The Comparison of the Effect of Carboprost Suppository Combined with Romethamine and Carboprost Suppository Combined with Oxytocin in the Prevention of Hemorrhage after Cesarean Section

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Abstract The postpartum hemorrhage increases with the increasing use of cesarean section, one of the common methods of delivery. In order to improve the postoperative safety of women with cesarean section, an effective strategy to prevent bleeding after cesarean section is extremely important. This study compares the preventive effects of carboprost with carboprost tromethamine and carboprost with oxytocin on postpartum hemorrhage of cesarean section, which will provide reference for clinical effective prevention of bleeding after cesarean section. A prospective analysis was performed on 349 cases of cesarean section puerperants. According to the treatment method, they were divided into two groups: carboprost suppository combined with oxytocin group (control group) and carboprost suppository combined with romethamine group (study group). The general data, hemodynamic parameters [heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and blood oxygen saturation(SpO2)], incidence of adverse reactions, bleeding, uterine recovery and drug efficacy of the patients were compared. There were no differences in hemodynamic indexes between the two groups before medication (P> 0.050). After medication, the HR, SBP, and DBP of the study group were lower than those of the control group, and SpO2 of the study group was higher than that of the control group (P <0.001). The HR and SpO2 of the two groups after medication were higher than those before medication, while the SBP and DBP were lower than those before medication (P <0.050). The total postoperative bleeding volume in the study group was lower than that in the control group (P <0.05); the postoperative bleeding rate in the study group was lower than that in the control group (P <0.05). The uterine return in the study group was better than that in the control group (P <0.05). The total effective rate of the control group was higher than that of the control group (P<0.05). The combination of carboprost suppository and romethamine can better prevent the bleeding after cesarean section, and it is worth popularizing and developing.

Key words: postoperative hemorrhage (POH), oxytocin, carboprost suppository, cesarean postpartum hemorrhage.

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Postpartum hemorrhage means that the amount of bleeding within 24 hours after delivery is more than 500 ml, and if the loss reaches 1000 ml, it is considered as severe postpartum hemorrhage (1-3). Postpartum hemorrhage is a common and serious complication in obstetrics and the main cause of death and morbidity in pregnant women worldwide (4). Postpartum hemorrhage occurs in 3% to 5% of obstetrical patients (5), and is common in patients without risk factors of hemorrhage (6). In recent years, with the increase of cesarean delivery rate in China (7), the problem of postoperative bleeding in cesarean section has been paid more and more attention. Some studies have shown that the risk of cesarean section bleeding is significantly higher than that of vaginal delivery (2,8-9). Uterine inertia is one of the main causes of postoperative bleeding (10), but it may also be caused by genital trauma, hysterorrhexis, mazischesis or maternal coagulation disorder (2). Although remarkable progress has been made in the treatment of postoperative bleeding, the development of preventive measures is worse than that of the former (11). Therefore, finding an effective way to prevent bleeding after cesarean section is the fundamental to improve the safety of cesarean section, which is also the current research hotspot and difficult point.

Studies have shown that active administration of oxytocins during the third stage of labor may reduce the incidence of postoperative bleeding (12-15). Carvedilol suppository is a kind of anti-early pregnancy drug commonly used in clinic, and belongs to the derivative of the natural prostaglandin F2a, which clinically used in combination with other drugs (such as oxytocin and romethamine) to obtain a better prevention effect. Oxytocin is a widely used uterine contraction agent, can stimulate the upper segment of the uterus, promote uterine contraction, but the action time is short. Romethamine is a prostaglandin drug that stimulates uterine contraction at any stage of pregnancy, and also promotes platelet aggregation and improves coagulation. However, few studies have reported its effectiveness in preventing postpartum hemorrhage. In dealing with the increasing incidence of postoperative cesarean section bleeding in the clinic, effective interventions are a key factor in improving the safety of cesarean section. Therefore, this study compares carboprost with carboprost tromethamine and carboprost with oxytocin for the prevention of bleeding after cesarean section to provide reference for the future clinical use of medication in cesarean section.

MATERIALS AND METHODS

General Materials

A prospective analysis was made of 349 cesarean section women from March 2017 to March 2019, who were divided into control group and research group according to the treatment methods. There were 184 puerperants in the study group, 142 primiparas (77.17%) and 42 multiparas (22.83%). Age: 22 to 30 years. Average age: (26.12 ±1.87) years. Gestational week: 36 to 41 weeks. Mean gestational week: (37.93 ±1.37) weeks. BMI: (25.61 ±0.95) kg/m2. Bigeminal pregnancy: 42 cases. Oligohydramnios: 39 cases. Placenta praevia: 33 cases. Macrosomia: 70 cases. Carbide suppository combined with oxytocin was used for the treatment. There were 165 puerperants in the control group, 124 primiparas (75.15%) and 41 multiparas (24.85%). Age: 21 -29 years. Average age: (26.05 ±1.79) years. Gestational week: 36 to 41 weeks. Mean gestational week: (37.82 ±1.37) weeks. BMI: (25.55 ±0.94) kg/m2. Bigeminal pregnancy: 41 cases. Oligohydramnios: 37 cases. Placenta praevia: 30 cases. Macrosomia: 57 cases. Carbide suppository combined with romethamine was used for the treatment.

Inclusion criteria: 1) According with the index of cesarean section; 2) No fibroid, endometrial carcinoma, cervical cancer and other benign and malignant uterine tumors; 3) No serious diseases of the blood system.

Exclusion criteria: 1) Having a history of mental illness or serious brain disease; 2) Anemia, hypertension, diabetes, etc. 3) a history of drug allergy treated in this study.

This study was approved by the Medical Ethics Committee of The Affiliated Hospital of Qingdao University. The patients signed an informed consent form.

Method

The puerperants in both groups were given spinal anesthesia combined with routine cesarean section, and analgesia pump was carried after operation. The control group was treated with 1 mg of sublingual calcitonin suppository (Nanjing Sukang Medicine Co., Ltd., SFDA Approval No. H10800007) immediately after fetuses were removed during the operation. The muscular layer at the upper edge of the lower uterine incision was injected and withdrawn. 250 μg of romethamine (Changzhou Siyao Pharmaceutical Co., Ltd., SFDA Approval No. H20094183) was injected into the uterine muscle after withdrawal of blood during injection. The dosage and injection frequency were adjusted according to the severity of

bleeding after operation. The interval of each injection was at least 15 minutes, and the maximum injection dose was 3. The study group was treated with 1 mg of sublingual carboprost suppository immediately after delivery. After determining that there was no blood in myometrium, 20 U of oxytocin (Gansu Dadali Pharmaceutical Co., Ltd., SFDA Approval No. H62020713) was injected into the puerpera. If uterine contraction was still poor, intramuscular injection of 20 U of oxytocin was given 2 hours after operation. Hemodynamic parameters, such as heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), saturation of pulse oxygen (SpO2) and so on, were monitored in both groups during the operation. The physical signs of the puerperant should be measured regularly after operation, and the adverse reactions, including nausea, vomiting, flushing of the face and diarrhoea, should be observed.

Observation Indices and Evaluation Criteria

1) The blood loss during operation, the blood loss at 2 hours and 24 hours after operation, and the total amount of bleeding after operation and the incidence of bleeding after operation were recorded in the two groups. Blood loss calculated by weighing method: Weigh the dressings and disinfection towel before delivery. After the operation, the above-mentioned material soaked by the blood is weighed and the initial weighing weight of the material is subtracted to be the blood loss during operation. After the operation, the puerperant was transferred to the manipulator, and then transferred to the bed of the ward. A one-time paper pad was used to absorb bleeding under the buttocks of the puerperant, and was replaced at 2 h and 24 h after operation. Weigh and record the weight of the pad before and after use. The increased weight is the amount of bleeding after the operation. The amount of blood loss in 24 hours after operation was added and accumulated, and the result was the total amount of bleeding after operation. The total blood loss after operation more than 500 mL was postoperative hemorrhage.

2) Hemodynamic parameters including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and saturation of pulse oxygen (SpO2) were recorded.

3) Adverse reactions (nausea, vomiting, facial flushing, diarrhoea, etc.) were recorded in both groups.

4) The uterine recovery of two groups of puerperant was recorded. If the height of the fundus uteri is 2 to 3 fingers below the umbilicus, the puerpera will recover well. If the height is flat to the umbilicus or one finger below the umbilicus, the recovery is not good.

5) Evaluation criteria for efficacy: a) markedly effective: stop bleeding or blood loss of 50 ml/ h and below after the patient's treatment, stable vital signs, progressive contraction of the uterus in the pelvic cavity, urine volume ≥ 30 ml/h ; b) effective: blood loss after treatment is 50 ml/h, stable vital signs; c) ineffective: the blood loss of the patients after treatment >100 ml/h, no effective contractions in pelvic uterus, deterioration of all life indicators of patients, urine volume < 30 ml/h. Total efficiency = significant efficiency + efficiency.

Data Handling

The resulting relevant data was input to the SPSS10.0 software package (Asia Analytics Formerly SPSS China) for statistical analysis. The measurement data was expressed by the mean ±standard deviation (x ±s). t-test was used to compare data between groups. Multiple time points were compared using repeated measurement variance analysis and Bonferroni post-test. Count data represented by example (n), percentage (%). $\chi 2$ test was used for comparison between groups. Take 95% as the confidence interval. $P<0.05$, the difference was of statistical significance.

RESULTS

Comparison of General Information

Table I General information

	Study Group(n=184)	Control Group(n=165)	χ^2/t	*p*
Primipara and Pluripara[n(%)]			0.196	0.658
Primipara	142(77.17)	124(75.15)		
Pluripara	42(22.83)	41(24.85)		

The Cause of Cesarean Section[n(%)]			0.505	0.918
Bigeminal Pregnancy	42(22.83)	41(24.85)		
Hydramnion	39(21.20)	37(22.42)		
Placenta Praevia	33(17.93)	30(18.18)		
Macrosomia	70(38.04)	57(34.55)		
Age(years)	26.12±3.51	26.05±3.21	194	0.847
gestational week(weeks)	37.93±1.89	37.82±1.86	0.547	0.585
BMI(kg/m^2)	25.61±0.95	25.55±0.94	0.592	0.554

The clinical data of parturient age, primipara, gestational week, BMI, and the cause of cesarean section were compared between the two groups. There was no statistical significance (P>0.05). See Table I for details. The above information showed that the two groups are comparable.

Comparison of Adverse Reaction

After statistical analysis of two groups of maternal postoperative adverse conditions, the results showed that there were no serious adverse reactions in both groups. Control group: 4 cases of mild nausea, 3 cases of mild vomiting, 5 cases of facial flushing and 5 cases of mild diarrhea, 7.61% of adverse reaction rate. Observation group: 5 cases of mild nausea, 6 cases of mild vomiting, 4 cases of facial flushing and 3 cases of mild diarrhea, 10.91% of adverse reaction rate.

The difference between the control group and the observation group was not statistically significant (P>0.05). See Table II for specific results. The above results indicated that the risk and safety of the two groups are comparable.

Table II Comparison of Adverse Reaction [n(%)]

	Nausea	Vomiting	Facial Flushing	Diarrhea	Adverse Reaction Rate
Study Group(n=184)	4(2.17)	3(1.63)	5(2.72)	2(1.09)	14(7.61)
Control Group(n=165)	5(3.03)	6(3.64)	4(2.42)	3(1.82)	18(10.91)
χ^2					1.138
p					0.286

Comparison of Blood Loss

Comparing the maternal hemorrhage between the two groups, the results showed that the total blood loss in the study group was lower than that in the control group (P<0.05); the postoperative bleeding rate in the study group was lower than that in the control group (P<0.05). See Table III for specific results. The above results indicated that the combination of carboprost suppository and romethamine has a better effect on preventing postoperative bleeding than that of the combination of carboprost suppository and oxytocin.

Table III Comparisons of intraoperative and postoperative hemorrhage among parturients [x±s, mL, n(%)]

	Study Group(n=184)	Control Group(n=165)	χ^2/t	*p*
Total Postoperative Bleeding	469.82±25.19	488.98±27.38	6.808	< 0.001
Postoperative Bleeding Rate	28(15.22)	58(35.15)	18.623	< 0.001

Comparison of Uterine Recovery

Comparing the uterine recovery of the two groups, the results showed that the study group had better recovery than the control group (P<0.05). The specific results are shown in Table IV. The above results showed that the uterine recovery in the study group was significantly better than that in the control group.

Table IV Comparison of Uterine Return [n (%)]

	Study Group(n=184)	Control Group(n=165)	χ^2	*p*
Good Recovery	174(94.57)	136(82.42)	12.923	< 0.001
Poor Recovery	10(5.43)	29(17.58)		

Comparison of Hemodynamics

There were no differences in hemodynamic indexes between the two groups before medication (P> 0.050). After medication, the HR, SBP, and DBP of the study group were lower than those of the control group, and SpO2 of the study group was higher than that of the control group (P <0.001). The HR and SpO2 of the two groups after medication were higher than those before medication, while the SBP and DBP were lower than those before medication (P <0.050). See Table V.

Table V comparison of hemodynamic parameters between the two groups before and after administration

	Study Group(n=184)	Control Group(n=165)	t	*p*
HR(times/min)				
Before administration	88.69±2.12	89.14±3.28	1.537	0.125
After administration	90.33±1.16#	91.72±4.85#	3.770	0.002
SBP(mm Hg)				
Before administration	127.94±1.21	128.05±0.83	0.979	0.328
After administration	124.33±1.22#	125.43±0.82#	9.770	< 0.001
DBP(mm Hg)				
Before administration	86.58±5.08	86.57±1.86	0.024	0.981
After administration	78.24±1.17#	83.50±1.39#	38.374	< 0.001
SpO_2(%)				
Before administration	98.41±0.08	98.37±0.33	1.593	0.112

After administration	98.63±0.35#	98.54±0.08#	3.228	0.001

Note: compared with pre-administration, # p<0.05

Comparison of Clinical Effect

Comparing the clinical effect of the two groups, the results showed that: In the control group, 71 cases (43.03%) were markedly effective; 64 cases (38.79%) were effective; 30 cases were ineffective (18.18%); and the total effective rate was 88.82%, while in the study group, 98 cases (53.26%) were markedly effective; 77 cases (41.85%) were effective, and 9 cases (4.89%) were ineffective; the total effective rate was 95.11%. The effective rate of the study group was significantly higher than that of the control group (P<0.001). The above results indicate that the effect of combination of carboprost suppository and romethamine is better than that of carboprost suppository combined with oxytocin. After emergency treatment in hospital, the patients whose curative effect was judged to be ineffective were effectively controlled. See Table VI.

Table VI Comparison of Clinical Effect between the Two Groups [n (%)]

	Markedly Effective	Effective	Ineffective	Total Effective Rate(%)
Study Group(n=184)	98(53.26)	77(41.85)	9(4.89)	95.11
Control Group(n=165)	71(43.03)	64(38.79)	30(18.18)	81.82
χ^2	3.646	0338	15.483	15.483
p	0.056	0.561	< 0.001	< 0.001

DISCUSSION

In recent years, with the development of cesarean section technology and the improvement of the living standard of human society, the rate of cesarean section is increasing year by year (16). However, because cesarean section is a traumatic operation, and maternal labor consumes a lot of energy, it is easy to cause many complications due to the decline of body function after operation. Postoperative hemorrhage is the most common one of the complications, but also the main cause of maternal postpartum death, and this death is often related to the incidence and consequences of hemorrhagic shock (17, 18). Therefore, how to avoid bleeding after cesarean section is one of the keys to the successful cesarean section. This study compared the effect of carboprost with carprost tromethamine and carboprost combined with oxytocin on preventing postpartum hemorrhage of cesarean section, which is of great significance for cesarean section in future clinical practice.

There was no statistical difference in the incidence of adverse reactions between the two groups since the incidence of adverse reactions in the control group was 10.34% and that in the research group was 8.62%, indicating that the risks and safety of the two groups of drugs are comparable. Some parturients have adverse reactions such as nausea, vomiting and diarrhoea due to the contractive effect of constrictive medicine on uterine muscle (19,20). The results showed that the incidence of adverse reactions was 10.34% in the control group and 8.62% in the study group. There was no statistical difference between the two groups, indicating that the risk and safety of the two groups were comparable. The results showed that the indexes of the two groups were improved after comparing the hemodynamic indexes of the two groups. The data of the two groups were significantly different before and after treatment, but the improvement of the study group was better than that of the control group. The results showed that the rate of good return was 82.76% in the control group and 94.83% in the study group after comparing the recovery of uterus in the two groups.

It is shown that the effect of oxytocin on the control of bleeding is not as good as the effect of romethamine (21). In this study, The total blood loss and the bleeding rate (35.15%) in the control group were higher than those of the study group. The possible cause of the difference in the results between our study and previous studies is that oxytocin has a short half-life and short acting time, so the puerperant may not be sensitive to oxytocin and the effect may be unstable. In addition, the results showed that the condition of markedly effective, effective and ineffective of the study group was better than that of the control group. In the study of Tang and others (22) of pelvic arterial embolization in the treatment of primary postpartum hemorrhage, the application of romethamine has also achieved good results, which

can support the results of this experiment. However, after evaluating the hemostatic effect of romethamine on laparoscopic hysteromyomectomy in women, Zhang (23) found that intramuscular injection of carboprost tromethamine before hysteromyomectomy may be an effective method to reduce intramural hemorrhage, especially when combined with intravenous infusion of oxytocin. The difference is that Zhang (23) used vasopressin and romethamine separately in the study and control group, but did not use carboprost suppository combined with romethamine. Tumor resection is more traumatic to the patients, and the tumor may have some influence on the blood flow function of the patients(24). What's more, the effect of tumor on the existence of carboprost suppository is not clear, but we will take it as a future research direction to analyze and discuss more deeply to understand the exact mechanism of the combination of carboprost suppository and romethamine.

In this experiment, we compared the preventive effect of carboprost suppository combined with romethamine and carboprost suppository combined with oxytocin. However, due to the limited experimental conditions, there are still shortcomings. For example, the subjects included in this experiment were women without other diseases, not excluding the combination of carboprost suppository and romethamine in pregnancy induced hypertension, diabetes mellitus with other maternal differences. In order to obtain the best experimental results, we will conduct a long-term follow-up investigation of the subjects in this experiment, and continue to expand the sample size of the study subjects and analyze in-depth the application value of the combination of carboprost suppository and romethamine in postpartum hemorrhage.

To sum up, Carboprost suppository combined with romethamine can significantly improve maternal hemodynamic indicators and is more effective in preventing bleeding after cesarean section, so it is worth promoting in clinical practice.

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