

## References

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PUBLICATION

**Quality of life and anxiety-depression relationship in female patients with metastatic malignancy**

H. Engin<sup>1</sup>, S. Ozer<sup>2</sup>, I. Celik<sup>3</sup>, A. Gogus<sup>2</sup>, G. Tekuzman<sup>3</sup>. <sup>1</sup>Karalimas University, Medical Oncology, Zonguldak, Turkey; <sup>2</sup>Hacettepe University, Psychiatry, Ankara, Turkey; <sup>3</sup>Hacettepe University, Medical Oncology, Ankara, Turkey

**Background:** Adaptive psychological symptoms or clinical psychological disorders can be seen and both are common problems during diagnostic, treatment, and metastatic periods in cancer patients. Depression and anxiety are the most common psychological issues in all three periods. If anxiety and depression can not be diagnosed and treated adequately, they both can affect the compliance with treatment, and quality of life negatively, as well. Anxiety and depression relationship and their effects on quality of life have been investigated in this cross-sectional study.

**Patients and methods:** The study group was formed of 61 female patients who were clinically followed up at Hacettepe University Oncology Institute. During these follow-ups, between January 2001 and March 2002, patients were diagnosed with metastatic cancer for the first time. EORTC QLQ C30 Version 2.0 and HAD Scale has been conducted 1 day before starting metastatic malignancy treatment. Definitive statistics and Mann-Whitney U test has been used during these analysis.

**Results:** Groups were set regarding the anxiety and depression cut-off score points (10 and 7, respectively) and compared for all parameters of quality of life. Between patients' anxiety standing lower than cut-off point and higher than cut-off point, there has been meaningful differences determined among quality of life parameters, emotional condition ( $z = -4.27$ ,  $p = 0.000$ ), and cognitive condition ( $z = -3.06$ ,  $p = 0.002$ ) ( $z = -2.03$ ,  $p = 0.042$ ); fatigue ( $z = -3.84$ ,  $p = 0.000$ ), and sleep ( $z = -2.85$ ,  $p = 0.004$ ) on symptom scale, and economical condition ( $z = -2.46$ ,  $p = 0.014$ ), general well-being ( $z = -2.16$ ,  $p = 0.031$ ). Between patients' depression standing lower than and higher than cut-off point, there also has been meaningful differences determined among quality of life parameters, physical condition ( $z = -2.32$ ,  $p = 0.020$ ), emotional condition ( $z = -2.28$ ,  $p = 0.023$ ), cognitive condition ( $z = -2.03$ ,  $p = 0.042$ ), and social condition ( $z = -2.03$ ,  $p = 0.042$ ) on functional lower scale; fatigue ( $z = -1.95$ ,  $p = 0.050$ ), appetite ( $z = -2.49$ ,  $p = 0.013$ ), general well-being ( $z = -2.86$ ,  $p = 0.004$ ) on symptom scale.

**Conclusions:** Among patients with metastatic malignancies, anxiety and depression should be screened with self-rating scales and the patients with a score higher than the threshold value and diagnosed with anxiety and depression should be evaluated psychiatrically and receive appropriate psychiatric treatment.

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PUBLICATION

**Impact of Hb intervention level on outcomes in cancer patients treated with epoetin beta: results of a meta-analysis**

J. Dunst<sup>1</sup>, B. Coiffier<sup>2</sup>, M. Nowrousian<sup>3</sup>, H. Burger<sup>4</sup>. <sup>1</sup>Martin Luther University Halle-Wittenberg, Department of Radiotherapy, Halle, Germany; <sup>2</sup>Centre Hospitalier Lyon-Sud, Lyon, France; <sup>3</sup>West Germany Cancer Centre, University Hospital of Essen Medical School, Department of Internal Medicine (Cancer Research), Essen, Germany; <sup>4</sup>F. Hoffmann-La Roche, Basel, Switzerland

**Background:** There is a lack of studies examining the effect of haemoglobin (Hb) intervention levels on treatment outcomes in patients with cancer who are receiving erythropoietic proteins. The aim of this analysis was to determine the impact of different Hb intervention levels on overall survival, disease progression, thromboembolic event (TEE) incidence and transfusion-free survival in patients treated with epoetin beta (NeoRecormon®).

**Methods:** Data were pooled from nine randomised, controlled (placebo or standard care) clinical trials of epoetin beta in anaemic patients with cancer. Follow-up was limited to the duration of study treatment plus a standard 4-week period. Patient records were grouped according to Hb level at baseline (Hb <9 g/dl, <10 g/dl, <10.5 g/dl, <11 g/dl, 11–12 g/dl or ≥12 g/dl). Data were analysed by standard Kaplan-Meier methods and Cox regression.

**Results:** A total of 1413 patients were included in this analysis (epoetin beta,  $n = 800$ ; control,  $n = 613$ ); 44% had solid tumours and 56% had haematological malignancies. In all patients with Hb <11 g/dl at baseline, there was no indication of a significantly increased risk of death (relative

risk [RR] 0.99, 95% CI: 0.69, 1.41), disease progression (RR 0.80, 95% CI: 0.62, 1.02) or TEE risk (RR 1.41, 95% CI: 0.80, 2.47) associated with epoetin beta. In the same patients, epoetin beta was associated with greater transfusion-free survival (RR 0.70, 95% CI: 0.59, 0.83). In patients with Hb levels of 11–12 g/dl at baseline there was no significant negative effect of epoetin beta treatment on survival (RR 0.90, 95% CI: 0.16, 4.95), disease progression (RR 1.30, 95% CI: 0.34, 4.93) or TEE risk (RR 0.39, 95% CI: 0.10, 1.46). Greater transfusion-free survival was associated with epoetin beta in these patients (RR 0.49, 95% CI: 0.20, 1.21).

**Conclusions:** In this large meta-analysis, treatment with epoetin beta at baseline Hb levels of <11 (or <12) g/dl has no negative impact on survival, disease progression or TEE risk and reduces transfusion need effectively in patients with cancer. These findings show that it is safe and effective to treat patients with epoetin beta at intervention levels of 9–11 g/dl (and <12 g/dl), as recommended in the EORTC guidelines.

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PUBLICATION

**Clonidine vs. Venlafaxine as treatment for hot flashes in breast cancer patients – a double-blind randomised study**

S. Loibl<sup>1</sup>, K. Schwedler<sup>1</sup>, G. von Minckwitz<sup>1</sup>, R. Strohmeier<sup>1</sup>, K.M. Mehta<sup>2</sup>, M. Kaufmann<sup>1</sup>. <sup>1</sup>J.W. Goethe University, Obstetrics and Gynaecology, Frankfurt am Main, Germany; <sup>2</sup>German Breast Group, Statistic, Neu-Isenburg, Germany

**Background:** Breast cancer patients are more susceptible to severe hot flashes due to the cytotoxic and endocrine treatment. This is one of the unsolved problems in cancer treatment because classical hormone replacement therapy is contraindicated in breast cancer especially in endocrine responsive disease.

**Patients and methods:** In a double blind, randomised phase III study 80 consecutive breast cancer patients (pts) who had hot flashes at least twice a day, and were not taking any medication against hypertension and depressions received either clonidine 0.075 mg b.d. or venlafaxine 37.5 mg b.d. for four weeks. The primary endpoint is defined as frequency of hot flashes at week 5. The sample size in each group is 35 with alpha 0.1, one-sided significance level and 80% power. The null-hypothesis is defined as no difference between the groups, and the alternative hypothesis assumes a difference of 20%. A self reported one week hot flash and other symptom questionnaire was kept prior to the start of treatment until the end of the treatment course.

**Results:** From 4/02–10/04 80 pts. were recruited of whom 69 were evaluable. 34 received clonidine and 35 venlafaxine, 4 pts. stopped early because of side effects and 7 pts. went missing. The median age was 53 years (range 35–76). All hot flashes were assigned a grade of 1, 2, 3 or 4 for mild, medium, severe and very severe, respectively. There was no difference in severity or frequency of hot flashes between the two groups at baseline. The frequency of hot flashes was reduced by clonidine by 22% and by venlafaxine by 62% ( $P = 0.0001$ ). Similar results appeared for the severity of hot flashes. Clonidine reduced the severity by 48% whereas venlafaxine reduced them by 67% ( $P = 0.05$ ).

The side effects were self reported by the patients. Most of the side effects appeared in the first week and decreased thereafter. Mouth dryness was the most commonly reported side effect in both groups. In the clonidine group tiredness was reported by 25% of the patients vs. 33% in the venlafaxine group. Nausea was more common in the venlafaxine group than in the clonidine group with 25%.

**Conclusion:** Hot flashes can be reduced in frequency and severity by clonidine and venlafaxine. Venlafaxine is significantly more effective in reducing hot flashes in severity and frequency than clonidine. Venlafaxine acts faster. Venlafaxine should be used to ameliorate hot flashes in breast cancer patients. Side effects have a peak in the first week of treatment and decrease thereafter.

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PUBLICATION

**Epithelial ovarian cancer in elderly patients (70 years or over): analysis of efficacy and tolerability of platinum-based chemotherapy**

N. Cacciari<sup>1</sup>, A. Bernardi<sup>1</sup>, F. Sperandi<sup>1</sup>, F. Massari<sup>1</sup>, S. Quercia<sup>1</sup>, M. Rosati<sup>1</sup>, P. De Jacobo<sup>2</sup>, F. Rosati<sup>2</sup>, C. Zamagni<sup>1</sup>, A. Martoni<sup>1</sup>. <sup>1</sup>S. Orsola-Malpighi Hospital, Medical Oncology Unit, Bologna, Italy; <sup>2</sup>University of Bologna, Dept. of Obstetrics and Gynaecology, Bologna, Italy

Data on the efficacy and the tolerability of chemotherapy for epithelial ovarian cancer (EOC) in women aged 70 and over are lacking because elderly patients are poorly represented in clinical trials.

We report an analysis on our experience concerning 50 elderly pts (median age 73 years, range 70–89) treated with first-line carboplatin-based chemotherapy for FIGO stage IC-IV EOC (41 pts) or second-line (9 pts) chemotherapy for relapsed EOC. The median Karnofsky PS was 90% (range 50–100%). Comorbidities were evaluated according to