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"COMPARATIVE STUDY BETWEEN PER RECTAL MISOPROSTOL AND INTRAMUSCULAR METHERGIN FOR PROPHYLAXIS AGAINST ATONIC POST PARTUM HAEMORRHAGE IN A TERTIARY CARE HOSPITAL"

Obstetrics and Gynaecology

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ABSTRACT

Background: Post partum haemorrhage (PPH) is one of the most common causes of maternal deaths throughout the world. Third stage labour is the most complicated part of the mother, which requires necessary attention. **Material and Methods:** This present randomized study is to compare the efficacy of intramuscular methergin and per rectal misoprostol in the management of third stage of labour to prevent Post partum hemorrhage **Results:** Group 1 comprises of patients in whom misoprostol 400 g was given after delivery of anterior shoulder of baby. Group 2 comprises of patients in whom methyl ergometrine (0.2mg intramuscularly) was given after delivery of anterior shoulder of baby. **Conclusion:** In conclusion, the intramuscular methyl ergometrine when used results in lower blood loss, more effective reduction in duration of third stage of labour, significantly lesser reduction in Hb level after delivery but is associated with unpleasant side effects like nausea, vomiting, shivering, hypertension and risk of retained placenta. PPH was seen in lesser number of cases as compared to misoprostol group.

KEYWORDS

Methylergometrine, Misoprostol, PPH and Third stage labour

INTRODUCTION:

Post partum haemorrhage (PPH) is one of the most common causes of maternal deaths throughout the world. Third stage labour is the most complicated part of the mother, which requires necessary attention. The most usual happen condition in this stage is postpartum haemorrhage defined as blood loss >500ml in the first 24hours of post-delivery.[1] It is an important cause of maternal morbidity and mortality.[2-4] The world health organization (WHO) reports that over 20 million morbidities results every year due to post-partum haemorrhage.[5] Preventive measures like early cord cutting, supplementation of Oxytocics and cord traction may decrease the probability rate of postpartum haemorrhage.[6-8] Conventional treatment for prophylaxis against postpartum haemorrhage include methyl ergometrine, oxytocin and 15 methyl PGF2α. Usage of oxytocic agents shown to decrease incidence of postpartum haemorrhage by 40%The use of uterotonic agent may reduce blood loss but often associated with nausea, vomiting, myocardial infarction, intracerebral haemorrhage and increased BP.[9] Misoprostol an effective uterotonic agent which binds selectively to EP2 or EP3 prostonoid receptor administering orally or rectal route to prevent postpartum hemorrhage and helpful in the management of third stage labour.[10] Methergine is a conventional oxytocic used extensively but is associated with unpleasant side effects like hypertension.[11] In the study of O Brien et al (1998)[12] haemorrhage that was unresponsive to oxytocin and ergometrine was controlled and contractions were produced within 3 minutes of rectal administration of 1000 µgm of misoprostol. The best management of the third stage would be one that effectively minimizes serious problems such as blood loss and retained placenta, while interfering as little as possible with the physiological mechanisms of placental delivery and bonding between mother and baby, and has fewer side effects. The present study is an attempt to compare intramuscular methyl ergometrine and per rectal misoprostol in the management of third stage of labour for prevention of post partum haemorrhage.

MATERIALS AND METHODS:

This present randomized study is to compare the efficacy of intramuscular methergin and per rectal misoprostol in the management of third stage of labour to prevent Post partum hemorrhage. The study was conducted in the Department of Obstetrics and Gynaecology at World College of Medical Sciences & Research and Civil Hospital, Jhajjar. 200 cases admitted to the above hospitals who fulfilled the selection criteria were included for the study. The study was conducted from November 2018 to October 2020.

Inclusion criteria :

All patients in the age group of 19-30 years, period of gestation ranging from 37-40 weeks and gravidity ranging from 1st to 4th gravida subjected to vaginal delivery.

Exclusion criteria :

Multiple pregnancy, intrauterine foetal death, previous caesarean section, pregnancy induced hypertension, antepartum haemorrhage, heart disease, bronchial asthma, renal disease, liver disease, allergy to drug.

The selected cases with inclusion criteria was divided into 2 groups :

Group 1 : Misoprostol 400mg was inserted per rectally immediately following birth of baby (100).

Group 2 : Injection methergin 0.2mg intramuscular was given at the delivery of anterior shoulder (100).

Each of the patients will be allotted to one of the groups by coloured coins method (self selection – random sampling method).

Methodology:

An informed consent was taken from the patients who met the inclusion criteria. These women underwent a thorough general and systemic examination like cardiovascular system, respiratory system, per abdomen and per vaginal examinations. The women were given either Intramuscular methergin (0.2mg) or per rectal misoprostol (400 mg) at the delivery of anterior shoulder of foetus.

Data Analysis:

Statistical analysis of the 2 groups was done by Chi-square test and t-test (normality test). Chi-square test was used to analyze categorical data and t test for comparing means of two groups. A two tailed $p < 0.05$ was considered statistically significant. Analysis was done in SPSS software package.

OBSERVATION AND RESULTS:

Present study included two hundred cases with low risk term pregnancy, who come for delivery in labour rooms.

Group 1 comprises of patients in whom misoprostol 400mg was given after delivery of anterior shoulder of baby. Group 2 comprises of patients in whom methyl ergometrine (0.2mg intramuscularly) was given after delivery of anterior shoulder of baby.

The maximum number i.e. 93 (46.5%) patients who came for delivery in labour rooms were in the age group of 23-26 years. 64 (32%) patients were in age group of 19-22 years and 43 (21.5%) patients were in the age group of 27-30 years. Mean age of patients' age was 24.3 years. Range was 19-30 years with a standard deviation of 2.9 years.

In misoprostol group, 51% of cases were multigravidas and 49% of cases were primigravidas. In methyl ergometrine group, 37% cases were multigravidas and 63% were primigravidas. In misoprostol group maximum number of patients were 46 (46%) who delivered at 39-40 weeks of gestation. 26% of cases were delivered at 38-39 weeks of gestation. Rest 28% cases 37-38 weeks of gestational age. Mean of period of gestation at which delivery occurred was 38.5 weeks. In methyl ergometrine group maximum number of patients 43(43%) delivered at 39-40 weeks of gestation. 31% cases delivered at 37-38 weeks of gestation. Rest 26% of cases delivered at 38-39 weeks of gestation. Mean of period of gestation at which delivery occurred was 38.4 weeks.

Table 1 : Amount Of Blood Loss In 3rd Stage Of Labour

Blood loss (ml)	Misoprostol	Methyl ergometrine
50-100	9	38
101-200	37	51
201-300	35	3
301-400	10	1
401-500	2	1
501-650	7	6
Total	100	100
Mean ± SD	236.8 ± 119.9	160.6 ± 127.5
	t = 4.36	P < 0.05, Sig.

Unpaired 't' test

In misoprostol group, blood loss of less than 100mL was observed only in 9% cases while maximum number of patients 37 (37%) had blood loss between 101-200 ml and in 35% cases blood loss was in between 301-400mL. Only 2% patients lost blood more than 400mL. There was postpartum hemorrhage in 7% of cases with blood loss more than 500mL. In methyl ergometrine group 38% patients had blood less than 100ml, whereas maximum patients 51% had blood loss between 101-200mL. Only 3% of this group were having blood loss between 201-300mL. In this group blood loss between 301-400mL was observed in 1% and 401-500mL also in 1% cases. There was postpartum hemorrhage in 6% cases mainly due to retained placenta with blood loss between 501-650ml.

In misoprostol group, only 1 patient has III stage duration of less than 4 mins. maximum number of cases i.e. 30 (30%) had duration of III stage between 6-8mins, 28% took 8-10 minutes during this stage, 23% had duration of III stage of 10-12 mins, 15% patients had duration between 4-6 mins, 1% took 12-14 mins and 3% had retained placenta.

In methyl ergometrine group, maximum patients 36% took 4-6 mins during their III stage, 23% had third stage duration of 2-4 mins, 28% patients had duration of 6-8 mins, 11% took 8-10 mins during their third stage. Among this group only 2% patients took 10-12 mins during this stage, whereas 5% had retained placenta.

In misoprostol group, average duration of III stage of labour was found to be 8.03 mins whereas in methyl ergometrine group it was found shorter, 5.26mins and it is significantly reduced statistically (P< 0.05).

In misorpostol group, additional oxytocics in the form of 10 IU, oxytocin in intravenous drip was required in 10 patients (10%) and retained placenta occurred in 3 (6%) patients. Average blood loss was found to be 236.9ml.

In methyl ergometrine group, additional oxytocics were needed in 6% patients. Retained placenta developed in 5% cases. Average amount of blood loss was found to be 160.5ml. In misoprostol group 8 (8%) patients had blood loss more than 500ml and required blood transfusion. In methyl ergometrine group 7 (7%) had blood loss more than 500ml and required blood transfusion.

In misoprostol group, maximum blood loss occurred when duration was more than 30mins, 275ml of blood was lost when duration was 12-14 mins, it was 236.9 ml when duration was 10-12 mins, 247.9ml blood loss occurred in duration range of 8- 10mins, 227.5ml of blood loss occurred with 6-8 mins duration, 213mL blood loss occurred when duration was 4-6 min and minimal blood loss in this group was 180ml when duration of IIIrd stage was 2-4 mins. In methyl ergometrine group, maximum blood loss occurred when duration was > 30min 215.9ml of blood loss occurred at 2-4 mins duration of third stage, 141.4ml at 4-6 mins duration, 146.4ml at 6-8 mins duration, 141.8ml at 8-10mins duration at 170ml at 10-12 mins duration of third stage.

Table 2 :Effect On Systolic & Diastolic Blood Pressure In Both Groups

Variables	Systolic blood pressure		Diastolic blood pressure	
	Misoprostol	Methyl ergometrine	Misoprostol	Methyl ergometrine
	No. of cases	No. of cases	No. of cases	No. of cases
No rise or insignificant change	72	60	82	68
Rise of 5-10 mm Hg	1	19	1	20
Fall of 5-10 mm Hg	27	21	17	12
Total	**100**	**100**	**100**	**100**

{(Systolic BP:x^2 = 18.04 p < 0.05, Sig.) & (Diastolic BP: x^2 = 19.04 p < 0.05, Sig.)}

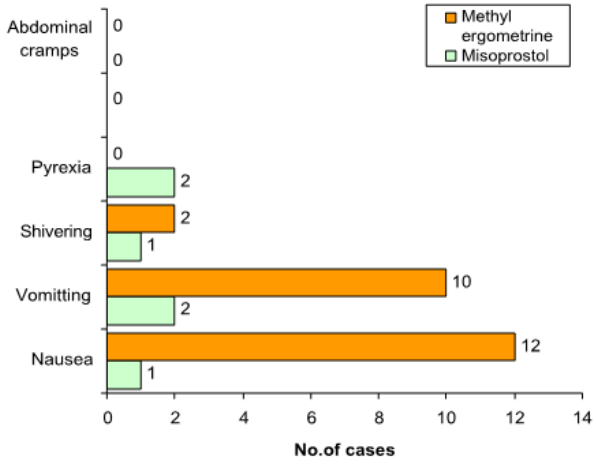
In misoprostol group no rise or insignificant change of blood pressure occurred in 72% cases. Rise in systolic blood pressure occurred by 5-10mmHg occurred in 1% and fall of 5-10mmHg was found in 27% cases. In methyl ergometrine group no rise or insignificant change in blood pressure occurred in 60% cases. Rise in systolic blood pressure occurred by 5-10 mmHg in 19% and fall of 5-10mmHg was found in 21% cases.

Average fall in Hb level was 0.69 g/dl in misoprostol group whereas in methyl ergometrine group it was 0.49 g/dl. It was significantly reduced in methyl ergometrine group compared to misoprostol group.

Side effects were seen more in methyl ergometrine group as compared to misoprostol group. In misoprostol group nausea was seen in 1% of cases, vomiting in 2% of cases, shivering in 1% of cases and pyrexia in 2% of cases.

In methyl ergometrine group nausea was seen in 12% of cases, vomiting in 10% of cases and shivering in 2% of cases.

Graph 1 : Side effects of drugs in both groups



DISCUSSION:

The present study showed intramuscular methyl ergometrine shortens duration of third stage of labour and amount of blood loss but it is associated with more side effects while per rectal misoprostol is less effective in preventing blood loss but it has lesser side effects.

In a similar study by Frederic et al[13], the mean age in misoprostoal form to be 29.8 yrs and in methyl ergonetrine group was 29.9 yrs. The different in age groups was not statistically significant.

In a similar study by Vrunda Joshi[14] (2006), the mean age in both the groups was 23 yrs which was statistically non-significant.

In the present study, the mean maternal age (years) in misoprostol group was 23.9 ± 3.2 years (table 2) and ergometrine group was 23.7 ± 2.5 years (table 2). The difference in age groups is not statistically significant.

The women included in the present study have maternal age ranging from 19- 30 years (table 2). In both the groups majority of the women belong to the age group 23-26 years, i.e. 42 in misoprostol group and 51 in ergometrine group.

The distribution of parity (table 3) shows that the majority of the women i.e. 51% in misoprostol group are multiparous and in ergometrine group majority are primigravidas i.e. 63%.

In the study by Vrunda et al, majority of women i.e is 54% in

misoprostol group were multigravidas and in methyl ergometrine group majority (51%) were primigravidas.

In study by Vrunda Joshi[14] (2006), when misoprostol was compared to methyl ergometrine, there was reduction in mean length of third stage from 4.18mins in methyl ergometrine group to 3.98 mins in misoprostol group.[76]

In a study by Frederic[13] the mean duration of labour was same in both groups. But incidence of PPH was more in misoprostol group compared to methyl ergometrine group (8.3%) in misoproostol group and 4.3% in ergometrine group.

In the present study, the duration of third stage is compared between the two groups. It is found that the duration of third stage in misoprostol group 2-32 mins with a mean of 3.23mins. In methyl ergometrine group, duration ranges from 2-32.5 mins and the mean is 1.90 minutes. By applying unpaired t-test $t = 7.37$, p value being < 0.05 is statistically significant.

Therefore intramuscular methyl ergometrine is more effective in reducing the duration of third stage of labour when compared to per rectal misoprostol in this study.

Maximum number of women in methyl ergometrine group i.e. 36 had duration of III stage of labour between 4-6 mins. In misoprostol group, maximum number i.e. 30 had a duration ranging between 6-8 mins.

The comparison of rise in systolic BP (in mmHg) between the two groups before delivery to after delivery shows $p < 0.05$ which is statistically significant. Therefore, intramuscular methyl ergometrine is exclusively associated with increase in systolic blood pressure. 19 cases showed rise in SBP in methyl ergometrine group as compared to 1 case in misoprostol group.

In a study by Frederic[13], it was found that one hour after birth of baby there was no difference in mean systolic blood pressure or the mean diastolic blood pressure in methyl ergometrine or misoprostol group respectively.

As regard to changes in diastolic blood pressure following delivery, in ergometrine group there is considerable rise in diastolic blood pressure with $p < 0.05$ which is significant as compared to misoprostol group. 19 cases showed rise in diastolic blood pressure in methyl ergometrine group as compared to 1 case in misoprostol group.

The comparison of Hb changes following delivery in both the groups are statistically significant with an average fall of 0.49gm/dl in methyl ergometrine group and 0.69 gm/dl in misoprostol group. Intergroup comparison applying unpaired t test shows $t = 3.40$, $p < 0.5$ which is statistically significant i.e. intramuscular methyl ergometrine results in significantly lesser reduction in Hb when compared to per rectal misoprostol.

In the study by Frederic[13] et al, the mean blood loss was same in both misoprostol and methyl ergometrine group.

In the study by Vrunda Joshi[14] (2006) when methyl ergometrine was compared to misoprostol, there was 200.87ml mean blood loss in methyl ergometrine group while lesser amount of blood loss i.e. 195ml mean blood loss was seen in misoprostol group.

In the present study, distribution of blood loss in the two groups showed mean blood loss of 160.6 ± 127.5ml in methyl ergometrine group, while in misoprostol group it was 236.8 ± 119.9ml. On application of unpaired t test $t = 4.36$, $p < 0.05$ which is significant i.e. intramuscular methyl ergometrine results in significantly lesser amount of blood loss when compared to per rectal misoprostol.

The need for additional oxytocics along with a primary drug indicates the risk of development of postpartum haemorrhage inspite of administration of the primary drug for its prevention.

In a similar study by Frederic[13] (1999) it was found that need of additional oxytocics was more in misoprostol group compared to methyl ergometrine group.

In a similar study, Vrunda Joshi[14] (2006) reported that the need of additional oxytocics was seen only in one out of fifty cases study, which was seen in methyl ergometrine group.

In the present study need of additional oxytocics was seen in 10 cases of misoprostol group and 7 cases in e methyl ergometrine group. Misoprostol group also had highest amount of blood loss thus indicating increased risk of postpartum haemorrhage and intramuscular methyl ergometrine showed better results than per rectal misoprostol.

In a similar study by Frederic[13] pyrexia was observed in 34% cases in misoprostol group compared to 3% in methyl ergometrine group. Shivering occurred in 42% cases of misoprostol group compared to 8.5% in methyl ergometrine group. There was no difference in two group in the occurrence of nausea, vomiting, diarrhoea, hot flushes, headache or vertigo.

In a similar study by Vrunda Joshi[14] in 2006, shivering, diarrhoea and fever were common side effects in misoprostol group. Nausea, vomiting, increase in BP were common in methyl ergometrine group.

In a similar study by Frederic[13] et al a higher incidence of retained placenta was found in misoprostol group compared methyl ergometrine group.

In a similar study, Vrunda Joshi[14] in 2006 reported a higher incidence of retained placenta associated with the use of methyl ergometrine compared with per rectal misoprostol.

In the present study misoprostol group had 10 cases of retained placenta whereas there was lesser number of cases of retained placenta i.e. 7 cases in methyl ergometrine group.

CONCLUSION:

In conclusion, the intramuscular methyl ergometrine when used results in lower blood loss, more effective reduction in duration of third stage of labour, significantly lesser reduction in Hb level after delivery but is associated with unpleasant side effects like nausea, vomiting, shivering, hypertension and risk of retained placenta. PPH was seen in lesser number of cases as compared to misoprostol group.

Per rectal misoprostol is safe with lesser side effects and can be used even in hypertensive patients for preventing PPH but is relatively less effective in preventing blood loss, results in higher fall of Hb level with greater number of cases requiring blood transfusion (8 cases as compared to 7 in methyl ergometrine group) and required additional oxytocics with a higher frequency. Residence of retained placenta was less, 3% as compared to 6% in methyl ergometrine group. Hence a cafetaria approach is required in usage of these drugs in general in reducing post partum haemorrhage and thereby maternal morbidity and mortality.

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