherapy or planned radiotherapy and not iron deficient. Patients were assigned sequentially to one of the following NESP doses: 0.5, 1.0, 2.25, or 4.5 μg/kg/wk for 12 doses.

Results: 102 patients (mean (SD) age: 70 (12) yrs; 53% men), mainly with breast, prostrate and lymphoid malignancies, received study drug. NESP was well tolerated no dose limiting toxicities were reported. Only 6 subjects were enrolled in the 0.5 μg/kg/wk cohort and therefore data are not presented. Increasing doses of NESP associated with an increase in efficacy. All doses demonstrate significant biological and clinical effect with a ≥66% of subjects achieving a Hb response in all cohorts.

NESP (μg/kg/wk)	1.0	2.25	4.5
Number of subjects	33	33	30
RBC tfs from wks 5–12/n	8	4	2
% (95% CI)[b]	36 (10, 62)	14 (1, 26)	7 (0, 17)
Δ in Hb from baseline to end of treatment, mean (SD) g/dL[a]	1.66 (2.22)	2.07 (2.14)	2.91 (1.99)
Hb Response/n	20	19	25
% (95% CI)[b]	68 (50, 86)	66 (49, 84)	92 (80, 100)
Time to Hb response (median no. wks)	8	6	7
Hb correction[d]/n	20	19	24
% (95% CI)[b]	65 (47, 82)	67 (49, 84)	86 (73, 100)
Time to Hb correction (median no. wks)	8	8	5

[a] Excluding Hb values within 28 d of a RBC tfs. Subjects who withdrew after 1 dose of study drug with no post treatment Hb value had a change score of 0.
[b] Determined from the Kaplan-Meier estimate: 1-S(t) at last non-censored time point;
[c] Hb response: ≥2 g/dL increase from the baseline Hb concentration in the treatment phase in the absence of RBC transfusion during the preceding 28 days.
[d] Hb correction: Hb concentration ≥ 12 g/dL in the treatment phase in the absence of any RBC transfusion on that day or during the preceding 28 days.

1321 POSTER

Is a physical training necessary for women post radical mastectomy?

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Purpose: Physical capacity depends on aerobic and anaerobic potential. Radical treatment of breast cancer can affect these factors and limitation of physical capacity can be a result of these disorders. The aim of the study was evaluation of change of physical capacity under an influence of physical training. It was assumed that limitation of physical capacity in women post radical mastectomy is reversible under an influence of systematic exercises.

Methods: Examination of physical capacity on the treadmill according to Bruce's protocol was performed in 60 women aged from 45 to 60 years (mean 54,5) post radical mastectomy divided into two 30-persons groups before and after 6-week physical training. Exercise test included passing the distance with defined speed and angle of inclination of treadmill together and the change of both of these parameters every 3 minutes. Average time of exercise test, oxygen consumption and metabolic equivalent were recorded. All women performed physical training 3 times a week during 6 weeks. Women from group I performed efficiency exercises including active exercises, increasing range of motion and strength of muscles, which lasted for 45 minutes. Women from group II performed endurance exercises on the bicycle ergometer for 30 minutes until submaximally heart rate (85% of maximally heart rate).

Results: After endurance exercises average time of test increased statistically significant (p=0,001) from 9,4 minutes before training to 12,4 minutes after training, oxygen consumption from 18,5 ml/min/kg to 37,0 ml/min/kg and metabolic equivalent from 5,2 met to 10,5 met. After efficiency exercises examined parameters increased statistically significant too (p=0,001) from 7,2 minutes to 8,5 minutes, from 10,3 ml/min/kg to 15,5 ml/min/kg and from 2,9 met to 4,4 met respectively. Increment of examined parameters was statistically significant (p=0,001) greater in women after endurance training than in women after efficiency exercises.

Conclusion: 6-week physical training caused considerable improvement of physical capacity in women post radical mastectomy, which was greater after endurance exercises than after efficiency exercises.

1322 POSTER

Effectiveness of "Supportive Care" for cancer patients

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Background: The terms 'Best Supportive Care' or 'Supportive Care' (BSC/SC) have been frequently used in randomised controlled trials of cancer treatments. However, BSC is usually not well defined, which questions the validity of these trials.

Aims of the Study: We aim to systematically review the literature of cancer trials which include BSC/SC in order to examine the effectiveness/outcomes and the quality of BSC interventions versus cancer therapies, with a view to propose an agreed definition and components of BSC/SC.

Methods: Of the 95 randomised BSC/SC cancer trials we found as a result of our searches of 15 databases, 44 are in non-small cell lung cancer (NSCLC), and 18 are in gastrointestinal cancer (includes colorectal/colon cancer, but excludes pancreatic cancer). We are currently developing two Cochrane-based systematic reviews:

1. 'Supportive Care' in NSCLC (Awaiting registration with Cochrane) and
2. 'Supportive Care' in Gastrointestinal Cancer (Registered with Cochrane).

We will use previously published criteria on the quality of palliative trials. The proposed definition and components of BSC will be linked to an existing EORTC project funded by the EC.

Main Outcome Measures: We will focus mainly on symptom control, pain relief and quality of life.

Findings: We intend to complete the literature review by the time of the conference, and present preliminary data.

Implications for Palliative Care: This work will help oncologists and researchers in palliative care to design better studies when symptom control, and quality of life issues are being evaluated as endpoints in the treatment of cancer.

1323 POSTER

Systemic treatment with granulocyte macrophage colony-stimulating factor (GM-CSF) of severe mucositis induced by 5-fluorouracil (5-FU) based chemotherapy

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Purpose: Mucositis is a common side-effect of the chemotherapy, in particular by 5-FU. Stomatitis causes pain, interferes with oral nutrition and can be a potential source of infection. Diarrhea gives discomfort and can be complicated by severe dehydration. Preliminary data suggest that GM-CSF can reduce dose-limiting side-effects and improve the quality of life.

Methods: We evaluated the effect of GM-CSF in 30 colorectal cancer patients suffering from ≥ grade 2 mucositis after a 5 days administration of 5-FU and leucovorin (LV). At the next cycle GM-CSF 4 μg/kg s.c. from days 6 to 10 was given without chemotherapy dose reductions. The mucositis disappearence or its decrease ≥ one grade were recorded as a success.

Results: Seventy-six GM-CSF cycles have been administered (median per patient, 2). We reported a success in 20 (66%) patients. In 6 (20%) cases there was not evidence of efficacy, while 4 (13%) patients stopped the treatment because of an allergic reaction. The efficacy was assesable in 13 patients affected by grade 2–3 stomatitis and in 7 cases suffering from grade 2–3 diarrhea. The responsive patients continued to have benefit from GM-CSF in the subsequent cycles of chemotherapy.

Conclusions: GM-CSF seems to reduce significantly the severity of 5-FU-based chemotherapy-induced mucositis. These data are preliminary because we have completed only 2 of the 3 planned steps of our study.