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THE EFFECT OF IRON POLYMALTOSE COMPLEX TABLET ADMINISTRATION TO INCREASE HEMOGLOBIN LEVEL AMONG PREGNANT WOMEN WITH ANEMIA

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ABSTRACT

Background: Anemia is a major cause of bleeding due to iron deficiency. Iron tablets which contain 60 mg of Ferrous Sulphate and 0.25 mg of folic acid did not show good results in changing the body's iron level and there are many perceived side effects. However, there is now exists an oral iron tablets in the form of available salt compounds of ferrous fumarate, ferrous sulphate, and ferrous gluconate. These tablets contain iron hydroxide polymaltose complex (III) or better known as IPC (Iron Polymaltose Complex) and have minimal side effects.

Aims: To understand the effect of IPC tablets in increasing the hemoglobin level in pregnant women with anemia.

Methods: This study used quantitative study with pre-experimental design, or experiments that have not been applied in real terms. This study used non-probability sampling technique and purposive sampling for the selected sample. The sample were 35 people based on the inclusion criteria. The design used was one group pre-test – post-test approach without the control group. The subjects undertook the anemia examination on the first day (pre-test) and afterwards were administered 100mg IPC tablets daily for the next 30 days. In the end of the intervention, the subjects were re-examined and the results were compared (post-test).

Results: The study showed that there is a significant increase of hemoglobin level in pregnant women with anemia with p value = 0.023 ($p < 0.05$) after the intervention in the form of IPC tablet administration was conducted for 30 days.

Conclusion: The intervention performed in administration of IPC tablets for pregnant women with anemia showed a significant increase of hemoglobin level before and after the provision of IPC tablets.

Keywords: Iron Polymaltose Complex Tablet, Hemoglobin Level, pregnant woman with anemia

INTRODUCTION

Currently the problem of maternal death is still a major problem in Indonesian. This can be seen from the high Maternal Mortality Rate in Indonesia. According to Indonesia Health Demographic Survey in 2012,

Maternal Mortality Rate in Indonesia was 359 per 100,000 live births. This number increased from 228 per 100,000 live births in 2007, this number is still relatively high compared to other ASEAN countries. Indonesian maternal mortality rate second position after Laos [1, 2]. Meanwhile, In order to improve the health status and nutritional status of the pregnant women community, the Ministry of Health's Strategic Plan of Indonesia 2015 had a target to reduce Maternal Mortality Rate to 306 per 100,000 live births [3].

The priorities of immediate cause maternal mortality are hemorrhage (35.1%), hypertension (27.1%), infection (7.3%), prolonged labor (1.8%) and others (34.5%). Anemia is a major cause of bleeding that is one of the largest contributors to high maternal mortality [1]. Most of anemia in Indonesia is due to iron deficiency [4]. Iron is one of the nutritional elements that is a component of the formation of hemoglobin or red blood cells. The report of Basic Health Research of Indonesia in 2007 found anemia in pregnant women 24.50%, a significant decrease when compared to the achievement of 1986 amounted to 73.3%. The 2012 report shows an increase in total prevalence of pregnant women with anemia reaching 37.1% where 36.4% live in urban areas and 37.8% live in rural areas with the highest cause of anemia being iron deficiency.

Results of maternal anemia survey in 15 districts in 2007 that the prevalence of anemia in Central Java was 57.7%, still higher than the national rate of 50.9% [5]. The prevalence of anemia in pregnant mothers in Semarang city based on the data recapitulation of anemia status of pregnant women in 2005 was 53%. Anemia during pregnancy can cause adverse effects in both the pregnant woman and the baby. Anemia in pregnant women will increase the risk of low birth weight, the risk of bleeding before and during labor that can cause death of the mother and her baby if the pregnant woman is suffering from severe anemia.

As pregnancy progresses, the need for iron for fetal growth increases with increasing fetal weight and this requirement peaks in the third trimester of pregnancy. The 2007 Danish Advisory National Board or Nutrition recommends that iron supplementation should be tailored to serum ferritin levels, which is a fairly sensitive indicator to estimate iron reserves in the body. If serum ferritin <30 µg / dl is recommended Fe 100 mg / day. Iron Polymaltose Complex slow release tablets are preferred because they are better tolerated and their absorption 29% larger than the standard Ferrous Sulphate preparations. At a dose <105 mg / day did not have a significant effect on the gastrointestinal tract. Given the magnitude of the adverse effects of iron deficiency anemia in pregnant women and the fetus it contains it needs considerable attention to this problem including the provision of iron tablets in accordance with the needs of pregnant women.

Iron is one of the nutritional elements as a component of the formation of hemoglobin or red blood cells. Anemia is one of the most common blood disorders when the level of red blood cells (erythrocytes) in the body becomes too low. This can cause health problems because red blood cells contain hemoglobin that carries oxygen to the body tissues. Anemia can cause various complications including fatigue and stress on the limbs [6, 7].

According to WHO, adult pregnant women are diagnosed to have iron deficiency anemia when hemoglobin level is <11 g / dl and serum ferritin is <12 ng / dl. According to the UK Guidelines in The Management of Iron Deficiency in Pregnancy 2011, anemia is defined as a hemoglobin level of <11g / dl in the first trimester, <10.5 g / dl in the second and third trimesters, and <10g / dl in the postpartum period [8].

The difference in upper limit values is associated with the incidence of hemodilution. In pregnancy the blood volume will multiply which is commonly called Hydremia or Hypervolemia. However, the increase in blood cells is less than the increase in plasma and results in blood dilution. The comparison is as follows: plasma 30%, blood cell 18%, and hemoglobin 19%. The increase in blood volume in pregnancy begins at 10 weeks of gestation and reaches the peak in between 32 and 36 weeks of pregnancy. Physiologically this blood dilution may help alleviate the increasingly heavy heart work related to pregnancy [9, 10].

Iron tablets which contain 60 mg of Ferrous Sulphate and 0.25 mg of folic acid did not show good results on changes in iron level in the body and there are many perceived side effects. [11] But now there is iron in the form of available salt compounds of ferrous fumarate, ferrous sulphate, and ferrous gluconate which have minimal side effects namely oral iron tablets containing iron hydroxide polymaltose complex (III) or better known as IPC oral iron tablet (Iron Polymaltose Complex). The slow-release tablet of Iron Polymaltose Complex (IPC) is preferred because it is better tolerated and its absorption of 29% is larger than the standard Ferrous Sulphate preparation. At a dose of <105 mg/day there is no significant effect on the gastrointestinal tract [7, 8, 12].

Iron Polymaltose Complex (IPC) iron tablet for the treatment of iron deficiency anemia during pregnancy is an alternative for patients who cannot tolerate Ferrous iron preparations. Giving Iron Polymaltose Complex in the broad realm has not spread thoroughly this is due to various factors such as side effects, effectiveness and different prices. So most people especially in poor and developing countries are still using sulphate ferrosus to pregnant women with anemia deficiency. Side effects in the sulphate ferrous group were higher than the IPC group ($p < 0.001$) [13]. The side effects of nausea were more in the ferrous sulphate group and better tolerance was found in the IPC group (80%) compared to ferrous sulphate (60%). The World Health Organization (WHO) states that 20% of 515,000 maternal deaths worldwide are caused by anemia. Maternal death of 15-20% is directly or indirectly caused by anemia [13].

In June 2014 a preliminary study was conducted on 20 third-trimester pregnant women with mild and moderate anemia, and had previously taken iron supplements of Ferrous Fumarate at a dose of 300mg/day and Ferrous Sulphate iron tablets at a dose of 60 mg/day and then the subjects received IPC iron tablet with a dose of 100mg/day for 30 days [14-16].

During supplementation, the mean of Hb level of the respondents before intervention was $9,8 \pm 0,8$ g / dl and after intervention was $10,6 \pm 1,1$ g / dl with $p = 0,01$, so statistically there was a significant difference between Hb level before and after the administration of IPC iron tablet. While the increase of Hb level mean after providing IPC iron tablet was 1,2 g/dl [8, 12, 13, 17, 18].

METHODS

The methodology of this study used quantitative study with Pre-experiment design and one group pretest-posttest approach not included control group, the subjects was given pretest and afterwards got a treatment and final measurement (Posttest). A single case is observed at two time points, one before the treatment and one after the treatment. Changes in the outcome of interest are presumed to be the result of the intervention or treatment. No control or comparison group is employed. There were 35 samples of pregnant women with anemia from 75 pregnant women population with inclusion criteria. The population in this study were all pregnant women with gestational age of 28-36 weeks who visited to check their pregnancy at Mardi Rahayu Maternity Hospital Semarang and meet the inclusion criteria in October until November 2014. This study used non probability sampling technique and for selected sampel used purposive sampling. This study compared hemoglobin level before and after administration of Iron Polymaltose

Complex tablets of 100 mg once daily for 30 days in pregnant women with anemia whose gestational age was 28-36 weeks. In this study, the intervention strategy used was the respondents came to check their pregnancy according to the inclusion criteria of 28-36 weeks gestation, and got routine pregnancy check including taken the blood samples for hemoglobin level assessment (Pre-test). After the hemoglobin level results were obtained and ascertain whether the results of this blood test could be included as the criteria of pregnant women with anemia, then the respondents were given intervention in the form of IPC iron tablets of 100mg/day for 30 days, and then on the 31st day, Pregnant Women were re-assessed for the second Hb level (post-test). Blood sampling results were tested in the CITO laboratory using the Analyzer Blood Count tool.

RESULTS

Table 3. The Effect of Iron Polymaltose Complex Tablet Administration to Increase Hemoglobin Level during 30 days intervention

Variable	n	Mean	Upper	Lower	P value
Hemoglobin level before	35	9,85	-0,44004	-0,03425	0,023
Hemoglobin level after	35	10,09			

The results of the showed a significant change in the change of hemoglobin level. In the intervention given before IPC tablets, the hemoglobin level mean was 9.85, with a standard deviation of 0.69. The lowest hemoglobin level was 6.3 and the highest was 10.8. The change occurred in the post-test intervention that was done with the result of hemoglobin level mean after given Iron Polymaltose Complex tablet of 10.09, with standard deviation of 0.850. The lowest hemoglobin level was 8.2 and the highest was 11.5. The administration of Iron Polymaltose Complex tablets for 30 days in pregnant women with anemia showed an increase of hemoglobin level with P value = 0.023 (P <0.05).

Based on WHO recommended criteria for anemia in pregnant women, which divided the criteria of anemia into severe anemia 7.00 gr%, 7.00-8.00 gr%, mild 9.00-10.00 gr% and no anemia 11 gr%. The results showed an increase in blood hemoglobin levels in respondents who were given IPC intervention. These results are able to change the criteria of anemia in most respondents from mild anemia to criteria above mild anemia criteria. Efficacy of these results will be able to help reduce complications caused by anemia in pregnant women and their fetuses. In addition, the provision of IPC will be able to assist the government in achieving anemia-free target of up to 100%.

DISCUSSION

From the study results showed a significant increase in hemoglobin level among pregnant women with anemia after taking Iron Polymaltose Complex tablet for two months (October – November 2014). Previous studies shows that medication using IPC tablet is more effective, safety, efficient, and higher tolerance and efficacy to the pregnant women than the Ferrous sulphate in improving the level of Hemoglobin, MCV, MCH and serum [9, 19, 20].

Iron is an important part of hemoglobin, which is an oxygen-carrying protein in the blood. The body usually gets iron through diet and recycles iron from old red blood cells. Without iron, blood cannot carry oxygen effectively. Oxygen is required for every cell in the body to function normally. Iron deficiency is the most common form of anemia. About 50% of pregnant women do not have enough iron in their bodies. Pregnant women often experience anemia because the baby in the uterus requires a large amount of iron for its growth. Iron deficiency can cause low birth weight babies and preterm labor [21].

Prevention of pregnancy anemia performed through the administration of iron tablets in women during pregnancy has not been able to overcome anemia in pregnant women. Iron-polymaltose complex, a combination of ferric iron (Fe^{3+}) with malitol is developed with some Iron Polymaltose Complex, Ferrous Sulfas, has advantages that can be dissolved at neutral pH and does not bind to the elements contained in the foodstuff. Another advantage is that IPC is a non-ionic preparation that does not cause oxidative stress reactions, so it is safer and can be tolerated by patients [22].

The incidence of pregnancy anemia can be prevented or reduced with iron. Iron Polymaltose Complex is a derivative of iron that can be consumed by pregnant women. Recently Ferri complex preparation is introduced, one of which is Iron Polymaltose Complex (IPC), a combination of ferric iron (Fe^{3+}) with malitol which is developed with some advantages such as can be dissolved at neutral pH and does not bind to the elements contained in the foodstuff. Another advantage is that IPC is a non-ionic preparation that does not cause oxidative stress reactions, so it is safer and can be tolerated by patients [8]. Several studies have shown that IPC was as effective as Sulfas Ferrous (SF), and some studies have shown that IPC results to be more effective than SF [23, 24].

Iron Polymaltose Complex (IPC) for the treatment of iron deficiency anemia during pregnancy is an alternative for patients who can not tolerate ferrous iron preparation. According to the British National Formulary (2010) Hb level should increase by about 2 g / dl after 3-4 weeks of iron tablet administration. Increased Hb levels depend on Hb and iron status at the onset of supplementation, ongoing Fe loss, iron absorption and other factors that affect the occurrence of anemia such as micronutrient deficiencies, infections, and renal impairment.

This research has no control group, thus for future study can put control group to make sure that hemoglobin level increases in experiment group because of the intervention, not because of another factor. Inability to control all the variables that affect changes of haemoglobin level.

CONCLUSION

From the study that has been conducted, it can be concluded that the intervention performed in administration of Iron Polymaltose Complex tablets for pregnant women with anemia showed a significant difference of hemoglobin level before and after provided Iron Polymaltose Complex tablets. Further study is needed in the intervention of Iron Polymaltose Complex tablets administered to pregnant women with anemia by considering other factors that may affect hemoglobin level such as pregnancy interval, maternal age and nutritional status. In addition, renewable innovations are needed on tools that can perform quick, efficient and accurate results inspection results.

REFERENCES

- [1] Indonesia KKR. Survei demografi kesehatan indonesia. In: Indonesia Kementerian kesehatan Republik, editor. Jakarta: Kementerian kesehatan Republik Indonesia 2012.
- [2] TR B. Maternal and child health situation in south east asia 2012; 7(13).
- [3] Indonesia KKR. Rencana strategi kementerian kesehatan tahun 2015-2019. 2015.



- [4] RI KK. Survei demografi dan kesehatan indonesia 2012. Jakarta Kemenkes RI. 2013.
- [5] Kesehatan PJTD. Profil kesehatan provinsi jawa tengah tahun 2015. In: Kesehatan Dinas, editor. Semarang 2015.
- [6] Kalaivani K. Prevalence & consequences of anaemia in pregnancy. *Indian J Med Res.* 2009;130(5):627-33.
- [7] Pavord S, Myers B, Robinson S, Allard S, Strong J, Oppenheimer C. Uk guidelines on the management of iron deficiency in pregnancy. *British journal of haematology.* 2012;156(5):588-600.
- [8] Smid MC, Strauss RA. Maternal anemia. *Maternal-Fetal Evidence Based Guidelines.* 2017.
- [9] Saha L, Pandhi P, Gopalan S, Malhotra S, kumar Saha P. Comparison of efficacy, tolerability, and cost of iron polymaltose complex with ferrous sulphate in the treatment of iron deficiency anemia in pregnant women. *Medscape General Medicine.* 2007;9(1):1.
- [10] Sari E. Perbandingan pemberian suplemen multi micronutrien dan tablet fe terhadap peningkatan hemoglobin, hematokrit pada ibu hamil di puskesmas prambanan klaten dan puskesmas prambanan sleman. *MOTORIK Jurnal Ilmu Kesehatan (Journal Of Health Science).* 2016;11(22).
- [11] Biesalski HK, Tinz J. Multivitamin/mineral supplements: Rationale and safety. *Nutrition.* 2017;36:60-6.
- [12] Taseer I-U-H, Mirbahar A, Safdar S, Awan Z. Anemia in pregnancy; related risk factors in under developed area. *Professional Medical Journal.* 2011;18(1).
- [13] Percy L, Mansour D, Fraser I. Iron deficiency and iron deficiency anaemia in women. *Best Practice & Research Clinical Obstetrics & Gynaecology.* 2017;40:55-67.
- [14] Mulyani S. Hubungan antara status gizi dengan kadar hemoglobin pada ibu hamil trimester ii di puskesmas bandarharo semarang utara. *Karya Ilmiah S 1 Ilmu Keperawatan.* 2013.
- [15] Sari E. Status gizi balita di posyandu mawar kelurahan darmokali surabaya. *Keperawatan.* 2017;6(1).
- [16] SyaBani IRN, Sumarni S. Hubungan status gizi dengan kejadian anemia pada santriwati di pondok pesantren darul ulum peteronang jombang. *Jurnal Keperawatan Muhammadiyah.* 2017;1(2).
- [17] Webster S, Chance B. *At guelph volume 36 number 21 to number 31, 1992.* 1992.
- [18] Eliagita C, Kuntjoro T, Sumarni S, Suwondo A, Hadisaputro S, Eliagita C, et al. Effect of consuming papaya (carica papaya linn.) on the level of hemoglobin and hematocrit in pregnant women with anemia. *Belitung Nursing Journal.* 2017;3(2):120-5.
- [19] Percy L, Mansour D. Iron deficiency and iron-deficiency anaemia in women's health. *The Obstetrician & Gynaecologist.* 2017;19(2):155-61.
- [20] Widyaningsih A, Setiyani O, Umaroh U, Sofro MAU, Amri F. Effect of consuming red dragon fruit (*hylocereus costaricensis*) juice on the levels of hemoglobin and erythrocyte among pregnant women. *Belitung Nursing Journal.* 2017;3(3):255-64.
- [21] Moll R, Davis B. Iron, vitamin b 12 and folate. *Medicine.* 2017.
- [22] Chandra I, Sun L-z. Iron status and choice of iron therapy during pregnancy: Advantages and disadvantages. *International Journal of Reproduction, Contraception, Obstetrics and Gynecology.* 2017;4(5):1264-71.
- [23] Alaofè H, Burney J, Naylor R, Taren D. Prevalence of anaemia, deficiencies of iron and vitamin a and their determinants in rural women and young children: A cross-sectional study in kalalé district of northern benin. *Public health nutrition.* 2017;20(7):1203-13.
- [24] Retnorini DL, Widatiningsih S, Masini M. Pengaruh pemberian tablet fe dan sari kacang hijau terhadap kadar hemoglobin pada ibu hamil. *JURNAL KEBIDANAN.* 2017;6(12):8-16.