evaluable patients 6 CR, 22 PR, 5 SD and 3 PD occurred. Follow up: out of 54 patients 4 died within therapy, 6 patients died within 2 month after completion of therapy. At least 39 patients are alive three, 15 after six, 4 after nine and 2 after 12 month of completion the therapy.

Conclusion: Combined radio-chemotherapy with topotecan as mentioned above is a very effective and tolerable regimen. Patients on therapy with high doses of dexamethason should not receive this regimen.

Symptom management & quality of life

1286 POSTER

Comparing the efficacy of fixed vs. weight-based dosing of epoetin alfa in anemic cancer patients receiving platinum-based chemotherapy

M. Merlano[1], S. Ricci[2], A. Martoni[3]. *[1]Az. Osp. S.Croce e Carle, Oncology, Cuneo, Italy; [2]Az. Osp S.Chiara, Oncology, Pisa, Italy; [3]Az. Osp. S.Orsola-Malpighi, Oncology, Bologna, Italy*

Purpose: Epoetin alfa has been shown to be effective and safe in decreasing transfusion requirements and improving hemoglobin (Hb) and quality of life (QOL) in anemic cancer patients (pts) receiving chemotherapy (CT).(1-3) A fixed dose of epoetin alfa (EPREX/ERYPO, Ortho Biotech/Janssen-Cilag) vs. weight-based dosing may offer a more convenient option to physicians for anemia management.

Methods: An open-label, randomized (1:1), 12-week trial was conducted to compare the effects of fixed (10,000 IU) vs. weight-based (150 IU/kg) dosing of epoetin alfa three times weekly (tiw) subcutaneously (sc) in anemic cancer pts receiving platinum-based CT. The primary efficacy endpoint was freedom from transfusion during Days 29-84.

Results: Of 546 pts enrolled, 510 fulfilled the protocol entry criteria. Mean age was 61 years. Tumor types included primarily lung (34%) and ovarian (22%), and most pts had advanced disease (stage III, 32%; Stage IV, 53%). During the 3 months before trial entry, 11.0% of pts had received one or more transfusions. During Days 29-84, 85.5% (CI95 82-89) were transfusion-independent as calculated by the lifetable method, with no statistically significant difference between the two groups (P>.3). Overall, 83% of pts in the 10,000 IU fixed dose arm were transfusion-independent vs. 86% pts receiving 7-9,000 IU and 85% pts receiving 11-15,000 IU in the weight-based arm. Of the 449 pts with baseline and final Hb levels, mean Hb increased 2.0 g/dL from 9.7 g/dL at baseline to a final Hb of 11.7 g/dL (CI95 11.4-11.9) in both groups. Of 315 pts who had both baseline and final LASA/CLAS QOL scores, the average of the three scores (Energy Level, Ability to Do Daily Activities, and Overall QOL) increased from 47 (±23) to 56 (±25) mm (mean±SD). In addition, QOL improvements correlated with Hb increases (P<.01, multiple linear regression), as well as to CT response, and were similar in both groups.

Conclusion: Both fixed (10,000 IU) and weight-based (150 IU/kg) dosing of epoetin alfa showed similar efficacy in maintaining transfusion independence, increasing Hb, and improving QOL scores. These findings, along with previously reported results of a large, open-label, community-based study,2 favor use of the more convenient fixed dose of 10,000 IU tiw sc in anemic cancer pts receiving CT.

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1287 POSTER

Effect of treatment of tumor patients with epoetin alfa on hemoglobin levels and exhaustion

U. Reinhardt. *Klinikum Bayreuth, University of Erlangen-Nuernberg, Department of Hematology & Oncology, Bayreuth, Germany, On behalf of the German Epoetin Alfa Study Group*

This German multicenter study assessed the efficacy of epoetin alfa to improve hemoglobin levels and exhaustion in tumor patients (pts). From Nov. 1998 until Dec. 2000, 701 pts were enrolled to receive epoetin alfa 10.000 IU t.i.w. for 8-18 weeks during chemotherapy and/or radiotherapy. At this time data from 578 pts are evaluable for intent-to-treat analysis, 405 (70.1%) females and 173 (29.9%) males with a median age of 61 (23-85)years. 535 pts (92.6%)were treated because of solid tumors and 43 (7.4%)because of hematological malignancies. The most frequent tumors were breast cancer (174 pts,30.1%), ovarian cancer (100 pts,17.3%), lung cancer (81 pts,14%), and colorectal cancer (57 pts, 9.9%). All pts were treated with chemotherapy, 94 received additional radiotherapy. Platinum was administered in 193 pts (33.4%). Exhaustion was measured as part of a standardized quality of life (QoL) questionnaire recording scores for separate aspects like social activities, mood, interest and exhaustion. QoL data were inquired from the physician, the patient, and a nurse.

Results: The mean number of epoetin alfa applications was 31 ± 14, the mean treatment duration with epoetin alfa was 12 ± 6 weeks. Complete tumor response was found in 97 pts (17%), partial response in 122 (21%), no change in 73 (13%), and progressive disease in 99(17%). 75 pts (13%) were not evaluable. 148 pts received blood transfusions with a median of 3 units (1-14). Hemoglobin levels increased from 10.1 ± 1 g/dl to 11.9 ± 2 g/dl during epoetin alfa treatment. This improvement was statistical significant (p<0.0001)in the total sample and in all tumor response groups. Changes in QoL were reflected above all in the reduction of exhaustion; according to the physician, exhaustion decreased significantly from 7.3 ± 1.2 to 4.8 ± 2.9 points on an 11-point rating scale (0-10) in the total sample. The increase of hemoglobin was strongly correlated with improvement of the exhaustion score (0.39,p<0.0001).

Conclusion: In patients with solid tumors as well as various hematological malignancies the treatment with epoetin alfa is accompanied by a significant increase of Hb-levels resulting in an improvement of exhaustion. The definition of subgroups with good or bad risk factors for epoetin alfa response is under exploration.

1288 POSTER

Review of the health related quality of life associated with irinotecan and 5FU/FA in the treatment of advanced metastatic colorectal cancer in the UK

A. Burrell, A. Bearne. *Aventis Pharma, Health Economics, West Malling, UK*

Background: Colorectal cancer (CRC) is the third most common form of cancer in the UK, with approximately 30,000 new cases and over 17,000 deaths registered annually. Whilst recent new chemotherapies have been shown to extend life, there are still questions concerning their impact on quality of life (HRQoL).

Objective: This study aims to review the published evidence on the HRQoL implications of irinotecan in the treatment of advanced CRC.

Methods: A systematic literature search was undertaken (cut-off date 25/10/00) to identify the HRQoL implications of irinotecan in Phase II and Phase III studies, within UK licensed indications, in advanced CRC. Databases included BIOSIS, EMBASE, Alert, HealthSTAR, CancerLit, MEDLINE, NEED, DARE, DEC reports, Cochrane Library, and ASCO/ESMO proceedings.

Results: Four Phase III clinical trials utilising irinotecan where identified, all of which used the EORTC QLQ-C30 to assess HRQoL. Two studies were conducted in the first line setting using irinotecan and 5-fluouracil/folinic acid (5FU/FA). Douillard et al, 2000 showed a significant delay in the time to definitive deterioration in HRQoL from baseline with irinotecan + 5FU/FA. Saltz et al, 2000 found no significant differences in global health status. However, univariate analyses showed smaller mean increases in severity of symptoms in the irinotecan plus 5-FU/FA group for fatigue, anorexia and pain but a smaller decrease from baseline in role functioning.

In the second line setting two studies were also identified, one which compared irinotecan to 5FU/FA and one which compared irinotecan to best supportive care (BSC). Rougier et al, 1998 showed significant differences in favour of 5FU/FA for nausea/vomiting and diarrhea. Median pain-free survival was 10.3 months for the irinotecan group compared with 8.5 months for the 5FU/FA group. In Cunningham et al, 1998 univariate analyses were significantly in favour of the irinotecan for cognitive functioning, global health status, pain, dyspnoea, appetite loss and financial impact. The diarrhea score was significantly better in the BSC group.

Conclusion:. The published evidence supports the fact that in the first line setting irinotecan plus 5FU/FA prolongs life in advanced CRC patients without compromising quality of life. Analysis also suggested that as second-line treatment in advanced CRC, the side effects of irinotecan monotherapy are favorably balanced by a reduction in tumour-related events.