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Original Research

Efficacy of oral iron therapy in cancer patients with chemotherapy-induced anemia: A real-world retrospective study

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Abstract

Objective: Chemotherapy-induced anemia (CIA) is one of the most common adverse effects found in cancer patients. This condition not only affects the quality of life of the patients but can also delay their regular chemotherapeutic administration. As erythropoiesis-stimulating agents (ESA) and parenteral iron therapy are not commonly affordable in Thailand, this study aimed to observe the clinical response of the patients receiving oral iron therapy for CIA. **Methods:** Patient medication charts of all patients with CIA and without other causes of anemia were reviewed. Baseline characteristics, clinical data, and blood-related laboratory results were collected before treatment. Clinical response, defined as hemoglobin ≥12.0 g/dL or an increase in hemoglobin ≥2.0 g/dL, was assessed at 3 months after treatment. **Results:** During the study period, there were 77 patients with oral 200 mg Ferrous Fumarate trice daily and 68 patients without oral iron therapy. Baseline characteristics of the patients in both groups were similar, especially the blood-related values. The response rate of the patients using oral iron was 10.39%, while the other group was 0% (p-value 0.007). In addition, the mean changes in hemoglobin of the patients receiving oral iron for 3 months and not receiving oral iron were 0.13 and -0.43 g/dL, respectively (p-value 0.005). **Conclusion:** Oral iron supplementation had a statistically significant benefit of hemoglobin development, despite not much increase. For patients with CIA who cannot afford ESA or parenteral iron, oral iron therapy should be taken into account.

Keywords: chemotherapy-induced anemia; oral iron; ferrous fumarate; ferrous sulphate

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INTRODUCTION

Anemia is defined as a condition that which patients have hemoglobin values lower than the normal lower limits. For instance, the World Health Organization (WHO) sets the lower level of hemoglobin at 12.0 g/dL for females and 13.0 g/dL for males, while the US National Cancer Institute (NCI) sets the lower level of hemoglobin at 12.0 g/dL for females and 14.0 g/dL for males[1]. Anemia can be caused by several factors, such as malnutrition of iron and vitamin B12, some diseases, as well as exposure of chemotherapeutic agents.

Chemotherapy-induced anemia is one of the most common adverse effects from cancer treatment, with the incidence as high as 50.0% - 60.0%[2]. A study in the United Kingdom reported that 33.0% of the patients with solid tumors required at least one blood transfusion, and approximately 16.0% of them required multiple transfusions[3]. In Thailand, unfortunately, there is no study published on the incidence of chemotherapy-induced anemia. However, there is a study that indicated the incidence of radiotherapy-induced anemia in Thailand, which was as high as 54.4%[4].

The management of chemotherapy-induced anemia was suggested by many organizations, including the National Comprehensive Cancer Network (NCCN), European Society of Medical Oncology (ESMO), American Society of Clinical Oncology (ASCO)/American Society of Hematology (ASH)[5-7]. Most of the recommendation involves blood transfusion, erythropoiesis-stimulating agents (ESA), and parenteral iron therapy. Nonetheless, in Thailand, access to erythropoietin and intravenous iron can be limited in a large number of patients due to the high cost of the drugs. Oral iron therapy is more affordable for the majority of cancer patients in Thailand, but the studies on its effectiveness are still very limited, particularly in patients without iron deficiency. Therefore, this study aimed to investigate the effectiveness of oral iron therapy in cancer patients who had chemotherapy-induced anemia in Thailand.

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METHODS

Patient population

All patients who had the diagnosis of cancer and received cancer treatment at the clinical setting between 1 January 2017 and 31 December 2022 were screened. The inclusion criteria were 1) age of more than or equal to 18 years old, 2) having any type of cancer without bone metastasis, and 3) having the diagnosis of anemia or having hemoglobin less than 12.0 g/dL based on Common Terminology Criteria for Adverse Events (CTCAE) version 5.0[8], or having hemoglobin reduction of more than 2.0 g/dL after chemotherapy treatment. Patients who received any oral iron therapy, including ferrous fumarate and ferrous sulfate, were in the treatment group, while the patients without any oral iron therapy were in the control group.

The exclusion criteria included the patients who did not have both necessary pre- and post-treatment laboratory values, i.e. hemoglobin and hematocrit, who had the diagnosis of the following diseases: iron deficiency anemia, vitamin B12 deficiency anemia, folate deficiency anemia, and chronic kidney disease, who had hematological malignancy, and who received blood transfusion, erythropoiesis-stimulating agents (ESA), or parenteral iron therapy.

Study design

Electronic patient medication charts of all recruited patients were reviewed. Patient demographic data were collected at the start of iron treatment, including age, gender, weight, height, and underlying disease. The clinical data, including the type of cancer, date of diagnosis, chemotherapy regimen, and cycle of chemotherapy. The blood-related laboratory values, including hemoglobin, hematocrit, red blood cell (RBC) count, mean corpuscular volume (MCV), serum iron, serum ferritin, and total iron binding capacity (TIBC), were collected at pre-treatment. Hemoglobin, hematocrit, and MCV levels were followed at 1-month, 2-month, and 3-month post-treatment.

The primary outcome of this study was the response rate of oral iron therapy at 3 months after starting of the iron supplement. The response was defined as either patient had hemoglobin higher than or equal to 12.0 g/dL or had an increase in hemoglobin more than or equal to 2.0 g/dL. The secondary outcomes were mean differences in hemoglobin, hematocrit, and MCV.

Statistical analysis

Baseline characteristics of the patients were analyzed using descriptive statistics and presented as numbers, percentages, means, and 95% confidence interval (95%CI). The comparison of response rates between the iron treatment and the control groups was analyzed using Fisher's Exact test. The comparison between pre- and post-treatment mean hemoglobin and mean hematocrit was analyzed with the Wilcoxon Signed Rank test. The differences in mean hemoglobin and mean hematocrit between the treatment and the control groups were analyzed using the Mann-Whitney U test. All statistical analyses were performed using IBM SPSS Statistics software version 28.0.0.0 (190), and statistical significance was set at p-value <0.05.

Ethical approval

This study was conducted in accordance with the Declaration of Helsinki, and approved by the Human Research Ethics Committee of Walailak University (registration number WUEC-22-355-01) for studies involving humans. Patient informed consent was waived due to the retrospective methodology of the study. All patient data were stored confidentially, and could only be accessed by the relevant researchers.

RESULTS

From 1 January 2017 to 31 December 2022, there were a total of 585 patients who had the diagnosis of cancer and received chemotherapeutic treatment. Of them, 329 patients had chemotherapy-induced anemia, based on the above-mentioned definition. However, only 77 patients with oral iron therapy and 68 patients without oral iron therapy passed the exclusion criteria and were recruited for the analysis.

Baseline characteristics

Baseline characteristics of 145 patients recruited in this study are shown in Table 1, divided into iron supplement (n=77) and non-iron supplement (n=68). The majority of the patients in both groups were female (88.31% and 88.23%, respectively), and the mean ages of the patients were similar in both groups (57.58 and 58.97 years, respectively). Moreover, the average body weight and body mass index of the patients receiving iron were similar to those who did not receive it.

Solid tumors were the most cancer diagnosed, with 79.22% of the patients in the iron therapy group and 89.56% of the patients in the non-iron therapy group (Table 1). However, the chemotherapeutic agents that the patients received were not the same. The patients in the iron therapy group mostly received carboplatin (48.05%) and cyclophosphamide (35.06%), whilst the patients in the non-iron therapy group mostly received cyclophosphamide (48.53%) and paclitaxel (27.94%). For the iron therapy that the patients received, all of them received Ferrous Fumarate 200 mg three times daily.

Regarding the blood-related laboratory values of the patients, the averages in hemoglobin, hematocrit, MCV, and MCHC were similar between the two groups. For the patients who received iron supplements, the averages in hemoglobin, hematocrit, MCV, and MCHC were 10.02 g/dL, 30.85%, 82.06 fL, and 32.87 g/dL, respectively. Likewise, for the patients who did not receive an iron supplement, the averages in hemoglobin, hematocrit, MCV, and MCHC were 10.53 g/dL, 32.38%, 83.46 fL, and 32.58 g/dL, respectively. Moreover, the levels of serum

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Table 1. Baseline characteristics of cancer patients who had chemotherapy-induced anemia and were treated with oral iron therapy

Characteristics	**Oral iron supplement (n=77)**	**No oral iron supplement (n=68)**
Female gender, n (%)	68 (88.31)	60 (88.23)
Age (year), mean (95%CI)	57.58 (54.50-60.65)	58.97 (55.60-62.34)
Weight (kg), mean (95%CI)	53.57 (50.94-55.80)	51.92 (49.74-54.09)
Body mass index (kg/m^2), mean (95%CI)	22.09 (21.11-23.07)	21.51 (20.65-22.37)
Cancer type, n (%)		
Solid tumors	61 (79.22)	61 (89.56)
Myelomas	6 (7.79)	2 (2.91)
Lymphomas	10 (12.99)	5 (7.53)
Chemotherapy received*, n (%)		
Cyclophosphamide	27 (35.06)	33 (48.53)
Paclitaxel	8 (10.39)	19 (27.94)
Docetaxel	1 (1.30)	2 (2.94)
Carboplatin	37 (48.05)	11 (16.18)
Cisplatin	2 (2.60)	6 (8.82)
Oxaliplatin	3 (3.90)	4 (5.88)
Laboratory test, mean (95%CI)		
Hemoglobin (g/dL)	10.02 (9.66-10.37)	10.53 (10.26-10.80)
Hematocrit (%)	30.85 (29.83-31.88)	32.38 (31.56-33.19)
RBC count (x 10^3 cell/dL)	3.76 (3.61-3.91)	3.96 (3.78-4.15)
MCV (fL)	82.06 (79.99-84.12)	83.46 (80.82-86.09)
MCHC (g/dL)	32.87 (32.52-33.24)	32.58 (32.51-32.65)
Serum iron (mcg/dL)	52.34 (39.42-65.26)	50.24 (37.91-62.58)
Serum ferritin (ng/mL)	982.04 (102.38-1861.70)	946.65 (55.71-1837.59)
TIBC (mcg/dL)	268.49 (203.97-333.01)	258.80 (196.97-320.63)

Note: Each patient could receive more than one chemotherapeutic agent.

iron, serum ferritin, and total binding capacity of the patients in both groups were not different (Table 1).

Response rates of oral iron supplements

After three months of receiving oral iron therapy, there were 8 out of 77 patients (10·39%) who had a response to chemotherapy-induced anemia, whilst none of the patients without oral iron therapy developed a response. The differences between the two groups of patients were statistically significant with a p-value of 0·007. Among the 8 patients with the response, 3 patients had hemoglobin levels above 12.0 g/dL, 2 patients had an increase in hemoglobin of more than 2.0 g/dL, and 3 patients had both.

Changes in blood-related values

The comparison between pre- and post-treatment in hemoglobin, hematocrit, and MCV is shown in Figure 1, Figure 2, and Figure 3, respectively. For hemoglobin (Figure 1), the patients who received oral iron therapy had a significant increase in mean hemoglobin at 3-month post-treatment compared to pre-treatment (10·65 vs. 10·10 g/dL, respectively, p-value 0·006). On the other hand, the patients without oral iron therapy have had a significant decrease in mean hemoglobin for 1 month after following (10·23 vs. 10·66, p-value 0·003), and continued decreasing at the second month (10·02 vs. 10·66, p-value <0·001) and the third month (10·03 vs. 10·66, p-value 0·006), as compared to pre-treatment.

Similar trends were observed in the hematocrit values (Figure 2). The patients who were treated with oral iron therapy had a significant increase in hematocrit at 3 months of treatment (p-value 0·004). The mean hematocrit values of the patients at baseline, 1 month, 2 months, and 3 months after treatment were 30·90%, 31·54%, 32·57%, and 32·85%, respectively. On the contrary, the mean hematocrit values of the patients without oral iron therapy were consistently significantly reduced from pre-treatment until 3 months. At baseline, 1 month, 2 months, and 3 months monitoring, the mean hematocrit values of the patients were 32·50%, 31·37%, 30·70%, and 30·90%,

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respectively.

Regarding the MCV, both patients in the iron therapy and non-iron therapy groups have had the same significant increases in mean MCV values since the first month of follow-up (Figure 3). The average MCV values of the patients with iron therapy were 81.89 fL at baseline and 85.99 fL at 3-month post-treatment (p-value <0.001), and of the patients without iron therapy were 85.46 fL at baseline and 88.80 fL at 3-month post-treatment (p-value <0.001).

When comparing hemoglobin changes between the patients receiving oral iron and not receiving oral iron, the results indicated significant differences since the first month of treatment (0.13 vs. -0.43 g/dL, respectively, p-value 0.005) (Figure 4). The significances still continued to the second month (0.48 vs. -0.64 g/dL, respectively, p-value <0.001) and the third month (0.55 vs. -0.62 g/dL, respectively, p-value <0.001).

DISCUSSION

Chemotherapy-induced anemia is one of the most prevalent side effects of chemotherapeutic agents, with the highest incidence of 53.0%[9]. Most clinical practice guidelines recommend ESA or parenteral iron therapy for the treatment of this side effect[5-7]; however, those therapies are not widely accessible in Thailand, particularly in rural areas of the country. Many patients, therefore, still have to receive oral iron therapy to ameliorate the anemia severity.

To the best of our knowledge, there are not many studies focusing on oral iron therapy alone in patients with chemotherapy-induced anemia. A phase III randomized trial by Noronha et al. reported 12% and 18% of the patients with oral iron therapy achieved hematopoietic response[10-11], which were higher than this study, which had 10.39% of response. However, the definition of response in those studies was different from the current study; those trials used the increases in hemoglobin of ≥1.0 and ≥1.5 g/dL as a response, while this study used an increase in hemoglobin of ≥2 g/dL. On the other hand, another study by Henry et al. showed a high response rate of the patients who received oral iron therapy of 46%[12]. Although the definition of response in the study by Henry et al. was similar to this study, it should be noted that the patients in the mentioned study, without any iron therapy, still had a 41% response rate, while none of the patients in the current study achieved a response. Nevertheless, the hematopoietic responses from oral iron without ESA are not comparable with the response of IV iron plus ESA, which resulted in 70.63% of response[13].

Regarding the changes in hemoglobin and hematocrit levels, this study showed significant increases in both hemoglobin and hematocrit in the patients treated with oral iron after three months, as compared to pre-treatment. In addition, these increases were significantly higher than those of patients without iron therapy. These results conformed with the study by Henry et al., which indicated an increase in hemoglobin of 1.6 g/dL in the patients receiving 325 mg of oral ferrous sulphate three times daily[12], even though the patients in the current study had a lower increase (maximum of 0.55 g/dL). Similarly, a study by Birgegård et al. showed a 1.64 g/dL increase in hemoglobin after 24-week treatment of oral iron sulphate[14]. Moreover, a study by Dangsuwan et al. indicated a 9.5 g/dL increase in hemoglobin in patients who received oral ferrous sulfate 600 mg/day[15]. On the contrary, several studies showed a decrease in hemoglobin level in the patients using oral iron; the study by Noronha et al. reported a 0.16 g/dL reduction in mean hemoglobin after 6 weeks of oral ferrous sulfate treatment[11]. Although the magnitude of hemoglobin increase seemed modest, several studies indicated clinical benefit of such increase. Each 1 g of hemoglobin increase can raise approximately 1.34-1.39 mL of oxygen carriage[16], thus it improved prognosis of cancer patients[17], reduced blood transfusion needs[18], and improved quality of life of the patients[19].

Different clinical practice guidelines recommend different uses of oral iron therapy in patients with cancer-induced anemia. The NCCN guideline recommends oral iron supplementation in cases where serum ferritin is less than 30 ng/mL and transferrin saturation is less than 20%[5]. The ESMO guideline recommends oral iron only for patients with serum ferritin levels less than 100 ng/mL and C-reactive protein less than 5 mg/L[6]. On the other hand, the ASCO/ASH guideline suggests that both oral and intravenous iron formulations are acceptable options, depending on patient and doctor preferences, formulation availability, cost, and comorbidities[7]. Nonetheless, all recommendations focus on patients with iron deficiency or receiving erythropoiesis-stimulating agents, who were not the cases in this study.

The health system in Thailand allocates erythropoiesis-stimulating agents and parenteral iron as the medicines for specific purposes[20]; meaning is that if the patients do not have either iron deficiency anemia or anemia related to chronic kidney disease, they have to pay for the medicines. This policy makes access to these drugs very difficult for many patients in Thailand. As a result, the anemic condition in many patients with cancer is never treated. The findings in this study suggests that Thai pharmacists should have roles in identifying patients with chemotherapy-induced anemia, and consulting the doctors to initiate oral iron supplementation for those patients because receiving the treatment is better than no treatment. This suggestion can apply to all pharmacists in resource-limited oncology settings. In addition, the pharmacists should frequently monitor hemoglobin of the patients taking oral iron and suggest further management strategies to the doctors, such as erythropoiesis-stimulating agents, in those who do not respond to the oral treatment.

Limitation

Several limitations in this study should be taken into account.

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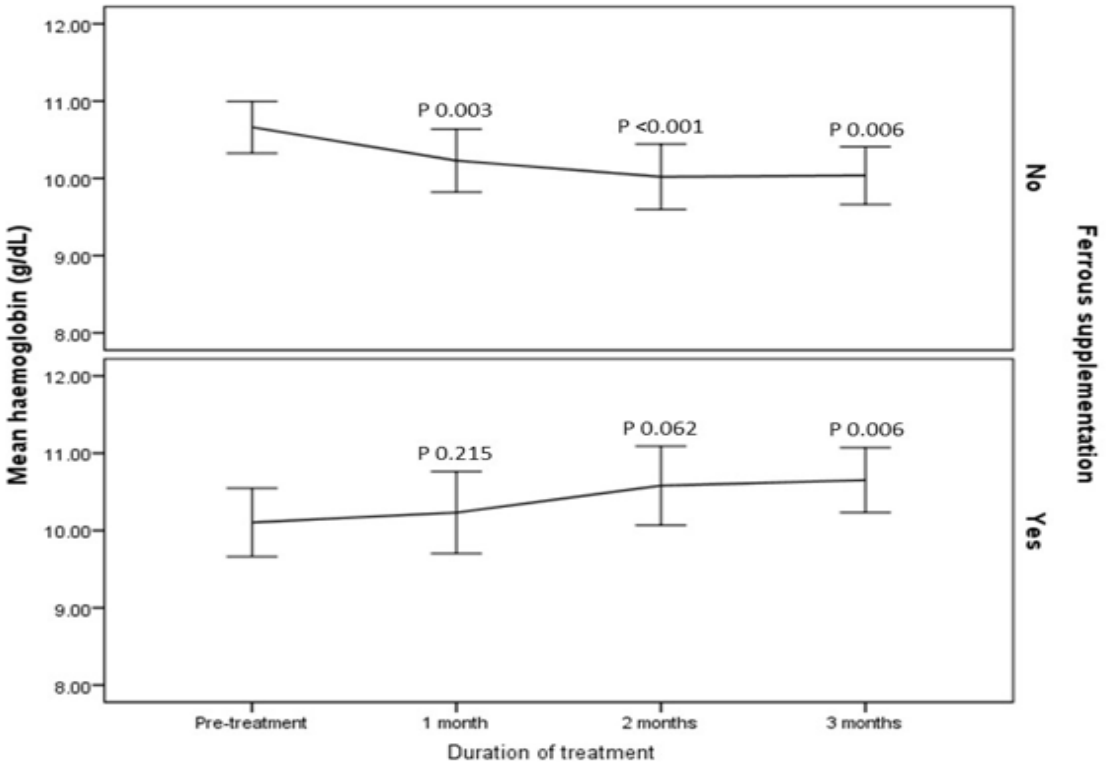
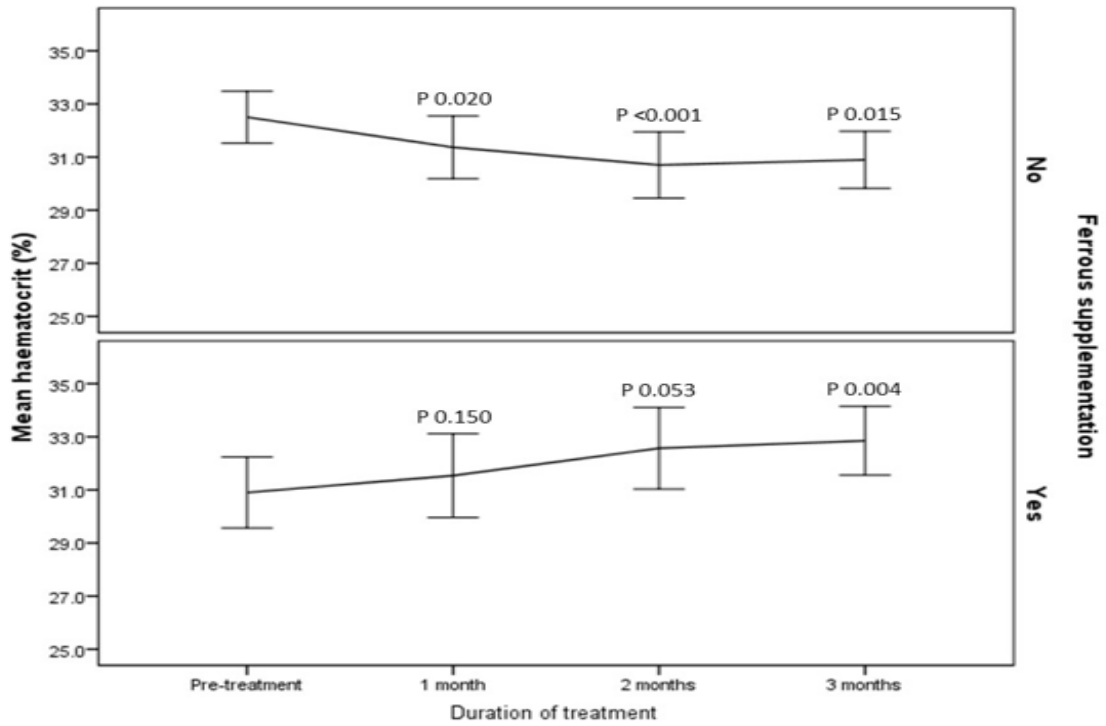


Note: All p-values were from the comparison with pre-treatment. Error bars represent 95%CI.
Figure 1. Mean changes in hemoglobin of the patients with chemotherapy-induced anemia who received and did not receive oral iron supplement



Note: All p-values were from the comparison with pre-treatment. Error bars represent 95%CI.
Figure 2. Mean changes in hematocrit of the patients with chemotherapy-induced anemia who received and did not receive oral iron supplement

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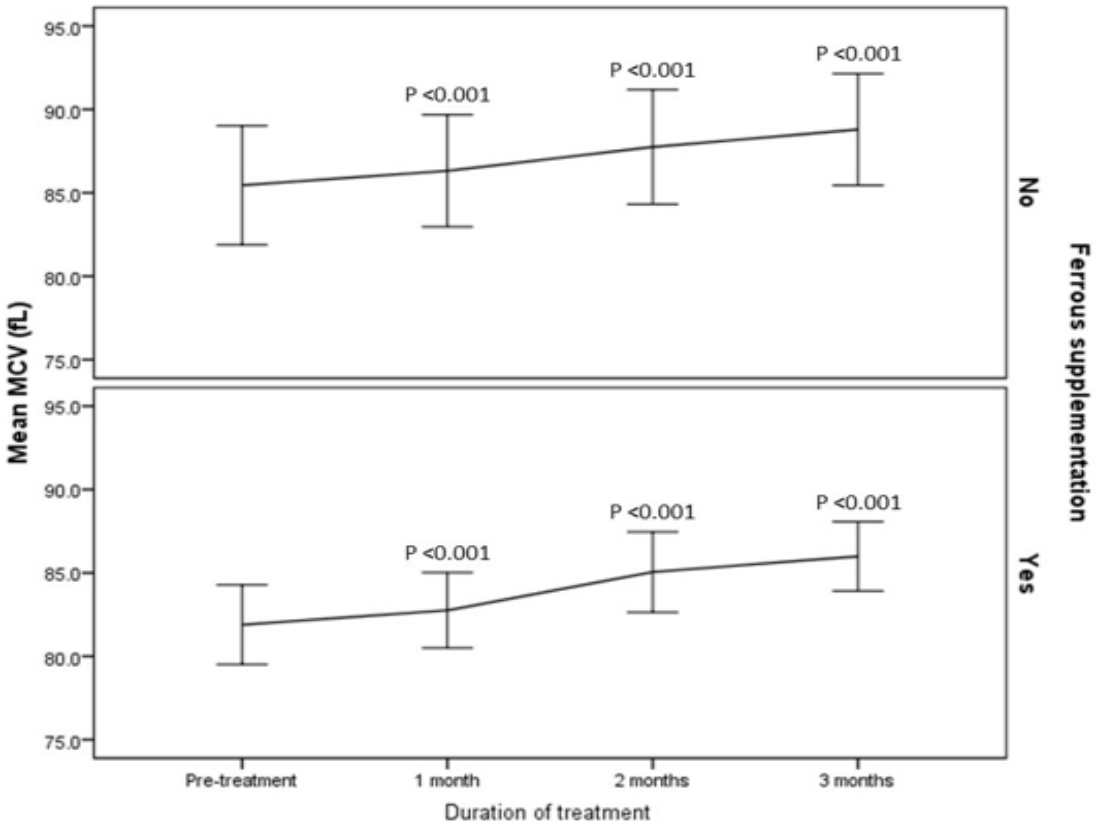
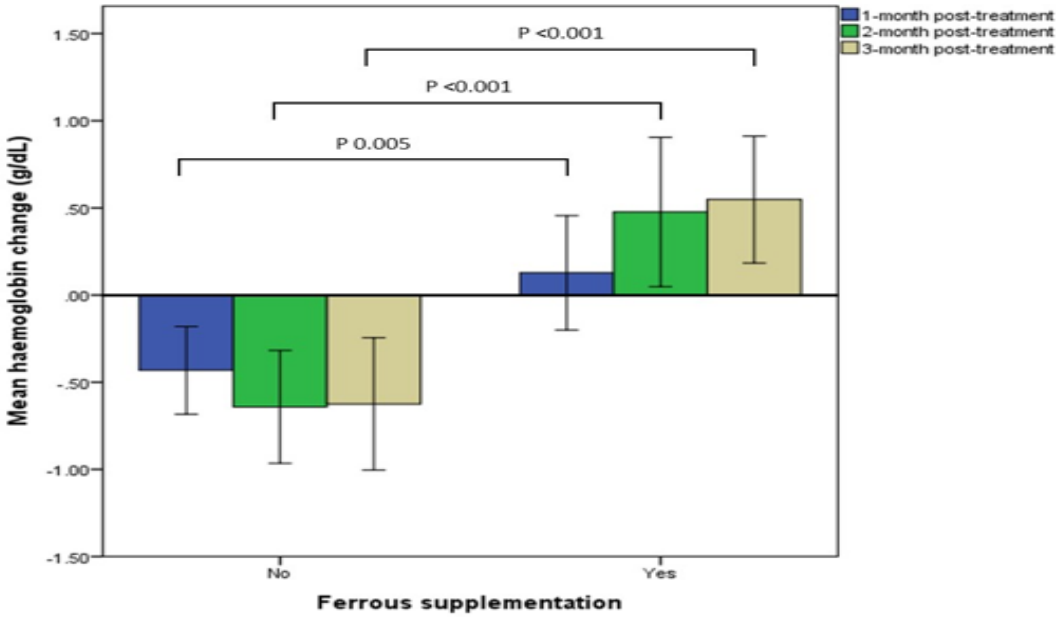


Note: All p-values were from the comparison with pre-treatment. Error bars represent 95%CI.
Figure 3. Mean changes in MCV of the patients with chemotherapy-induced anemia who received and did not receive oral iron supplement



Note: Error bars represent 95%CI.
Figure 4. Comparison of hemoglobin change between the patients with chemotherapy-induced anemia who received and did not receive oral iron supplement

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Firstly, the sample size of this study was low despite there was only one cancer patient in the clinical setting. This resulted from the strict exclusion criteria of this study, which excluded patients with other anemia-related diseases, such as iron deficiency anemia, chronic kidney disease, as well as patients who received blood transfusions, erythropoiesis-stimulating agents (ESA), or parenteral iron therapy. Secondly, this retrospective cohort study could not control for any confounding factors, so the effects on hemoglobin could be interfered with by other factors, such as diet and compliance of taking oral iron. Furthermore, as the proportion of patients who received each chemotherapy regimen was not comparable between the treatment and control groups, it could also confound the outcomes. Implication of the results in this study should be performed with care. Lastly, this study could not report the clinical effects of the increased hemoglobin of the patients. Although the results indicated a statistical increase in hemoglobin from oral iron, the actual clinical advantage of the drug should be further studied.

CONCLUSION

The findings in this study showed a statistically significant increase in hemoglobin and hematocrit of the patients with cancer-related anemia who received oral iron supplements, as compared to the patients who did not receive iron supplements. Additionally, the anemic patients with oral iron therapy had a significantly higher response rate for anemia than those without iron therapy.

AUTHOR'S CONTRIBUTION

US, JA, JS conceived the study; US, BT, JT, KN, JS obtained funding; all authors contributed to the design of the trial; US, BT, JT, KN, JS collected data, analyzed and interpreted the data, and wrote the first draft of the manuscript; US, JS, AE reviewed, edited, and approved the final version of the manuscript.

CONFLICTS OF INTEREST

The author reports no conflicts of interest in this work.

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