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## To study the effectiveness of intraumbilical vein oxytocin injection along with active management of third stage of labour: A randomized control trial

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### Abstract

**Objective:** To determine the effectiveness of intra umbilical vein Oxytocin injection along with active management of third stage of labor

- The amount of blood loss during the third stage of labour
- Duration of third stage of labour
- Change in the hemoglobin level
- PPH occurred
- Incidence of retained placenta
- Need for blood transfusion
- Side effects of the drug if any

**Design:** Randomized control trial

**Setting:** Bangalore Baptist Hospital, Bangalore

**Methods:** Source of Data: 230 women, who underwent vaginal delivery with/without episiotomy at Bangalore Baptist Hospital, were enrolled. The study was done for a period of 1 year from September 2012 to August 2013. The ethical clearance was taken before the study.

**Results:** Intramuscular oxytocin was observed to be equally effective as intravenous methylergometrine in prevention of post-partum hemorrhage.

There was no difference in the duration of third stage of labour, amount of blood loss, need for additional uterotonic agents, and need for blood transfusion in both the groups. There were no significant side effects in both the groups.

**Conclusion:** Intramuscular oxytocin is as efficacious as Intravenous methylergometrine in the prevention of postpartum hemorrhage with no side effects.

**Keywords:** Third stage of labour; postpartum hemorrhage; normal saline; oxytocin; retained placenta

### Introduction

The third stage of labour is that period from delivery of the foetus to complete delivery of the placenta and its attached membranes. Average length of third stage of labour is 5-15min.

Postpartum hemorrhage (PPH) is one of the most common causes of maternal death throughout the world. Most common complication is postpartum hemorrhage which remains leading cause of maternal mortality (25%) in developing countries. In developed countries, 3-5% deliveries are complicated by post-partum hemorrhage, in developing countries it is 50 times more common<sup>[1]</sup>. Retained placenta is another complication of third stage of labour which occurs in 0.1 to 2% deliveries and is associated with high risk of hemorrhage. Principle of management of third stage of labour is aimed at reducing the time of delivery of placenta, thereby minimizing the serious adverse effects such as blood loss and retained placenta<sup>[2]</sup>.

Uterine atony, which complicates 1 in 20 deliveries, results in excessive blood loss when adequate myometrial contraction fails to occur after placental expulsion. Risk factors for uterine atony include conditions where the uterus is overdistended (polyhydramnios, multiple gestation, fetal macrosomia, fatigued, rapid or prolonged labour, chorioamnionitis), or simply unable to contract (use of uterine relaxing agents like tocolytics or general anesthesia)<sup>[1, 3]</sup>.

World Health Organization (WHO) also estimated 20 million annual maternal morbidities due to hemorrhage. Reducing even a small amount of blood loss after delivery is very much useful on parturient mothers of our country where majority of women are already anemic. Inadequate uterine contractions after the placental expulsion causes uterine atony resulting in excessive blood loss after delivery and the incidence of uterine atony is 1 in 20 deliveries<sup>[4]</sup>.

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In developing countries, where maternal mortality rates are exponentially higher, PPH plays an even greater role<sup>1</sup>. Where maternal mortality is high and resources are limited, the introduction of low cost evidence based practices to prevent postpartum hemorrhage can improve maternal and infant survival.

Active management of third stage of labour, includes

- administration of prophylactic uterotonic after delivery of baby
- controlled cord traction of umbilical cord
- Uterine massage after delivery of placenta.

Oxytocin is the current drug of choice for prevention of PPH. The main advantages are rapid onset of action and the lack of side effects such as elevated blood pressure or tetanic contractions.

Earlier intra umbilical vein oxytocin injection was used to treat retained placenta. Using this information, some authors have suggested this technique as a measure to reduce the length of third stage of labour and amount of post-partum blood loss. Intra umbilical injected oxytocin reaches the placental bed at relatively higher concentration, causing myometrial contraction thus decreasing the placental attachment site decreasing the blood loss.

### Objective

To determine the effectiveness of intra umbilical vein Oxytocin injection along with active management of third stage of labor

- The amount of blood loss during the third stage of labour
- Duration of third stage of labour
- Change in the hemoglobin level
- PPH occurred
- Incidence of retained placenta
- Need for blood transfusion
- Side effects of the drug if any

### Methodology (Materials and Method)

Source of Data: 200 women who underwent full term normal vaginal delivery with/without episiotomy at Banagalore Baptist Hospital, were enrolled from January 2011 to December 2011.

### Methods of collection of data

#### Ethical clearance taken

The study was conducted on 200 women enrolled and were randomly distributed into two groups

- 100 women in group A received 10 IU of Oxytocin i.m.
- 100 women in group B received 0.2mg of methyl ergometrine i.v.

### Treatment Regimen

- Group A-Following delivery of anterior shoulder, 10 IU of oxytocin was given intramuscularly
- Group B following delivery of anterior shoulder, 0.2mg of methyl ergometrine was given intravenously
- Hb assessment on admission and was repeated on post-partum day one (it notes the differences, in the values which individually reflect the blood loss).
- Placenta was delivered by controlled cord traction in both groups.

### Inclusion Criteria

Full term normal vaginal delivery with or without episiotomy.

### Exclusion Criteria

Patients predisposing to atonic / traumatic PPH for example -

- Severe anemia (Hb < 7gm/dl),
- over distended uterus[multiple pregnancy, polyhydramnios, Macrosomia],
- Coagulation defects
- placenta previa, placental abruption and abnormal placentation
- Chorioamnionitis
- h/o bleeding disorders
- instrumental deliveries

### Procedure

Informed written consent was taken at the time of admission to labour ward.

History taken and clinical examination done. Hb measured before delivery. By block randomization. Patients allocated into 2 groups in 2<sup>nd</sup> stage of labour. After fetal delivery umbilical cord clamped at 4cm from intritus, group 1 received 20IU oxytocin (4ml) in 26ml normal saline and group 2 received 30 ml of normal saline without oxytocin. After the injection the solution was milked towards the cord insertion and another clamp was placed just proximal to the puncture site to prevent leakage. Active

Management of third stage practiced and time for delivery of placenta recorded and blood loss also measured. Volume of blood lost was calculated assuming 1 gm is equivalent to 1ml. Hb was obtained again after 24hrs after delivery.

### Statistical Methods

**Statistical Methods:** Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean  $\pm$  SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. The following assumptions on data is made,

### Assumptions

1. Dependent variables should be normally distributed,
2. Samples drawn from the population should be random, Cases of the samples should be independent

Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Levene's test for homogeneity of variance has been performed to assess the homogeneity of variance. Student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

### Significant figures

+ Suggestive significance (P value:  $0.05 < P < 0.10$ )

\* Moderately significant (P value:  $0.01 < P \leq 0.05$ )

\*\* Strongly significant (P value:  $P \leq 0.01$ )

### Results

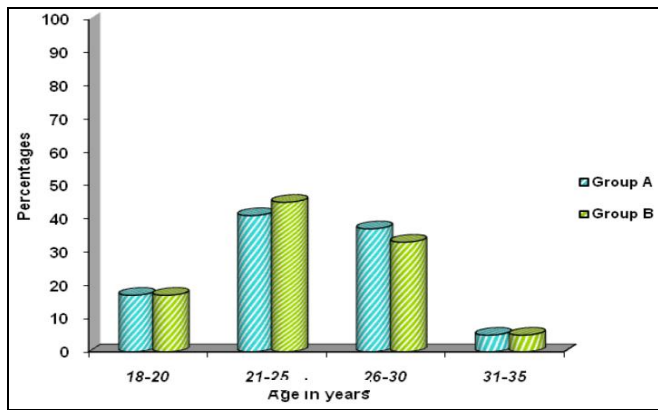
**Study design:** A Comparative Clinical obstetric study with 200

patients, 100 patients in Group A (Administered with 10 units i.m. Oxytocin) and 100 patients in Group B (administered with 0.2 mg i.v. Methergin) is undertaken to study the safety and effect based on Blood loss, duration of third stage of labour, Hemoglobin and Hamodynamics.

**Table 1:** Age distribution of patients studied

Age in years	Group A		Group B	
	N0	%	No	%
18-20	17	17.0	17	17.0
21-25	41	41.0	45	45.0
26-30	37	37.0	33	33.0
31-35	5	5.0	5	5.0
Total	100	100.0	100	100.0
Mean ± SD	24.47±3.49		24.38±3.49	

Samples are age matched with p=0.856



Above table and chart shows the age range of the 200 women included in the present study. The age group ranged between 18-35 years. The mean age of Group A was 24.47±3.49 years and mean age group of Group B was 24.38±3.49 years. p=0.856. It was statistically not significant.

**Table 2:** Parity distribution of patients studied

Parity	Group A		Group B	
	N0	%	No	%
Primi	72	72.0	76	76.0
Multi	28	28.0	24	24.0
Total	100	100.0	100	100.0

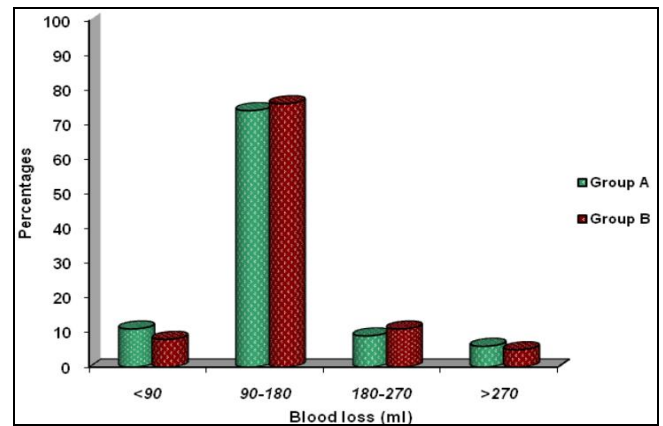
Duration of 3 <sup>rd</sup> stage in minutes	Group A		Group B	
	N0	%	No	%
<3 minutes	0	0.0	0	0.0
4-5 minutes	69	69.0	69	69.0
>5 minutes	31	31.0	31	31.0
Total	100	100.0	100	100.0
Mean ± SD	5.42±1.04		5.44±1.06	

Gestational age	Group A		Group B	
	No	%	No	%
28-32	2	1.7	1	0.9
32-37	11	9.6	9	7.8
37-40	71	61.7	76	66.1
40 & ABOVE	31	27	29	25.2
TOTAL	115	100.0	115	100.0

**Table 4:** Comparison of blood loss in two groups of patients studied  
Mean Blood Loss (ml) is statistically similar in two groups with p=0.640

Blood loss	Group A	Group B
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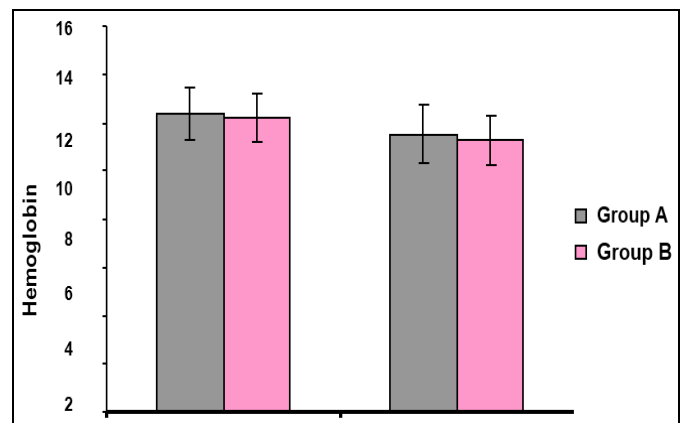
(ml)	N0	%	No	%
<90	11	11.0	8	8.0
90-180	74	74.0	76	76.0
180-270	9	9.0	11	11.0
>270	6	6.0	5	5.0
Total	100	100.0	100	100.0
Mean ± SD	149.90±75.32		155.00±77.92	



The table shows that the mean blood loss in group A (Oxytocin) was 149.90±75.32 while that in group B (Methyl ergometrine) was 155.00±77.92. The difference between the two groups was insignificant, Mean Blood Loss (ml) is statistically similar in two groups with p=0.640

**Table 5:** Comparative Evaluation of Hemoglobin in two groups of patients studied

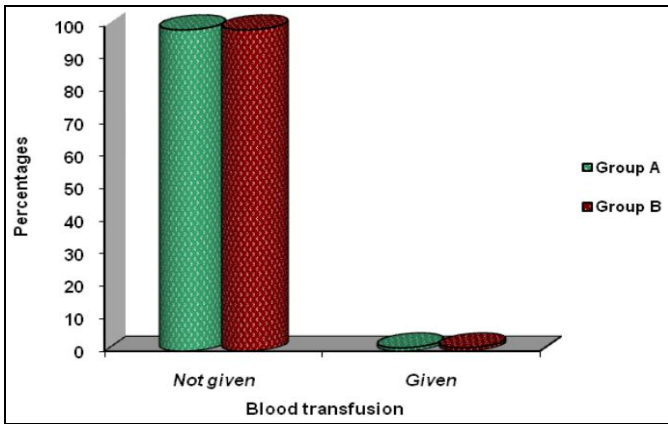
Hemoglobin	Group A	Group B	P value
Before Delivery	12.34±1.09	12.19±1.04	0.321
After delivery	11.52±1.22	11.28±0.99	0.128
Difference	0.82	0.90	-
P value	<0.001**	<0.001**	-



This table shows that the difference in the Hemoglobin percentage before delivery and 24 hours after delivery is insignificant, with P value (<0.001 in group A) and (<0.001 in group B). Mean fall in the percentage in group A was 0.82% as compare to 0.90% in group B.

**Table 9:** Comparison of Incidence of blood transfusion in two groups of patients studied

Blood transfusion	Group A (n=100)	Group B (n=100)	P value
Not given	99 (99.0%)	99 (99.0%)	1.000
Given	1 (1.0%)	1 (1.0%)	



There was one blood transfusion each in both the groups.

### Discussions

Postpartum hemorrhage is one of the most important cause of maternal deaths throughout the world. Active management of third stage of labour has reduced its incidence in many countries. The primary aim in the management of postpartum haemorrhage should be its prevention. The active management of the third stage with routine prophylactic administration of oxytocics at the time of delivery of the anterior shoulder of the fetus has been shown to reduce the risk of postpartum haemorrhage by about 40%.

Recent studies show that there are still wide variations in practice around the world in the management of third stage of labour. Methyl ergometrine is a conventional oxytocic used extensively but is associated with unpleasant side effects like hypertension. Intramuscular oxytocin used alone has been found effective in preventing postpartum hemorrhage and results in fewer side effects and is recommended by world health organization.

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.

200 women who underwent full term normal vaginal delivery with/without episiotomy at Bangalore Baptist Hospital, were enrolled for this study. The study was conducted on 200 women enrolled and were randomly distributed to two groups

- 100 women in group A received 10 IU of Oxytocin i.m following delivery of anterior shoulder.
- 100 women in group B received 0.2mg of methyl ergometrine i.v following delivery of anterior shoulder.

The study was done to compare the efficacy (effectiveness) of 10 IU of oxytocin i.m. With 0.2mg methyl ergometrine i.v. in prevention of post-partum hemorrhage with regard to their influence on:

Duration of the third stage of labour, The amount of blood loss during the third stage of labour and the immediate post-partum period, side effects of the drug.

The present study showed that 10 IU oxytocin i.m. is as effective as 0.2mg methylergometrine i.v. in preventing blood loss with relatively no side effects. There was one blood transfusion in each of the groups.

In the present study, the mean maternal age (years) is  $24.47 \pm 3.49$  and mean age group of Group B was  $24.38 \pm 3.49$  years. The women included in the present study have maternal age ranging from 18-35 years (table-1). The distribution of

parity (table-2) shows that the majority of women are primigravida.

In a similar study by Choy *et al.* (2002) [5], where IV oxytocin was compared with syntometine, the mean maternal age group was 28 years in both the groups and statistically insignificant.

Duration of third stage of labour in group A (Oxytocin) the mean duration was  $5.42 \pm 1.04$  minutes. In group B (Methyl ergometrine), the mean duration was  $5.44 \pm 1.06$  minutes. Duration of third stage is statistically similar in two groups with  $p=0.893$

In another study by Choy *et al.* (2002) [5], where oxytocin was used intravenously, prolonged third stage ( $>30$  min) was reported in 9 cases i.e. 1.8%. 43. In our study there are no cases with prolonged third stage

In the present study, the mean blood loss in group A (Oxytocin) was  $149.90 \pm 75.32$  while that in group B (Methyl ergometrine) was  $155.00 \pm 77.92$ . The difference between the two groups was insignificant, Mean Blood Loss (ml) is statistically similar in two groups with  $p=0.640$ .

Therefore in our study the mean blood loss in third stage is significantly low.

In the study by Choy *et al.* (2002) [5] where IV oxytocin was used the mean blood loss in third stage is 200ml (100-250 ml) 43.

In our present study the difference in the Hemoglobin percentage before delivery and 24 hours after delivery is insignificant, with P value ( $<0.001$  in group A) and ( $<0.001$  in group B). Mean fall in the percentage in group A was 0.82% as compare to 0.90% in group B.

In a study at Choy *et al.* (2002) [5] where oxytocin was given intravenously, the fall in haemoglobin (g/dl) is 0.8 (0.2-1.8) [43]. In 61.6% case the% reduction in haemoglobin level was  $<10\%$ , in 26.1% between 10-20% and in 12.3% case it is  $>20\%$  drop.

In our study, there was one blood transfusion each in both the group.

In a study by Choy *et al.* (2002) [5] there were 7 cases (1.4%) which needed blood transfusion

The need for additional oxytocics (table-12) along with primary drug of study indicates the risk of development of postpartum haemorrhage.

In our study, 3% cases needed additional oxytocics in the form of Prostaglandin given intramuscularly.

In a study by Choy *et al.* (2002) where oxytocin was given intravenously 7.3% cases needed additional oxytocics [43]

In our study there is not a single case that needed manual removal.

In a similar study by Choy *et al.* (2002) [5] where oxytocin was used intravenously, there were 8 cases (1.6%) of retained placenta that required manual removal

### Conclusion & Recommendations

The third stage of labour is a period of great potential hazard. Postpartum haemorrhage is a major obstetrical complication and is one of the prime causes of maternal morbidity and mortality

It is concluded from this study that both oxytocin 10 units i.m. and methergin 0.2 mg i.v. are equally effective in the prevention of post-partum hemorrhage.

However Oxytocin given at dose 10 units intramuscularly is technically easier to use and can be used in situations where intravenous access is unavailable.

Oxytocin is very safe to use with least side effects and can be used even in high risk women. It can be used even in hypertensive women, women with Rh negative pregnancy and those with cardiovascular disease as suggested in the earlier studies [1b].

Oxytocin is the recommended for prevention of post-partum hemorrhage since it is more thermostable than ergometrine as suggested in the earlier studies <sup>[1b]</sup>.

Hence intramuscular oxytocin can be used safely in preventing postpartum haemorrhage as recommended by WHO in the active management of third stage of labour.

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