(NS before radiotherapy minus NS after radiotherapy) yields (duration of response/survival) toxicity.
Results: Median age was 64.1±10.7 years, 57.5% males and 42.5% females. Tumour frequencies were breast (26.9%), lung (25.6%) and prostate (25%). The most frequent site of pain treated were the pelvis (39.4%) and spine (36.2%). Overall response, complete response, relapse, gain, net pain relief toxicity is show in Table 1. No differences were observed between these two schedules in any variable studied.

Table 1

Schedule	Overall response %	Complete response %	Relapse %	Gain	Net pain relief %	Toxicity %
30 Gy	86.6	13.4	43.7	4	71.7	28
8 Gy	75.6	15.4	28.8	3.5	68.5	12.7
p	0.076	0.723	0.081	0.222	0.553	0.120

Conclusions: We concluded that, a single fraction of 8 Gy is a safe and effective as multifraction regimen for the palliation of metastasic bone. Lower cost makes 8 Gy simple fraction the treatment of choice for the majority of patients.

1339 PUBLICATION

How to reveal the zone of the most effective psychological care

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Background: The involvement of professional psychologists, such as psychological resources in general is still very limited in cancer treatment in Russia today. Therefore there is a challenge to find out the zones of the main importance of the psychological diagnostics, support and therapy in cancer patients. The optimal use of psychological help optimize the patients' attitudes and behavioral individual stereotypes during treatment courses and rehabilitation, the adequate emotional support and psychotherapeutic help lets to improve the quality of the life. Organ-oriented analysis shows the difference in the psychological meaning of different parts of body and as a result – different reactions for the types and stadiums of cancer diagnostics and treatment. The breast cancer is one of the most representative with it's psychological, emotional experience for patients, their families and medical professionals.
Method: The results of testing in 100 breast cancer patients in age 20–80 years old were examined. We used questionnaires for patients and medical oncologists, aimed on the clarification of the most problematic patients and stadiums in treatment experience, we also used the methods of the psychological diagnostics (Spilberger and depressive scale tests, the patient's drawings and other projective tests). 50 patients were directed to psychologist, 50 were not supposed to know for sure, that they can get psychological help in complex treatment.
Results: The need of psychological help is more high in young women with primary breast cancer on the stadium of diagnostics, after surgery and before and during chemotherapy in all age groups. All patients under hormonal treatment need psychotherapy. There is need of psychological diagnostics and optimization of communication in 60% of cancer patients in elderly. All the patients after the treatment are very recommended to have the systematic psychological rehabilitation and supervision of the risk reducing behavior (positive effect in quality of the life in 80%). During the control testing in group, who had no excess to psychologists, 94% of the patients experienced the need of the psychological help on early stadiums of diagnostics and treatment.
Conclusion: In situation of limited resources of psychological help, it should be provided acordingly to the results of the psychological express testing on early stages of diagnostics and preferably started before surgery and chemotherapy.

1340 PUBLICATION

Analysis of haematological risk factors for thromboembolic events in anaemic cancer patients treated with epoetin beta

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Background: The frequency of thromboembolic events (TEEs) can be slightly elevated in anaemic cancer patients treated with erythropoietic proteins, although the cause of this is unclear. A meta-analysis was conducted to help determine if an association exists between haemoglobin (Hb)-related parameters and the frequency of TEEs in patients receiving epoetin beta (NeoRecormon®).
Methods: Data were pooled from nine randomised, controlled (placebo or standard care) trials of epoetin beta in patients with cancer. All TEEs were assessed during treatment and for a further 4 weeks. All randomised patients who received at least one dose of study medication were included in the analysis. Cox regression analyses were performed to assess for correlations between Hb-related parameters and TEE risk.
Results: A total of 1413 patients (epoetin beta, n = 800; control, n = 613) were included in the analysis. Baseline demographics were similar in both groups (mean Hb level at baseline = 9.9 g/dl). In the epoetin beta group, no significant change in relative risk of TEE was found for the majority of Hb-related measures. An inverse association was found between increased Hb Area Under the Curve (Hb-AUC) (mean 1.02±1.5 g/dl) and incidence of TEE (relative risk 0.73, p = 0.0164). Hb increase up to Week 4 (mean 0.84±3.4 g/dl) was also inversely correlated with incidence of TEE (relative risk 0.72, p = 0.0325). Treatment at a baseline Hb of < 11 g/dl was not significantly correlated with increased TEE. Furthermore, a sub-analysis of TEE risk versus maximum Hb level achieved in the epoetin beta group showed that there was no increase in risk when comparing Hb ⩾ 11 vs < 11 g/dl, ⩾ 12 vs < 12 g/dl or ⩾ 13 vs < 13 g/dl (Table).

Maximum Hb level achieved	Hazard ratio	95% CI	p-value
Hb ⩾ 11 vs < 11 g/dl	0.79	0.41–1.50	0.46
Hb ⩾ 12 vs < 12 g/dl	0.86	0.48–1.56	0.63
Hb ⩾ 13 vs < 13 g/dl	0.98	0.54–1.75	0.94

Conclusions: Epoetin beta therapy is not associated with a significantly increased TEE risk with regard to baseline Hb, Hb increase and highest achieved Hb value. Furthermore, these findings correspond with current EORTC guideline recommendations for initiating erythropoietic protein treatment at Hb 9–11 g/dl and treating to a level of 12–13 g/dl (Bokemeyer et al 2004).

References

[1] Bokemeyer C, et al. *Eur J Cancer* 2004; 40: 2201–16

1341 PUBLICATION

Patient information – patients in clinical trials are more satisfied

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Background: The paradigm that patients in clinical trials have better clinical outcome has recently been refuted1. In this study, we aimed to explore whether there were other benefits for patients within clinical trials, particularly in the area of information provision and satisfaction.
Materials and methods: We have recently produced and published an information satisfaction questionnaire (ISQ) based on the 5 highest specific information needs of patients following a diagnosis of malignant disease2. This was given to 250 consecutive patients attending the Primrose Oncology Unit between Jan-Feb 2005. Of the 199 returned (80%) 80 were male, 119 female, average age 58 years, 4% from ethnic minorities, 82 (69%) had been involved at one stage in their management in a prospective clinical trial (CT). All patients, following their diagnosis had received our standard post medical consultation information package which includes a verbal interview with a specialist nurse, a bespoke written information file, website signpost information, free internet access and an information video.
Results: Almost twice as many non-clinical trial (NCT) patients indicated they were either very unsatisfied or unsatisfied with information they received as opposed those who had entered a clinical trial (NCT 18/117[15.4%] v CT 6/82 [7.3%], Chi squared < 0.05). This difference was greatest in the area of explanation of illness and treatment options (NCT 12.5% v CT 5.8%, Chi squared < 0.05). The lowest satisfaction sub-category in both the CT & NCT patients was advice on lifestyle & practical issues (28%) compared to 12% in the remaining categories (Chi squared < 0.01).
Conclusions: Patients who have entered a clinical trial reported higher satisfaction with the information they had received as opposed to those who had not. As better informed patients are generally more satisfied, have improved compliance and better psychological well-being, this may be a reassuring point to discuss with patients when counselling for trial recruitment. For all patients, this study also highlighted that we needed to improve lifestyle, diet, exercise, complementary therapies and sexuality information, and these information sheets have been written and added to our website.

References

[1] Peppercorn J et al. The Lancet; Jan 24, 2004; 263–270
[2] Thomas R et al European J. Cancer Care 2004
[3] ISQ available in 10 languages: *cancernet.co.uk/isq.htm*

1342 PUBLICATION

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

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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 sypmtom scale, and economical condition ($z = -2.46$, $p = 0.014$), genaral 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 recieve appropriate psychiatric treatment.

1343 PUBLICATION

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

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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.

1344 PUBLICATION

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

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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.

1345 PUBLICATION

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

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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