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Original Research Article

Role of methylergometrine versus oxytocin in the active management of third stage of labour: a randomised control trial

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ABSTRACT

Background: Postpartum haemorrhage (PPH) is the leading cause of maternal death globally. The routine practice of active management of third stage of labour has been shown to reduce haemorrhage by up to 60%. The present study evaluated the role of methylergometrine versus oxytocin in active management of third stage of labour in reducing the risk of PPH.
Methods: This study was conducted on a total of 400 women admitted in the labour ward of PESIMSR hospital, by using simple randomized design. The first study group included women who received intramuscular oxytocin (n=200) and, the second group included women who received intravenous Methylergometrine (n=200) within, one minute of delivery of the baby.
Results: The mean blood loss among study first and the second study group were 172.8 ml and 148.9 ml respectively ($p<0.05$) and, the mean duration of third stage of labour were 5.9 and 5.1 minutes respectively ($p<0.05$). The mean pre- and post-delivery haemoglobin values among the first and second group were 11.76 mg/dl, 10.46 mg/dl and, 11.76 mg/dl, 10.6 mg/dl respectively ($p<0.05$). There was an increase in the blood pressure in the ergometrine group and, slight decrease of blood pressure in oxytocin group.
Conclusions: The use of methyl ergometrine as part of active management of third stage of labour was associated with a significant reduction in mean blood loss value, duration of third stage of labour, and the additional need of oxytocic though, methylergometrine has significant side effects like nausea, vomiting and rise in blood pressure.

Keywords: Haemorrhage, Labour, Methylergometrine, Oxytocin

INTRODUCTION

Postpartum haemorrhage (PPH) is the leading cause of maternal death globally.[1] According to world health organization (WHO) estimates worldwide about 20 million maternal morbidities are due to haemorrhage and nearly 51,500 maternal deaths occur yearly because of postpartum hemorrhage.[2,3] India has one of the world's highest maternal mortality rates, at 560/100,000 live births (UNICEF, 2005-2009) and PPH is found to be the major direct cause accounting for 35-56% of all maternal deaths.[4]

According to WHO 25.7% of maternal deaths are contributed by India.[5] Two third of PPH occur in women with no identifiable risk factors, without proper management PPH can rapidly progress to cause life threatening blood loss, often within few hours because of this unpredictability and rapid progression, reducing the incidence of PPH and improving PPH outcome it does often remain a challenge.[6]

Where maternal mortality is high and resources are limited, the introduction of low-cost evidence-based practices to prevent and manage PPH can improve maternal and infant survival. Routine practice of active management of third stage of labour has been shown to dramatically reduced haemorrhage by up to 60%.[7] Also, it reduces the need for more complex medical interventions

to stop bleeding and reduces the need for blood transfusion. An ideal uterotonic agent should promote prompt, strong and sustained uterine contractions without any significant adverse effects. While few would dispute the role of routine prophylactic administration of uterotonic drugs in preventing PPH, the choice of uterotonic drugs remains controversial.[8]

Uterotonic drugs studied in the active management of the third stage of labour (AMTSL) include oxytocin, methylergometrine, oxytocin/ergometrine, prostaglandin analogues in varying doses and different routes of administration with different results.

The present randomized study was conducted to evaluate the methylergometrine and oxytocin in AMTSL, in terms of efficacy, duration of third stage, blood loss, reduction in incidence of PPH, effect on haematocrit (HCT), blood pressure and other side effects.

METHODS

This prospective randomized control study was conducted on four hundred women admitted in the labour ward of PESIMSR hospital and research centre, Kuppam, Andhra Pradesh, India between January 2017, and 15th October 2018 by using simple randomized design. Institutional Ethical committee clearance was obtained prior to conducting the study.

Inclusion criteria

It includes women between 20-35 years, more than 37 weeks of gestation, with singleton pregnancy, in vertex presentation without any fetal distress on admission.

Exclusion criteria

It includes women with previous caesarean section, multiple pregnancy, breech presentation, intrauterine fetal demise, previous scarred uterus (myomectomy/hysterotomy), cardiac/ renal/ hepatic/ epileptic/severe PIH/ severe anemia and the coagulopathies.

The eligible women admitted in the labour ward delivering at term by vaginal were included. The sample size was calculated based on the study of 400 women with 95% confidence level and 80% power was needed to detect significant change in the PPH. The first study group included two hundred women and received intramuscular oxytocin and second group included two hundred women who received intravenous methylergometrine within one minute of delivery of baby. The amount of blood loss, duration of third stage, need for MRP, incidence of PPH, need for repeated oxytocic and its side effects were evaluated between the study groups. On admission to labour room detailed history was taken and clinical examination was conducted.

Patient vitals were noted, obstetric examination, fetal-maternal monitoring were evaluated and progress of labour was monitored with partogram. The patient received intramuscular oxytocin 10 IU or, IV methylergometrine 0.2 mg in a randomized order. Once delivered, the baby placenta was delivered by controlled cord traction, the duration of the third stage was noted. The blood loss was measured using 18×18-inch dry sponges, and by measuring the amount of blood collected in the container placed in the edge and, beneath the delivery table. The outcome measures were amount of blood loss, duration of third stage, blood pressure, incidence of PPH, need for repeated oxytocic and the side effects.

Method of collection of data

All study participants meeting the inclusion criteria were recruited into two groups by computer-generated random carts, a pre structured proforma was used to collect data and after administration of the drug the subject was evaluated clinically, and laboratory evaluations were conducted.

Statistical analysis

Qualitative test analysis was conducted by t test and the quantitative data was conducted by chi-square test. The statistical analysis conducted by using the software stata version 14.

RESULTS

A total of four hundred women in labour ward were part of the study. The mean age in the oxytocin group was 21.14 years and in the methylergometrine group was 21.04 years. There is no mean age difference between both the groups (Table 1). The mean gestational age in the oxytocin group was 39.24 weeks and in the methylergometrine group was 39.03 weeks. There is no mean gestational age difference between both the groups (Table 2). The mean value of the duration of labour in the oxytocin group was 5.9 minutes and in the methylergometrine group it was 5.1 min. This difference in the duration of labour between two groups was statistically significant ($p<0.05$) (Table 3).

Table 1: Mean scores of age (years) distribution in two groups of patients studied, (n=200).

Variable	Group 1		Group 2	
Age (years)	Mean	SD	Mean	SD
	21.14	2.6	21.04	2.6

Table 2: Mean gestational age distribution in two groups of patients studied, (n=200).

Variable	Group 1		Group 2	
Gestational age (weeks)	Mean	SD	Mean	SD
	39.24	1.10	39.03	1.16

Table 3: Comparison of mean value of duration of 3rd stage of labour 2 groups of patients studied, (n=200).

Variables	Group 1		Group 2		P value
Duration	Mean	SD	Mean	SD	
(min)	5.9	0.6	5.1	0.3	*<0.001

*P<0.05 significant

The mean haemoglobin value in oxytocin group was 11.76 g/d and 10.45 g/dL pre-and post-delivery, respectively. The mean haemoglobin value in methylergometrine group was 11.76 g/dL and 10.6 g/dL pre- and post-delivery, respectively. This difference in post-delivery haemoglobin value among both the groups was statistically significant (p<0.05). The mean value of value of HCT in the oxytocin group was 35.5% and 32.1%, pre-and post-delivery, respectively. The mean value of value of HCT in the methylergometrine group was 34.3% and 32.4%, pre-and post-delivery, respectively. This difference in HCT concentration pre-and post-delivery among both the groups was significant (Table 4).

In study groups, mean value of the blood loss in oxytocin group was 172.8 mL and among the methylergometrine group was 148.9 ml. This difference in the amount of blood loss between 2 groups was statistically significant (p<0.05).

The observed incidence of PPH (blood loss more than 500 ml) seen for three participants in the oxytocin group and for one participant in the methylergometrine group (Table 5). Among the study groups the oxytocin group only 1.02% of them experienced side effects. In the methylergometrine group 5.67% of the study participants of them experienced nausea and vomiting. This difference in occurrence of side effects among two groups was statistically significant (p<0.05). The Pearson's chi-squared statistical test was applied to know the relationship between the study groups (Table 6).

Systolic and diastolic blood pressure before delivery, after 1 and 4 hours of post-delivery was raised in ergometrine group and decreased in oxytocin group (Table 6 and 7).

Table 4: Comparison of mean value of pre and post HCT value in two groups of patients studied, (n=200).

Variables	Group 1		P value	Group 2		P value
HCT	Mean	SD		Mean	SD	
Pre-delivery HCT	35.5	4.6	<0.001	34.3	6.2	<0.001
Post-delivery HCT	32.1	4.6		32.4	3.6	

Table 5: Comparison of the mean blood loss values in two groups of patients studied, (n=200).

Variable	Group 1		Group 2		P value
Blood loss (ml)	Mean	SD	Mean	SD	
	172.75	51.6	148.85	43.3	*<0.000

*P<0.05 significant

Table 6: Comparison of the side effects between two study groups, (n=200).

Variables	Group 1		Group 2		P value
Side effects	Frequency	Percentage (%)	Frequency	Percentage (%)	
Yes	2	1.02	11	5.67	0.011
No	194	98.98	183	94.33	
Total	196	100	194	100	

Table 7: The comparison of mean systolic blood pressure pre-delivery, 1 hour and 4 hours after delivery in oxytocin versus ergometrine group, (n=200).

Variables	Group 1		Group 2		P value
	Mean	SD	Mean	SD	
Before delivery	122	6.2	122	6.2	0.56
After 1 hour delivery	120.4	6.42	127.4	5.77	0.000
After 4 hours of delivery	120.5	5.07	126.80	6.78	0.000

Table 8: The comparison of mean diastolic blood pressure pre-delivery, 1 hour and 4 hours after delivery in oxytocin versus ergometrine group, (n=200).

Variables	Group 1		Group 2		P value
	Mean	SD	Mean	SD	
Before delivery	78.1	3.8	78.2	3.9	0.5
After 1 hour delivery	78.9	3.93	82.0	4.32	0.000
After 4 hours of delivery	76.9	3.9	80.8	4.2	0.000

*P<0.000 significant

DISCUSSION

This randomised study compares the efficacy of oxytocin versus methylergometrine in the active management of third stage of labour. PPH is a significant contributor to severe maternal morbidity and mortality, especially in developing countries like India. The prophylactic use of oxytocic in the third stage of labour has been found to decrease threat of post-partum bleeding. However, there are limited evidence regarding the type and route of administration of oxytocic drugs which offers the best efficacy and safety profile.

A randomized study was carried out on four hundred women. The women allocated under oxytocin group were given 10 IU oxytocin intramuscularly at delivery of the anterior shoulder, while in the women in the ergometrine group women were given 0.25 mg methyl ergometrine intravenously at delivery of the anterior shoulder. The mean age in oxytocin group was 21.14 years, while in methylergometrine it was 21.04 years. There is no significant difference between the two groups. The mean gestational age in the oxytocin group was 39.24 weeks and in the methylergometrine group was 39.03 weeks, there was no mean gestational age difference between the groups. The findings of our study were similar to the study conducted by Suman et al where the mean age and gestational age were comparable in the study.[9]

The mean value of duration of third stage of labour in the oxytocin group was 5.9 min while in methylergometrine group was 5.1 min, the difference in the duration of third stage of labour in between the two groups was statistically significant. In the study population, the mean value of the blood loss among participants who received methylergometrine was 148.9 ml and among the participants who received oxytocin was 172.8 ml. This difference in the amount of blood loss between two groups was statistically significant ($p<0.05$). The incidence of PPH (blood loss more than 500 ml) noted for 3 participants in oxytocin group and for 1 participant in methylergometrine group. In a study conducted by Boopathi et al on three hundred women, showed that methylergometrine to be more effective than oxytocin in reducing the duration of the third stage of labour.[10]

In our study population, the mean value of haemoglobin among participants who received methylergometrine were 11.76 g/dl and 10.6 g/dl pre-and post-delivery, respectively. The mean value of haemoglobin among the participants who received oxytocin was 11.76 g/dl and 10.46 g/dl pre-and post-delivery, respectively. This difference in haemoglobin concentration of post-delivery among both the groups were statistically significant ($p<0.05$).

In a prospective study conducted by Rajendran et al from the JSS Medical College and Hospital JSS University, Mysore, India, in April 2016, on one hundred women, the mean duration of third stage of labour in the methylergometrine group was 6.44±2.426 min and in the oxytocin group 6.28±2.556 min. Mean blood loss was 224.80±50.759 ml and 237.0±69.583 ml. The mean fall in Hb was 0.82±0.29 % and 0.86±0.007%.[11]

A similar randomized control study in 2015 by Ramya et al from Adichunchanagiri institute of medical sciences, Karnataka on two hundred and ten women found the mean blood loss at delivery in oxytocin group was 741.66 ml and methylergometrine group was 492.7 ml with $p=0.036$, which was statistically significant. The mean duration of third stage of labour in the oxytocin group was 7.35 min and, in the methylergometrine was 6.21 min. The study concluded that methylergometrine is a better uterotonic when compared to intramuscular oxytocin to reduce the amount of blood loss to prevent complications like atonic PPH.[12]

In our study population, the systolic and diastolic blood pressure after delivery showed a significant difference between both the groups ($p<0.05$). There was increase in blood pressure in ergometrine group and slight decrease in blood pressure in oxytocin group. In a study conducted by Rajendra et al 19% women who received methylergometrine had risen in blood pressure.[11] The similar finding was noted in the study conducted by Suman et al.[9]

Among the study population the group who received oxytocin experienced only 1.02% of them experienced side effects. Among the participants who received methylergometrine 5.67% of them experienced nausea and vomiting. This difference in occurrence of side effects among two groups was statistically significant ($p<0.05$). Pearson's chi-squared statistical test applied to know the relationship between the groups. The same result was observed in the other studies conducted by Suman et al and Boopathi et al.[9,10]

Limitations

This study has been done over small size of population. While post-partum hemorrhage remains a dreaded event, there is an aggressive need to do research of this type on large scale of population to decide on the choice of an uterotonic to prevent and reduce its incidence of post-partum hemorrhage in our women.

CONCLUSION

Administering uterotonic drug within one minute of birth is the component of AMTSL that has greatest impact on the prevention of PPH. This study concluded that the mean blood loss, duration of the third stage of labour and fall in the hemoglobin-HCT values was more in the women who received oxytocin compared, with the women who received methylergometrine. In the study it was observed that there was an increased need for additional oxytocic in the oxytocin group. On the other hand, methylergometrine showed side effects like both increase in systolic blood

pressure and diastolic blood pressure, nausea, and vomiting. The choice of drug depends on cost, facilities for storage, refrigeration and assessment of trade-off between benefits and side-effects.

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