respectively. The percentage of patients with hgb $\geqslant$ 11 g/dL or with an increase of 1.5 g/dL was 61.5%. No adverse events related to darbepoetin alfa were reported.

	Baseline	3rd week	6th week	12th week
N	24	22	19	11
Hgb mean $\pm$ SD, g/dL	10.1$\pm$1.0	10.9$\pm$1.1	11.2$\pm$1.4	11.3$\pm$1.1
Hgb mean difference from baseline, g/dL		0.88	1.34	1.27

Conclusions: Darbepoetin alfa once every 3 weeks was effective and well tolerated with a rapid onset of action in anemic patients under chemotherapy. This new indication may provide benefits to the patients and significantly diminish injection burden.

1336 PUBLICATION

Emotional states and anxiety before a One-stop diagnosis for breast lesions: a prospective study

F. Zenasni[1], P. Auguste[2], V. Forte[2], S. Dauchy[1], P. Vielh[3], H. Marsiglia[2], F. André[2], J.R. Garbay[4], S. Delaloge[2]. *[1]Gustave Roussy Institute, Department of Psycho-Oncology, Villejuif, France; [2]Gustave Roussy Institute, Department of Medicine, Villejuif, France; [3]Gustave Roussy Institute, Department of Pathological Anatomy, Villejuif, France; [4]Gustave Roussy Institute, Department of General Surgery, Villejuif, France*

Background: One-stop diagnosis for breast lesions may have significant clinical and economical impact. However, certain clinical aspects of this approach, such as affective and cognitive functioning, have not been much explored. Thus, it remains uncertain how individuals perceive this kind of diagnosis procedures. We were particularly interested in exploring patients' emotional state during the days before one-stop diagnostic procedures, in order to adapt our procedures and care of individuals.
Material and methods: We are currently conducting a prospective study within 300 individuals seen at the one-stop diagnosis unit for breast lesions in a single institution, Institut Gustave Roussy, during a six month period. The aim of this study is to examine emotional states, anxiety and fears that can occur two days before the one stop diagnosis and to determine which factors (socio-demographical, medical) favour the increase of anxiety. For that purpose, we assessed the three significant dimensions of emotional states (emotional valence, arousal and dominance) using the Self Assessment Manikin (Bradley & Lang, 1994). We also assessed anxiety using the anxiety state scale from Spielberger (1993). Participants have also completed a specific questionnaire in order to indicate to which degree they dread the one stop diagnostic and to explain what they were precisely anxious about. Socio-demographical and medical data have been prospectively recorded.
Results: As expected first results (n = 120) indicate that participants are more anxious (two days before diagnostic mean anxiety score: 52.4), than general population (mean = 41). 84.1% of the participants reported to be globally worried about the one day diagnostic. 79.9% of the participants linked this anxiety to the persistence of an unknown situation, 61.2% to their venue in a medical institute; 37% to their planned meeting with physicians; 92.2% to the risk of a cancer diagnosis. Moreover, participants mainly reported that potential cancer diagnosis and nature of potential treatment (chemotherapy, mastectomy) and/or pain due medical analyses favour global anxiety about the one day diagnosis. Results indicate that socio-demographical and medical situation modulate, at least in part, the degree of felt anxiety. Mature results will be presented during the meeting.
Conclusion: Results of this research help understand perception of the one-stop diagnosis by individuals and favour specific actions in order to reduce anticipated/actual anxiety.

1337 PUBLICATION

Medical change with clinical guidelines program on medical practice: a controlled study in a cancer network

I. Ray-Coquard[1], T. Philip[2], J.P. Jacquin[3], X. Froger[4], P. Suchaud[5], B. Mayer[6], H. Mathieu-Daude[7], P. Castel[8], P. Biron[1], F. Chauvin[9]. *[1]Centre Léon Bérard, Médecine, Lyon Cedex 08, France; [2]Centre Léon Bérard, Pédiatrie, Lyon Cedex 08, France; [3]Institut de Cancérologie de la Loire, Oncologie Médicale, St Priest En Jarez, France; [4]C.H. Chambery, Hémato-oncologie, Chambery, France; [5]C.H. Roanne, Radiothérapie, Roanne, France; [6]Polyclinique de Rillieux, Chirurgie Générale, Rillieux La Pape, France; [7]C.A.C. Val D'aurellE, Département d'information Médicale, Montpellier, France; [8]Centre Léon Bérard, Oncora, Lyon Cedex 08, France; [9]Institut de Cancérologie de la Loire, Département de Santé Publique, St Priest En Jarez, France*

Objectives: A regional cancer network (RCN) of 57 general and private hospitals was set up in the French Rhône-Alps region in 1995 with the aim of improving quality of care and rationalizing medical prescriptions. The Clinical Practice Guidelines (CPGs) derived from an extensive literature review and opinion of experts from Lyon cancer centre have been shown to modify medical practice (JAMA 1997, 278, 1591–1595). After review by all physicians participating in the RCN, CPGs were used in a continuing medical educational program comprising 12 specific meetings and reminders mailed to each physician in 1995. In 1996, we assessed the impact of the implementation of the CPG project by assessing the conformity of practice with the guidelines and comparing with an external control group from another French region without a regional cancer network. In 1999, we re-evaluated the persistence of conformity to guidelines through a new medical audit.
Design: A controlled transversal study using institutional medical records of patients with breast or colon cancer compared the experimental group (cancer network) and the control group (no regional cancer network).
Setting: In 1994, 1996 and 1999, hospitals of both experimental and control groups accepted to assess the impact of CPGs on medical practice for the management of patients with breast and colon cancers.
Patients: In 1994, 1996 and 1999, all new patients with colon cancer (184, 211 and 199 patients in the experimental group, and 97, 125 and 100 patients in the control group, respectively), and women with non metastatic breast cancer (382, 444 and 381 patients in the experimental group, 194, 172 and 204 patients in the control group, respectively) were selected. Medical decisions concerning these patients were analyzed to assess their compliance with CPGs.
Results: In the experimental group, compliance rates were significantly higher in 1999 than in 1994 and 1996 for both breast and colon cancer: 14% (55/382) vs. 40% (178/444) vs. 36% (138/381) ($p < 0.001$); 28% (51/184) vs. 56% (118/211) vs. 70% (140/199) ($p < 0.001$), respectively. In the control group, compliance rates were identical for the three periods: 7% (13/194) vs. 7% (12/172) vs. 4% (8/204) ($p = 0.36$) for breast cancer, whereas significantly higher in 1999 than in 1994 and 1996 for colon cancer: 33% (32/97) vs. 38% (48/125) vs. 67% (67/100) ($p < 0.001$).
Conclusions: The development and implementation strategy of the CPG program for cancer management produced significant, persistent changes in medical practice in term of conformity with CPGs. Regarding colon cancer, however, changes were also noted in the control group in 1999, suggesting that the behavior change was more rapidly obtained in the experimental group than in a region with no organizational network, and that validated information could reach the target more rapidly.

1338 PUBLICATION

Randomized clinical trial comparing two schedules of bone metastases treatment: 30 Gy multifraction vs. 8 Gy single fraction

P. Foro[1], M. Algara[1], A. Valls[1], J. Carles[2], N. Rodriguez[1], X. Sanz[1], F. Ferrer[1], D. Gomez[1], P. Viñals[1]. *[1]Radiation Oncology Institute, Barcelona, Spain; [2]Oncology, Barcelona, Spain*

Purpose: The role of radiotherapy in the palliation of symptomatic bone metastases is well established. Recent randomized studies have reported that single fraction radiotherapy is as effective as multifracction radiotherapy. However the most used is multifracction irradiation. The aim of this study was to compare two therapeutic schedules of 8 Gy versus 30 Gy
Materials and methods: A total of 160 pacientes with painful bone metastases requiring palliative therapy for symptomatic bone metastases were randomized. Pain intensity was measured with a nominal score (NS) before and after treatment, and thereafter every three months for one year or until patient's death. Assessment variables considered were: response (pain relief of 2 points in NS) complete response (no pain without increased analgesia) relapse (pain worsening 2 points in NS), gain

(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

J. Malova. *Russian Scientific Centre of Radiology, Psychological Rehabilitation, Moscow, Russian Federation*

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

M. Aapro[1], M. Boogaerts[2], B. Coiffier[3], C. Hayward[4], H. Burger[4]. [1]*Institut Multidisciplinaire d'Oncologie, Clinique de Genolier, Genolier, France;* [2]*University Hospital Gasthuisberg, Leuven, Belgium;* [3]*Centre Hospitalier Lyon-Sud, Lyon, France;* [4]*F. Hoffmann-La Roche, Basel, Switzerland*

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

R. Thomas[1], M. Williams[2]. [1]*Addenbrooke's Hospital NHS Trust, Department of Oncology, Cambridge, United Kingdom;* [2]*Bedford Hospital NHS Trust, Primrose Oncology, Bedford, United Kingdom*

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.