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Original Research Article

To Compare Uterine Contractility, Haemodynamic Changes of Intravenous Infusion versus Bolus Dose of Oxytocin in Elective Caesarean Delivery: A Prospective, Randomised Study

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ABSTRACT
Background: Caesarean Delivery is the most commonly performed surgery in women all over the world. These patients are always at increased risk of uterine atony, obstetric haemorrhage, postpartum haemorrhage and its related morbidities. Postpartum haemorrhage (PPH) remains a significant cause of maternal mortality and morbidity. The main cause of postpartum haemorrhage is uterine atony. Among the various uterotonics, oxytocin stands out as the preferred option for preventing and managing postpartum uterine atony, and it is utilized globally either as a bolus or via continuous infusion.
Methods: Pregnant women posted for elective caesarean surgeries under subarachnoid block admitted in district hospital, the study design was prospective, Randomised, double blinded study.
Result: The mean age in Group I was 24.62 ± 3.91 years and 25.24 ± 4.15 years in Group B (p = 0.568). The mean weight was 75.45 ± 12.61 kg in Group I and 72.21 ± 12.20 kg in Group B (p = 0.259). The mean height was 162.39 ± 8.79 cm in Group I and 160.18 ± 7.24 cm in Group B (p = 0.235). The mean BMI was 28.58 ± 4.00 kg/m² in Group I and 28.10 ± 4.12 kg/m² in Group B (p = 0.608). None of the differences were statistically significant.
Conclusion: The study suggests that the Bolus group exhibited faster achievement of uterine contractility, requiring higher oxytocin doses, but also demonstrated notable cardiovascular changes, including increased heart rate and reduced blood pressure.

Keywords: Oxytocin, Caesarean delivery, Postpartum haemorrhage (PPH).

INTRODUCTION

Caesarean Delivery is the most commonly performed surgery in women all over the world.[1] In India, Caesarean delivery rates have crossed the WHO threshold of 15%.[2] these patients are always at increased risk of uterine atony, obstetric haemorrhage, postpartum haemorrhage and its related morbidities.[1]

Postpartum haemorrhage (PPH) remains a significant cause of maternal mortality and morbidity. The main cause of postpartum haemorrhage is uterine atony. The incidence of PPH is estimated to be 6% following LSCS.[3] various uterotonics have been used over the years. Oxytocin, Ergometrine, Misoprostol and PGF2 -alpha have been extensively studied. However, the optimal route and dose of these drugs are still being investigated.[4] Oxytocin is routinely administered during both vaginal as well as caesarean delivery to initiate and maintain adequate uterine contractility and decrease the risk of postpartum haemorrhage after the placental delivery.[5-9] Various uterotonics have been used over the years. Among the various uterotonics, oxytocin stands out as the preferred option for preventing and managing postpartum uterine atony, and it is utilized globally either as a

bolus or via continuous infusion. Rapid and larger doses of OT cause adverse effects like hypotension, tachycardia, chest pain, ECG changes, myocardial ischemia, headache flushing, nausea, vomiting and even convulsions.[10]

In spite of repeated use of oxytocin, the minimum effective dose of oxytocin and its proper regimen of administration is not clear and the IV bolus route of oxytocin is faster in compared to IM route. Hence, this study was conducted to compare intravenous (IV) infusion and bolus dose of oxytocin with the primary aim to compare the uterine contractility, hemodynamic changes (heart rate and blood pressure) and the secondary aim to assess the adverse events.

MATERIALS & METHODS

Source of Data

Pregnant women posted for elective caesarean surgeries under subarachnoid block admitted in district hospital, Tumakuru from the period of May 2023 to April 2024.

Study Design

The study design was prospective, Randomised, double blinded study.

Sample Size

Sample Size (n) = $\frac{2[Z(1-\alpha/2) + Z(1-\beta)]^2 * \sigma^2}{d^2}$

-Key Outcome variable = Heart Rate
-Z (1-α/2) with 5% level of significance = 1.96
-Z (1-β) with 80% power = 84
-Pooled standard deviation σ = 10.2
-Effect Size (d) = 7
Minimum required Sample Size (n) = 38 in each group (Total=76).

Inclusion Criteria

- Pregnant women undergoing elective caesarean surgeries under subarachnoid block.
- Pregnant women between the age group of 21 to 40 years.
- Pregnant women fulfilling American Society of Anaesthesiologists physical status II

Exclusion Criteria

- Participant Refusal.
- Previous Lower Segment Caesarean Section.
- Contraindications to spinal anaesthesia.
- Known drug allergies to oxytocin.

After obtaining the ethical clearance and taking the written informed consent, the participants meeting the inclusion criteria and willing to participate voluntarily were included in the study. They were randomly allocated using computer generated method into 2 groups (group A and group B).

Selected participants were kept nil by mouth 6 hours for solid food and 2 hours for clear fluids before induction of anaesthesia. After securing vein cannulation with 18 G IV cannula, premedicated with ranitidine 50 mg and ondansetron 4mg. Co-loading of fluids was done with a crystalloid solution with 20 mL/kg which was divided into two halves. The first half was given at the rate of 10 mL/kg and the second half (10 mL/kg) was given after giving spinal anaesthesia. Standard monitoring like Pulse oximetry, non-invasive blood pressure (NIBP) and ECG will be recorded. HR, mean blood pressure (MBP) and electrocardiogram (ECG) changes were recorded every 3 min. The patients who had a fall in the MBP before the administration of Oxytocin were treated with an IV bolus of 5 mg ephedrine and such cases were excluded from the study.

Group A: Oxytocin 10 IU in 60 ml Normal saline (NS) was infused at the rate of 1 IU /min, that was,6 ml/min (360ml/hr) by infusion pump.

Group B: The oxytocin dose was prepared by diluting 10 IU oxytocin in 10 ml 0.9% NS and bolus/loading dose of 3 IU will be given over 15 sec.3 min intervals total of 3 bolus doses (if rescue is required).

The infusion was stopped when the uterine tone was adequate in group A, While in group B, if the uterus is not adequately contracted after 3 min, then a bolus of 3 IU was administered as a rescue dose, maximum of 2 rescue doses was given.

Patients in both groups were monitored from 1st to 7th minute after giving Oxytocin. The first 15 s were taken to note the baseline data. After starting Oxytocin infusion or giving bolus dose, the hemodynamic changes were monitored from 1st minute to 7th minute. The heart rate and MBP was measured at 1st minute to 7th minute, then at 8 and 10th min. Any adverse effects occurring after administration of oxytocin such as hypotension, electrocardiographic changes, nausea, vomiting, chest pain and headache and flushing was recorded[1].Patient was monitored for 6 hours postoperatively.

Uterine tone was assessed at 2, 3, 6 and 9 min by operating obstetrician using Likert scale after giving Oxytocin.[11]

- 0 floppy
- 1 Soft
- 2 poorly contracted
- 3 well contracted
- 4 hard rock

Scale 0-2 was considered inadequate uterine tone.

Scale 3-4 was considered adequate uterine contraction.

Statistical Analysis

The data was entered in an Excel spreadsheet. Descriptive statistical analysis was carried out by mean and standard deviation for quantitative variables and frequency and percentages for categorical variables. The association between categorical variables was analysed by using Chi-square test. Significance difference mean between groups will be tested by applying ANOVA test. Statistical software SPSS version-25 was used for the analysis.

RESULTS

Variable	Group I	Group B	t-value	P-value*
Age (years)	24.62±3.91	25.24±4.15	0.573	0.568
Weight (Kgs)	75.45±12.61	72.21±12.20	1.137	0.259
Height (cms)	162.39±8.79	160.18±7.24	1.196	0.235
BMI (kg/m2)	28.58±4.00	28.10±4.12	0.515	0.608

Table 1: Comparison of Age, Weight, Height and BMI between groups

**Independent Sample t-test*

Box plot of Age (Years), Weight (Kgs), Height (Cms), BMI (Kg/m2)

This table compares age, weight, height, and BMI between Group I and Group B using an independent sample t-test. The mean age in Group I was 24.62 ± 3.91 years and 25.24 ± 4.15 years in Group B (p = 0.568). The mean weight was 75.45 ± 12.61 kg in Group I and 72.21 ± 12.20 kg in Group B (p = 0.259). The mean height was 162.39 ± 8.79 cm in Group I and 160.18 ± 7.24 cm in Group B (p = 0.235). The mean BMI was 28.58 ± 4.00 kg/m² in Group I and 28.10 ± 4.12 kg/m² in Group B (p = 0.608). None of the differences were statistically significant.

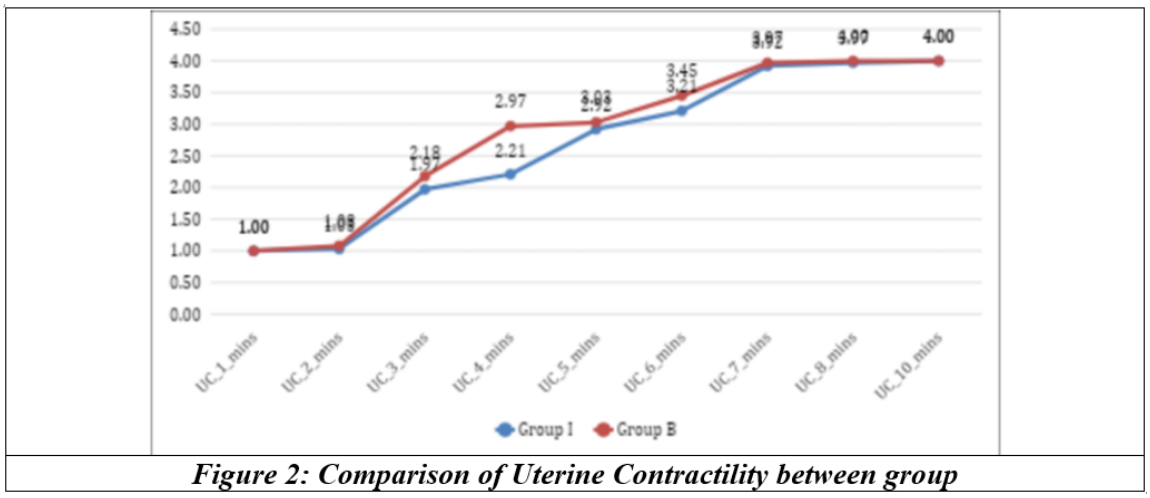

Figure 2: Comparison of Uterine Contractility between group

This figure compares uterine contractility (UC) at different time intervals post-intervention in Group I and Group B using an independent sample t-test. Uterine contractility remained similar at 1 minute (1.00±0.00 in both groups). However, at 3 minutes, Group B exhibited significantly higher contractility (2.18±0.39) compared to Group I (1.97±0.16, P = 0.003). The difference became more pronounced at 4 minutes (2.97±0.16 in Group B vs. 2.21±0.41 in Group I, P < 0.001). By 5 minutes, contractility remained significantly higher in Group B (P = 0.045) and 6 minutes (P = 0.038).

Group	N	Mean ± SD	t-value	P-value
Group I	38	4.82±0.77	-2.770	0.007
Group B	38	5.45±1.18		

Table 2: Comparison of total dose Oxytocin between groups

This table compares the total oxytocin dose administered in Group I and Group B. The mean total oxytocin dose was significantly higher in Group B (5.45±1.18) compared to Group I (4.82±0.77), with a P-value of 0.007, indicating a statistically significant difference.

Heart Rate	Group I	Group B	t-value	P-value*
HR_ Baseline	83.89±13.10	84.84±11.31	-0.337	0.737
HR_1_mins	88.89±10.33	95.74±11.49	-2.730	0.008
HR_2_mins	92.95±10.89	104.82±9.39	-5.088	<0.001
HR_3_mins	97.58±11.35	116.37±8.05	-8.322	<0.001
HR_4_mins	99.37±11.28	124.26±5.37	-12.289	<0.001
HR_5_mins	98.79±11.15	122.00±10.36	-9.404	<0.001
HR_6_mins	96.89±11.52	112.45±9.76	-6.350	<0.001
HR_7_mins	94.08±9.64	101.92±8.60	-3.741	<0.001
HR_8_mins	89.18±9.40	94.34±7.89	-2.590	0.012
HR_10_mins	85.76±7.94	90.95±8.04	-2.829	0.006

Table 3: Comparison of Heart Rate between groups

****Independent Sample t-test***

This table compares heart rate changes over time in Group I and Group B. Heart rate was similar at baseline (P = 0.737). However, Group B exhibited significantly higher heart rates at1 minute (P = 0.008), 2 minutes (P < 0.001), and subsequent time points, peaking at 4 minutes (124.26±5.37 in Group B vs. 99.37±11.28 in Group I, P < 0.001). The difference persisted at 10 minutes (P = 0.006).

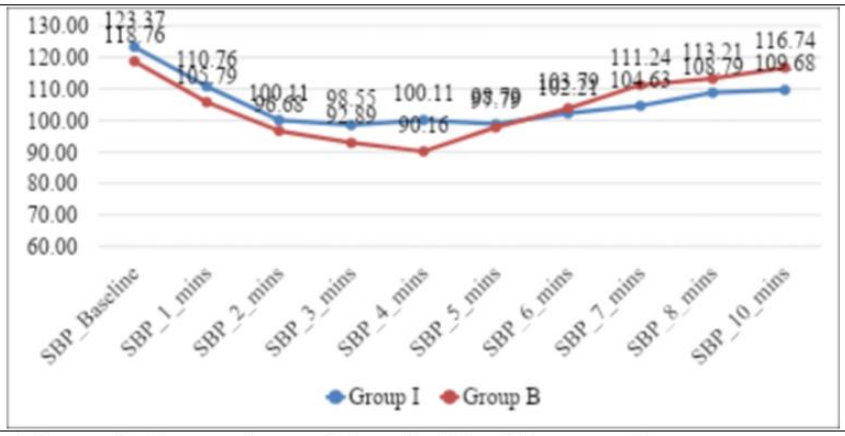

Figure 3: Comparison of Systolic Blood Pressure between groups

This table compares systolic blood pressure (SBP) changes over time in Group I and Group B. SBP was significantly lower in Group B at multiple time points, with the largest difference observed at 4 minutes (90.16±5.59 in Group B vs. 100.11±4.33 in Group I, P < 0.001). The difference persisted up to 10 minutes.

DBP	Group I	Group B	t-value	P-value*
DBP_Baseline	75.26±5.37	71.82±5.59	2.742	0.008
DBP_1_mins	67.47±4.94	62.08±4.43	5.016	<0.001
DBP_2_mins	56.74±3.20	55.18±3.34	2.070	0.042
DBP_3_mins	56.74±3.93	50.79±3.03	7.386	<0.001
DBP_4_mins	56.29±4.34	48.84±4.57	7.281	<0.001
DBP_5_mins	58.34±5.36	54.63±4.86	3.161	0.002

DBP_6_mins	62.03±5.38	61.00±4.36	0.914	0.363
DBP_7_mins	63.79±5.29	66.18±4.81	-2.063	0.043
DBP_8_mins	69.21±5.51	70.11±4.01	-0.809	0.421
DBP_10_mins	71.03±2.39	72.97±4.44	-2.379	0.020
Table 6: Comparison of Diastolic Blood Pressure between groups				
****Independent Sample t-test***				

This table compares diastolic blood pressure (DBP) changes over time in Group I and Group B. DBP was significantly lower in Group B at multiple time points, with the largest drop at 4 minutes (48.84±4.57 in Group B vs. 56.29±4.34 in Group I, P < 0.001).

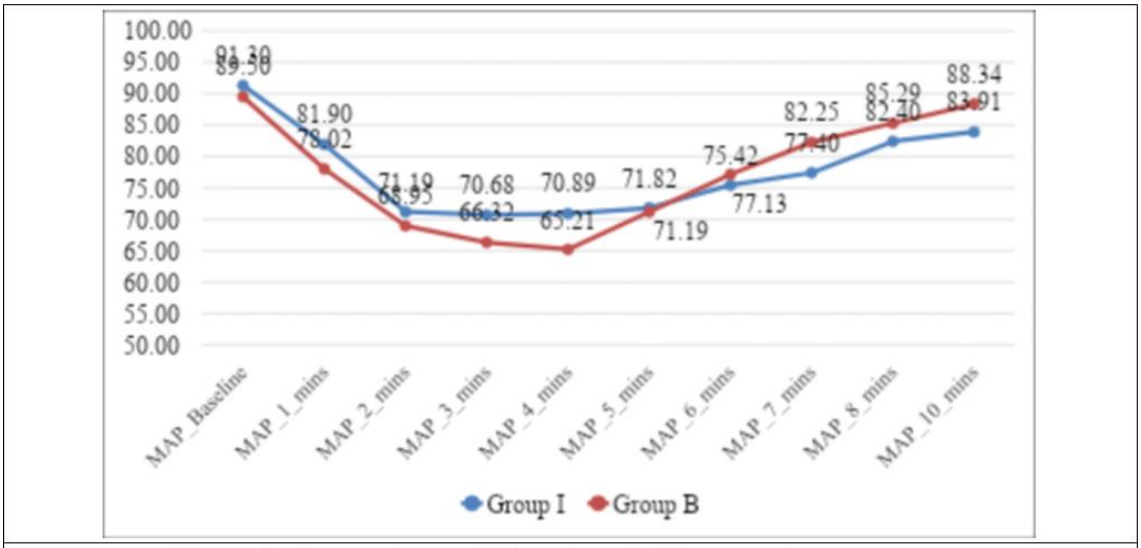

Figure 3: Comparison of Mean Arterial Pressure between groups

This table compares MAP changes between groups. Group B showed significantly lower values at multiple time points (e.g., 65.21±7.52 vs. 70.89±3.51 at 4 minutes, P < 0.001) and then elevates till 10 min (P < 0.001).

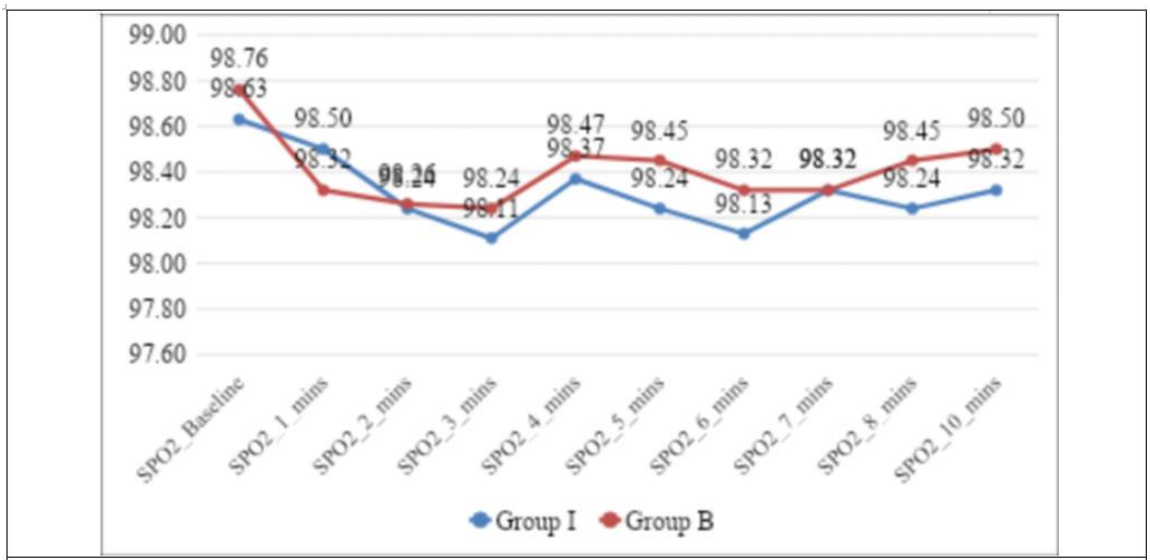

Figure 4: Comparison of SPO2 between groups

This table compares oxygen saturation (SPO2) levels. Oxygen saturation remained stable across groups, with no significant differences. Baseline SPO2 was 98.63±0.81 in Group I and 98.76±0.71 in Group B (P = 0.458). The trend remained similar at 10 minutes (98.32±0.90 vs. 98.50±0.76, P = 0.340. No significant

differences were observed at any time point, with P-values consistently above 0.05.

Side Effects	Group		Total
	Group I	Group B	
Headache	1	2	3
Nausea	2	3	5
Vomiting	1	2	3
Chest Pain	0	1	1
ECG changes	0	0	0
Flushing	0	0	0
Total	4	8	12

Table 9: Side effects

This table compares side effects between groups. Group B reported a slightly higher incidence of nausea (3 cases), vomiting (2 cases), and chest pain (1 case) as compared to Group I with nausea (2 cases), vomiting (1 cases), and chest pain (1 case). In both the group 0 patient had ECG changes or Flushing.

DISCUSSION

Oxytocin exerts its effects through binding to G-protein coupled receptors. Oxytocin receptors are expressed widely in the body, including myometrium and endometrium, cardiovascular system and central nervous system. It is routinely administered by intravenous bolus and infusion after both normal and caesarean delivery to initiate and maintain adequate uterine contractility after placental delivery. Obstetric haemorrhage and uterine atony are the two main complications for mothers undergoing caesarean delivery. In uterine atony, uterus does not contract after delivery; it will remain relaxed resulting in heavy bleeding.[12] Oxytocin induced uterine contractions assists the uterus in clotting the placental attachment point and prevents severe blood loss.[13] Oxytocin is used prophylactically in most obstetric patients along with uterine massage in the prevention and treatment of PPH. Prophylactic routine use of oxytocin has been shown to reduce the incidence of postpartum haemorrhage by up to 40%.[14]

Synthetic oxytocin used clinically is identical to the hormone normally released from the posterior pituitary. Vasodilatation is the primary cardiovascular effect after the use of oxytocin. Tachycardia, increased stroke volume and cardiac output occur as compensatory effects to vasodilatation. The hemodynamic changes that occur during caesarean section have multifactorial causes, such as sympathetic blockade secondary to the spinal anaesthesia, removal of aortocaval compression, maternal auto transfusion after placental delivery and blood loss. The use of oxytocin is just one of these causes and is directly dependent on the way it is administered (dose and rate of infusion).

In spite of repeated use of oxytocin, the minimum effective dose of oxytocin and its proper regimen of administration are not clear and the IV bolus route of oxytocin is faster in compared to IM route. This study was conducted with the objective of comparing uterine contractility and various hemodynamic parameters like the heart rate, systolic blood pressure, diastolic blood pressure and mean arterial pressure after giving either oxytocin bolus in Group B or 10U in 60 NS infusion alone in Group I in caesarean delivery.

The comparison of weight, height, and BMI and age between Group I and Group B showed no statistically significant differences, ensuring baseline homogeneity. Group I had a mean weight of 75.45±12.61 kg, slightly higher than Group B's 72.21±12.20 kg (P = 0.259). Similarly, height was marginally greater in Group I (162.39±8.79 cm) than in Group B (160.18±7.24 cm, P = 0.235), and BMI was comparable between the two groups (28.58±4.00 vs. 28.10±4.12, P = 0.608), The mean age (Years) was lower in Group-I was 24.62±3.91 and in Group-B, the mean age was 25.24±4.15 and the difference was not statistically significant (p=0.568). These results indicate that body composition was evenly distributed across groups, eliminating anthropometric variations as confounding factors. Since BMI influences metabolic rate, energy expenditure, and response to medications, the comparable values reinforce that differences in study outcomes are unlikely to be affected by body composition. Fitrisyah A et al. reported that the mean weight in the Bolus group was 60.60±11.34 kg, while in the Infusion group, it was 61.36±12.76 kg.[15] the difference was statistically insignificant

(p=0.123), indicating that weight did not influence the outcomes between the two administration methods.

Uterine contractility was significantly higher in Group B at multiple time points, particularly at 3 minutes (2.18±0.39 vs. 1.97±0.16, P = 0.003) and 4 minutes (2.97±0.16 vs. 2.21±0.41, P < 0.001). The increased contractility in Group B persisted at 5 minutes (P = 0.045) and 6 minutes (P = 0.038). Administration of the drug in bolus form as in group B produced faster achievement of uterine contractility as supported by the findings of many other studies. Well contracted uterus in Group B at 3 to 6 minutes suggests better drug performance in bolus form. The efficient response in group B makes it statistically significant. Avinash S et al. reported significantly higher uterine contraction levels, as assessed by the Linear Analogue Scale (LAS: 0-atonic to 10-full contracted) in a bolus oxytocin group (Group IB) compared to a standard infusion group (Group I) at 5 and 10 minutes post-injection (P < 0.05).[16]

The total oxytocin dose was significantly higher in Group B (5.45±1.18) compared to Group I (4.82±0.77, P = 0.007). This increased oxytocin requirement in Group B may be related to stronger uterine contractions observed earlier. The correlation between oxytocin dose and uterine contractility further validates the intervention of oxytocin impact on Caesarean Delivery.

Given that oxytocin plays a crucial role in stimulating contractions, the increased requirement in Group B suggests a potential difference in uterine responsiveness between the groups, warranting further exploration of underlying physiological factors. The need for increased oxytocin could suggest variations in physiological response between groups. Our study shows that the cardiovascular side effects can be effectively minimized by slower oxytocin injection of a bolus dose without compromising the therapeutic benefits.

Heart rate remained similar at baseline but significantly increased in Group B at multiple time points, peaking at 4 minutes (124.26±5.37 vs. 99.37±11.28, P < 0.001) and remaining elevated at 10 minutes (P = 0.006). The higher heart rate in Group B correlates with the increased oxytocin dosage, indicating a possible physiological response to the intervention. The sustained elevation in heart rate may suggest a more pronounced adrenergic response in Group B, which could have implications for cardiovascular stability during labor. Statistically significant differences strengthen the validity of the observed trend.

Bhattacharya S et al. reported that the mean heart rate values in the Bolus group were consistently higher than those in the Infusion group, with the differences reaching statistical significance.[9] These findings suggest that bolus administration induces a more rapid and intense cardiovascular response.

These collective findings suggest that bolus administration of oxytocin results in a more immediate and significant cardiovascular response compared to infusion, highlighting the need for careful monitoring in clinical practice.

Systolic blood pressure (SBP) was significantly lower in Group B, particularly at 4 minutes (90.16±5.59 vs. 100.11±4.33, P < 0.001), and remained lower up to 10 minutes. The observed SBP drop aligns with increased uterine contractility and oxytocin dosage in Group B. Similarly, diastolic blood pressure (DBP) showed a significant reduction at 4 minutes (48.84±4.57 vs. 56.29±4.34, P < 0.001), further supporting the cardiovascular response to oxytocin. The SBP drop aligns with the increased uterine contractility and oxytocin dose in Group B. The DBP decline aligns with SBP reduction, further supporting the cardiovascular response. The decline in blood pressure suggests vasodilatory effects due to oxytocin administration. Fitrisyah A et al. and Avinash S. et al. reported no significant differences in systolic (SBP) or diastolic (DBP) blood pressure between oxytocin bolus and infusion groups. Specifically, Fitrisyah A et al. observed mean SBP of 122.1 ± 17.98 (bolus) and 126.5 ± 10.80 (infusion), and mean DBP of 75.23 ± 9.63 (bolus) and 77.18 ± 6.77 (infusion), with no significant intergroup variation.[15] Similarly, Avinash S. et al. found no significant SBP or DBP differences at 2 minutes post-delivery between bolus and infusion groups.[16] Avinash SH et al. also concluded there was no significant difference between the SBP or DBP between the two groups.

Mean arterial pressure (MAP) followed a similar trend, with Group B showing significantly lower values at multiple time points (e.g., 65.21±7.52 vs. 70.89±3.51 at 4 minutes, P < 0.001). The statistically significant decrease in MAP highlights the systemic circulatory effects that may accompany increased oxytocin administration, reinforcing the need for balanced fluid and

pharmacological management. The MAP drop is consistent with observed hemodynamic changes. This magnitude of decrease in MAP may be well tolerated normally, but in case of severe blood loss or unsuspected myocardial disease it may not be tolerable.

Bhattacharya S et al. observed that the maximum MAP reduction occurred at 3 minutes in the Bolus group, while no significant changes were noted in the Infusion group.[9] Overall, bolus administration leads to a more rapid and substantial MAP decline than infusion, emphasizing the need for close hemodynamic monitoring to prevent hypotensive effects.

The consistent reductions in SBP, DBP, and MAP indicate hemodynamic changes potentially associated with the intervention.

Oxygen saturation remained stable across groups, with no significant differences ($P > 0.05$). Baseline SPO2 was 98.63±0.81 in Group I and 98.76±0.71 in Group B ($P = 0.458$). The trend remained similar at 10 minutes (98.32±0.90 vs. 98.50±0.76, $P = 0.340$), indicating that both techniques provided adequate oxygenation. The stability of SPO2 values suggests that oxygen delivery was maintained, ruling out any significant respiratory compromise associated with the intervention. Fitrisyah A et al. analyzed oxygen saturation levels at multiple time points (0, 3, 6, 9, 12, and 15 minutes) in patients receiving either a 5 IU bolus of oxytocin or a 20 IU infusion of oxytocin. The results indicated no statistically significant difference between the two groups ($p > 0.05$), suggesting that both methods of oxytocin administration maintained comparable oxygenation levels.[15]

This finding implies that neither bolus nor infusion delivery of oxytocin had a notable impact on maternal oxygen saturation during the observation period. This reassures that maternal oxygenation remains adequate despite cardiovascular fluctuations.

Side effects were slightly more frequent in Group B, with increased cases of nausea (3 vs. 2), vomiting (2 vs. 1), and chest pain (1 case in Group B). These mild adverse events may be associated with the higher oxytocin dosage and corresponding cardiovascular responses. Side effects were mild and manageable. The trend toward increased side effects in Group B suggests a dose-dependent relationship, highlighting the importance of individualized dosing strategies to minimize discomfort while ensuring therapeutic efficacy. Fitrisyah A et al. found no instances of nausea, vomiting, headache, or flushing in either the 5 IU slow bolus oxytocin group or the 20 IU infusion oxytocin group, suggesting minimal adverse effects in their sample.[15] Avinash S et al. observed that in the comparison between the two groups, two participants in Group I experienced nausea and vomiting, whereas one participant in Group IB reported shivering as a side effect.[16]

Overall, while mild side effects such as nausea, vomiting, headache, and flushing were reported in some studies, they remained minimal and were effectively managed. The findings indicate that both bolus and infusion methods of oxytocin administration are well tolerated, with no significant difference in adverse effects between the two groups.

CONCLUSION

The study suggests that the Bolus group exhibited faster achievement of uterine contractility, requiring higher oxytocin doses, but also demonstrated notable cardiovascular changes, including increased heart rate and reduced blood pressure. These results emphasize the importance of monitoring hemodynamic parameters when administering higher oxytocin doses. Infusion of oxytocin can effectively minimize the cardiovascular side effects without compromising the uterine effects. The overall outcomes reinforce the necessity of individualized dosing strategies to balance efficacy and safety, particularly in managing maternal cardiovascular responses during Caesarean delivery.

The study concludes that the oxytocin infusion is well tolerated and requires lesser dose as well avoid significant hemodynamic changes. Our finding support the use of oxytocin infusion could be implemented safetly and rationally into current clinical practice.

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