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psychological structuring of his disease. Throughout a survey, we would like to evaluate the needs of psychological help of cancerous patients.

Background: Since the opening of the Breast Cancer Clinic in 2008, a psychologist is integrated into the multidisciplinary consultation. The patient meets the gynaecologist, the oncologist, the radiotherapist and the psychologist several times: (1) before the operation, (2) after the operation, (3) during the treatments.

The psychologist describes his role in the breast cancer team and explains which support he can provide to the patient. He listens to the patient's concerns: her anxiety in regard to the surgical intervention and the treatment. Furthermore, many patients don't know how they should announce their disease to their family, especially to their children and the psychologist could give her advice.

Purpose: We try to figure out the interest of a systematic follow up with the psychologist. Through our survey, we would like to:

- study the percentage of patients who contact the psychologist after a first meeting.
- understand why the patient contacts the psychologist
- investigate why some patients don't want a regular follow-up with a psychologist.

Method: We sent a questionnaire relating to socio-demographic and clinic informations and a questionnaire of evaluation of the needs and the expectations concerning psychological support to 150 patients who have met a psychologist during the multidisciplinary consultation of the Breast Cancer Clinic. There are no exclusion criteria.

Results: We started this survey in April 2009 and we hope to finish it in August 2009.

Conclusion: Our aim is to evaluate the needs of patients who have breast cancer. Our next step will be to offer a systematic psychological support in order to help the patients to adapt themselves to the disease and to prevent psychiatric disorders.

4263 POSTER

Development of palliative care in Albania

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Background: Presentation of the history of naissance and development of palliative care in Albania, sharing experiences, problems and achievements

Materials and Methods: The history of three palliative care centers operating in the territory of the Republic of Albania, was considered, their pathways to development and consolidation, the efforts of National Albanian Association for Palliative Care to make palliative care wellknown in Albania

Results: Frequent negotiations with policy-makers in order to include palliative care in the healthcare governmental schemes. Participation of palliative care as a subject in the curriculas of medicine and nursing faculties. Foundation of new palliative care teams, extending this service in South and North of Albania.

Education of healthcare professionals on Palliative Care through organized trainings and printed information, such as manuals and booklets. Education of community on palliative care through promotion in visual and written media.

Conclusions: Palliative care in Albania has been developing becoming in this way an integral part of healthcare services in South and North. The number of palliative care teams has increased from three in 1993 in seven in 2009. The service is now offered by trained specialists. The entire population is now aware of the importance and neccesity of palliative care.

4264 POSTER

Intravenous iron supplementation and erythropoiesis stimulating agents (ESAs): mata-analysis of randomized trials in patients with chemotherapy-induced anemia

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Background: currently available guidelines for use of ESAs in chemotherapy-induced anemia (CIA) do not provide definitive recommendations on iron supplementation. The aim of this meta-analysis was to estimate the effectiveness of IV iron supplementation in patients with CIA undergoing ESA therapy.

Materials and Methods: We conducted a comprehensive review of the published literature and reviewed presentations at annual meetings of the American and European Oncology societies. Endpoints were haemoglobin (Hb) response, time to reach Hb response and transfusion requirements. Homogeneity of effects across studies was assessed using the 2 statistic.

Fixed-effects models were used to estimate pooled Odd Ratio (OR) and Hazard Ratio (HR).

Results: Five randomized trials investigating IV iron in conjunction with ESAs (darbepoetin in 3, epoetin alfa in 2) including 1127 patients (IV iron = 597; no iron or oral iron = 530) were identified. The addition of IV iron to ESAs provided a significant advantage in term of Hb response (pooled OR: 2.74, CI 95%:2.07;3.62) and time to Hb response (pooled HR: 0.75, 95% CI, 0.64;0.88). Transfusion requirement was reduced the IV iron group (OR: 0.74, CI 95%: 0.53;1.04). IV iron does not improve the incidence and severity of adverse events related to ESAs.

Conclusion: In patients with CIA, IV iron supplementation enhances responses to ESAs without additional toxicity. Iron supplementation represents a strategy to improve the cost-effectiveness of ESAs in oncology.

4265 POSTER

Pegfilgrastim on day 2 vs. day 4 within the prospective, multicentered GAIN study: A phase III trial to compare ETC vs. EC-TX and ibandronate vs. observation in patients with node-positive primary breast cancer (GBG 33)

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Background: Möbus et al. showed that dose dense (dd) epirubicin (E), paclitaxel (T), cyclophosphamide (C) results in a superior disease free survival (DFS) and overall survival (OS) compared to conventionally dosed EC-T. However, all patients need GCSF support. Preliminary data suggest that pegfilgrastim (P) given on day 4 might be superior to P on day 2 in reducing grade 4 leucopenia. This hypothesis was further evaluated in this setting.

Methods: Pts with N+ primary breast cancer were randomised within the GAIN study to receive either ETC (E: 150 mg/m², T: 225 mg/m², C: $2000 \, \text{mg/m}^2$, i.v. day 1, q15 for 3 cycles each = A1); or EC \rightarrow TX (E: $112.5 \text{ mg/m}^2 + \text{C}$: 600 mg/m^2 , i.v. day 1 q15 for 4 cycles followed by T: $67.5 \, \text{mg/m}^2$ i.v. day 1, q8 for 10 weeks + X: $2000 \, \text{mg/m}^2$ p.o. day 1–14, q22 for 4 cycles = A2). Pts were further randomised in a 2:1 ratio to receive ibandronate 50 mg/day p.o. for 2 years (B1) or observation (B2). Primary prophylaxis for febrile neutropenia consisted of P on day 2. After recruitment of 1500 pts prophylactic ciprofloxacin was implemented during treatment with C. After amendment 4 pts eligible for the GAIN study who have been randomized to ETC were further randomised to receive P on day 2 (P2) vs day 4 (P4). Primary endpoint was leucopenia grade 4 amongst other secondary endpoints. It is assumed that the rate of leucopenia grade 4 with ETC is around 50% with P2. A risk reduction of 1.98 with P4 was estimated. a is set to 5%, using two-sided significance test with a power of 80%. A drop out rate of 10% will be assumed. The estimated pts per arm will be at least n = 68. Therefore 152 (136 plus 10% drop out rate) patients treated with ETC will be needed to be randomised 1:1 to P2 vs P4.

Results: 3023 pts were recruited between 06/2004 and 08/2008. Of these, 352 pts in the ETC arm were further randomised to P2 (n = 175) vs P4 (n = 177) and received at least one cycle of chemotherapy. The median age in this subgroup was 49 years (24–69). The first exploratory analysis demonstrated that leucopenia grade 4 was 47.5% with P2 and 42.3% with P4

Conclusion: This exploratory analysis does not show a benefit for P4 for in reducing grade 4 leucopenia. Nevertheless it seems feasible to apply P either on day 2 or day 4 without compromising the safety of the pts. Final data of all endpoints will be presented at the meeting.