**Scholars Journal of Applied Medical Sciences (SJAMS) ISSN: 2347-954X (P) & 2320-6691(O)**
**Sch. J. App. Med. Sci., 2013; 1(5):595-599**
©Scholars Academic and Scientific Publisher
(An International Publisher for Academic and Scientific Resources)
www.saspublishers.com DOI: 10.36347/sjams.2013.v01i05.0061

**Research Article**

# A Comparative Study Of Ergometrine With Oxytocin In Controlling Third Stage Blood Loss –A Randomized Control Trial

**Suman Kumar De[1], Dhrubajyati Saha[1], Arnab Kumar Koley[1], Apurba Saha[1], Tapan Kumar Ganguly[2], Babul Chandra Dey[3]**

[1]Senior Resident, Department of Gynaecology and Obstetrics ,Chittaranjanseva Sadan, Kolkata.
2Senior Resident, Department of Gynaecology and Obstetrics ,Burdwan Medical College, Burdwan.
[3]Meadical officer, Jangipur Subdivision Hospital

**Corresponding author**
Dr. Suman Kumar De
**Email:** sumankumarde@gmail.com

**Abstract:** The present study was to determine the degree of fall in hemoglobin , hematocrit and need for blood transfusion following delivery in those receiving intramuscular methylergometrine and intramuscular oxytocin and also to compare the safety and efficacy of those two drugs. This was a randomized, comparative, prospective, single blinded, interventional,Hospital based clinical trial conducted in the labour room and maternity ward at R.G.Kar Medical College and Hospital, Kolkata. , recruiting 400 women after matching, 200 in each two groups- Group A receiving intravmuscularmethylergometrine, Group B receiving intramuscular oxytocin. 3rd stage blood loss, systolic blood pressure, diastolic blood pressure, hemoglobin and hematocrit value before and after giving uterotonic are measured and recorded..Side effect of both uterotonic were recorded. Data were analysed by using SPSS Software version 18. The mean duration of the 3rd stage was 6.40 minute in ergometrine group compared to 7.31 minute in oxytocin group. The difference was not statistically significant. The average blood loss was 194.7 ml in ergometrine group compared to 188.9 ml in oxytocin group. The fall in hemoglobin percentage was 0.89 g/dl in ergometrine group compared to 1.118 g/dl in oxytocin group. The difference in observation of both groups was statistically not significant ($p>0.05$). The fall in hematocrit was 2.41 ergometrine group compared to 2.65 in oxytocin group. The difference in observation of both groups was statistically not signifanat ($p>0.05$). The incidence of post partum hemorrhage was 3% in both the groups. There were 1 case of retained placentain either of the groups. Need for additional oxytocics was 4% in both the groups as they were given only when the blood loss is more than 500 ml in the present study. There was increase in blood pressure in ergometrine group and slight decrease in blood pressure in oxytocin group. Vomiting, leg cramp and chest pain were associated with inj methyl ergometrine. We found that both the drugs were equally effective in management of 3rd stage of labor. However a comparison between two groups revealed that vomiting, leg cramp and rise in mean blood pressure were more common side effects with methyl ergometrine, and the two drugs did not confer any significant advantage over the other in terms of duration of 3rd stage, blood loss during 3rd stage, fall in hemoglobin percentage, fall in hematocrit, and need for additional oxytocics.
**Keywords:** hematocrit, methylergometrine, oxytocin, randomized

**INTRODUCTION**:

Pregnancy and childbirth involves significant health risks, even to women with no pre-existing health problems [1]. The World Health Organization estimates that nearly 51,500 women across the world die from complications of pregnancy and childbirth and approximately 99% of such deaths occur in developing countries[2], mostly due to lack of access to life saving cure. Besides peripartum blood loss is often underestimated as traditionally blood loss in the third stage of labour is visually estimated with variations in accuracy, mainly due to subjective assessment. Postpartum hemorrhage, defined as bleeding in excess of 500ml. in the 1st 24hrs following childbirth(WHO 1990), accounts for a large proportion of huge maternal morbidity and mortality rate worldwide.

India has one of the world's highest maternal mortality rates, at 560/100,000 live births (UNICEF, 2005-2009), and postpartum hemorrhage is found to be the major direct cause accounting for 35-56% of all maternal deaths

For India, the National Family Health Survey of 1992-1993, was the first to provide a national level estimate of approximately 437 maternal deaths/ 100,000 live births for the two year period preceding the survey (International Institute for Population Sciences, 1995). To fill in the data gap, currently the Sample Registration System and the 'sisterhood method' developed by Graham *et al*, in 1989 have come into focus.

When compared to expected management, it is seen that active management not only reduces the duration of the third stage of labour by 50%, it also reduces blood loss by 20%[3]. Therefore, active management of third stage of labour is now adapted by most countries across the world as a strategy to reduce blood loss during childbirth. On analysis of the several

components of active management, it is seen that almost all the beneficial effects are due to the use of uterotonic agents alone.

Administration of uterotonics prophylactically, as a part of the active management of third stage of labour, has now become a routine practice worldwide. Various drugs like ergometrine, oxytocin, a combination of both ergometrine and oxytocin (syntometrine), prostaglandin and carbetocin have been used according to time, place and situation.

The oxytotic drugs included in the study was- oxytocin and methylergometrine. The Aim of this study was to determine the degree of fall in hemoglobin , hematocrit andneed for blood transfusion following delivery in those receiving intramuscular methylergometrine (Group A) and intramuscular oxytocin (Group B) and also to compare the safety and efficacy of those two drugs.

**METHOD**

This was a randomized, comparative, prospective, single blinded, interventional clinical trial conducted in the labour room and maternity ward at R.G.Kar Medical College and Hospital, Kolkata. , recruiting 400 women, 200 in each two groups- Group A receiving intravmuscularmethylergometrine, Group B receiving intramuscular oxytocin. The duration of the study was 1 year , from July 2010 to June 2011. . Informed consent was taken from all the mothers and the study was approved by ethical committee of this institution.

Only those women who delivered between 8 am and 2 pm during the period of the trial were included in this study. This time limit was set because at our hospital most women who have a normal vaginal delivery are discharged the following day after the morning rounds. The morning rounds are done at 9am each day but the discharge procedure takes some time. It is only at around 2 pm that women can leave the hospital and by this time all women could have a repeat blood sample drawn for Hb and Hct estimated after 6 completed hours of delivery.

Pregnant mother with singleton normal pregnancies having Gestational age ≥ 37 weeksanticipating vaginal delivery with spontaneous onset of labour was included in this study. Pregnant mother havinghypertension, gestational age <37 weeks and >41 weeks, multigravida ,induction of labour ,instrumental delivery, C.Section ,muiltiple pregnancy ,Hydramnios ,IUFD, Placenta prevea or other causes of APH, past history of PPH, sepsis, heart disease ,asthma / Allergic disorders were excluded from this study.

During the period of the study 19546 women delivered at RGKMCH, out of them 13445(68.78%) had normal vaginal delivery and among them 435 were enrolled into the study. Later 35 of them were excluded because they either failed to have a normal vaginal delivery (26) or failed to have their postpartum blood sample taken for repeat Hb/Hct estimation (9). Finally a total of 400 women completed the study, 200 in each group. Women were enrolled by probability sampling, systematic sampling technique..

After getting informed consent blood sample(5ml venous blood) was taken for estimation of haemoglobin and hematocrit from all the 400 study subject from antecubital vein using all aseptic precaution before delivery.After that 200 subjects fulfilling criteria will receive 0.2mg methyl ergometrine maleate IM during delivery of anterior shoulder and variables compared with 200 matched subjects who received 10 iu oxytocin IM at similar stage of delivery. Data were statistically analysed by chi-square test and significance was expressed in term of 'P' value. Data were analysed by using SPSS Software version 18.

**RESULT AND ANALYSIS:**

Both the groups were comparable in respect of mean age.The mean duration of first stage and second stage was comparable in both the groups statistically.Duration of 3$^{rd}$ stage of labour was less than 6 minute in maximum number of patients in both the groups.

The duration was 10 minute or more in 28% of cases in oxytocin group compared to 19% of cases in ergometrine group. The mean duration of 3$^{rd}$ stage of labour in both the groups were comparable statistically and p value >.05 that is insignificant.

The episiotomy required in both the groups was comparable with the difference between them being statistically not significant.

In both the group blood loss in most of the cases was upto 200ml. Both the groups have equal number of cases with blood loss more than 500 ml.

**Table 1:Comparison of mean blood loss between both groups (ml)**

| Groups | Mean blood loss | SD | Mean( log transformed) | SD( log transformed) | t | df | p |
|---|---|---|---|---|---|---|---|
| Ergometrine | 194.75 | 152.75 | 5.03 | .66 | 1.545 | 398 | .123 |
| Oxytocin | 188.9 | 85.38 | 5.12 | .51 | | | |

The average third stage blood loss is slightly more in ergometrine group. But the difference between two groups was statistically not significant., Number of cases who received additional oxytocicswere 8 in each group
There were equal number of cases of postpartum hemorrhage and retained placenta in the each group.

**Table 2:Comparison of systolic blood pressure in both the groups (mm of Hg)(before delivery and 1 hr and 4 hr after delivery)**

| Time interval | Ergometrine group | | Oxytocin group | | Z value | p value |
|---|---|---|---|---|---|---|
| | Mean | ±SD | Mean | ±SD | | |
| Before delivery | 122.22 | 6.6 | 122.6 | 6.53 | 0.578 | 0.563 |
| 1 hr after delivery | 127.4 | 5.77 | 120.4 | 6.42 | 11.465 | 0.000 |
| 4 hr after delivery | 126.80 | 6.78 | 120.5 | 5.07 | 10.52 | 0.000 |

Systolic blood pressure 1 hour after delivery was raised in ergometrine group and decreased in oxytocin group Systolic blood pressure 4 hour after delivery remained raised in ergometrine group and decreased in oxytocin group

**Table 3: Comparison of diastolic blood pressure in both the groups (mm of Hg) )(before delivery and 1 hr and 4hr after delivery)**

| Time interval | Ergometrine group | | Oxytocin group | | Z value | p value |
|---|---|---|---|---|---|---|
| | Mean | ±SD | Mean | ±SD | | |
| Before delivery | 78.87 | 3.96 | 78.9 | 4.13 | 0.074 | 0.941 |
| 1hr after delivery | 81.0 | 4.32 | 76.9 | 3.93 | 9.92 | 0.000 |
| 4hr after delivery | 80.8 | 4.2 | 76.3 | 3.93 | 12.58 | 0.000 |

Diastolic blood pressure 1 hour after delivery was raised in ergometrine group and decreased in oxytocin group Diastolic blood pressure 4 hour after delivery remained raised in ergometrine group and decreased in oxytocin group
The increase in mean pulse rate was noted in both the groups after delivery.

**Table 4:Comparison of hemoglobin change in both the groups (g/dl)**

| Time interval | Ergometrine group | | Oxytocin group | | Z value | p value |
|---|---|---|---|---|---|---|
| | Mean | ±SD | Mean | ±SD | | |
| Before delivery | 10.44 | 0.82 | 10.33 | .708 | 1.475 | 0.141 |
| After delivery (6hr) | 9.55 | 0.75 | 9.15 | 0.62 | 5.805 | 0.000 |
| Difference | 0.89 | | 1.18 | | | |
| Reduction(%) | 8.52% | | 11.42% | | | |

There was reduction of postpartum hemoglobin value in both groups. The difference between both groups was not statistically significant.

**Table 5:Comparison of hematocrit change in both the groups (g/dl)**

| Time interval | Ergometrine group | | Oxytocin group | | Z value | p value |
|---|---|---|---|---|---|---|
| | Mean | ±SD | Mean | ±SD | | |
| Before delivery | 35.87 | 0.71 | 35.781 | 0.74 | 2.56 | 0.011 |
| After delivery (6hr) | 33.46 | 0.671 | 33.13 | 0.807 | 4.376 | 0.000 |
| Difference | 2.41 | | 2.65 | | | |
| Reduction(%) | 6.71% | | 7.4% | | | |

There was reduction of postpartum hematocrit value in both groups. The difference between both groups was not statistically significant.

**Table 6:Side effects in both groups**

| Side efects | Ergometrine group (n=200) | Oxytocin group (n=200) |
|---|---|---|
| Vomiting | 30 | 1 |
| Leg cramp | 15 | 0 |
| Chest pain | 5 | 3 |

Vomiting and leg cramp were noted mostly in the ergometrine group.
Need for blood transfusion was comparable in both the groups and statistically not significant.

## DISCUSSION

In most of the early studies comparing oxytocin with ergometrine in the prevention of postpartum haemorrhage, oxytocin was given intramuscularly at a dose of 5 units[4-6]. In the study published by Dumoulin in 1981, it was clearly stated that the dose of intramuscular oxytocin had to be changed from 5 units to 10 units during the course of the trial because of the high incidence of postpartum haemorrhage associated with the lower dose (12.4% versus 8.6%)[7].

In this study both the groups were comparable in respect of mean age .The mean duration of first stage and second stage was comparable in both the groups statistically.Duration of 3rd stage of labour was less than 6 minute in maximum number of patients in both the groups. The duration was 10 minute or more in 28% of cases in oxytocin group compared to 19% of cases in ergometrine group.The mean duration of 3rd stage of labour in both the groups were comparable statistically.The episiotomy required in both the groups was comparable with the difference between them being statistically not significant.

In both the group blood loss in most of the cases was upto 200ml. Both the groups have equal number of cases with blood loss more than 500 ml.The average third stage blood loss is slightly more in ergometrine group. But the difference between two groups was statistically not significant. In a series of 1378 subjects, Nieminen and Jarvinen[8]reported no difference in the postpartum haemorrhage rate between the two drugs when given intramuscularly with an odds ratio of 0.56 (95% CI 0.20–1.61). Mitchell et al.[10] reported a significant reduction in postpartum haemorrhage rate in the ergoometrine group with an odds ratio of 0.37 (95% CI 0.16–0.85). Combiningthese studies, intramuscular ergoometrine was associated with a significantly lower rate of postpartum haemorrhage than 5 units of oxytocin alone with an overall summary odds ratio of 0.36 (95% CI 0.23–0.55).
Dochertyand Hooper[9] reported that oxytocin was associated with a40% increase in mean blood loss, but the absolute rate ofpostpartum haemorrhage was not stated. McDonald et al.and Khan et al. reported no difference in the postpartumhaemorrhage rate with an odds ratio of 0.90 (95% CI 0.75–1.07) and 0.89 (95% CI 0.53–1.51), respectively. However,the use of ergometrine was associated with an increase inthe incidence of nausea, vomiting, headache and hypertension.On the contrary, Yuen et al. reported a 40%reduction of the risk of postpartum haemorrhage (OR0.60, 95% CI 0.21–0.88) and the need for repeated oxytocicinjections (OR 0.63, 95% CI 0.44–0.89) in the ergometrinegroup compared with oxytocin and side effects wereuncommon in both groups.

Number of cases who received additional oxytocics were 8 in each group.There were equal number of cases of postpartum hemorrhage and retained placenta in the each group.

Systolic blood pressure 1 hour and 4 hour after delivery was raised in ergometrine group and decreased in oxytocin group .Diastolic blood pressure 1 hour and 4 hour after delivery was raised in ergometrine group and decreased in oxytocin group .The increase in mean pulse rate was noted in both the groups after delivery.

There was reduction of postpartum hemoglobin and hematocrit value in both groups. The difference between both groups was not statistically significant.In a study ofC.M.Y. Choyet al shows that despite the low incidence of postpartum haemorrhage in both groups, the drop in haemoglobin level within 24 hours was more than 10% in about 40% of our patients and over 20% in about 13%. This agrees with the findings from another study conducted in a similar population[13]. It would be of interest and importance to see if similar findings occur in other populations. Clinical estimation of blood loss is notoriously inaccurate[14,15]. The traditional definition of postpartum haemorrhage of blood loss of 500mL carries little clinical significance. Postpartum haemorrhage would be better defined as the peripartum fall in haemoglobin (or haematocrit) level of at least 10% as suggested by the American College of Obstetricians and Gynecologists[16]. Future studies of the efficacy of uterotonic agents inreducing the rate of postpartum haemorrhage should be based on the peripartum haemoglobin change rather thanclinical estimation of blood loss[13].

Vomiting and leg cramp were noted mostly in the ergometrine group. Unpleasant maternal side effects have been well reported with the use of ergoometrine in the western studies was as high as 20%–30%[10].
Need for blood transfusion was comparable in both the groups and statistically not significant. Yuen et al.[12] reported a higher incidence of retained placenta associated with the use of ergometrine compared with intramuscular oxytocin, but a similar finding was not observed in our current study. This might be related to the different way of delivering the placenta.

## CONCLUSION

It is concluded from this study that both methyl ergometrine and oxytocin are equally effective in the active management of the 3rd stage of labor. However a comparison between two groups revealed that vomiting, leg cramp and rise in mean blood pressure were more common side effects with methyl ergometrine, and the two drugs did not confer any significant advantage over the other in terms of duration of 3rd stage, blood loss during 3rd stage, fall in hemoglobin percentage, fall in hematocrit, and need for additional oxytocics. Same numbers of cases of retained placenta were in the both groups.

Due to its unwanted side effects inj. methyl ergometrine should not be recommended as a routine drug for active management of 3rd stage of labor (AMTSL). Because oxytocin is equally effective in AMTSL with very few side effects it should be the preferred drug.

Half-life of oxytocin in human body is very transient in comparison to methyl ergometrine and it is applicable to its side effects too. So oxytocin is safer drug for use in AMTSL.

Oxytocin should be the 1st preferred drug for use in the active management of 3rd stage of labor.

**REFERENCES**


1. Outlook: Preventing Postpartum Hemorrhage: Managing the third stage of labour; 2001; 19 (3)
2. AbouZahr C, Wardlaw T. Maternal mortality in 2000: Estimates developed by WHO, UNICEF and UNFPA. Geneva: World Health Organization, 2000.
3. Prendiville W.J., ElbourneD.and McDonald S. (2000) Active versus expectant management in the third stage of labour. Cochrane Database Systematic Review, 2, CD000007.www.pubmed.com.
4. Nieminen U, Jarvinen PA. A comparative study of different medical treatments of the third stage of labour. Ann ChirGynaecolFenn 1963;53:424 –429.
5. Docherty PW, Hooper M. Choice of an oxytocic agent for routine use at delivery. J ObstetGynaecol 1981;2:60.
6. Mitchell G, Elbourne DE, Ashurst HA, et al. The Salford third stage trial: oxytocin plus ergometrine versus oxytocin alone in the active management of the third stage of labour. Online J Current Clin Trials 1993;Doc.No.83.
7. Dumoulin JG. A reappraisal of the use of ergometrine. J ObstetGynecol 1981;1:178 – 181.
8. Nieminen U, Jarvinen PA. A comparative study of different medical treatments of the third stage of labour. Ann ChirGynaecolFenn 1963;53:424 –429.
9. Docherty PW, Hooper M. Choice of an oxytocic agent for routine use at delivery. J ObstetGynaecol 1981;2:60.
10. Mitchell G, Elbourne DE, Ashurst HA, et al. The Salford third stage trial: oxytocin plus ergometrine versus oxytocin alone in the active management of the third stage of labour. Online J Current Clin Trials 1993;Doc.No.83.
11. Soriano D, Dulitzki M, Schiff E, Barkai G, Mashiach S, Seidman DS. A prospective cohort study of oxytocin plus ergometrine compared with oxytocin alone for prevention of postpartum haemorrhage. Br J ObstetGynaecol 1996;103:1068–1073a
12. Yuen PM, Chan NST, Yim SF, Chang AMZ. A randomised double blind comparison of syntometrine and Syntocinon in the management of the third stage of labour. Br J ObstetGynaecol 1995;102:377– 380.
13. Ng PS, Chan ASM, Sin WK, Tang LCH, Cheung KB, Yuen PM. A multicentrerandomised controlled trial of oral misoprostol and imsyntometrine in the management of the third stage of labour. Hum Reprod 2001;16:31 –35.
14. Duthie SJ, Ven D, Yung GL, et al. Discrepancy between laboratory determination and visual estimation of blood loss during normal delivery. Eur J ObstetGynecolReprodBiol 1991;38:119 –124.
15. Razvi K, Chua S, Arulkumaran S, et al. A comparison between visual estimation and randomisedatory determination of blood loss during the third stage of labour.Aust NZ J ObstetGynaecol 1996;36: 152– 154.
16. American College of Obstetricians and Gynecologists.Quality Assurance in Obstetrics and Gynecology, 1989. Washington, DC: American College of Obstetricians and Gynecologists.