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Use of Intramyometrial Versus Intravenous Oxytocin of 10IU in Prevention of Postpartum Haemorrhage During Cesarean Section

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Abstract

Postpartum hemorrhage from uterine atony, a major global and local health burden, remains to be a leading cause of maternal mortality. Intravenous oxytocin infusion has become the conventional first-line drug in the active management of third stage of labor in most countries. This, however, has been associated with refractory uterine atony and major hemodynamic side effects; hence the need to explore on the possibility of a better alternative such as intramyometrial oxytocin administration. *Objectives:* To compare the efficacy of 10IU of Intramyometrial Oxytocin and 10IU of Intravenous Oxytocin in prevention of Postpartum Haemorrhage during Cesarean Section. *Settings and Design:* A prospective randomised control study was conducted in the department of obstetrics and gynaecology at R.L Jalappa Hospital, Kolar. *Methods and Material:* Blood loss was considered as the primary measure variable and uterine tone at 1 min and 5 min of oxytocin administration and diasystolic blood pressure at 1 min and 5 mins post oxytocin administration were secondary outcomes measured. *Statistical analysis used:* Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram. *Results:* A total of 186 subjects were included in the study. A total of 92 intravenous and 94 intramyometrial were included in the final analysis. The mean blood loss in ml patient was 624.78±132.85 in intravenous oxytocin group and it was 455.85 ±119.5 in intramyometrial, with a mean difference of 168.93 (p value < 0.001), which was statistically significant. *Conclusions:* Intramyometrial oxytocin at the same dose as i.v. administration both initiate contractions at similar intervals post administration. Intramyometrial infusion has a better safety profile when assessed using fall in diastolic blood pressure. It also resulted in lesser blood loss when compare to intravenous oxytocin.

Keywords: Oxytocin; Post partum haemorrhage; cesarean section; uterine atony.

Introduction

Post partum haemorrhage is one of the leading causes of maternal morbidity. The major cause of PPH is uterine atony. Globally 11% of women having a live birth have severe PPH which accounts to 14 million per year [1]. Oxytocin is routinely administered during cesarean section to stimulate uterine

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contraction and decrease blood loss from the placental implantation site. When administered as a rapid intravenous (i.v.) bolus injection, oxytocin sometime causes adverse hemodynamic events, such as hypotension, tachycardia, [2] and electrocardiogram (ECG) changes with even cardiovascular collapse and death in hypovolemic patients [3,4]. Use of Intramyometrial oxytocin also helps in contractility of the uterus and it has been hypothesized that direct administration should cause rapid onset of action and fewer sideeffects. The comparative efficacy of Intramyometrial & Intravenous oxytocin with regards to reduction to blood loss when administered after caesarean section has not been studied extensively. Hence in a randomized controlled trial, we decided to investigate the estimated blood loss and blood pressure changes following 10IU of Intamyometrial Oxytocin and 10IU of Intravenous Oxytocin after Cesarean Section delivery.

Subjects and Methods

This prospective randomised control study was conducted in the department of obstetrics and gynaecology at R.L Jalappa Hospital, Kolar. The women admitted to the labour ward during the study period (June 2015 to June 2016) who fulfilled the inclusion criteria were included in the study after obtaining informed consent. These women were then randomised into 2 groups to receive intra-myometrial and intravenous oxytocin after caesarean section as a prophylaxis to prevent post-partum haemorrhage.

Inclusion Criteria:

- Term 37-42 weeks of gestation .
- Single live Intrauterine gestation
- Vertex Presentation
- Written informed consent

Exclusion Criteria:

- Medical Disorders
- Overdistended Uterus – Polyhydraminos
- Multiple Gestation
- More than 2 prev Caesarean Sections
- Antepartum Haemorrhage

All data was collected in structured proforma. Blood loss was considered as the primary measure variable and uterine tone at 1 min and 5 min of oxytocin administration and diasystolic blood pressure at 1 min and 5 mins post oxytocin administration were secondary outcomes measured.

Sample size: Was estimated by using the Mean SBP on Day 2 from the pilot study done at the institution. Mean difference of 5 mmHg was observed between two groups and a standard deviation of 10 was used to obtain the sample size at 95%. Confidence limit and 90% power sample size of 85 was obtained in each group. With 10% non response sample size of 85+8.5≈94 cases will be included in each group.

Statistical methods: The blood loss was considered as primary outcome variable. mode of oxytocin administration parameters were considered as explanatory variables obstetric index, previous mode of delivery, uterine tone at 1 min, 5 min, changes in blood pressure before anesthesia at 1 min and 5 mins etc. were considered as other explanatory variables.

Descriptive analysis: Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram.

Inferential statistics:

Quantitative outcome

The association between categorical explanatory variables and quantitative outcome was assessed by comparing the mean values. The mean differences along with their 95% CI were presented. Independent sample t-test was used to assess statistical significance. The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance.

p value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Results

A total of 186 subjects were included in the analysis.

A total of 92 intravenous and 94 intramyometrial were included in the final analysis (Table 1 & Fig.1).

There was no significant difference in the age

distribution in the two groups. Both groups had the maximum subjects aged between 20 and 25 yrs. 62% of women who received intravenous oxytocin were primigravida as compared to 46.80% in the group receiving intra-myomerial oxytocin (p=0.11). 70 women and 66 women were of the gestational age between 37 completed weeks to 40 weeks in the intravenous and intra-myometrial group respectively. The distribution of subjects in both the group based on gestational age was not statistically significant (p=0.37).

Among the people who received intravenous oxytocin administration, 10 (28.57%) had previous vaginal delivery, and 25 (71.42%) were LSCS. Among the people with intramyometrial, 8 (16.32%) had previous vaginal delivery, and 41 (83.67%) were LSCS. The difference in the proportion of mode of oxytocin administration based on previous mode of delivery was statistically not significant (p value 0.18)(Table 2).

Among the group administered intravenous oxytocin, 26 (28.26%) underwent caesarean for fetal distress, 26 (28.26%) for previous LSCS, 14 (15.21%) for malpresentation, 9 (9.782%) in view of CPD, 7 (7.61%) for contracted pelvis and 10 (10.86%) for severe oligohydramnios Among the patients administered intramyometrial oxytocin, the indication for caserean was fatal distress in 24 women and in 45 (47.87%), 6 (6.38%), 9 (9.57%), 2 (2.13%), 7 (7.45%) and 1 (1.06%) the indication was previous LSCS, Malpresentations, CPD, contracted and severe oligohydramnios respectively. (Table 2 and Fig. 2).

Uterine tone after 1 min of intravenous oxytocin administration - 87 (94.56%) were contracted, and 5 (5.43%) were not contracted.

Uterine tone after 1 min of intramyometrial oxytocin administration - 86 (91.48%) were in contracted, and 28 (8.51%) were not contracted. The difference of uterine tone at 1 min dependiong on the mode of oxytocin administration was statistically not significant (p value 0.41) (Table 4).

Uterine tone after 5 min of intravenous oxytocin administration - 88 (95.65%) were contracted, and 4 (4.35%) were not contracted. 94 (100%) were in contracted.

Uterine tone after 5 min of intramyometrial oxytocin administration The difference in the proportion of

Table 1: Descriptive analysis of mode of oxytocin administration in study population (N=186)

Mode of oxytocin administration	Frequency	Percentage
Intravenous	92	49.46%
Intramyometrial	94	50.54%

A total of 92 intravenous and 94 intramyometrial were included in the final analysis

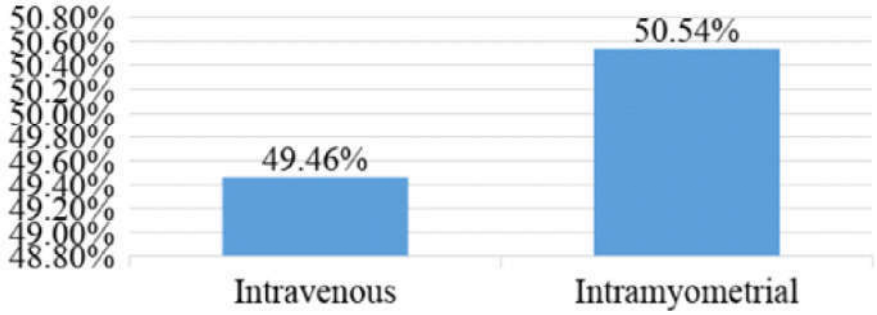

Fig. 1: Bar chart of mode of oxytocin administration in study population

Table 2: Comparison of mode of oxytocin administration with indication for Lower segment Cesarian section of study population (N=186)

Indication for Lower segment Cesarian section	Mode of oxytocin administration	
	Intravenous (N=92)	Intramyometrial (N=94)
fetal distress	26 (28.26%)	24 (25.53%)
previous LSCS	26 (28.26%)	45 (47.87%)
Malpresentations	14 (15.21%)	6 (6.38%)
CPD	9 (9.78%)	9 (9.57%)
contracted	7 (7.61%)	2 (2.13%)
severe oligohydramnios	10 (10.86%)	7 (7.45%)
failed induction	0 (0%)	1 (1.06%)

mode of oxytocin administration between previous uterine tone at 5 min was statistically significant (p value 0.041) (Table 4).

The diastolic blood pressure before anesthesia mostly belonged to 81 to 100 mm Hg range in both intravenous and intramyotmetrial oxytocin group (65.2% vs 65.14%). The difference was statistically not significant (p value 0.50) (Table 5).

Among the receiving intravenous oxytocin, 26 (28.26%) women had in 60 to 80 diastolic BP after oxytocin at 1 min, 64 (69.56%) women had diasytolic BP in 81 to 100 mm hg range and 2 (2.173%)women in >100 mm hg. Among the people with intramyometrial, 12 (12.76%) woman had a diastolic BP of 60 to 80 mm hg after oxytocin at 1 min, 76 (80.85%) were in 81 to 100 mm hg range and 6 (6.382%) were in >100 mm hg. The fall in Diastolic blood pressure after administration of oxytocin at 1 min was statistically significant in both groups (p value 0.02).

The fall in diastolic blood pressure was significantly more intravenous oxytocin administration group with 82 women having a diastolic BP in the range of 60 to 80 mm hg when compared to only 6 women in the intramyometrial group. 83 women in the group receiving intramyometrial oxytocin had a diastolic BP in 80 to 100 mm hg range with no much fall. (p value <0.001)(Table 7).

- No statistical test was applied –due to 0 subjects in one of the cells.

4 women in the group administered intravenous oxytocin had mild anemia prior to surgery whileno women was anemic in the intramyometrial oxytocin group. (p value <0.001) (Table 8 and Fig. 3).

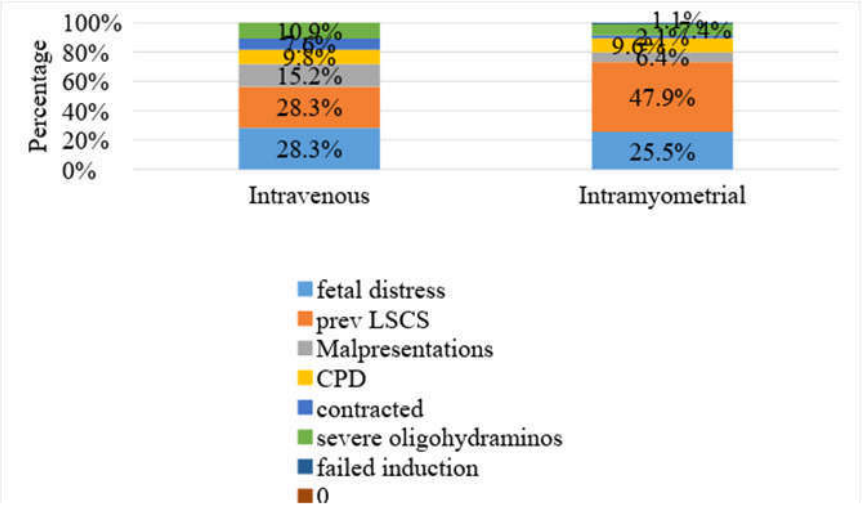

Fig. 2: Bar chart of mode of oxytocin administration with indication for Lower segment Cesarian section of study population (N=186)

Table 3: Comparison of mode of oxytocin administration with uterine tone at 1 min and 5 mins in study population (N=186)

Uterine tone at 1 min	Mode of oxytocin administration		P-value
	Intravenous (N=92)	Intramyometrial (N=94)	
contracted	87 (94.56%)	86 (91.48%)	0.41
Not contracted	5 (5.43%)	8 (8.51%)	
Uterine tone at 5 mins			
Contracted	88 (95.65%)	94 (100%)	0.041
Not contracted	4 (4.35%)	0 (0%)	

Table 4: Comparison of mode of oxytocin administration with diastolic Blood pressure before anaesthesia of study population (N=186)

Diastolic Blood pressure before anaesthesia	Mode of oxytocin administration		Chi square	p-value
	Intravenous (N=92)	Intramyometrial (N=94)		
60 to 80	18 (19.56%)	20 (21.27%)		
81 to 100	60 (65.21%)	65 (69.14%)	1.371	0.50
>100	14 (15.21%)	9 (9.57%)		

23 and 8 women in intravenous oxytocin and intrmyometrial oxytocin group had haemoglobin <11 gm% 24 hours after surgery pointing towards more blood loss in the group receiving intravenous oxytocin the diffrerence in the haemoglobin between the 2 groups after 24 hrs was statistically significant (p value =0.003) (Table 9 and Fig. 4).

Table 5: Comparison of mode of oxytocin administration with diastolic Blood pressure after oxytocin administration at 1 min and 5 mins in study population (N=186)

Diastolic Blood pressure after oxytocin at 1 min (mm Hg)	Mode of oxytocin administration		p-value
	Intravenous (N=92)	Intramyometrial (N=94)	
60 to 80	26 (28.26%)	12 (12.76%)	0.02
81 to 100	64 (69.56%)	76 (80.85%)	
>100	2 (2.17%)	6 (6.32%)	
Diastolic Blood pressure after oxytocin at 1 min (mm Hg)			
60 to 80	82 (89.13%)	8 (8.51%)	<0.001
81 to 100	10 (10.86%)	83 (88.29%)	
>100	0 (0%)	3 (3.19%)	

Table 6: Comparison of mode of oxytocin administration with haemoglobin(g/dL.) before of study population (N=186)

Haemoglobin before	Mode of oxytocin administration	
	Intravenous (N=92)	Intramyometrial (N=94)
Normal(>11g/dl)	88 (95.65%)	94 (100%)
Mild (10 to 10.9g/dl)	4 (4.347%)	0 (0%)

No statistical test was applied –due to 0 subjects in one of the cells

Table 7: Comparison of mode of oxytocin administration with haemoglobin after of study population (N=186)

haemoglobin after	mode of oxytocin administration		Chi square	p-value
	Intravenous	Intramyometrial		
Normal (>11g/dl)	69 (75%)	86 (91.48%)	9.102	0.003
Mild (10 to 10.9g/dl)	23 (25%)	8 (8.51%)		

Table 8: Comparison of mode of oxytocin administration with packed cell volume after 24 hours of study population (N=186)

Packed cell volume after 24 hours	Mode of oxytocin administration		Chi square	p-value
	Intravenous (N=92)	Intramyometrial (N=94)		
>33 to38%	66 (71.73%)	87 (92.55%)	13.80	<0.001
28 to 33%	26 (28.26%)	7 (7.44%)		

Table 9: Comparison of mean blood loss in ml between study groups (N=186)

Mode of oxytocin administration	Blood loss Mean±STD	Mean difference	95% CI		p value
			Lower	Upper	
Intravenous	624.78±132.85	168.93	132.39	205.47	<0.001
Intramyometrial	455.85 ± 119.5				

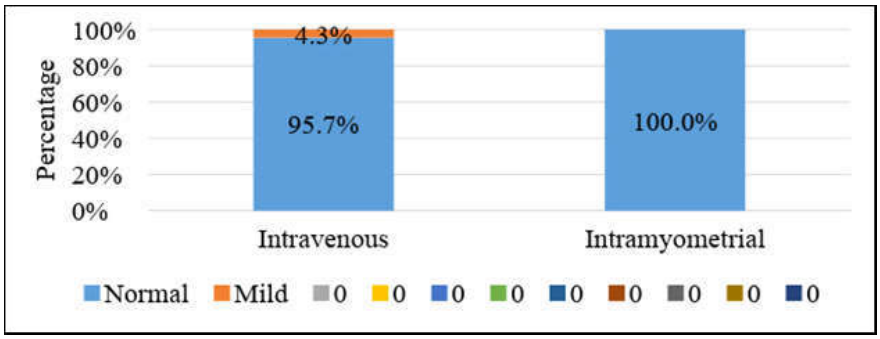

Fig. 3: Bar chart of mode of oxytocin administration with haemoglobin before of study population (N=186)

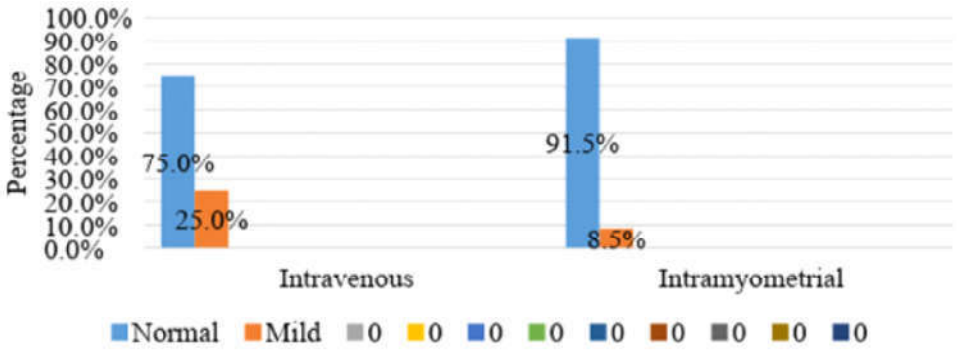

Fig. 4: Bar chart of mode of oxytocin administration with haemoglobin after of study population (N=186)

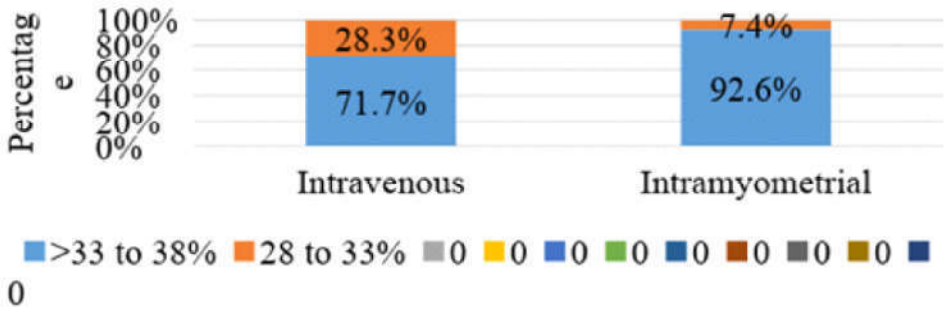

Fig. 5: Bar chart of mode of oxytocin administration with Packed cell volume after 24 hours of study population (N=186)

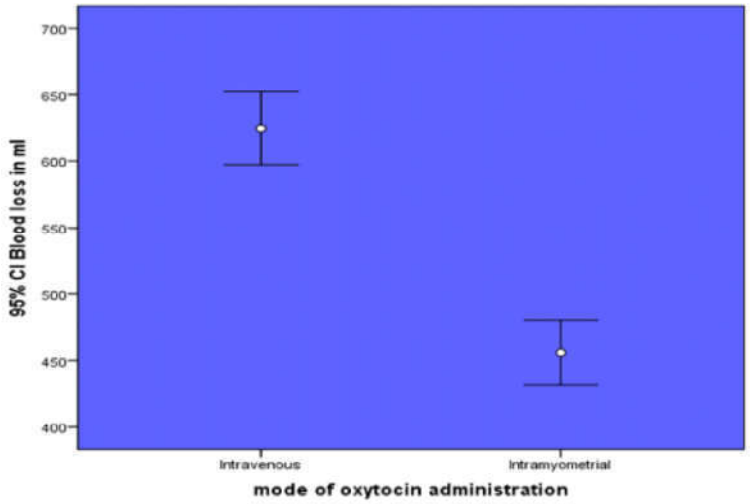

Fig. 6: Error bar showing comparison of blood loss between study groups (N=186)

Packed cell volume after 24 hours The difference in the proportion of mode of oxytocin administration between packed cell volume after 24 hours was statistically significant (p value <0.001) (Table 8 & Fig. 5)

The mean blood loss in ml patientwas 624.78 ±132.85 in intravenous oxytocin group and it was 455.85±119.5 in intramyometrial, with a mean difference of 168.93 (p value <0.001), which was statistically significant (Table 9 & Fig. 6).

Discussion

Blood loss during Caesarean delivery occurs from abdominal wall incision, myometrium and the placental bed. Uterine atony may result in severe post-partum hemorrhage. Oxytocin is commonly administered after Caesarean delivery to promote uterine contraction, thus reducing blood loss from the myometrium and the placental insertion site.

Though this drug reduces the blood loss it is not

free from side effects. Intravenous administration of oxytocin had been associated with transient hypotension and tachycardia which might be deleterious in a hemodynamically compromised women. Therefore other routes of administration like intramyometrial oxytocin are being investigated to reduce the side effect profile of the drug and also means to produce faster action thereby reducing the amount of blood loss. The uterine tone at 1 and 5 mins after administration of oxytocin was not statistically siginificant in both group. This finding was correlating with study conducted by Dennehy et al. [5] In our study we found that fall in diastolic blood pressure after intravenous oxytocin was statistically significant at both 1 mins and 5 mins of administration when compared to intramyometrial administration which was similar to the outcomes seen in the study conducted by Mangala et al. [6]. The total blood loss was significantly less in the intramyometrial oxytocin group when compared to intravenous oxytocin which was quantified by both measured blood loss and fall in hemoglobin after 24 hours. This study did not determine the minimal effective dose of iv oxytocin after Caesarean and whether a lower dose would have reduced the side effects was not investigated. A dose response study of intramyometrial oxytocin administration after Caesarean section is also warranted considering the results of our investigation.

Conclusions

Intramyometrial oxytocin at the same dose as i.v. administration both initiate contractions at similar intervals post administration. Intramyometrial infusion has a better safety profile when assessed using fall in diastolic blood pressure. It also resulted in lesser blood loss when compare to intravenous oxytocin. Although further investigation should be performed to determine an appropriate intramyometrial and intravenous dose to minimize hemodynamic side-effects.

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