Evaluation of a Pharmaceutical Care Program with Pregnant Women with Iron Deficiency Anemia

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บทคัดย่อ

ภาวะโลหิตจางเป็นปัญหาสาธารณสุขที่สำคัญของประเทศไทย โดยเฉพาะอย่างยิ่งภาวะโลหิตจางที่มีสาเหตุมาจากการขาดธาตุเหล็กในหญิงตั้งครรภ์ มีส่วนสำคัญที่ทำให้เพิ่มอัตราการป่วยและอัตราการเสียชีวิตของทั้งมารดาและทารก รวมทั้งส่งผลให้เกิดการเจริญเติบโตของทารกในครรภ์ช้า การศึกษานี้เป็นงานวิจัยกึ่งทดลอง (Quasi-experimental study) มีวัตถุประสงค์เพื่อศึกษาผลของการบริบาลทางเภสัชกรรมในหญิงตั้งครรภ์ที่มีภาวะโลหิตจางจากการขาดธาตุเหล็ก คลินิกฝากครรภ์ โรงพยาบาลแก่งคอย จังหวัดสระบุรี กลุ่มตัวอย่างเป็นหญิงตั้งครรภ์ที่มีคุณลักษณะตามที่กำหนดไว้และลงชื่อยินยอมการเข้าร่วมโครงการวิจัยตามรูปแบบของคณะกรรมการจริยธรรมของโรงพยาบาล แบ่งออกเป็นกลุ่มทดลองและกลุ่มควบคุมจำนวนกลุ่มละ 27 คน ทั้งกลุ่มทดลองและกลุ่มควบคุมจะได้รับคำแนะนำปกติจากคลินิกฝากครรภ์ แต่กลุ่มทดลองจะได้รับการบริบาลทางเภสัชกรรมจำนวน 3 ครั้งตลอดการวิจัย การศึกษานี้จะเปรียบเทียบผลการให้บริบาลทางเภสัชกรรมในหัวข้อความรู้เรื่องภาวะโลหิตจางจากการขาดธาตุเหล็กในหญิงตั้งครรภ์ ความร่วมมือในการกินยาเม็ดธาตุเหล็ก และ ระดับค่าฮีมาโตคริต ทำการวิเคราะห์ข้อมูลโดยใช้โปรแกรมสำเร็จรูป SPSS V 11.5

ผลการวิจัยพบว่าเมื่อสิ้นสุดการบริบาลทางเภสัชกรรมหญิงตั้งครรภ์ในกลุ่มทดลองมีคะแนนเฉลี่ยความรู้สูงกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (7.48 ± 2.40 และ 4.63 ± 2.35 คะแนนตามลำดับ, p = 0.000) ความร่วมมือในการกินยาเม็ดธาตุเหล็กหลังให้การบริบาลทางเภสัชกรรมของหญิงตั้งครรภ์กลุ่มทดลองสูงกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (2.34±1.37 และ 3.33±1.45 คะแนนตามลำดับ, p = 0.04 โดยคะแนนสูงบ่งชี้ว่ามีความร่วมมือในการกินยาลดลง) หลังการบริบาลทางเภสัชกรรมพบว่า ค่าเฉลี่ยฮีมาโตคริตของหญิงตั้งครรภ์ในกลุ่มทดลองเพิ่มขึ้นอย่างมีนัยสำคัญทางสถิติ (31.79 ± 1.46, 32.31 ± 2.27 และ 33.04 ± 2.73% ตามลำดับ, p = 0.028) ส่วนในกลุ่มควบคุมพบว่าค่าเฉลี่ยฮีมาโตคริตไม่มีความแตกต่างกัน (31.43 ± 1.99, 31.52 ± 2.33 และ 32.08 ± 2.68, p = 0.178) ถึงแม้ว่าค่าเฉลี่ยฮีมาโตคริตหลังการบริบาลทางเภสัชกรรมเปรียบเทียบระหว่างกลุ่มทดลองและกลุ่มควบคุมจะไม่มีความแตกต่างกัน (33.04 ± 2.73 และ 32.08 ± 2.68%, p = 0.188) แต่เมื่อวิเคราะห์ข้อมูลเพื่อเปรียบเทียบค่าเฉลี่ยระดับฮีมาโตคริตหลังการทดลองกับเกณฑ์ระดับฮีมาโตคริตเป้าหมาย พบว่าหญิงตั้งครรภ์ในกลุ่มทดลองเท่านั้น มีค่าเฉลี่ยระดับฮีมาโตคริตมากกว่าหรือเท่ากับ 33% ที่ระดับนัยสำคัญ 0.05 ผลการวิจัยนี้แสดงให้เห็นว่า การบริบาลทางเภสัชกรรมสามารถเพิ่มความรู้เกี่ยวกับภาวะโลหิตจางจากการขาดธาตุเหล็กในหญิงตั้งครรภ์ เพิ่มความร่วมมือในการกินยาเม็ดธาตุเหล็กทำให้หญิงตั้งครรภ์สามารถแก้ไขภาวะโลหิตจางจากการขาดธาตุเหล็กได้

คำสำคัญ : โลหิตจางจากการขาดธาตุเหล็ก หญิงตั้งครรภ์ การบริบาลเภสัชกรรม ฮีมาโตคริต

Abstract

Anemia is a major public health problem in Thailand. In pregnant women, it results from iron deficiency and is associated with increased risks of maternal and fetal mortality and morbidity and intrauterine growth retardation. The aim of this quasi-experimental study was to evaluate the effects of a pharmaceutical care program with pregnant women with iron deficiency anemia at the ante-natal clinic at Kaengkhoi Hospital, Saraburi, Thailand. The participants were recruited and enrolled by specific criteria, gave informed consent based on the hospital ethics committee agreement, and were assigned into two groups of 27, an experimental group and a comparison group. Both groups received health education provided by the routine system but the experimental group also attended a pharmaceutical care program three times throughout the study. The program focussed on: participants' knowledge of iron deficiency anemia in pregnant women; compliance of pregnant women regarding iron supplementation; and levels of hematocrit (Hct). Data analysis was performed by SPSS V11.5. Results showed that 3 months after implementation of the program, the experimental group had average scores of knowledge significantly higher than those of the control group (7.48±2.40 vs. 4.63±2.35, p = 0.000). The compliance of pregnant women regarding iron supplementation in the experimental group was also significantly higher than the control group (2.34±1.37 vs. 3.33±1.4, p = 0.004). During the 3 month period, there were significant increases in Hct levels in the experimental group (31.79±1.46, 32.31±2.27, 33.04±2.73%, p = 0.028), whereas there were no significant increases in the control group (31.43±1.99, 31.52±2.33, 32.08±2.68%, p=0.178). Although Hct levels between the experimental group and the control group were not significantly different (33.04±2.73% vs. 32.08±2.68%, p=0.188), only the experimental group showed greater Hct levels based on the WHO criterion (Hct≥33%). In conclusion, this study demonstrated that the implemented pharmaceutical care program can be used as a guideline to increase the knowledge and compliance, and thus the Hct levels, in pregnant women with iron deficiency anemia.

Keywords: Iron deficiency anemia: Pregnant women: Phamaceutical care: Hematocrit

Introduction

Anemia (defined by the World Health Organization as hemoglobin levels of ≤ 11 g/dl) is the most common form of malnutrition in the world, affecting more than 2 billion people globally [1]. Iron deficiency anemia (inadequate amount of red blood cells caused by a lack of iron) is highly prevalent in less-developed countries but also remains a problem in developed countries where other forms of malnutrition have already been virtually eliminated. Iron deficiency is not the only cause of anemia, but where anemia is prevalent iron deficiency is usually the most common cause [2]. In pregnant women, anemia resulting from iron deficiency is associated with increased risks of maternal and fetal mortality and morbidity and intrauterine growth retardation [3]. The Department of Health (Thailand) recognizes the importance of the problem of anemia in pregnant women and there is a policy of monitoring anemia in pregnant women by assigning the rate of indicator of anemia in pregnant women should not be greater than 10%. The report of the fifth National Nutrition survey of Thailand 2003 found that anemia in pregnant women was equal to

26.1% [4]. The Maternal and Child Health of Kaengkhoi Hospital found that the rates of anemia of pregnancy were 20.1%, 21.56%, and 17.24% from 2009 to 2011. Although the hospital has special practical guidelines for pregnant women with anemia, the problem was still unsolved. According to these guidelines for the prevention and control of iron deficiency anemia during pregnancy, the most important are eating iron-rich foods and appropriate iron supplementation. WHO recommended a daily dose of two tablets, each containing 60 mg of element iron plus 400 µg of folate, taken until 3 months after delivery or abortion [5]. A study of iron supplementation in Thai pregnant women showed that 120 mg element iron given daily from mid-pregnancy until delivery significantly reduced the prevalence of anemia [6], [7], [8]. Unfortunately, most iron supplementation programs have been less effective than expected. The main obstacle to iron supplementation programs is low compliance associated with undesirable gastrointestinal side-effects, such as nausea, vomiting, constipation, and gastrointestinal discomfort [9], [10]. Also, there were incorrect perceptions about the side-effects of medicine, such as the fear of obesity and the beliefs that extra iron resulted in a large body, increased bleeding, and a large baby [5]. Important standard care for pregnant women according to the World Health Organization 2006 are iron supplementation, motivation on compliance with iron treatment, and provison of frequent counseling, such as examination of local perceptions about iron treatment and the females' concerns about mediation, and advice about the essential nature of iron for health during and after pregnancy, how to take tablets, how to manage side-effects, and eating iron-rich foods [5].

This research studied the pharmaceutical care program for pregnant women with anemia due to iron deficiency at Kaengkhoi Hospital's antenatal clinic, and was based on the standard of care for pregnant women of the World Health Organization 2006 together with individual counseling. The objectives were to investigate the operation of the pharmaceutical care program for pregnant women, to improve knowledge, and to motivate patients' compliance with iron treatment to reduce anemia in pregnant women due to iron deficiency.

Materials and Methods

Research Design

This study was of a quasi-experimental design. Two groups, an experimental group of 27 participants and a control group of 27 participants (total n = 54) received health education provided by the routine system, but the experimental group also attended a pharmaceutical care program three times during the study. Data were collected three times, before, during, and after the program.

Population

The population selected for this study was pregnant women with iron deficiency anemia who requested services at the ante-natal clinic at Kaengkhoi Hospital, Saraburi, Thailand from 1 August 2013 to 31 July 2014.

Sample selection

Specific criteria and simple random sampling were used to select the sample. The inclusion criteria were that the women were pregnant, aged 18-35 years, 8-22 weeks gestation, hematocrit level $\leq$ 33%, osmotic fragility test = negative, and had no other

complications. The participants were able to read and write Thai. The criteria for exclusion were pregnant women with complications, such as diabetes, hypertension, heart disease, hemorrhoids, blood disease, threatened abortion, and twin pregnancy, hematocrit levels <27%, discrete treatment, and lost follow-up.

From 1 August 2013 to 31 July 2014, there were 460 pregnant women who used the services of the ante-natal clinic at Kaengkhoi Hospital. Of these, 74 qualified according to the selection criteria. During the experiment, four pregnant women moved to rural hospitals and 16 pregnant women did not complete the program. This resulted in 27 pregnant women in each study group.

Implementation of the Program

This research was permitted by the ethic committee of the Faculty of Pharmacy, Silpakorn University (Ref. No. 2/2556, Research No./ID 7/2555). The participants read the Participant Information Sheet and signed the Informed Consent Form.

Data were collected from 1 August 2013 to 31 July 2014. The experimental group attended the pharmaceutical care program three times and both groups received health education provided by the routine system. On the first visit, participants in both groups were interviewed and answered a questionnaire measuring knowledge of iron deficiency anemia (pre-test) with the first hematocrit test (Hct1). On the second visit (after 1 month), participants in both groups were given the second hematocrit test (Hct2). When the gestational age was 32 weeks, participants in both groups answered the questionnaire measuring knowledge of iron deficiency anemia (post-test), had the Morisky Medication Adherence Scale (MMAS 8-item) test for measuring compliance, and were given the third hematocrit test (Hct3). The pharmaceutical care program was conducted with individual counseling three times by a pharmacist.

1. The first session of the pharmaceutical care program lasted 30 minutes and gave information about iron deficiency anemia and advice about taking tablets, managing side-effects, eating iron-rich food, discussed incorrect perceptions, and distributed a manual.

2. The second session of the pharmaceutical care program (after 4 weeks) took 15-20 minutes to distribute topics “pill for beloved baby” and summarized, ask about the iron supplement pill taking and high iron food intake, and managing adverse drug reaction, and summarized the problem of preventive planning.

3. The third session of the pharmaceutical care program (after 4 weeks) summarizing the knowledge of iron deficiency anemia and evaluated behavior related to iron supplementation and the taking of high iron-rich food.

Outcome Measurement

Measurement of outcomes was as followed:

1. Knowledge of iron deficiency anemia in pregnant women compared before and after the experiment between the experimental group and the control group by the use of the prepared questionnaire. The Cronbach’s alpha reliability coefficient for the questionnaire was 0.73.

2. The compliance of pregnant women regarding iron supplementation using Morisky Medication Adherence Scale (MMAS 8-item) [11]. The Cronbach’s alpha reliability coefficient for MMAS 8-item was 0.69.

3. Hematocrit levels at the first measurement (Hct1), second measurement (Hct2), and third measurement (Hct3).

Statistical Analysis

Data analysis was performed by SPSS for Windows V11.5. Data were presented as means and ±SDs. Chi-square test was used for categorical data, while other statistical tests were based on normality of data: t-test and repeated ANOVA for data with normal distribution, Mann-Whitney U Test, and Wilcoxon Signed Rank Test for data with non-normal distribution.

Results

The experimental and the control groups' characteristics of age, education level, number of pregnancies, gestational age, coffee/tea drinking, and medicine/supplementation/herb intake were not significantly different (p>0.05). Results showed that the average age of the women in the experimental group was 23.44±4.61 years and the control group was 24.11±5.7 years. The education level of the pregnant women of both groups was mainly secondary school (51.9%, 51.9%). The number of pregnancies was 2 in the experimental group (37.0%) and 1 in the control group (44.4%). The gestational age of both groups was between 20-22 weeks (51.9%, 51.9%). The experimental group and the control group had no underlying diseases (96.3%, 85.2%), did not drink coffee/tea (74.1%, 81.5%), and did not take any medicine/supplementation/herb (96.3%, 100%) (Table 1).

Evaluation of the pharmaceutical care for pregnant women with anemia due to iron deficiency was divided into 3 parts.

1. Knowledge of iron deficiency anemia in pregnant women: the results showed that 3 months after implementing the program the experimental group had average scores of knowledge significantly higher than before implementing the program (7.48±2.40 vs.5.26±2.72, p=0.0005) but the control group was not significantly higher (4.63±2.35 vs.5.52±2.13, p=0.0515). After 3 months, the experiment group showed significantly higher scores than the control group (p=0.000) (Table 2).

2. Compliance of pregnant women regarding iron supplementation: the experimental group and the control group were significantly different in the scores (2.34±1.37 vs. 3.33±1.45, p=0.004) (Table 3), indicating that the pregnant women had higher compliance for iron supplementation.

3. Hematocrit levels of pregnant women: The hematocrit levels (Hct1, Hct2, and Hct3) of the experimental group were significantly different (p=0.028), whereas those of the control group were not significantly different (p=0.178). Comparisons between the two groups indicated that there were no significant differences (p=0.1888) (Table 4).

Table 1 Number and Percentage of Samples categorized by Age, Education, Number of Pregnancies, Gestational Age, Underlying Diseases, Coffee/Tea Drinking, and Medicine/Supplementation/Herb Intake

General Information	Number (Percentage)		*p*-value
	Experimental Group	Control Group	
1. Average of Age (Years) ±SD	23.44 ± 4.61	24.11 ± 5.7	0.861[a]
2. Education			
2.1 Uneducated	0 (0)	2 (7.4)	0.720[a]
2.2 Primary School	4 (14.8)	4 (11.1)	
2.3 Secondary School	14 (51.9)	14 (51.9)	
2.4 High School or Equivalent	8 (29.6)	6 (22.2)	
2.5 Diploma or Equivalent	1 (3.7)	1 (3.7)	
2.6 Bachelor Degree	0 (0)	1 (3.7)	
3. Number of Pregnancies			
3.1 1 Time	9 (33.3)	12 (44.4)	0.993[a]
3.2 2 Times	10 (37.0)	6 (22.2)	
3.3 3 Times	8 (29.6)	4 (14.8)	
3.4 4 Times	0 (0)	4 (14.8)	
a. 5 Times	0 (0)	1 (3.7)	
4. Gestational Age			
4.1 8 – 10 Weeks	2 (7.4)	1 (3.7)	0.844[a]
4.2 11 – 13 Weeks	3 (11.1)	3 (11.1)	
4.3 14 – 16 Weeks	5 (18.5)	5 (18.5)	
1.4 17 – 19 Weeks	3 (11.1)	4 (14.8)	
4.5 20 – 22 Weeks	14 (51.9)	14 (51.9)	
5. Underlying Diseases			
5.1 Yes	1 (3.7)	4 (14.8)	0.175[b]
5.2 No	26 (96.3)	23 (85.2)	
6. Coffee/Tea Drinking			0.351[b]
6.1 No	20 (74.1)	22 (81.5)	
6.2 Infrequently	5 (18.5)	5 (18.5)	
6.3 Daily	2 (7.4)	0 (0)	
7. Medicine/Supplementation/Herb			0.500[b]
7.1 No	26 (96.3)	27 (100)	
7.2 Yes	1 (3.7)	0 (0)	

[a] Mann-Whitney U test

[b] Chi-square

Table 2 Average Scores of Knowledge Before/After Experiment

Sample groups	Average Values* (Score)		*p*-value
	Experimental Group	Control Group	
Before experiment	5.26±2.72	5.52±2.13	0.349 [a]
After experiment	7.48±2.40	4.63±2.35	0.000 [a]
p-value	0.0005 [b]	0.0515 [b]	

*Average Values±Standard deviation

[a] Independent t-test

[b] Paired t-test

Table 3 Comparison of the Two Groups' Average Scores of Compliance of Pregnant Women Regarding Iron Supplementation

Average Scores of Compliance* (Score)		*p*-value
Experimental Group	Control Group	
2.34±1.37	3.33±1.45	0.004 [a]

*Average Values ± Standard deviation

[a] Mann-Whitney U test

Table 4 Average Values of Hematocrit Levels of Pregnant Women (Hct1, Hct2, and Hct3).

Follow up	The Average Values of Hematocrit levels* (%)		*p* - value
	Experimental Group	Control Group	
Before Experiment (Hct1)	31.79±1.46	31.43±1.99	0.188 [a]
In Process (Hct2)	32.31±2.27	31.52±2.33	
After Experiment (Hct3)	33.04±2.73	32.08±2.68	
p - value	0.028 [a]	0.178 [a]	

*Average Values ± Standard deviation

[a] Repeated Measures ANOVA

Discussion

The study found that after pregnant women with iron deficiency anemia attended pharmaceutical care program, they improved their knowledge following individual counselling by pharmacists based on the standard of care for pregnant women of the World Health Organization 2006, together with getting the documents about anemia due to iron deficiency and books which had iron-rich food information. This study was in accordance with previous studies about the effects of a health education program on the prevention of iron deficiency anemia among pregnant women conducted by Jancha-um [12]. In this study, the experimental group was required to attend the health education program three times which consisted of lectures with videos, group discussion, demonstration and

practice modeling, and a reminder given by village health volunteers. The results showed that the knowledge of iron deficiency anemia of the women significantly improved. A study by Prattana Pienthong [13] determined the effects of a nutrition education program based on health belief model and self-care to prevent and control iron deficiency anemia in pregnant women at an ante-natal care unit of Pathumthani Hospital. The results of the study showed that, after intervention, the experimental group had statistically significantly higher average score in knowledge of iron deficiency anemia than the control group. The compliance of pregnant women regarding iron supplementation in the experimental group was higher than the control group. The reason was that the plan of the pharmaceutical care programs had surveyed and made the women understand anemia due to iron deficiency, and thereafter provided advice about the importance of awareness of iron supplementation and adverse drug reaction. The findings were also in accordance with the studies of Sawangwongsin [14]. The main purpose of this study was to investigate changes in iron deficiency prevention behaviors among pregnant women. Protection Motivation Theory and a group process were used to plan a health education program. The result showed that after participation in the health education program, the experimental group had significantly more preventive behavior than the comparison group. The objective of research by Prathanee [15] was the development of the counseling model for pregnant women with iron deficiency anemia. The experimental group was individually counseled by the use of a handbook based on the Health Belief Model. The results showed that the scores of behavior related to eating habits and taking medicine were significantly different.

Although hematocrit levels between the experimental group and the control group were not significantly different (similarly the study of Sawangwongsin [14]) only the experimental group showed greater hematocrit levels based on the WHO criterion (Hct≥33%). This could be explained by the fact that the pharmaceutical care program promoted the pregnant women to take care of themselves, for instance daily iron supplementation which should not be taken with tea, coffee, or milk. They should take iron supplementation immediately after a meal to reduce side-effects such as nausea and vomiting. Behavioral change regarding the taking of iron-rich food was also advised. This present study corresponded with the research of Kunkitti [16] of the effects of a nutrition promoting program on the hematocrit levels among adolescent pregnant women with anemia. Jancha-um [12] studied the effectiveness of a health education program on the prevention of iron deficiency anemia among pregnant women. The research found that the hematocrit levels between the experimental group and the comparison group were not different after the experiment. This result showed that the knowledge of iron deficiency anemia, the perceived severity and susceptibility about iron deficiency anemia, and the preventive behaviors of the study women significantly improved. Thus, this study program should be applied in other health promotion programs for pregnant women in rural communities.

Conclusion

The pharmaceutical care program for pregnant women with iron deficiency anemia implemented by pharmacists can play a role in

the improvement of the iron deficiency status of Thai pregnant women. The pregnant women did have an awareness of anemia due to iron deficiency and complied regarding iron supplementation. As a result, the program showed a trend in improvement of iron deficiency status and thus prevention of adverse effects of iron deficiency among the pregnant women.

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