Clinical evaluation of once-weekly dosing of epoetin alfa
40,000 units in anemic cancer patients receiving chemotherapy

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Background: Anemia is a common problem in cancer population, mainly attributed by clinical consequences and possible adverse effects of treatment on patients’ perceived quality of life. Good management of anemia in cancer population is therefore essential. Recent published clinical trials have demonstrated statistically significant increases of hemoglobin levels and significantly increased QOL assessment following administration of recombinant erythropoietin.

Objective: To evaluate the effectiveness, safety and quality of life by using once weekly dosing of epoetin alfa (Eprex®, Janssen-cilag) 40,000 Units in the treatment of anemia in cancer patients receiving chemotherapy.

Setting: Division of Medical Oncology, Department of Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand

Patients: This was an open label, non-randomized study, in 25 adult male and female anemic cancer patients who had non-myeloid malignancies in the upper part of the body, whose hemoglobin ranged from 9-11 g/dl and were on chemotherapy for least 8 weeks, with or without concurrent radiotherapy.

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Methods: The subjects were treated with subcutaneous epoetin alfa 40,000 units once a week. If, the patient's hemoglobin did not increase by > 1.0 g/dl after 4 weeks of treatment, the dose of epoetin alfa would then be increased to 60,000 units per dose subcutaneously at week 5. The epoetin alfa treatment would be continued for 16 weeks. The clinical outcome was then evaluated based on the quality of life accessed by linear analog scale assessment (LASA) and the functional assessment of cancer therapy-anemia (FACT-An) instrument. Analyses were performed to determine the incremental change of QOL associated with the increase of hemoglobin.

Results: Seventy-five percent of the patients who received epoetin alfa subcutaneously showed good responses with the rise of hemoglobin ≥ 1 g/dl (Hb level before and after = 9.95 ± 0.78 g/dl and 12.59 ± 1.83 g/dl, respectively; P < 0.001). Improvement of all primary cancer- and anemia-specific QOL domains, including energy level and the patient's ability to do daily activities evaluated by LASA and fatigue assessed from Fact-An, were significantly greater (P < 0.01) at week 16 (252.00 ± 38.02 and 13.13 ± 11.28) as compared to baseline (200.00 ± 34.76 and 23.88 ± 11.64). In addition, the hemoglobin levels may be related to LASA and FACT-An scores as tested by Pearson correlation (P < 0.001; r = 0.435 and < 0.001; r = -0.431, respectively). Epoetin alfa was well tolerated in all patients. Five patients, however, discontinued their participation before the planned study ended. The most common reason for their discontinuation came out of the patients' choices such as their lack of time or progression of the disease.

Conclusions: Once weekly dosing of epoetin alfa (Eprex®, Janssen-cilag) 40,000 units therapy is safe and effective in remodeling anemia and significantly improves the quality of life in cancer patients receiving chemotherapy. Therefore, the treatment allows physicians to maintain the hemoglobin concentration of their cancer patients in normal level to improve their quality of life through the course of chemotherapy.

Keywords: Non-myeloid malignancy, Epoetin alfa, Anemia, Quality of life.

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กรณีนี้ ว่ามีผลต่อประสิทธิผลทางคลินิกของการใช้ยาอิซีโอฟิดิน อย่างเพิ่ม ขนาด 40,000 ยูนิต ชนิดเม็ดเข้าได้ในหน้าที่ต่างๆรวมถึงในรักษาการผลิตจดในผู้ป่วยมะเร็งที่ก้าวล้างได้รับแคมป์บานท์

บริเวณ รางวัล การประเมินประสิทธิผลทางคลินิกของการใช้ยาอิซีโอฟิดิน อย่างเพิ่ม ขนาด 40,000 ยูนิต ชนิดเม็ดเข้าได้ในหน้าที่ต่างๆรวมถึงในรักษาการผลิตจดในผู้ป่วยมะเร็งที่ก้าวล้างได้รับแคมป์บานท์ จุฬาลงกรณ์มหาวิทยาลัย 2546 น.ศ.; 47(12): 773 – 84

วัตถุประสงค์: เพื่อประเมินประสิทธิผล ความปลอดภัย และผลทางคลินิกของการใช้ยาอิซีโอฟิดิน อย่างเพิ่ม (อิซีโอฟิดิน, Janssen cilag) ขนาด 40,000 ยูนิต สัปดาห์ละครั้งเพื่อรักษาการมะเร็งจดในผู้ป่วยมะเร็งระยะสั้นบางชนิด ของร่างกายที่ก้าวล้างได้รับแคมป์บานท์

สถานที่ทำการศึกษา: หน่วยมะเร็งวิทยา ภาควิชาวิทยาการยุทธศาสตร์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย

วิธีการ: ศึกษาแบบเป็นกลุ่ม

สูตรแบบการวิจัย: ผู้ป่วยที่ทำการศึกษา: ผู้ป่วยมะเร็งระยะสั้นบางชนิด ของร่างกายที่ก้าวล้างได้ มะเร็งระยะสั้นบางชนิด ซึ่งมีแผนการรักษาด้วยยาคีโตสำนักปนเป็นเวลาอย่างน้อย 8 สัปดาห์โดยไม่ได้รับการรักษาวดีที่สุดหรือไม่ก็ได้ และมีระดับเอนไซม์กลับสั้นระหว่าง 9 – 11 กิโลกรัม/ลิตร

วิเคราะห์ทางสถิติ: ข้อมูลที่มาเป็นตัวอย่างจากกลุ่มดัชนีสถิติ และการวิเคราะห์ตัวแปรที่มีความแตกต่างของระดับเอนไซม์กลับสั้น โดย คุณสมบัติที่มีและระดับการได้รับยาอิซีโอฟิดิน อย่างเพิ่ม โดยใช้สถิติเครื่อง t-test ศึกษาความสัมพันธ์ระหว่างระดับเอนไซม์กลับสั้นและคุณสมบัติโดยใช้สถิติเครื่อง Pearson correlation

ผลการศึกษา: ผู้ป่วยจำนวนคนละ 75 คน ตอบสนองต่อยาอิซีโอฟิดิน อย่างเพิ่ม ได้เป็นอย่างดี โดยมีระดับของเอนไซม์กลับสั้นเพิ่มมากกว่าหรือเท่ากับ 1 กิโลกรัม/ลิตร หลังได้รับยาโดยการฉีดเข้าได้รับกว้าง (ระดับเอนไซม์กลับสั้นก่อนได้รับยาคือ 9.95 ± 0.78 กิโลกรัม/ลิตร และระดับเอนไซม์กลับสั้นก่อนได้รับยาคือ 16 หลังมีได้รับยาคือ 12.59 ± 1.83 กิโลกรัม/ลิตร) ผู้ป่วยที่ได้รับยาอิซีโอฟิดินอย่างเพิ่ม มีคุณสมบัติที่ดีที่สุด จากการประเมินด้วยแบบสอบถามคีโตสำนักปน LASA และ FACT-AN (P < 0.01) โดยแบบสอบถาม LASA ถูกนำมาใช้เพื่อประเมินระดับของการก้าวล้าง ความสามารถในการทำกิจวัตรประจำวัน และคุณภาพชีวิตโดยรวมของผู้ป่วย ขณะที่ FACT-AN ถูกนำมาใช้เพื่อประเมินความเหนื่อยล้าของผู้ป่วย ซึ่งทำให้ผลิตผลการศึกษาความสัมพันธ์
ระหว่างระดับฮีโมโกล賓 และคุณภาพชีวิตของผู้ป่วยที่ได้จากการสอบถามผ่านระบบ LASA และ FACT-AN พบว่า ระดับฮีโมโกลอกร่มมีความสัมพันธ์เป็นสัดส่วนกับคุณภาพชีวิต (P < 0.001; r = 0.435 and < 0.001; r = -0.431, ตามล่าดับ). นั่นคือหากระดับของฮีโมโกลอกร่มเพิ่มขึ้น คุณภาพชีวิตของผู้ป่วยจะดีขึ้นแต่ก็ยังไม่สามารถทดแทนอาการเจ็บ病ที่มากอีก ฮีโมโกลิน แต่ไม่ได้คิดว่าผู้ป่วยเพียง 5 รายที่ตอบข้อตกลงจากโครงสร้างที่สูงสุดของกลับเพื่อนำส่งผลให้การวิเคราะห์ของวิคฤติจะอยู่ในช่วงและผู้ป่วยไม่สามารถตนเองทางขั้นตอนมาได้

สรุปผลการวิจัย : ผู้ป่วยมะเร็งส่วนบนของลำไส้ที่มีการแปลดากลางส่วนตัวจากการได้รับยาเครมีบัลสด หลังจากได้รับยาฮีโมโกลิน ฮีโมโกลิน (ฮีโมโกลิน, Janssen cilag) ขนาด 40,000 ยูนิต ชนิดเจ้าตัว แต่ยังไม่ได้รับยาฮีโมโกลินวิคฤติ (12 กรณี/เดือน) หรือที่แต่ ให้คุณภาพชีวิตของผู้ป่วยดีขึ้น ดังนั้นการประเมินระดับฮีโมโกลิน แต่คุณภาพชีวิตตลอดช่วงที่ผู้ป่วยได้รับยาเครมีบัลสดก็เป็นสิ่งที่จำเป็นสำหรับผู้ป่วยมะเร็ง

คำสำคัญ : ผู้ป่วยมะเร็งส่วนบนของลำไส้, ฮีโมโกลิน, ฮีโมโกลิน, ภาวะโรคที่ร้าย, คุณภาพชีวิต
Anemia in cancer patients may be directly related to the disease itself or an effect of concomitantly administered chemotherapeutic agents. Eprex® (Epoetin alfa), a glycoprotein hormone which stimulates red cell production and manufactured by recombinant DNA technology, has been shown to increase hematocrit and decrease the requirement of transfusion after the first month of its therapy (months two or three of the therapy) in anemic cancer patients undergoing hemotherapy;¹ and is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.²

Two recent studies³,⁴ conducted in over 1000 community-based oncology practices to measure clinically relevant outcomes, including evaluations of the quality of life (eg., energy level, activity level, and overall well-being through visual analog scales), hemoglobin changes, and transfusion requirements. Over 4,300 patients, diagnosed with various types of tumors who were anemic and on chemotherapy (2,030 - Study I; 2,289 - Study II), treated with a starting dose of 10,000 units of epoetin alfa subcutaneously three times weekly, which could be doubled (after 8 weeks - Study I or 4 weeks - Study II) if the response was not satisfactory. In Study I, 23% of the patients and in Study II, 22% of the treated patients had hematological malignancies, including; lymphoma, multiple myeloma, Hodkin’s disease, and chronic lymphocytic leukemia. The rest had solid tumors including (Study I/Study II); lung cancer (22% / 24%), breast cancer (18% / 17%), gynecological malignancies (14% / 13%), gastrointestinal malignancies (6% / 9%), prostate cancer (4% / 3%), head and neck tumors (2% / 2%), bladder cancer (2% / 2%), and pancreatic, esophageal and renal cancers (1% each of both studies), other (4% / 5%) and unknown (1% / 1%). In both studies, the energy level, activity level, and overall quality of life improved significantly (p≤0.001) over baseline levels. In addition, these improvements of the quality of life directly correlated with hemoglobin change from baseline. As hemoglobin increased with epoetin alfa treatment, the parameters of the quality of life significantly improved. It is important to note that where there was no increase in hemoglobin, there was no improvement in energy level, activity level, and the overall quality of life.

The starting dose in this study is 40,000 units, subcutaneous once a week. The selection of the dose was based on clinical experience and the results of a published study⁵ in which normal volunteers received two doses of epoetin alfa 600 U/kg (approximately 40,000 units) given 10 days apart showed significant increases in both hemoglobin levels and reticulocyte counts. A clinical trial⁶, involving subjects undergoing surgical hip and knee replacements surgery with pretreatment hemoglobin values of ≥10 to ≤13 g/dl, showed patients who received four doses of epoetin alfa 600 U/kg Day -21, Day -14, Day -7, and Day 0 of surgery had comparable hematologic and transfusion response compared with a group which received 15 daily doses of epoetin alfa. A pharmacokinetic/pharmacodynamic study was completed in normal male volunteers that compared 150 U/kg Sc tiw with 600 U/kg Sc qwk for 28 days. All subjects received oral iron supplementation. Reticulocytes and hemoglobin were measured. The data indicate that, in 28 days, there was no difference between the two groups in terms of
change either in reticulocyte count or hemoglobin level.\(^\text{10}\)

This study was designed to evaluate the effectiveness, safety of once-weekly dosing of epoetin alfa (Eprex\(^\text{\textregistered}\), Janssen-cilag) 40,000 units in the treatment of anemia in cancer patients receiving chemotherapy as expressed in their assessed quality of life.

**Patients and methods**

**Patients**

This study was an open label, and non-randomized study. Adult patients eligible for recruitment were aged ≥ 18 years with a confirmed diagnosis of non-myeloid malignancy in the upper part of the body and scheduled to receive chemotherapy for at least 8 weeks, with or without concurrent radiotherapy. All patients had a hemoglobin level between 9 – 11 g/dl, serum ferritin more than 100 ng/dl and had a life expectancy of at least 6 months. None of the patients had secondary metastases (other than nodal disease), poorly controlled hypertension, defined as diastolic blood pressure persistently greater than 100 mmHg, hypersensitivity to epoetin alfa or mammalian cell-derived products, pregnancy or lactation, history of seizure, anemia due to other factors (i.e., iron or folate deficiencies, hemolysis, gastrointestinal bleeding, or any active bleeding), presence of chronic inflammatory conditions (e.g., rheumatoid arthritis) or infectious disease which might impair any response to erythropoietin, acute major illness within 7 days prior to the study, or major infection within 28 days of prior to the study. All patients gave their written informed consents before entering the study, and the study protocol and its amendments were reviewed by an independent ethics committee.

**Study procedure**

Patients suitable for the recruitment were initially treated with epoetin alfa (Eprex\(^\text{\textregistered}\), Janssen-cilag) 40,000 units administered subcutaneously once weekly. If, after 4 weeks of therapy, the hemoglobin level did not increase by > 1.0 g/dl, the dose of epoetin alfa was to be increased to 60,000 units subcutaneously once weekly at week 5. The epoetin alfa treatment was continued in total for 16 weeks. However, if the hemoglobin rose above 13 g/dL, epoetin alfa therapy would be withheld until the hemoglobin level decreased below 12 g/dL and then reinstated at 75% of the original dose. The dose of epoetin alfa should also be reduced if there was an increase of hemoglobin of > 13 g/dL in 2-week period. Blood transfusion was permitted during the study at the discretion of the physician but this was to be avoided in patients with a hemoglobin level greater than 8 g/dL unless it was clinically indicated. An oral daily dose of 325 mg of ferrous sulfate administered three times a day was also recommended to avoid depletion of iron storage and to adequately support erythropoiesis by epoetin alfa.

**Efficacy Assessments**

The primary efficacy end point was the proportion of responders (patients with an increase in hemoglobin level from baseline to the last value ≥ 1 g/dl). Evaluation of hemoglobin concentration was performed every 4 weeks after the start of the study drug. Secondary efficacy evaluation was seen in the change of QOL scores from baseline to the last value.
QOL was measured by patient-completed QOL battery consisting of the Linear Analog Scale Assessment (LASA) and Functional Assessment of Cancer Therapy-Anemia (FACT-An) scale. The FACT-An is a 20-item questionnaire evaluating the symptoms of anemia: 13 of which assess fatigue symptoms and 7 of which assess non-fatigue-related symptoms. The score of FACT-An contains 5 grades (0, 1, 2, 3 and 4) by 0 as best and 4 as worst QOL. The LASA consists of three linear analog scales, each was 100 mm long, that measures the level of energy, ability to do daily activities, and overall QOL related to cancer symptoms. Subjective QOL assessments were completed before the start of the study, at weeks 4, 8, 12, and 16 after the treatment with epoetin alfa. Patients scored their own perceptions of these domains by placing a mark along the line, with 0 as worst and 100 as best QOL. The FACT-An and LASA scales are cancer-specific and have been demonstrated to be sensitivity to hemoglobin levels. Therefore the two scales were considered particularly suitable for detecting any change in QOL due to administration of epoetin alfa and subsequent increase in hemoglobin.

Statistical Analysis

Change in hemoglobin level and QOL score from baseline to value in every four weeks through the course of study were compared by t-tests, and the proportions of responders (patients with an increase in hemoglobin $\geq$ 1 g/dl) were observed. Pearson correlation coefficients were calculated to assess the relationship between hemoglobin level and QOL scores. For all statistical analyses, $P < 0.05$ was considered significant.

Results

Patients

In total, there were 25 patients (13 men and 12 women) recruited into the study. The anemia problem of the patients was resolved after 16 weeks of treatment with epoetin alfa. There were no major differences in the demographics and baseline clinical characteristics of the patients as illustrated in Table 1. Most patients were in their advanced stages of malignancies: 23 patients (92 %) were in either grade III or IV. Cancer types of these patients included, namely: lung cancer (60 %), breast cancer (16 %), head & neck cancer (4 %) and others (20 %). Prestudy means of hemoglobin levels and hematocrit levels at baselines (9.95 $\pm$ 0.78 g/dl and 29.93 $\pm$ 2.34 %, respectively) determined their status of anemia. Low quality of life of the patients was showed as measured by LASA and FACT-An score (200.00 $\pm$ 34.76 and 23.88 $\pm$ 11.64, respectively).

Proportion of responder

Of the total 25 patients, five patients dropped out from the study (20 %). Their reasons for refusing to participate included, namely: their lack of time and disease progression. At the end of the study, the proportions of responders were 15 of 20 patients (75 %), illustrated in Figure 1. These patients completed the course of the study (16 weeks) and showed good response (patients who achieved an increase of $\geq$ 1 g/dl in hemoglobin level) after receiving epoetin alfa. Whereas, 5 of 25 patients had incremental mean of hemoglobin concentration less than 1 g/dl, compared to baseline although these patients were treated with additional dose of epoetin alfa 60,000 units subcutaneously once a week.
Table 1. Demographic and Baseline Clinical Characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Epoetin alfa (n=25)</th>
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<tr>
<td></td>
<td>N (range)</td>
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<tr>
<td>Gender</td>
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<tr>
<td>Male</td>
<td>13</td>
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<tr>
<td>Female</td>
<td>12</td>
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<tr>
<td>Age, years</td>
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<tr>
<td>Median</td>
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<tr>
<td>Range</td>
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<tr>
<td>Body weight, kg, mean ± SD</td>
<td>55.87 ± 7.47</td>
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<tr>
<td>Stage of disease</td>
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<tr>
<td>I</td>
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<tr>
<td>II</td>
<td>2</td>
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<tr>
<td>III</td>
<td>12</td>
</tr>
<tr>
<td>IV</td>
<td>11</td>
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<tr>
<td>Cancer type</td>
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<tr>
<td>Lung cancer</td>
<td>15</td>
</tr>
<tr>
<td>Breast cancer</td>
<td>4</td>
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<tr>
<td>Head &amp; Neck cancer</td>
<td>1</td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
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<tr>
<td>Hemoglobin, g/dl, mean ± SD</td>
<td>9.95 ± 0.78</td>
</tr>
<tr>
<td>Hematocrit, %, mean ± SD</td>
<td>29.93 ± 2.34</td>
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<tr>
<td>QOL scores</td>
<td></td>
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<tr>
<td>LASA</td>
<td>200.00 ± 34.76</td>
</tr>
<tr>
<td>FACT-AN (20 items)</td>
<td>23.88 ± 11.64</td>
</tr>
</tbody>
</table>

Hematopoietic response

The mean hemoglobin values measured every four weeks throughout the 16 weeks of the study for all cancer patients with anemia treated by epoetin alfa were shown in Figure 2. Their mean hemoglobin levels increased gradually from week 4 to approximately 12 g/dl by week 8 and were maintained at this level through week 16. The significant difference in the mean hemoglobin level over the baseline value was initially found after 1 month of treatment (10.88 ± 1.87 g/dl; p= 0.01 v. baseline).
to obtained score every four weeks in order to evaluate the improvement of the quality of life. As for the LASA scale, the score increased significantly in all of three items including the level of energy, ability to do daily activities, and overall QOL related to cancer symptoms after the patients received epoetin alfa (Figure 3). Accordingly, the anemic symptoms in cancer patients measured by FACT-AN score was statistically significantly improved over the baseline level after receiving epoetin alfa (23.88 ± 11.64 and 13.13 ± 11.28 at baseline and week 16, respectively) as illustrated in Figure 4. Moreover, the improvement of the quality of life of the cancer patients was significantly apparent over the baseline level at the end of the first month after the start of epoetin alfa. When QOL of responders and non-responders was particularly considered, it was found that QOL of non-responders didn’t improve in both LASA scale and FACT-AN as shown in Figure 5 and 6.
Figure 5. Baseline and Change From Baseline in Linear Analog Scale Assessment (LASA) between responders and non-responders

**Analog Scale Assessment (LASA)**

**Relationship between Hemoglobin levels and QOL**

The relationship between hemoglobin levels and QOL scores calculated from LASA and FACT-AN among the patients also suggested that patients with higher hemoglobin levels experienced better QOL. The association between hemoglobin level and QOL was examined by Pearson correlations analysis as illustrated in Figure 7 and 8. There were strong and statistically significant correlation in linear pattern between hemoglobin concentration and QOL score in both LASA and FACT-AN variables ($P \leq 0.001$; $r = 0.435$ for LASA and $P \leq 0.001$; $r = -0.431$ for FACT-AN).

Figure 6. Baseline and Change From Baseline in Functional Assessment of Cancer Therapy-Anemia (FACT-AN) between responders and non-responders

Figure 7. Correlation between change in quality of life (QOL; measured by linear assessment analog scales) and hemoglobin (Hb) level in cancer patients treated with Epoetin alfa.

Figure 8. Correlation between change in quality of life (QOL; measured Functional Assessment of Cancer Therapy-Anemia) and hemoglobin (Hb) level in cancer patients treated with Epoetin alfa.
Safety

Treatment with epoetin alfa was well tolerated. The most common adverse event was fatigue. Of the In total 25 patients, 5 patients (20%) had fatigue during the study and a patient (4%) had cough. Nevertheless, there was not patient who discontinued their participation in study because of side effect of the treatment.

Discussion

The results of this non-randomized, open label trial demonstrated that most cancer patients with anemia had good response by an increase ≥ 1 g/dl increase in hemoglobin level when administered epoetin alfa 40,000 - 60,000 units once weekly via subcutaneous route. Additionally, the mean hemoglobin concentration of the patients gradually increased to normal level (12 g/dl) within week 8 after the start of the treatment with epoetin alfa. An increase of hemoglobin concentration to normal level had to be taken for a period because epoetin alfa is a glycoprotein that as a mitosis-stimulating factor and differentiating hormone stimulates erythropoiesis pathway. From graph shown in Figure 1, the patients had hemoglobin concentration over 13 g/dl at week 12 of treatment therefore epoetin alfa was withheld to reduce hemoglobin level to 12 g/dl approximately at week 16. This condition was mentioned in the study procedure. Nevertheless, QOL of the patients including the of energy, ability to do daily activities, and overall QOL related to cancer symptoms determined by LASA and fatigue symptoms evaluated by FACT-AN scale were also improved after receiving epoetin alfa. Interestingly, when the correlation between hemoglobin level and QOL score was considered, it was found that hemoglobin concentration and QOL score from LASA and FACT-AN illustrated a strong relationship. The consequence could be explained that anemia might be one of the factors that reduce quality of life in cancer patients who were on chemotherapy. Therefore hemoglobin level and QOL measurement were crucial evaluations for patients receiving chemotherapy. Additionally, the physician should maintain hemoglobin concentration of cancer patients in normal level to improve their quality of life through the course of chemotherapy.

This finding suggested that epoetin alfa (Eprex® , Janssen-cilag) 40,000 - 60,000 units once-weekly subcutaneously was safe and effective in remodeling anemia which significantly improved the quality of life in cancer patients receiving chemotherapy.

References


