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A comparative study of intraumbilical oxytocin versus Intravenous methylergometrine in active management of third stage of labour

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Abstract
The use of oxytocics immediately after the delivery of the baby is one of the most important intervention, to prevent postpartum blood loss, as uterine atony is the most important and common cause of postpartum haemorrhage. This study aims to evaluate whether intra-umbilical oxytocin in the AMTSL can reduce the duration and amount of bleeding as compared to intravenous methergine. The mean estimated blood loss in women treated with intraumbilical oxytocin was 213.50 whereas in intravenous methergine was 215ml; *P*<.001). Mean duration of third stage of labor was 3.32±1.50min in oxytocin whereas 3.36±1.41min in methergine group; *P*<.001). We concluded that the method of intra-umbilical injection of oxytocin immediately after the delivery of the baby, significantly reduced the duration of the third stage of labour and the amount of blood loss in the third stage of labour is comparable to the intravenous methergin.

Keywords: AMTSL, oxytocin, PPH, methergin

Introduction
India has Maternal Mortality Ratio of 167/1,00,000 live births, Maternal Mortality Rate 11.7. The most common cause of maternal mortality is haemorrhage which accounts for 25-30% of maternal mortality of which postpartum haemorrhage is a significant cause and one of the most dreaded and common complication of third stage of labour accounting for 15-25% of maternal deaths in India [1, 2] The duration of third stage of labour is from the birth of the baby to the delivery of the placenta. The incidence of the PPH is 3.9% of vaginal deliveries and 6.4% of CS. [3]

Postpartum bleeding or postpartum haemorrhage (PPH) is defined as more than 500 ml of blood following childbirth, or 10% drops in haematocrit from the admission to post-delivery or till the end of puerperium. Active pharmacologic management of the third stage of labour is common today and has resulted in a significant decrease in early and late postpartum haemorrhage and in total maternal peri-partum mortality and morbidity [4]. AMTSL involves the use of prophylactic uterotonic drug within 1-2 minute of birth, expulsion of placenta by controlled cord traction followed by uterine massage. Drugs used for prophylaxis of atonic postpartum haemorrhage include oxytocin, ergometrine and prostaglandins. The routine practice in AMSTL is oxytocin 10U I/M given within 2 mins of delivery of baby. The onset of action of I/M oxytocin is 3-5mins and persist for 2-3hrs. One of these methods is the administration of oxytocin via the umbilical vein for the delivery of placenta. Umbilical vein oxytocin injection directs treatment to the placental bed and uterine wall, resulting in earlier uterine contraction and placental separation.
The mechanism of this method is that oxytocin injected into umbilical vein reaches the placental bed in a relatively high concentration. This stimulates contraction of the uterine muscle and a decrease in the area of placental implantation site. The resulting tension causes the decidua spongiosa, the weakest layer, to give way and cleavage takes place at this site. The hematoma formed in this area accelerates the process, and the placenta eventually separates and is delivered [5]. This method was found to be quick, noninvasive, simple and safe method for separation and delivery of placenta in third stage of labor.
This study aims to evaluate whether intra-umbilical oxytocin in the AMTSL can reduce the duration and amount of bleeding as compared to intravenous methergine.

Materials and Methods

The study was conducted as randomized controlled study. In study population of 400 cases undergoing normal vaginal delivery in the labour room of Zenana hospital, attached to S.M.S. Medical College Jaipur from a duration of January 2019 to December 2019i.e. 12 months.
Cases were allocated randomly in 1:1 ratio.

Group A: With intra-umbilical oxytocin injection in 200 cases. **(Study Group)**

Group B: With intravenous methylergometrine injection in 200 **(Control group)** cases.

Inclusion criteria: All women who aged between 18-35 years ranging in parity from 1-7 with normal vaginal delivery with

- Cephalic presentation,
- Singleton pregnancies,
- Gestational age more than 37 weeks,
- Previous normal vaginal delivery,
- Hb ≥ 11g/dl.

Exclusion criteria

- Patients with prolonged first & second stage of labour, uterine inertia & instrumental deliveries.
- Previous caesarian section.
- Antepartum haemorrhage.
- Multiple gestation.
- Polyhydromnios.
- Preterm deliveries.
- Malpresentations.
- Medical disease like heart disease, hypertension, severe anemia.
- Uterine malformation.

After informed consent, simple randomization using a random number table was performed by the nursing staff, who took no further no further part in the study. In Group A, 10 Unit of oxytocin diluted in 20 ml of normal saline with mild force into the umbilical vein about 2 inches away from vulva immediately after clamping the cord after delivery is given in 200 patients whereas in group B, intravenous 0.2mg of methylergometrine at the time of delivery of anterior shoulder of baby was given.
Approximate blood loss was measured in both groups by measuring the blood in kidney tray and blood-stained linens and pads excluding the dry weight of these items.
In both group hemoglobin was measured before delivery and 24 hours after delivery.

Outcomes measured were

1. **Primary outcome**
   - Duration of 3rd stage of labour.
   - Amount of blood loss during third stage of labour.
   - Maternal hemoglobin measured on admission and repeated 24 hours after delivery.
2. **Secondary outcome**
   - Need for manual removal of placenta.
   - Need for additional oxytocics like methylergometrine and 15 methyl $PGF_{2\alpha}$.
   - Any other 3rd stage complication.

Results

Majority of patients were in age group 20-30 yrs. The distribution of cases in both the groups was approximately matched. In intra-umbilical oxytocin group 56(28%) patient were primi para, 64(32%) patients were second para and 80(40%) patient were multi para.
In I.V. methergin group 76(38%) patient were primi para, 60(30%) patient were second para and 64(32%) patient were multi para. Both two groups were approximately matched.
Out of 200 cases, 180 were booked and 20 were unbooked in intra umbilical oxytocin group. In I.V. methergin group 168 were booked & 32 were unbooked.
56% patient in intra-umbilical oxytocin group and 64% patient in I.V. methergin group had right medio lateral episiotomy. Rest of the patient had intact perineum.
Table 1 shows that in 72 (36%) patients in intra-umbilical oxytocin group, placenta was delivered within 2 minutes and 72 (36%) delivered within 3-4 minutes and remaining 56(28%) delivered in 5-7 minutes. In same way in I.V. methergin group 72 (36%) placenta was delivered within 2 minutes and 80(40%) delivered within 3-4 minutes and remaining 48 (24%) delivered within 5-7 minutes.

Table 1: Duration of 3rd stage of labour (in minutes) in intra-umbilical oxytocin group and I.V. methergin group

	Duration of 3rd stage in minutes			
	1-2	**3-4**	**5-7**	**7-10**
Intra Umbilical Oxytocin Group				
No. of Patient	72	72	56	-
%	36	36	28	-
I.V. Methergin Group				
No. of Patient	72	80	48	-
%	36	40	24	-

The mean duration of third stage of labour in intra-umbilical oxytocin group was 3.32 minutes, with median of 3 minutes. The range was 1-6 minutes. In I.V. methergin group, mean duration of third stage was 3.36 minutes, median was 3 minutes and range were 2-7 minutes. The difference in average duration of third stage of labour in two groups was statistically not significant (p =0.891). (Table 2)

Table 2: Mean Duration of 3rd stage of labour in intra-umbilical oxytocin group and I.V. methergin group (in minutes)

Parameters	**Intra-Umbilical Oxytocin Group**	**I.V. Methergin Group**
Mean±SD	3.32±1.50	3.36±1.41
Median	3	3
Range	1-6	2-7

Table 3 shows that 12(6%) patients in intra-umbilical oxytocin group had blood loss less than 100 ml, 84(42%) patients had blood loss between 100-200ml and 92(46%) patients had blood loss between 201-300ml. Only 12(6%) patient had blood loss more than 300 ml. In I.V. methergin group, 12(6%) of the patients had blood loss less than 100ml, 82(42%) patients had blood loss between 100-200ml, 96(48%) patients had blood loss between 201-300ml and 8(4%) patients had blood loss greater than 300ml.

Table 3: Blood Loss compared in intra-umbilical oxytocin group and I.V. methergin group

	Blood Loss (in ml)			
	<100	100-200	201-300	>300
Intra-Umbilical Oxytocin Group				
No. of Patients	12	84	92	12
Percentage	6	42	46	6
I.V. Methergin Group				
No. of Patients	12	84	96	8
Percentage	6	42	48	4

Mean blood loss in intra-umbilical oxytocin group was 213.50 ml while in I.V. methergin group it was 215.00 ml. Median in intra-umbilical oxytocin group was 225.00 ml with range of 50-380 ml. In I.V. methergin group, median was 220.00 ml with range 50-350 ml. The difference was statistically not significant (p =0.33).

Table 4 shows that mean change in hemoglobin almost equal in both groups. In intra-umbilical oxytocin group in 26% patients, mean hemoglobin change was 0.33gms, in 46% patients was 0.80gm, in 24% patients was 1.30gm and 4% patients it was 2 gm. In I.V. methergin group in 18% patients was 0.35gm, in 54% patients was 0.77gm, in 24% patients was 1.39gms and in 4% patients was 1.75gm. Mean hemoglobin change in intra-umbilical oxytocin group was 0.84 gm while in I.V. methergin group it was 0.88 gm. Median in intra-umbilical oxytocin group was 0.8 gm with range of 0.2-2 gm. In I.V. methergin group, median was 0.75 gm with range 0.2-1.8 gm. The difference was statistically not significant (p =0.63).

Table 4: Correlation of hemoglobin changes in intra-umbilical oxytocin group and I.V. methergin group

	Hemoglobin change in gms			
	≤0.5	0.6-1	1.1-1.5	1.6-2
Intra-umbilical oxytocin group				
No. of Patients	52	92	48	8
Percentage	26	46	24	4
Mean difference in Hb	0.33	0.80	1.30	2
I.V. Methergin group				
No. of Patients	36	108	48	8
Percentage	18	54	24	4
Mean difference in Hb	0.35	0.77	1.39	1.75

Correlation of blood loss with placental weight is shown in table 5. In intra-umbilical oxytocin group, mean blood loss was 75ml with placental weight less than 400 gms, it was 190.38ml when placental weight was between 400-500 gms and was 293.05ml when placental weight was more than 500 gms. This almost same trend of blood loss was also seen in I.V. methergin group. It was 76ml with placental weight less than 400 gms, 186.80ml with placental weight between 400-500 gms and 285ml for placental weight more than 500 gms.

Table 5: Placental weight and its correlation with blood loss

	Placental weight (in gms)		
	<400	400-500	>500
Intra-Umbilical Oxytocin Group			
No. of Patients	24	104	72
Percentage	12	52	36
Mean Blood Loss	75 ± 40.82	190.38 ± 55.85	293.05 ± 38.97
I.V. Methergin Group			
No. of Patients	20	100	80
Percentage	10	50	40
Mean Blood Loss	76 ± 25.09	186.80 ± 46.57	285 ± 34.10

In both groups, amount of blood loss increases with increase in placental weight.

Table 6 shows that average blood loss increased with parity in both groups in intra-umbilical oxytocin group, mean blood loss in primipara was 108.92ml, in second para 210.93ml and in multipara 288.75ml. In I.V. methergin group mean blood loss in primipara was 140.00ml, in second para 226.00ml and multipara 293.75ml.

Table 6: Correlation of blood loss with parity in intra-umbilical oxytocin group and I.V. methergin group

	Average blood loss in parity		
	Primi	Second	Multi
Intra-umbilical oxytocin group (Blood Loss)	108.92 ml (±88.71ml)	210.93 ml (±87.15)	288.75 ml (±73.04)
I.V. Methergin group (Blood Loss)	140.00ml (±83.02)	226.00 ml (±73.21)	293.75 ml (±66.01)

It is shown in table 7 that mean blood loss was more in patients with episiotomy than in patients with intact perineum. In intra-umbilical oxytocin group, mean blood loss with episiotomy was 271.42ml and it was139.77ml in patients with intact perineum. In I.V. methergin group it was 259.06ml and 136.66 ml respectively. The number of patients with episiotomy and intact perineum was comparable in both groups.

Table 7: Correlation of blood loss with episiotomy

Group	Episiotomy		Intact Perineum	
	No.	Average blood loss (ml)	No.	Average blood loss (ml)
Intra-umbilical oxytocin group	112	271.42 (±83.83)	88	139.77 (±72.94)
I.V. methergin group	128	259.06 (±73.95)	72	136.66 (±61.85)

Table 8 shows that incidence of side effects in patients receiving intra-umbilical oxytocin was nil, whereas 7(14%) of patients in I.V. methergin group had nausea and vomiting, 8(16%) patients had headache and vertigo, 12(24%) patients head tachycardia (pulse rate >120/min.) and change in B.P. in 9(18%) patients there was increase in blood pressure by 10mmHg.

Table 8: Comparison of side effect in intra-umbilical oxytocin group and I.V. methergin group

Side Effects	Intra-umbilical oxytocin group		I.V. methergin group	
	No. of patients	%	No. of patients	%
Nausea and Vomiting	0	0	7	14
Headache and vertigo	0	0	8	16
Tachycardia	0	0	12	24
Change in B.P.	0	0	9	18
PPH	0	-	0	-
Retained Placenta	0	-	0	-
Use of additional oxytocics	0	-	0	-

This table shows that there was no case of primary postpartum haemorrhage and retention of placenta in both intra-umbilical oxytocin group and I.V. methergin group. There was no need of additional oxytocics in both groups.

Discussion

The use of oxytocics immediately after the delivery of the baby is one of the most important intervention, to prevent postpartum

blood loss, as uterine atony is the most important and common cause of postpartum haemorrhage. The active management of third stage of labour 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 [6, 7]

Several studies have reported intraumbilical oxytocin to be effective in reducing the duration of third stage of labour and blood loss. Dahiya *et al*. managed 50 study cases with 10 units of oxytocin diluted in 20ml saline given through umbilical vein immediately after cord clamping and 50 control, managed actively with 10 units of oxytocin diluted in 250 ml saline at rate of 125 ml/hr I/V, given after delivery of the baby.8 He reported significant reduction in duration of third stage of labour (1.48min vs 3.27min), fall in haemoglobin (<1.2g/dl vs 1.96g/dl) and fall in haematocrit (<3.88% vs 7.2%) in cases as compared to control.

Recent studies show that there are still wide variations in practice around the world in the management of third stage of labour [9] Methyl ergometrine is a conventional oxytocic used extensively but is associated with unpleasant side effects like hypertension.

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 take place far from hospitals and are supervised solely by birth attendants.

The present study showed that 10 IU oxytocin Intaumbilical is as effective as 0.2 mg methyl ergometrine IV in preventing blood loss with relatively no side effects. Several studies and systematic reviews have been published on the use of intraumbilical oxytocics, but these studies assessed the use of intraumbilical oxytocin for the treatment of retained placenta instead of postpartum hemorrhage.10 –13 The National Institute for Health and Clinical Excellence (NICE) guidelines in the United Kingdom have recommended the use of umbilical oxytocin for the treatment of retained placenta [14] A few trials have investigated the routine use of intraumbilical oxytocin with active management of the third stage of labor [15-17] However, the findings of those trials are conflicting. From the existing evidence, it would appear that the routine use of intraumbilical oxytocin for the prevention of postpartum hemorrhage is questionable.

Conclusion

We concluded that the method of intra-umbilical injection of oxytocin immediately after the delivery of the baby, significantly reduced the duration of the third stage of labour and the amount of blood loss in the third stage of labour is comparable to the intravenous methergin. We need large randomarized trial to implement its use in the active management of third stage of labour.

Hence, the results of the review are applicable in under-resourced settings where complications of third stage of labor are common and facilities for immediate blood transfusion and surgical intervention are limited.

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