Medical Science Journal for Advance Research

Vol. 6, No. 3, September 2025
e-ISSN: 2774-4892

Effect of Ijin Granules on Nausea and Vomiting Symptoms in Pregnant Women with Hyperemesis Gravidarum

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ABSTRACT

Objective: *To identify the effectiveness of traditional medicine, Ijin Granules on PUQE score and the change of intake in pregnant women with hyperemesis granvidarum who complaints of severe nausea and vomiting.* ***Background:*** *Hyperemesis Gravidarum (HG) is a common early pregnancy syndrome that usually occurs around 4 to 5 weeks of gestation, which is initiated with sour throw-up from the empty stomach in the morning, disgusting to smell, change of appetite, and exacerbated with severe nausea, frequent vomiting, and inability to eat, which gives side effects on quality of life and health of the pregnant woman. Generally GH causes malnuturition and dehydration, if it is not treated in time, some complications such as Wernick's encephalopathy and low-weight neonate birth can be caused. Now antiemetics involving antihistamine, phenothiazine, Vitamin B6, metoclopramide and ondansetrone are used for HG, and steroids are recommended for the last choice but they are limited in use from the fear that chemical medicine is a risk to pregnancy.* ***Subject and Method:*** *Between Jaunary 2024 and December 2024, 60 cases of HG were enrolled in the study at Pyongyang Maternity Hospital, Pyongyang, Democratic People's Republic of Korea. The patients were randomly divided into study group (30 cases) and control group (30 cases). The control group was given only fluid replacement therapy and the study group orally given Ijin Granules (5g) 3 times daily with the fluid therapy for 7 days. The effectiveness was analyzed between the two groups with PUQE score, QOL score, SDS score and the amount of intake.* ***Result:*** *After 7 days of the treatment the PUQE and SDS scores in the study group were lower as compare to the control group, QOL score and intake in the study group were higher as compare to the control group. The total effective rate of treatment in the study group (93.33%) was significantly greater than that in the control group (66.67%).* ***Conclusion:*** *Ijin Granules had a significant effect on nausea and vomiting, improved QoL and intake in pregnant women with HG, when combined with fluid replacement therapy, it promotes the healthy pregnancy.*

Key words: Ijin Granules, Hyperemesis Gravidarum, Pregnant Women.

Article Information

Received: June 13, 2025; Revised: July 30, 2025; Online: September 2025

1. INTRODUCTION

Hyperemesis Gravidarum (HG) is a common early pregnancy syndrome that usually occurs around 4 to 5 weeks of gestation, which is initiated with sour throw-up from the empty stomach in the morning, disgusting to smell, change of appetite, and exacerbated with severe nausea, frequent vomiting, and inability to eat, which gives side effects on quality of life and health of the pregnant woman. Usually the symptoms resolve naturally after 12 weeks of pregnancy, but some pregnant women continue to have severe early pregnancy reactions. The pregnant women with HG easily vomit food,

https://doi.org/10.46966/msjar.v6i3.299

gastric juice and even bile juice, which repeats over 10 to 20 times a day. They can't take water as well as food so that the body weight decreases, and might cause the detection of ketone bodies in blood and acetone bodies in urine, electrolyte imbalance and dehydration. HG, of which incidence is 0.5-2.0%, causes maternal and fetal complications such as Mallary-Weiss syndrome, Wernicke's encephalopathy, hypokalemia, low birth weight and so on. If not treated in time or properly it gives great side-effects on maternal and fetal health[1]. The etiology of this syndrome remains unclear, but appears to be significantly related to multiple pregnancy, digestive dysfunction, hormonal change, vestibular disturbance, Helicobacter pylori infection, genetic factors and so on[2]. The important things in non-pharmacological treatment of HG are to avoid the environmental factors such as smell of food and smoke, irritating perfume, staying in the room with poor air-condition, noise, flickering light, and the life factors such as brushing teeth after meal, sudden change in body position, insufficient rest, and to take the soft, plain and unstimulating meals in small amount in several times (4 to 6 times a day) so that the pregnant women don't feel hungry.

Now antiemetics involving antihistamine, phenothiazine, Vitamin B1 and B6, metoclopramide and ondansetrone are used for HG, and steroids are recommended for the last choice but they are limited in use from the fear that chemical medicine is a risk to pregnancy. Ijin granules is made in the granular form from the Ijin broth that is a traditional phlegm-resolving medicine, which consists of prepared Pinellia ternate, orange peel, poria cocos, licorice and ginger, which is used for the treatment of feeling oppressed in the chest, feeling heavy in the stomach, coughing, a large amount of sputum, nausea and vomiting, and also modern medically used in many fields including internal medicine, surgery, gynecology, pediatrics, ENT and so on. Therefore we performed the clinical study on the treatment of HG with Ijin granules consisted of some Koryo medicines such as ginger that is generally used for the control of nausea and vomiting, combined with fluid replacement therapy.

2. SUBJECTS AND METHODS

2.1. Subjects

Between Jaunary 2024 and December 2024, 60 cases of HG were enrolled in the study at Pyongyang Maternity Hospital, Pyongyang, Democratic People's Republic of Korea. The patients were randomly divided into study group (30 cases) and control group (30 cases).

The clinical information of the subjects is shown in the **(Table 1**).

Table1. Clinical information of the subjects.

Variables	Control group(n=30)	Study group(n=30)	P-value
Age (year)			
<=25	**14(46.7)**	**12(40.0)**	**0.602**
>25	**16(53.3)**	**18(60.0)**	
Gestational age(week)			
≦12	**26(86.7)**	**25(83.3)**	**0.718**
＞12	**4(13.3)**	**5(16.7)**	
Gravidity			
Primigravida	**16(53.3)**	**17(56.7))**	**0.795**
multigravida	**14(46.7)**	**13(43.3)**	
PUQE-score			
≦12	**16(53.3)**	**15(50.0)**	**0.796**
＞12	**14(46.7)**	**15(50.0)**	

P-value: comparison of control group and study group.

- Inclusion Criteria

1) Pregnant women who has met the diagnostic criteria for HG described in the "Obstetrics and Gynecology" 6th edition [3] (persistent vomiting, weight loss greater than 5% of prepregnancy body weight, and ketonuria).

2) Normal cognition, basic communication and understanding ability.

- Exclusion criteria

1) Hydatidiform mole.

2) Vomiting caused by medical diseases such as viral hepatitis, cholecystitis, entrance of roundworm into biliary tract, pancreatitis.

3) Pregnancy-related diseases such as preeclampsia and acute hepatic steatosis during pregnancy.

4) Those who suffers from severe disease in the vital organs such as heart, liver, kidney and so on.

5) History of mental disease.

6) Poor communication with the patient.

2.2. Method

2.2.1. Control group

The patients were generally advised to eat the soft, not-salty-enough, not-hot and vitamin rich food in a small amount and in several times a day, and to take sufficient rest and sound sleep.

In addition the patients were informed about the cause, symptoms, treatment and experience in the treatment of the HG so that they could get the basic knowledge on the HG and they might have the confidence in the treatment. Fluid replacement therapy involves the instillation of Ringer lactate and 5% glucose of which total amount is set according to the patient's condition. Commonly 500~1 500mL of fluid was given intravenously a day. In the patients with severe dehydration the fluid therapy is given as soon as possible, a large amount of fluid on day 1 and then the amount was reduced according to how improved the patient's vomiting and intake. 7 days was a course of the treatment.

2.2.2. Study group

In addition to the same treatment in the control group, Ijin Granules was orally given at a dose of 5.0g 60 to 90 minutes after meal with warm water 3 times a day. 7 days was a course of the treatment. The ingredients of Ijin Granules are processed ternate pinella, orange peel, poria cocos, licorice and ginger.

2.2.3. Observation indicators

1) Pregnancy-unique quantification of emesis and nausea (PUQE) score was used to evaluate the improvement of nausea, vomiting and dry vomiting in pregnant women respectively before and 7 days after the treatment[4, 9].

2) Quality of life (QOL) and self-rating depression scale (SDS) were used to evaluate the improvement of life quality and mental status of the pregnant women respectively before and 7 days after the treatment.QOL was assessed from score 0 (the worst) to 10 (as best as before pregnancy) to be good or poor in pregnant women. SDS score consists of 20 items and the score was assessed by the frequency of the symptom.

3) The improvement of intake amount 7 days after treatment was assessed as compare to that before treatment on the basis of that before pregnancy (100%).

4) Observing acetone bodies in urine before and during the treatment the period to get negative was assessed, and the period to discontinue vomiting was also assessed.

5) The clinical effect between the two groups was compared.

2.2.4. Efficacy evaluation[5]

Obviously effective: disappearance of nausea and vomiting, recovery of the intake amount to that before pregnancy, negative ketone bodies in urine. Effective: Marked disappearance of nausea and vomiting, improved appetite and increased intake amount, lowered ketone bodies in urineIneffective: continuance of nausea and vomiting, no

improvement in intake amount, positive ketone bodies in urine. Total effective rate=obviously effective rate + effective rate.

2.2.5. Statistical analysis

We used Chi-square test and t test, and considered P < .05 as statistically significant. All analyses were performed with SPSS version 24.0.

3. RESULTS

3.1. Comparison of PUQE-score between the study group and the control group

Before treatment, the scores of question 1(length of nausea) and Question 2(rate of vomiting), Question 3(rate of retching) and PUQE-score (Sum of Question 1, 2 and 3) were not significantly different between the study group and the control group. After treatment, PUQE-scores in the study group were significantly lower than those in the control group (P < 0.01, P < 0.001), as shown in **(Table 2).**

Table 2. Comparison of PUQE-scores before and after treatment in the study group and the control group ($\bar{X}$±*SE*).

Variables	Control group(n=30)			Study group(n=30)		P-value
	Before treatment	After treatment		Before treatment	After treatment	
Question 1 score (length of nausea)	4.17±0.23	3.43±0.20**		4.20±0.23	2.50±0.19***	0.001
Question 2 score (rate of vomiting)	3.90±0.21	2.17±0.22***		4.03±0.21	1.57±0.16***	0.033
Question 3 score (rate of retching)	4.03±0.21	2.90±0.28***		4.00±0.28	2.13±0.22***	0.034
PUQE-score	12.10±0.47	8.50±0.51***		12.23±0.40	6.20±0.45***	0.001

P-value: Comparison of scores after treatment in control group and study group **: P < 0.01, ***: P < 0.001.

3.2. Comparison of QOL-scores, SDS scales and the amount of intake between the study Group and the control Group

Before treatment, QOL-scores, SDS scales and the amount of intake were not significantly different between the study group and the control group. After treatment, QOL-scores and the amount of intake in the study group were significantly lower than those in the control group (P < 0.001), and SDS scales was significantly lower than those in the control group (P < 0.05, P < 0.01), as shown in **(Table 3)**.

Table 3. Comparison of QOL-scores, SDS scales and the amount of intake before and after treatment in the study group and the control group ($\bar{X}$±*SE*).

Variables	Control group(n=30)			Study group(n=30)		P-value
	Before treatment	After treatment		Before Treatment	After Treatment	
QOL-scores	4.17±0.23	3.43±0.20**		4.20±0.23	2.50±0.19***	0.001
SDS scales	3.90±0.21	2.17±0.22***		4.03±0.21	1.57±0.16***	0.033
the amount of intake (%)	12.10±0.47	8.50±0.51***		12.23±0.40	6.20±0.45***	0.001

P-value: Comparison of scores after treatment in control group and study group **: P < 0.01, ***: P < 0.001.

3. 3. Comparison of urine ketone body negative time and antiemetic time between the study group and the control group

The study group had significantly shorter Urine ketone body negative time and antiemetic time than the control group. The difference was statistically significant (P < 0.05). See **(Table 4)**.

Table 4. Comparison of urine ketone body negative time and antiemetic time between the study group and the control group ($\bar{X}$±*SE*,).

Variables	Control group(n=30)	Study group(n=30)	P-value
Urine ketone body negative time	5.37±0.39	3.88±0.25	0.002
Antiemetic Time	5.70±0.40	4.26±0.30	0.009

P-value: Comparison of control group and study group.

3. 4. Comparison of clinical efficacy between the study group and the control group

After 7 days of the treatment, the total effective rate (93.33%) in the experimental group was significantly higher than the 66.67% in the control group. See **(Table 5)**.

Table 5. Comparison of clinical efficacy between the study group and the control group

Group	Most effective	Less Effective	No effect	Total effectiveness rate (%)
Study group (n=30)	20	8	2	28(93.33)
Control group(n=30)	10	10	10	22(66.67)
P-value				0.010

P-value: Comparison of control group and study group.

3.5. Safety

During the study no side-effects such as stomachache, diarrhea and so on were reported.

4. DISCUSSION

Early pregnancy reactions are more common in the early stages of pregnancy, which is generally mild and naturally relieved without any specific treatment. The response does not have a significant impact on normal life. However, in severe HG, frequent nausea and vomiting, inability to eat and electrolyte imbalance are caused, which seriously threatens the life and health of pregnant women. Studies have shown that HG can reduce the weight of pregnant women, prolong the labor process, increase the rate of cesarean section and the risk of low birth weight infants[6]. Recently HG appears to be related to some factors such as changes in hormone level, mental disorder, malnutrition, Helicobacter pylori infection and psychological disorder[7]. The diagnosis criteria of HG according to ACOG involves nausea and vomiting without other causes, laboratory findings of malnutrition (ex: ketonuria, electrolyte imbalance, acid-base imbalance), and body weight loss that is a reduction less that 5% of pre-pregnency weight[8].International classification of diseases 10 (ICD 10) defines HG as lasting weakness, nausea and vomiting before 22 weeks of gestation, which is divided into the mild form

and the severe form such as metabolic diseases involving metabolic alkalosis and dehydration, or electrolyte imbalance involving hypokaliemia and hypochloremia[9].

The pathophysiology of HG is not understood and there is no specific treatment for it. In the treatment the fluid replacement therapy is firstly recommended and the antiemetic drugs (antihistamine, phenothiazine, serotonin receptor antagonists, proton pump inhibitor, vitamin, corticosteroids) are also proposed. However some women avoid using these drugs during embryogenesis from the fear of teratogenesis. The treatment of HG involves some traditional medicines, such as Yirentang[10], Jiaweirenshentutang[11] and ginger[12], which has some effectiveness to improve nausea and vomiting in HG. We performed the clinical study to treat HG with Ijin granules in addition to fluid replacement therapy. Ijin granules consists of some Koryo medicines including ginger, which is widely used in many fields such as internal medicine, gynecology, pediatrics, ENT and so on. According to our study results, PUQE score after the treatment in study group was 6.20±0.45, which was significantly lower than the score 8.50±0.51 in control group (P=0.001). And the QOL score and intake amount after treatment in the study group was significantly increased comparing to that in the control group (respectively P=0.047, P=0.008), but SDS scale after treatment in the study group was significantly decreased comparing to that in the control group (P=0.043).Our study results demonstrated that the period to get negative of acetone bodies in urine and the period to discontinue vomiting in study group were significantly decreased comparing to those in control group (respectively P=0.002, P=0.009).The above study results show that Ijin granules is an effective drug to treat HG, which is suggested by the pharmacological action of natural substances including zingerone, the major constituent of ginger and glycyrrhizin, the major constituent of licorice.No significant side-effects in both study and control groups were observed, which indicates Ijin granules and fluid replacement therapy are safe.

However, to establish the more generalized treatment requires the comprehensive study with different age groups. And further study should be done for the clinical introduction.

5. CONCULSION

This study used Ijin Granules and fluid replacement therapy for pregnant women with HG. The total effective rate of treatment in the study group (93.33%) was significantly greater than that in the control group (66.7%). 7 days after treatment PUQE score and SDS score in the study group was lower than that in the control group, and QOL score and intake amount in the study group was significantly higher than that in the control group. This shows that Ijin Granules combined with fluid replacement therapy improves markedly nausea and vomiting in pregnant women with HG, and can promote their quality of life and healthy pregnancy.

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