Research Paper

Clinical Efficacy and Hemorheology Study of Combination of Three Drugs for Puerperal Hemorrhage Treatment

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The main objective of this study is to explore the clinical effect and hemorheology changes of the three drugs combination (misoprostol tablets and Chanfukang granules combined with oxytocin) in the treatment of postpartum hemorrhage in puerpera. 80 postpartum women admitted from November 2014 to January 2022 were divided into study and control groups and were given different drug treatments. After taking the medication, the total efficacy, changes in bleeding scores, height of uterine fundus after 3 d of medication, uterine involution after 10 d of medication, blood rheology changes, milk secretion volume, breast fullness, etc. were observed at different time periods before and after postpartum. After taking the medication, the bleeding score of the study group was better than that of the control group, and the height of uterine fundus was higher than that of the control group. After 10 d of medication, there were statistically significant differences in whole blood low-shear, high-shear viscosity, plasma viscosity, fibrinogen, and red blood cell aggregation index between the study group and the control group ($p<0.05$). After 3 and 10 d of medication, the lactation scores of the study group were significantly better than those of the control group ($p<0.05$). The combined application of misoprostol tablets, Changfukang granules and oxytocin can effectively treat postpartum hemorrhage in postpartum women and increases postpartum milk production with high safety.

Key words: Chanfukang granules, misoprostol tablets, oxytocin, puerperal hemorrhage, hemorheology

Currently, with the adjustment of China's family planning policy, the number of pregnant women in multiple regions of the country is showing an upward trend. According to relevant data in recent years, there have been over 20 million of postpartum women in China every year. During the process of postpartum involution, nearly 70 % of women have varying degrees of uterine involution, which is known as postpartum hemorrhage in Tradititional Chinese medicine. A hemorrhage that lasts for more than 10 d and still cannot be fully drained is called "postpartum hemorrhage", also known as "incomplete bleeding" or "continuous bleeding"[1]. Meanwhile, with the increasing awareness of the importance of breastfeeding in society, breastfeeding is becoming increasingly popular in modern households[2]. Even for a very healthy and uncomplicated postpartum woman, there is a possibility of postpartum hemorrhage and milk deficiency. We use modern medical methods and corresponding detection methods to conduct scientific statistical analysis of the obtained clinical research data and preliminarily explore the clinical efficacy of misoprostol tablets and Chanfukang granules combined with oxytocin in the treatment of postpartum hemorrhage in postpartum women. At the same time, we observed its impact on lactation and the safety of drug use, promoting a safe, convenient, and effective method for clinical development of a specific formula with precise therapeutic effects.

MATERIALS AND METHODS

Patient's data:

80 postpartum women were all selected from the obstetrics and gynecology inpatients of Tongde Hospital in Zhejiang Province from November 2014 to January 2022.

Inclusion criteria:

Patients with age >20 y old and <35 y old with around 37 w to 41 w of pregnancy; patients who have undergone transvaginal delivery in our hospital; newborns with a birth weight between

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2500 and 4000 g; women who are willing to breastfeed; pregnant women without coagulation disorders; no prostaglandin inhibitors have been used in the last few months and there are no contraindications to misoprostol; patients with postpartum hemorrhage caused by uterine atony and vaginal bleeding exceeding 500 ml and patients who volunteered to participate in research and sign an informed consent form.

Exclusion criteria:

Patients with twins or multiple pregnancies; patients with serious comorbidities such as hematological diseases, mental illnesses, malignant tumors, etc.; patients with breast dysplasia and individuals with anatomical defects in the breast; women with age >35 y old or <20 y old; contraindications to misoprostol in pregnant women; pregnant women with underlying diseases, such as liver and kidney dysfunction, hypertension, heart disease, etc.; pregnant women with abnormal coagulation function and pregnant women who are unwilling to participate are excluded from the study.

Termination criteria:

Pregnant women who experience adverse reactions during the medication process, such as rashes, stomach discomfort, etc.; mother experienced other complications during the clinical observation; patients who fail to complete all observation indicators as required; patients who withdraw their consent midway and during the clinical medication observation period, the mother underwent other treatments due to complications.

Research methods:

Grouping method: A single blind, randomized controlled design was conducted on the enrolled postpartum women for clinical research. Based on the allocation principle of minimum imbalance index and based on age, gestational age, and infant weight factors patients are randomly divided into two groups, namely the study group and the control group.

Study group: Oral administration of misoprostol tablets combined with Chanfukang granules on the day of postpartum delivery.

After the fetus is delivered and the amniotic fluid is drained, a disposable sterile waterproof paper pad is placed under the buttocks of the postpartum woman. When the perineum is sutured, the bleeding amount is calculated using the gauze weighing method (1.05 g of blood is equivalent to 1 ml as per the standard)-

Blood loss=Wet weight of the dressing after delivery-dry weight of the dressing before delivery

After the fetus is delivered, the vaginal bleeding amount before and after the placenta excluding the bleeding from soft birth canal lacerations is determined as >500 ml. Immediately administer routine 20 IU intramuscular injection of oxytocin to postpartum women, while also administering 600 μg misoprostol tablets orally with 30 ml of warm water or 10 % glucose water or insert misoprostol into the rectum of the postpartum woman at a depth of 6 cm. After fully dissolving the misoprostol, remove the finger. Observe the amount of bleeding, duration of bleeding, and enhancement of uterine contractions, and repeat administration if necessary.

Chanfukang granules were administered orally on the day of postpartum among postpartum women. 1 bag of Chanfukang granules (Shenzhen Sanshun Pharmaceutical Co., Ltd. Production national drug approval number: Z20003385) was given 3 times a day (in the form of a decoction) continuously for 10 d.

Control group: Pregnant women were immediately given routine 20 IU intramuscular injection of oxytocin after delivery and similarly Chanfukang granules were administered orally on the day of postpartum as study group.

Clinical observations:

Observation of drug efficacy: The changes in bleeding volume, color, and quality were recorded before medication, every 2 h and 24 h after medication, and every 3rd d and 10th d after medication. After 10 d of delivery, follow up was conducted at the outpatient clinic and if the postpartum bleeding occurs, symptoms were recorded and patients were guided with proper medical treatment.

To determine the uterine involution, the height of the uterine fundus was determined and recorded for every 3rd d and 10th d after medication. Hemorheology test was conducted once before medication and 3rd d and 10th d after medication. The breast filling, lactation volume and neonatal lactation status of the two groups of postpartum

women was observed on the 3rd d and 10th d after delivery.

Observation of drug safety: All patients were checked for blood routine, urine routine, liver and kidney function, and electrocardiogram before and after medication. Potential adverse events that may occur during the medication process were recorded including the date of onset, duration of adverse event, severity, whether measures were taken, and relationship with the study drug, outcome of adverse events that occurred, and whether the mother withdrew from observation as a result of adverse event.

Evaluation criteria for efficacy:

Based on the "Standards for the Diagnosis and Efficacy of Tradititional Chinese Medicine Diseases and Syndrome", the clinical observation and evaluation criteria like postpartum hemorrhage scoring table; record form of postpartum uterine floor height; evaluation form for postpartum lactation in maternal women were observed. This standard was issued by the State Administration of Tradititional Chinese Medicine and published by China Medical Science and Technology Press in November 2012.

Based on the integral method to determine the total therapeutic effect of Tradititional Chinese medicine syndromes:

Efficacy index (N)=((Pre medication bleeding score-bleeding score after 10 d of medication)/Pre medication bleeding score)×100 %

The score implies N≥90 % means complete recovery, 66.67 %≤N<90 % indicates significantly effective, 33.3 %≤N<66.67 % indicates effective and N<33.3 % indicates invalid.

Statistical analysis:

The data obtained during clinical observation were represented by mean ($\bar{x}\pm s$), standard deviation for measurement data, t-test for count data, Chi-square (χ^2) test for count data and rank sum test for ranking data. All data were analyzed using Statistical Package for the Social Sciences (SPSS) version 16.0 statistical software.

RESULTS AND DISCUSSION

The general characteristics between two groups of postpartum women were compared as shown in Table 1. There was no significant difference in general information such as age, weight, gestational age and infant weight between the two groups of postpartum women (p>0.05).

The therapeutic effects between two groups of postpartum women were compared as shown in Table 2. After medication, the total effective rate of the study group is 100 %, while the total effective rate of the control group is 97.5 %. There was no significant difference in the total effective rate between the two groups after 10 d of medication (p=0.314>0.05).

TABLE 1: COMPARISON OF GENERAL INFORMATION BETWEEN THE TWO GROUPS OF POSTPARTUM PATIENTS ($\bar{x}\pm s$)

Group (n=40)	Age (years)	Weight (kg)	Gestational week (weeks)	Infant weight (kg)
Study	27.80±2.11	70.03±3.11	38.75±1.72	3.32±0.28
Control	28.12±2.05	70.15±3.18	38.80±0.85	3.24±0.27
t	-0.07	-0.18	-0.17	1.11
p	0.49	0.86	0.87	0.27

TABLE 2: COMPARISON OF EFFICACY RATES BETWEEN THE TWO GROUPS OF POSTPARTUM PATIENTS (%)

Group (n=40)	Recovery	Significant effective	Effective	Invalid	Total effective rate
Study	26 (65 %)	10 (25 %)	4 (10 %)	0 (0 %)	100 %
Control	17 (42.5 %)	16 (40 %)	6 (15 %)	1 (2.5 %)	97.50 %

Before and after medication, the bleeding volume scores between two groups of postpartum women were compared as shown in Table 3. This study adopted a weighing method by using gauze, toilet paper or non-woven fabric to make a menstrual pad to absorb blood. Weigh it before use and then weigh the blood-stained pad and plug it into the formula to get the blood volume.

Bleeding volume (ml)=(Blood cushion (g)-weight before use)/1.051 g

Before medication, the bleeding volume scores between the two groups was $p>0.05$. After 3 d and 10 d of medication, the bleeding volume scores between the two groups were $p<0.05$ and $p>0.05$, respectively. Before and after medication, the bleeding volume scores of the control group and study group were $p<0.05$ and $p>0.05$, respectively.

Before and after medication, the height of uterine fundus between two groups of postpartum women was compared as shown in Table 4. There was a significant difference between the study group and the control group on the 3rd d of postpartum ($t=3.88$, $p=0.00<0.05$). The height of uterine fundus decline in the study group was higher than that in the control group, indicating that the uterine involution in the study group was better than that in the control group after 3 d of medication.

There was no significant difference in uterine involution between the study group and the control group on the 10th d of postpartum ($\chi^2=0.56$, $p=0.46>0.05$), indicating that the study group and the control group had similar therapeutic effects on uterine involution after 10 d of medication (Table 5).

Before medication, there was no significant difference in the data of hemorheology between the study group and the control group ($p>0.05$), indicating that there was no difference in hemorheology indicators between the two groups. After 3 d of medication, there was no significant difference ($p>0.05$) between the study group and the control group in terms of whole blood low shear reduction viscosity, whole blood high shear reduction viscosity, fibrinogen and red blood cell aggregation index. However, there was a significant difference in plasma viscosity indicators between the two groups ($t=-3.36$, $p=0.00<0.05$). After 10 d of medication, there were significant differences ($p<0.05$) between the study group and the control group in terms of whole blood low shear reduction viscosity, whole blood high shear reduction viscosity, plasma viscosity, fibrinogen, and red blood cell aggregation index. All the indicators in the study group were lower than those in the control group and there was a significant difference in all the indicators between the two groups before and after 10 d of medication.

TABLE 3: COMPARISON OF BLEEDING VOLUME SCORES BETWEEN THE TWO GROUPS OF POSTPARTUM PATIENTS

Group (n=40)	Postpartum bleeding volume				
	Before medication	After 2 h of medication	After 24 h of medication	After 3 d of medication	After 10 d of medication
Study	538±12.84	110.45±14.34	174.65±12.89	6.73±1.66	1.30±1.13
Control	539±11.73	198±14.78	282.58±12.76	12.28±1.67	5.60±1.39

TABLE 4: COMPARISON OF THE HEIGHT OF UTERINE FUNDUS BETWEEN THE TWO GROUPS OF POSTPARTUM PATIENTS ON THE 3rd D OF POSTPARTUM (mm)

Group	Number of cases	Medication for 3 d	t	p
Study	40	31.68±2.99	3.88	<0.05
Control	40	28.88±3.44		

TABLE 5: COMPARISON OF UTERINE INVOLUTION BETWEEN TWO GROUPS OF POSTPARTUM WOMEN ON THE 10th D AFTER DELIVERY

Group	n	Palpable on the pubic symphysis	Not palpable on the pubic symphysis	χ^2	p
Study	40	3	37		
Control	40	5	35	0.56	0.46
Total	80	8	72		

Through the above observation, we found that there is a difference in hemorheology indicators of the enrolled women before and after medication, but the differences were within the normal range. Various indicators of hemorheology can reflect the blood viscosity. From the test results of various indicators, we found that both the study group and the control group can reduce the blood viscosity, but the study group decreased more, indicating that the study group improved the blood viscosity especially after 10 d of medication (Table 6).

After medication, lactation scores between two groups of postpartum women were compared as shown in Table 7. There is a significant difference in lactation scores between the study group and the control group after 3 d of medication (Wilcoxon W=1412, p=0.04<0.05). The lactation score of the study group and control group above 4 points is 70 % (28/40) and 37.5 % (15/40), respectively. The lactation performance of the study group is significantly better than that of the control group after 3 d of medication.

There is a significant difference in the lactation score between the study group and the control group after 10 d of medication (Wilcoxon W=1264, p=0.00<0.05). The lactation score of the study group and control group above 4 points is 92.5 % (37/40) and 70 % (28/40), respectively. After 10 d of medication, the lactation performance of the study group is significantly better than that of the control group (Table 8).

After medication, the breast fullness scores between two groups of postpartum women were compared as shown in Table 9. There is a significant difference in breast fullness scores between the study group and the control group after 3 d of medication (Wilcoxon W=1390, p=0.02<0.05). The breast fullness score of the study group and control group above 4 points is 72.5 % (29/40) and 37.5 % (15/40), respectively. The breast fullness of the study group after 3 d of medication is significantly better than that of the control group.

There is a significant difference in breast fullness scores between the study group and the control group after 10 d of medication (Wilcoxon W=1201, p=0.00<0.05). The breast fullness score of the study group and control group above 4 points is 92.5 % (37/40) and 67.5 % (27/40), respectively. The study group had significantly better breast fullness scores than the control group after 10 d of medication (Table 10).

TABLE 6: CHANGES OF HEMORHEOLOGY INDICATORS IN THE STUDY GROUP AND THE CONTROL GROUP BEFORE AND AFTER MEDICATION

Hemorheology indicators	Study group (n=40)			Control group (n=40)		
	Before medication	Medication for 3 d	Medication for 10 d	Before medication	Medication for 3 d	Medication for 10 d
Whole blood low shear	41.23±2.51	36.78±1.96	30.69±1.59$^{\Delta}$	40.36±2.84$^{\#}$	36.77±2.06$^{\#\#}$	31.79±3.01**$^{\Delta}$
Whole blood high shear	7.23±0.44	6.22±0.33	5.25±0.27$^{\Delta}$	7.08±0.50$^{\#}$	6.27±0.35$^{\#\#}$	5.43±0.51**$^{\Delta}$
Plasma viscosity	1.38±0.08	1.24±0.07	1.32±0.07$^{\Delta}$	1.35±1.10$^{\#}$	1.29±0.07*	1.38±0.09**$^{\Delta}$
Fibrinogen	4.13±0.25	3.47±0.20	2.87±0.15$^{\Delta}$	4.04±0.28$^{\#}$	3.50±0.20$^{\#\#}$	3.02±0.19**$^{\Delta}$
Erythrocyte aggregation index	5.85±0.32	4.93±0.23	4.24±0.22$^{\Delta}$	5.74±0.36$^{\#}$	4.99±0.25$^{\#\#}$	4.69±0.21**$^{\Delta}$

Note: $^{\#}$p>0.05, indicates no significant difference in hemorheology indexes between the two groups before medication; $^{\#\#}$p>0.05, indicates no significant difference in hemorheology indexes (except plasma viscosity) between the two groups after 3 d of medication; *p<0.05, indicates significant difference in plasma viscosity between the two groups after 3 d of medication; **p<0.05, indicates significant difference in hemorheology indexes between the two groups after 10 d of medication and $^{\Delta}$p<0.05, indicates significant difference in hemorheology between the two groups before and after treatment

TABLE 7: COMPARISON OF LACTATION SCORES BETWEEN THE STUDY GROUP AND THE CONTROL GROUP AFTER 3 D OF MEDICATION

Group	n	0 points	2 points	4 points	6 points	Wilcoxon W	p
Study	40	2	10	22	6		
Control	40	8	17	12	3	1412	0.04
Total	80	10	27	34	9		

TABLE 8: COMPARISON OF LACTATION SCORES BETWEEN THE STUDY GROUP AND THE CONTROL GROUP AFTER 10 D OF MEDICATION

Group	n	0 points	2 points	4 points	6 points	Wilcoxon W	p
Study	40	0	3	10	27		
Control	40	2	10	14	14	1264	<0.05
Total	80	2	13	40	45		

TABLE 9: COMPARISON OF BREAST FULLNESS BETWEEN THE TWO GROUPS OF POSTPARTUM WOMEN AFTER 3 D OF MEDICATION

Group	n	0 points	2 points	4 points	6 points	Wilcoxon W	p
Study	40	2	9	24	5		
Control	40	9	16	13	2	1390	0.02
Total	80	11	25	37	7		

TABLE 10: COMPARISON OF BREAST FULLNESS BETWEEN THE TWO GROUPS OF POSTPARTUM WOMEN AFTER 10 D OF MEDICATION

Group	n	0 points	2 points	4 points	6 points	Wilcoxon W	p
Study	40	0	3	13	24		
Control	40	2	11	13	14	1201	<0.05
Total	80	2	14	26	38		

Western medicine is used to treat incomplete uterine involution in postpartum women[3-5]. For patients with low vaginal bleeding, antibiotics and drugs that promote uterine contractions are usually given. For patients with high vaginal bleeding, curettage should be performed and sufficient broad-spectrum antibiotics, uterine contractions, and symptomatic supportive therapy should be given[6,7]. In order to promote uterine contractions, except for the use of medication, breastfeeding is a win-win method. Clinical studies have shown that if postpartum women breastfeed in a timely manner, i.e. suck early, it can promote the production of oxytocin, which causes uterine contractions and helps prevent postpartum bleeding, which can promote uterine involution to some extent[8-12]. Breast milk is rich in nutrients, easy to absorb and utilize, and helps babies grow[13-16]. However, Western medicine lacks a convenient and effective method for treating postpartum milk deficiency in postpartum women. Lin *et al.* reported that metoclopramide can increase the secretion of prolactin, thereby promoting milk secretion, but it is difficult to be widely applied in clinical practice[16-20]. We have summarized years of experience in clinical practice, combined with the basic theories of Tradititional Chinese medicine and the research viewpoints of past renowned experts in this study. Misoprostol tablets combined with Chanfukang granules have the effects of tonifying qi and nourishing blood, promoting blood circulation and resolving stasis, and clearing the meridians to improve the milk flow. They can enhance maternal immunity, promote uterine involution, reduce postpartum bleeding, promote the secretion of postpartum milk and improve breastfeeding rates[21-25]. These two complement each other and achieve good results in treating postpartum hemorrhage in postpartum women.

Based on the observations of this study, it was found that the combination of misoprostol tablets and Chanfukang granules with oxytocin can significantly improve the postpartum bleeding score of postpartum women, alleviate maternal pain and change the bleeding score after 3 d of oral administration. The study group was significantly better than the control group ($p<0.05$). There was no significant difference in bleeding score between the study group and the control group after 10 d of oral administration ($p>0.05$), indicating that the efficacy of the study group and the control group was comparable. After 10 d of oral administration compared to before medication, there was a significant decrease in bleeding scores between the study group and the control group ($p<0.05$). This indicates that both groups of drugs can improve patient bleeding, while the study group has a

better improvement effect than the control group after 3 d of oral administration. This indicates that the combination of misoprostol tablets and Chanfukang granules with oxytocin and oxytocin combined with Chanfukang granules can improve maternal bleeding earlier.

We found that there was a significant difference in the height of uterine fundus between the study group and the control group on the 3rd d of postpartum ($p \leq 0.05$). The height of uterine fundus in the study group was higher than that in the control group, indicating that the uterine involution in the study group was better than the control group on the 3rd d of postpartum. There was no significant difference in uterine involution between the study group and the control group on the 10th d of postpartum ($p > 0.05$). The comparative efficacy of the study group and the control group on uterine involution after 10 d of medication is similar. After 3 d of medication, the height of uterine decline in the study group was higher than the control group, indicating that misoprostol tablets and Chanfukang granules combined with oxytocin can promote uterine involution earlier than Chanfukang granules combined with oxytocin.

Misoprostol tablets and Chanfukang granules combined with oxytocin can significantly improve the hemorheology indicators of pregnant women. Through clinical observation, we found that misoprostol tablets and Chanfukang granules combined with oxytocin can reduce the whole blood low shear reduction viscosity, whole blood high shear reduction viscosity, plasma viscosity, fibrinogen, and erythrocyte aggregation index indicators, improve the blood viscosity. After 10 d of medication, by observing the hemorheology indexes of the parturient, it was found that they were all reduced, and there was a significant difference before and after medication ($p < 0.05$). From the data obtained, we found that misoprostol tablets and Chanfukang granules combined with oxytocin can improve the maternal hemorheology indicators more significantly compared to Chanfukang granules combined with oxytocin. Hemorheology indicators indicate the fluidity, stagnation and viscosity of blood in the body. We found that the data of hemorheology of the enrolled puerpera before medication were on the high side, indicating that the blood fluidity in the body was lower than normal, the blood viscosity was high, and it was easy to be silted up into thrombi. Through oral medication, all indicators of hemorheology of parturient women decreased, indicating that misoprostol tablets and Chanfukang granules combined with oxytocin can improve the blood fluidity and blood viscosity of parturient women compared with Chanfukang granules combined with oxytocin.

During the clinical medication process, we always monitor maternal blood and urine routine, liver and kidney function, and other indicators. All pregnant women did not show significant abnormalities in various indicators during the oral medication process, and no adverse reactions such as decreased appetite, nausea, vomiting, or drug allergies such as rashes were found during the medication period. Therefore, this formula is safe for clinical use.

This study confirms that the combination of misoprostol tablets and Chanfukang granules with oxytocin has a certain therapeutic effect on postpartum hemorrhage in postpartum women. The combination of misoprostol tablets and Chanfukang granules with oxytocin can improve the Tradititional Chinese medicine symptoms of postpartum women, reduce pain, promote uterine involution, increase lactation and breastfeeding rates[26-28]. However, further research is needed to determine it true mechanism of action.

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Conflict of interests:

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