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Comparative Study of Efficacy and Safety of Intramuscular Oxytocin with Intramuscular Methylergometrine in the Active Management of Third Stage of Labour.

Dhananjaya BS, and Charishma S*

Department of OBG, Sri Siddhartha Medical College, Tumkur, Karnataka, India.

ABSTRACT

To determine the amount of blood loss in those receiving intramuscular oxytocin and intramuscular methylergometrine by quantitative estimation, the degree of blood loss by hemoglobin and hematocrit estimation following delivery.To determine the need for additional uterotonics and side effects. This is a randomized trial. Hundred women undergoing vaginal delivery are recruited,50 in each group receiving 10IU of oxytocin intramuscularly and 0.2mg methylergometrine intramuscularly alternately immediately following delivery.The efficacy and safety of both drugs were analyzed by comparing quantitative measurement of amount of blood loss, percentages fall in haemoglobin and haematocrit level,need for additional uterotonics,duration of third stage,need for blood transfusion and side effects. Mean blood loss was less in oxytocin than in methylergometrine group[219.8±86.3ml versus 345.2±109.53ml(p-value-0.00)].Percentage of haemoglobin loss was less in oxytocin than in methylergometrine group[4.78±5.23% versus 8.40±6.33%(p-value 0.01)].Percentage of PCV loss was less in oxytocin than in methylergometrine group[4.66±4.29% versus 7.58±5.84%(p-value-0.00)].Side effects were seen in 13% of cases of methylergometrine group and no side effects seen in oxytocin group. Additional uterotonics were used in 18% of cases in methylergometrine and in 2% of cases in oxytocin group. Blood transfusion were required in 8% of cases in methylergometrine and none in oxytocin group. Intramuscular oxytocin is more efficacious than intramuscular methylergometrine in the prevention of third stage blood loss with fewer side effects.

Keywords: Oxytocin, Methylergometrine, Active Management of Third Stage of Labour, Blood loss, Side effects, PPH

Corresponding author

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INTRODUCTION

"There are many who believe that the delivery of women is easy --- and in truth there is no mystery when things go normally. But, when an accouchement is preternatural it becomes the most difficult, laborious and dangerous of all procedures."- Francois Mauriceau,1964. The third stage of labour is defined as the period from the delivery of the baby until the complete expulsion of the placenta and membranes. This normally takes between 15 to 30 minutes [1].

Post partum haemorrhage(PPH)is the most common complication of third stage of labour and is defined as blood loss in excess of 500ml after the birth of baby.World Health Organization (WHO) also estimated 20 million annual maternal morbidities due to hemorrhage.In developing countries, where maternal mortality rates are exponentially higher, PPH plays an even greater role. [2] One mother dies every 10 minutes(WHO-2007).In India, MMR is-254/lakhs with pregnancy related hemorrhage accounting for 22.6%.All pregnant women is "at risk" for this catastrophic event.Active management of third stage of labour(AMTSL) has been shown to reduce the incidence of severe PPH by approximately 60%–70% [3], shortens the duration of third stage of labour by almost 50% and blood loss by 20%.1 .As the golden rule says, "prevention is better than cure", preventing PPH is better than managing it and the first step towards its prevention is the AMTSL.Commonly used uterotonics are oxytocin ,methylergometrine and prostaglandins during the active management of third stage of labour. Intramuscular oxytocin is now strongly recommeneded by WHO and also by SBA(Skill Births Attendents) training programme [4].It is the drug of choice in third stage of labour and is supposed to be safer than methylergometrine with fewer side effects. Since, methylergometrine is widely used in hospital setup, there is a need for study of efficacy intramuscular oxytocin in preventing PPH and its side effects [4, 5].

MATERIALS AND METHOD

The present study was conducted in department of Obstetrics and Gynaecology, of Sri Siddhartha Medical College Hospital and Research centre, Tumkur, Karnataka, in the period of 18 months between December 2011 and May 2013. 100 pregnant woman after 28 weeks of gestation delivering vaginally were selected. Women who are grand multiparae, rhesus negative women, women with medical disorders like heart disease, diabetes,those with bleeding diathesis,precipitated labour,overdistened uterus, traumatic PPH, PROM/Chorioamnionitis, IUD, previous caesarean section/scar on uterus and inability to obtain the informed consent were excluded from the study.Selection of cases were done by systematic random sampling method, assigned to intramuscular oxytocin administration or intramuscular methylergometrine administration alternatively during third stage of labour followed by clamping and cutting of the umbilical cord and the placenta delivered by amount of blood collected in drapes, and the blood absorbed in the pre-weighed mops and weight of the clots added, duration of third stage,vitals examination at 5,15,30,60 mins, need for additional uterotonic, side effects/ adverse affects of the uterotonic used- nausea, vomiting, headache, rise in blood pressure and others, need for blood transfusions.A sample of venous blood (5 ml)

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before delivery and 24 hours after the birth for haemoglobin and haematocrit measurement from each woman in the study is collected as an objective index of blood loss.

OBSERVATION

Among the 100 women enrolled in the study, 50 subjects received 10 IU of oxytocin intramuscularly and 50 subjects received 0.2mg of methylergometrine.

Mean age, parity, and socioeconomic status were comparable in both the groups (table 1). The outcome data is shown in (table 2). The mean blood loss was 219±86.3ml in oxytocin group and 345±109.53ml in methylergometrine group (p value= 0.003) which was highly significant and z value of 6.36. The mean duration of third stage of labour in oxytocin group was 8.69±1.41 mins and in methylergometrine group was 8.67±1.63 mins (p value=1.96) were statistically not significant. The percentage of hemoglobin reduction in oxytocin group 24 hours post delivery was 4.78±5.23% and in methylergometrine group was 8.40±6.33% with a p value=0.001 and z value=2.80,which was statistically highly significant.The percentage of hematocrit reduction in oxytocin group 24 hours post delivery was 4.66 ± 4.29% and in methylergometrine group was 7.58 ± 5.84 % with a p value=0.001 and z value=2.82,which was statistically highly significant.

Table 1 Sociodemographic pattern

Factors	Oxytocin group N=50	Methylergometrine group N=50
Age(years)		
18-24	41	40
25-35	09	10
Parity		
Primigravida	15	19
Multigravida	35	31
Urban	41	41
Rural	09	09
Antenatal care		
Booked	46	45
Unbooked	04	05

Table 2 Distribution of cases according to the outcome of the study

Outcome	Oxytocin N=50	Methylergometrine N=50	P value
Mean amount of blood loss(ml)	219±86.3	345±109.53	0.001
Mean duration of third stage(mins)	8.69±1.41	8.67±1.63	1.96
Mean percentage fall in haemoglobin level(%)	4.78±5.23	8.40±6.33	<0.003
Mean percentage fall in hematocrit level(%)	4.66±4.29	7.58 ± 5.84	0.001

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Table 3 Distribution of cases according to occurrence of PPH, need for blood transfusion and additional uterotonics.

Outcome	Oxytocin N=50	Methylergometrine N=50	P value
Occurrence of PPH	1	6	0.001
Need for additional utrotonics	0	9	
Need for blood transfusion	0	4	

Table 4 Comparison of side effects between both the groups

Side effects	Oxytocin group	methylergometrine group
Nausea	0	1
Vomiting	0	4
Headache	0	7
Diarrhea	0	1

According to quantitative estimation of blood loss, Post partum hemorrhage(blood loss >500ml) was seen in 2% of oxytocin group and 12% of methylergometrine group.(p value-0.001). Additional oxytocics were required in 18% of cases of methylergometrine group and none in oxytocin group. Blood transfusion was required in 8% of cases in methylergometrine group and none in oxytocin group (table 3).

Side effects was seen in 26% of methylergometrine group i.e nausea-2%, vomitting-8%, headache-14% and diarrhea-2% and no side effects were seen in oxytocin group (table 4).

DISCUSSION

Current oxytocic drugs are far from ideal particularly for routine use in developing countries, where simple route of administration, and stable, inexpensive drugs are needed because many deliveries takes place far from hospitals or medical facilities and are supervised solely by birth attendants and Oxytocin is one such drug which has few side effects. The present study shows intramuscular oxytocin is more efficacious and safe than intramuscular methylergometrine in management of third stage of labour. The majority of women in the study were between the age group of 20 to 25 years constituting 58% in oxytocin group and 68% in methylergometrine group. In our present study percentage of primigravida and multigravida between the two groups were comparable with the study of Shilu adhikari et al(2007) [1] and Choy et al(2002) [6].In our present study, the mean duration of third stage of labour was comparable to the studies done by Shilu adhikari et al(2007)1 and Suman kumar de et al(2013) [7]

The mean blood loss in oxytocin group was 219±86.3ml in oxytocin group and 345±109.53ml in methylergometrine group, p value= <0.001, which was highly significant. As observed in our present study the mean blood loss was comparatively less in the oxytocin group than in the methylergometrine group. Similar observations were seen in other studies

[1,6,7]. In this study the overall incidence of PPH using volume criteria i.e. a blood loss of 500ml or more was 7% and this is comparable to that reported in most of the other studies. In the studies conducted in India by Vimal et al, [8] in 2004 the observed incidence of PPH was 3.1% and in that conducted by Goyal et al, [9] in 1998, it was 5.07%. Another study done by Choy et al [6], in Hong Kong reported an incidence of 4.64%.

Also, in our present study, the incidence of PPH is slightly higher compared to other studies because ours is a referral hospital, where most of the cases before reaching our hospital are handled outside and and not referred in time. Razvi et al [10], clearly stated in his study that PPH cannot be detected by visual estimation of blood loss, unless there are associated signs of haemodynamic instability.

Therefore all further studies on postpartum hemorrhage should be based on the peripartum Hb and or Hct changes rather than quantitative estimation of blood loss.

The need for additional uterotonics and incidence of side effects are slightly more in methylergometrine group.

CONCLUSION

Post partum hemorrhage is a major killer in our part of the world so every measure to prevent excessive blood loss in the third stage of labour is worthwhile Oxytocin administered is associated with lesser mean blood loss, lesser fall in Hb% and Hct% and as a result there was lesser need for blood transfusion.

Methylergometrine loses its efficacy at room temperature and has to be stored at 2◦C-8◦C and in a setup like PHCs where power cuts are a major issue and for skilled birth attenders it is not feasible, hence in such places and for people like SBA's oxytocin proves to be a better oxytocic in this regard.

Need for additional oxytocics were required in methylergometrine group and none in oxytocin group.

However in the view of occurrence of fewer side effects in the intramuscular oxytocin group compared to intramuscular methylergometrine group, it can be concluded that intramuscular oxytocin is more safe and efficacious and is a preferable prophylactic uterotonic in the active management of the third stage of labour.

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