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Role of Rectal Misoprostol Combined with Intravenous Methergine in the Prevention of Post Partum Haemorrhage

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Abstract:
Objective: *To study the efficacy of use of 1000 micrograms per rectal Misoprostol combined with 0.2mg IV Methergine in comparison with conventional use of 0.2mg of IV Methergine in the active management of third stage of labour, in preventing atonic post partum haemorrhage.*
Materials &Methods: *The present study was conducted from June 2016 to Nov 2016 on 200 cases of vaginal deliveries at labour ward of Department of Obstetrics and Gynaecology, Guntur Medical College, Guntur.The cases were divided into two groups, 100 for each treatment regimen- 0.2 mg IV Methergine and Per rectal 1000 micrograms of Misoprostol in addition to IV Methergine respectively.*
Data regarding age,parity,gestational age,mode of delivery, duration of the third stage, amount of blood loss,the need for further oxytocic supplementation, the presence of any side effects and complications, the haemoglobin values obtained on the second postnatal day were taken and analysed.
Results:*The duration of the third stage was 4-6mins in 66%of control group and 58% in study group.The average blood loss in third stage of labour in control group was more(123.60ml) when compared to study group(62.20ml) with a P value of <0.0001 and the incidence of PPH was 2% & retained placenta was 4% in the control group while these were not noted in the study group.*
Conclusion: *Prophylactic administration of per rectal Misoprostol 1000 micrograms in conjunction with routine uterotonic drug i.e., IV Methergine 0.2mg served effectively in reducing the blood loss in third stage of labour.*
Keywords: *Methergine, Misoprostol,Post Partum Haemorrhage.*

I. Introduction

Post partum haemorrhage is an obstetrical emergency and it still remains one of the leading causes of maternal mortality and morbidity in both developing and developed countries.

Approximately 3.9% of vaginal deliveries and 6.4% of caesarean deliveries are complicated by post partum haemorrhage.

The third stage of labour begins immediately after the delivery of the fetus and ends with the delivery of the placenta and the fetal membranes .This is the stage of separation and expulsion of the placenta.

Of all the stages of labour , the third stage is the most critical one for the mother because, the complications such as post partum haemorrhage, retained placenta, acute uterine inversion and obstetric shock are life threatening.

Post partum haemorrhage is defined as blood loss in excess of 500ml after delivery of the baby-but any amount of blood loss(even if less than 500ml) that leads to deterioration of maternal haemodynamics also constitutes post partum haemorrhage hematocrit change of 10% or need for red cell transfusion is also currently accepted as definition of post partum haemorrhage.

Primary PPH-is defined as blood loss of more than 500ml within 24 hrs after delivery. This is the major form encountered.

Secondary PPH- is defined as blood loss more than 500ml beyond 24hrs after birth to six weeks after delivery.

PPH is the third major cause of maternal mortality next to PIH/Eclampsia and infection.

Causes of PPH:-
1) Uterine Atony (Atonic PPH)
2) Traumatic PPH
3) Mismanagement of third stage of labour
4) Abnormalities of coagulation system

II. Materials And Methods

Source of Data:
The present study was conducted from June 2016to Nov 2016
Primary data was collected by studying pregnant women in labour at labour ward of Department of Obstetrics and Gynaecology, Guntur Medical College, Guntur.
Study Design: Prospective randomized comparative study.

Sample size:
The study was conducted on 200 cases of vaginal deliveries which were divided into two groups 100 for each treatment regimen.

Control Group : 0.2 mg of IV Methergine was given at delivery of anterior shoulder of the baby.
Study Group : Per rectal 1000 micrograms of Misoprostol was kept at the stage of clamping of the cord in addition to IV Methergine.

III. Selection Of The Cases

Inclusion criteria:
Women in all age groups who were planned for vaginal delivery.

- Spontaneous or induced with any parity with term, preterm or post term gestation.
- With live or still birth
- With any presentation which would allow vaginal delivery.

Exclusion criteria:

- Previous scar on the uterus.
- Hypertensive disorders.
- Intra uterine death.
- Uterine malformations.
- Multiple pregnancy.
- Known hypersensitivity to Prostaglandins.
- Women with traumatic Post Partum Haemorrhage.
- Women in whom Prostaglandin usage is contraindicated.

The women thus chosen for the study were randomly allocated either to the study group or the control group by the envelope method.

IV. Method

After following the inclusion and exclusion criteria, the women were asked to participate in the study and an informed consent was obtained from them. Following this, a blood sample was taken for haemoglobin estimation and the blood pressure was recorded. Once vaginal delivery became imminent, the women were assigned to either the study group or the control group, randomly, by envelope method.

In the study group, the women were given 1000micrograms of Misoprostol at the time of clamping of the cord and 0.2 mg IV Methergine at the time of delivery of anterior shoulder of the baby while the women in the control group received only 0.2 mgIV Methergine and the stop watch was started.

Immediately following the birth of the baby, a sterilized receptacle was placed in close approximation to the vulva to collect the blood. The uterus was massaged and when the signs of placental separation were noted, the placenta was extracted by traction/counter traction method.

The stop watch was then stopped.

The blood lost was initially collected directly into the receptacle and the remaining intrauterine ooze was later collected from tampons that had been previously obtained and the difference in the weights gave us the approximate volume of blood loss. The blood loss from the episiotomy wound was excluded, i.e., by discarding the tampons that were used to mop them.

The total blood collected was then measured in a graduated measuring flask. In the cases where the placenta was not delivered even after 30 minutes, they were either removed manually under general anaesthesia or they responded to further oxytocic supplementation.

One hour after delivery, vitals are recorded and the women were asked to quote side effects like nausea, vomiting, diarrhoea, headache, fever, shivering, muscle cramps etc. On the second postnatal day, a haemoglobin estimation was again obtained.

The main outcome measures assessed were:
1. Duration of the third stage.
2. Amount of blood loss.
3. The need for further oxytocic supplementation.
4. The presence of any side effects and complications.
5. The haemoglobin values obtained on the second postnatal day.

The demographic characteristics recorded were:
- Age
- Parity
- Gestational age

V. Results And Analysis

Table No.I Age Wise Distribution Of The Cases

Age in Years	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
15-20	45	45%	46	46%
21-25	39	39%	39	39%
26-30	12	12%	12	12%
31-35	2	2%	2	2%
>35	2	2%	1	1%

Table No.II Distribution According To Parity

Parity	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
Primi	50	50%	45	45%
Gravida 2	39	39%	42	42%
Gravida 3	7	7%	10	10%
Gravida 4	4	4%	3	3%

Table No.III Distribution According To Gestational Age

Gestational age (in weeks)	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
34-36	3	3%	6	6%
37-40	75	75%	75	75%
41-42	22	22%	19	19%
42+	Nil	Nil	Nil	Nil

Table No.IV Average Duration Of The Third Stage

Group	No. of cases	Average duration of the third stage (in minutes)
Control	100	5.82minutes
Study	100	3.73 minutes
Statistical significance(P)=0.0005		

Table No.V Average Blood Loss In Third Stage

Average blood loss (ml)	Control Group	Study Group	P Value
Immediate	45.75ml	47.65 ml	0.5757
After 2 Hrs	77.85 ml	14.55 ml	<0.0001
Total	123.60 ml	62.20 ml	<0.0001

Table No.VI Pre & Post Delivery Haemoglobin Difference

HB difference	Control Group	Study Group
<1 gm%	30	95
1 gm%	47	4
>1 gm%	23	1

Table No.VII Pre And Post Delivery Pcv Difference

PCV difference	Control Group	Study Group
1 vol%	22	88
2 vol%	8	7
3 vol%	47	4
>3 vol%	23	1

Table No.VIII Side Effects

Side effect	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
Shivering	-	-	11	11%
Pyrexia	-	-	6	6%
Nausea	13	13%	-	-
Vomiting	13	13%	-	-
Diarrohea	-	-	8	8%
Headache	1	1%	-	-
Muscle cramps	-	-	2	2%
Abd .pain	-	-	-	-
Hypertension	17	17%	14	14%

Table No.IX Incidence Of Complications

Nature of complications	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
Postpartum Haemorrhage	2	2%	-	-
Retained placenta	4	4%	-	-

Table No.X Requirement Of Therapeutic Oxytocic Supplementation

Type of supplementation	Control Group		Study Group	
	No. of cases	Percentage	No. of cases	Percentage
15-20 units Oxytocin IV drip	4	4%	2	2%
INJ.$PGF_2\alpha$ (250mcg)IM	4	4%	-	-
Both Oxytocin and $PGF_2\alpha$	2	2%	-	-
Total	10	10%	2	2%

Table-I,II,III- Both the groups were comparable in age,parity and gestational age.

Table-IV- The average duration of the third stage was 5.82 minutes in the control group and it was 3.73 minutes in the study group with a P value of 0.0005. This difference was found to be extremely statistically significant.

Table-V-The average blood loss, immediately at delivery was similar in both the groups. It was 47.65ml and 45.75ml in the control group. It has been noted that in the study group, the uterus remained well retracted in the two hour period following delivery and the vaginal bleeding during this period was considerably less than that in the control group. The average blood loss within two hours of delivery was 14.55ml in the study group and that in the control group was 77.85ml. This was due to the sustained effect of Misoprostol.

Table-VIII- Methergine caused a mild rise in BP in 17% of cases in the control group and 14% in the study group. Gastrointestinal side effects occurred in 13% of the control group while there was diarrhea in 8% of the study group. Shivering occurred in 11% and pyrexia accounted for 6% in the study group while they were none in the control group.

Table-IX- The incidence of Post partum Haemorrhage was 2% and that of Retained placenta was 4% in the control group while these complications were not noted in the study group.

Table-X- For the third stage, therapeutic oxytocic supplementation was given, whose bleeding was more than the expected normal amount, or, it was required for the treatment of PPH.10 cases of the control group required oxytocic supplementation and out of these 10 cases, there were 2 cases of PPH. The requirement of oxytocic supplementation was slightly more in the control group, 10% compared to 2% of the study group.

VI. Discussion

PPH is the leading cause of maternal mortality in India, contributing 27% of all the maternal deaths which contribute to1% of total deaths. PPH amounts to 2.5% of all female deaths and 12.5% of all deaths in child bearing age. So, minimizing the third stage blood loss is essential. Even the normal amount of blood loss of 300-500ml may not be tolerated by women with associated anemia and malnutrition. Nowadays active management of third stage of labour with proper use of uterotonics is in vogue, as it reduces the risk of PPH **(Prendiville et.al).**

Methergine is used as a conventional uterotonic drug to prevent PPH, which is administered immediately after the delivery of the anterior shoulder of the baby. The action of Methergine starts 1-2 min after an intravenous injection and hence it reduces the immediate blood loss from the uterus by causing tetanic uterine contraction.

The blood loss which occurs within 2 hrs of delivery is as important as the immediate blood loss, as this also contributes to Primary PPH. So, preventing this blood loss is also a part of prevention of Primary PPH which is done by an agent which can maintain a sustained effect on the uterine contraction.

So, the search for an effective, easily administered, affordable uterotonic agent in preventing PPH is of importance especially in the developing world **(Bamigboye AA et.al).** One therapeutic option is the use of Misoprostol (Mategrano VA et.al).The efficacy and role of Misoprostol in the prevention and management of PPH is well documented.

Misoprostol is safe and stable at room temperature. It is cheaper, had long shelf life, easy to administer and does not require refrigeration **(O'Brien P A et.al).** Dose & Route of Misoprostol: Even though Misoprostol is well absorbed vaginally, it cannot be used vaginally, as the drug gets washed away in the presence of bleeding. Oral Misoprostol has good pharmacokinetics but associated with more side effects **(Sukumar B et.al ISBN 81-8061).**Rectal administration of Misoprostol is also well absorbed with few side effects **(El Rafaey et.al BJOG -1977).** Higher doses are needed rectally, to achieve efficacy without the disadvantages of oral, vaginal routes (American Family Physician issue-Jan 15, 2004). "Cochrane review 2003", concluded that per rectal Misoprostol 800mcg is a useful first line drug in the treatment and prevention of PPH.

VII. Conclusion

From this study, it has been observed that prophylactic administration of per rectal Misoprostol 1000 micrograms in conjunction with routine uterotonic drug i.e., IV Methergine 0.2mg served effectively in reducing the blood loss in third stage of labour. Hence it may be concluded that Misoprostol need not replace but can be used as an adjuvant with conventional oxytocics for prophylaxis of Postpartum haemorrhage.

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