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A prospective observational study comparing the effects of two doses of post-delivery oxytocin on uterine contractility in parturients undergoing elective caesarean section in a tertiary level hospital

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ABSTRACT

Introduction: Oxytocin is commonly used in caesarean sections following delivery of baby to prevent haemorrhage, but the optimal dose is not clear. This study compared intravenous one international unit (IU) versus (vs) five IU oxytocin on uterine contractility during elective caesarean sections.

Objective: To compare the efficacy and safety of intravenous one IU and five IU oxytocin in terms of uterine contractility and side effects.

Methodology: A prospective observational study among 114 pregnant women undergoing elective caesarean sections under spinal anaesthesia was done at the Department of Anaesthesiology and Perioperative Critical Care at Kathmandu Medical College Teaching Hospital from 2021 September to 2023 January. Ethical approval was taken before data collection. One group received intravenous one IU oxytocin and the other five IU, followed by infusion. Uterine contraction adequacy was assessed at three minutes (primary outcome) and at two, five, six, and nine minutes (secondary outcomes), along with uterine tone, need for rescue uterotonics, and side effects.

Result: No significant difference in uterine tone was observed at three minutes (93.1% vs. 98.2%, p-value 0.183) or at two, five, and six minutes. However, tone was significantly lower at nine minutes with one IU (82.76% vs 96.43%, p-value 0.017). Palmar erythema and facial flushing were more frequent with five IU.

Conclusion: Intravenous one IU oxytocin is comparable to five IU for maintaining uterine contraction in the short term during elective caesarean sections, with fewer side effects.

Keywords: Anaesthesia; elective caesarean section; one IU vs five IU oxytocin; oxytocin; uterine contractility.

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INTRODUCTION

The complications related to pregnancy and childbirth are major causes of morbidity and mortality in women of reproductive age group, especially in developing countries. Postpartum haemorrhage (PPH) is a leading cause of maternal mortality, accounting for 27.1% of maternal deaths globally, 72.6% of these attributed to PPH.[1] Oxytocin is the drug of choice for managing third stage of labour, preventing and treating uterine atony after delivery. However, its administration lacks standardised guidelines, leading to wide variability in dosing. Doses of intravenous oxytocin boluses range

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from 0.5-5 International Units (IU), the most commonly used dose being three to five IU followed by continuous infusion.[2] Bolus doses as low as 0.35 IU have been found to be effective in non-labouring women.[3] Factors like delivery mode, haemodynamics, and oxytocin receptor desensitisation influence dosing. Enhanced recovery after caesarean delivery (ERAC) guidelines recommend one IU bolus for elective and three IU for intrapartum caesareans, followed by 2.5-7.5 IU/hour.[4] Due to lack of standardised protocol of administration of oxytocin we are frequently giving larger dose of oxytocin to get the effect we would achieve with a lesser dose.[5] This study aimed to compare the efficacy of intravenous one IU versus (vs) five IU oxytocin in achieving uterine contractility and assess associated adverse effects, hypothesising that lower doses may be equally effective with fewer complications.

METHODOLOGY

This was a prospective, observational study done at the Department of Anaesthesiology and Perioperative Critical Care at Kathmandu Medical College Teaching Hospital, Sinamangal, Kathmandu, Nepal among term pregnant patients undergoing elective lower segment caesarean section (LSCS) with Pfannenstiel incision under subarachnoid block (SAB). The study was conducted from 2021 September to 2023 January after obtaining ethical approval from the Institutional Review Committee of Kathmandu Medical College (Reference number: 1507202108). All healthy women with gestational age ≥37 weeks, age between 20-35 years, singleton pregnancies, body mass index ≤with no obstetric complications, and undergoing LSCS under spinal anaesthesia were included in the study. Those who had active labour, drug allergy to oxytocin, multiple gestation, significant obstetric diseases, risk factors for postpartum haemorrhage (abnormal placentation, uterine fibroids, past history of PPH or atony, grand multiparity), coagulation disorders or thrombocytopenia were excluded.

The sample size was calculated based on a previous study where 86% of patients had significant uterine tone at three minutes.[5] Utilising the formula, $n=z^{2*}pq/e^2$ was used, where z is the z score at 95% confidence interval (1.96), p is the proportion of patients who achieved adequate uterine tone at three minutes with one unit of oxytocin (0.86), q is 1-p (0.14) and e is the allowable error at 10%. The sample size was calculated to be 46.25 in each group and considering a dropout of 10%, a sample size of 52 would be enough. Hence, in total, the minimum required sample size was 104.

Preanesthetic evaluation was done a day before surgery and informed consent was taken for enrollment in the study. All patients were premedicated with Tablet Ranitidine 50 milligrams (mg) two hours prior to surgery. They were kept nil per oral for at least six hours for solid foods and clear liquids was allowed until two hours prior to surgery. In the operating room, monitors including electrocardiography (ECG), automated non-invasive blood pressure (NIBP) and pulse oximeter were attached to the patient and baseline haemodynamics was recorded as average of first three readings. Intravenous access was achieved with an 18 G cannula and co-loading was done with 10 ml/kg of crystalloid, which was followed by five ml/kg/hour infusion. Baseline haemoglobin was also recorded. Injection (Inj.) ondansetron four mg was also given. The SAB was performed in sitting position at either L3-L4 or L4-L5 with a 27 G dura separating needle and 2.2 ml of 0.5% Hyperbaric Bupivacaine (Anawin Heavy™: Neon Laboratories Ltd, India) was administered at the rate of 0.2 ml/second. They were then placed supine with a left lateral tilt of 15 degrees using a wedge to prevent aorto-caval compression. Surgery was allowed to proceed after sensory level of T4-T6 was attained. Hypotension, defined as fall in >20 % of the Mean arterial pressure (MAP) of the baseline was treated with a bolus of six mg of Inj. Mephentermine or additional doses as required. Bradycardia, defined as a heart rate of <50/min was treated with Inj. Atropine 0.6 mg or additional doses as required and noted. After clamping of the cord and delivery of the baby, oxytocin was administered intravenously, either one IU or five IU, both diluted in five ml of 0.9% Normal Saline (NS) and given over 15 seconds.[5] Uterine tone was assessed by the obstetrician, who was blinded to the mode of oxytocin used, by manual palpation at three, five, six and nine minutes following the administration of oxytocin bolus. The uterine tone score (UTS) was scored as follows: one=atonic; two=partial but inadequate contraction; three=adequate contraction; four=well contracted; and five=very well contracted.[6] At three minutes, if the uterine tone was three or more, oxytocin was started as an infusion (10 U in 500 ml of Ringer Lactate at 250 ml/hour, five IU/hour or 0.08 IU/min) and continued until the end of surgery. If the uterine tone was inadequate, a rescue bolus of 2.5 IU of oxytocin was administered and infusion started once UTS was more than two. Rescue boluses were given for a total of two times if the uterine tone was inadequate at two points of assessment. If the tone was still not adequate, intramuscular Inj. Methyl Ergometrine 0.2 mg, Inj. Carbaprost 250 µg or rectal Misoprostol 800 µg was given at the discretion of the attending anesthesiologist and obstetrician. Uterine

exteriorisation and uterine massage were performed as per the decision of the attending obstetrician, which was noted. Use of Inj. Tranexamic acid, if advised by the obstetrician was given and noted.

Haemodynamic parameters: heart rate (HR), blood pressure (BP): systolic, diastolic and MAP; oxygen saturation (SpO_2); and respiratory rate were recorded every 2.5 minutes from the start of SAB until the delivery of the baby. The HR just before the administration of oxytocin was noted. Following oxytocin administration, HR and MAP was taken at an interval of one minute until the first 10 minutes of assessment and then after every five minutes until the end of surgery by a second investigator. The patient was observed for possible side effects of oxytocin bolus such as tachycardia, hypotension, electrocardiographic changes like ST depression or T-wave flattening/inversion, nausea, vomiting, shortness of breath, flushing, palmar erythema and headache, which was recorded. Other side effects, if noted, were also recorded. Tachycardia was defined as an increase in HR more than 20 beats per minute above the baseline value before the injection of oxytocin. Hypotension was defined as a decrease in MAP by ≥20% from baseline before oxytocin bolus administration and six mg of Inj. Mephentermine was given. The administration of fluid, vasopressors, atropine to all patients was recorded in both groups. The total amount of blood loss was determined by the provider's best clinical estimate by visually assessing the suction bottles and drapes.

On completion of surgery, the patient was transferred to post-operative ward and oxytocin infusion was continued for a total of four hours, at the rate of 125 ml/hour, 2.5 IU/hour or 0.04 IU/min. The need for additional uterotonics in the first 24 hours was also noted. A haemoglobin level was sent to lab when the patient was shifted to the post operative ward and noted. Blood transfusion was given if the post operative Hb was less than seven grams per decilitre (gm/dl). Any other post-operative complications in the first 24 hours were also recorded along with the total urine output. The primary outcome was adequacy of uterine contraction within first three minutes of administration of bolus dose of oxytocin. Secondary outcomes were uterine tone score, adequacy of uterine tone at five, six and nine min. of oxytocin bolus, use of additional uterotonic agents, blood loss, need of blood transfusion and pre- and post-operative haemoglobin. Also, side effects of oxytocin like tachycardia, hypotension, chest pain, nausea, vomiting, ECG changes were noted.

The IBM SPSS Statistics for Windows, version 20 (IBM Corp., Armonk, N.Y., USA) was used for data analysis. Descriptive data have been expressed as mean ± standard deviation and frequency (percent). Chi-square test or Fisher Exact test was used for comparing nominal measurements. Student's independent t-test was used to compare quantitative variables and $p \leq 0.05$ was used as level of significance.

RESULT

A total of 118 patients were enrolled although the calculated minimum sample size was 104, anticipating exclusions and 114 completed the study. Two patients were excluded as the obstetrician requested for supplemental oxytocin though UTS was adequate; one was excluded because the obstetrician did not request for supplemental oxytocin though the UTS was low and one was excluded as she had to be given general anaesthesia for failure of SAB (Figure 1).

The patient demographics and baseline characteristics were similar among both the groups (Table 1).

The percentage of patients with adequate uterine tone at three minutes following the bolus dose of oxytocin showed no significant difference between the two groups. Adequate uterine tone was seen in 53 (91%) patients in Group one IU and 55 (98.1%) in group five IU (p=0.102). The uterine contractility was also similar between the two groups at five and six minutes. However, the uterine contractility was significantly low in Group A at nine minutes following bolus dose of oxytocin (p = 0.017). It was also seen that the UTS at three minutes was comparable between the two groups. The maximum percentage of patients had moderate uterine contraction in both the groups (p-value >0.05). Significantly, more patients required oxytocin boluses in group receiving one IU of oxytocin (p = 0.005). Similarly, the incidence of uterine massage was also higher in the group receiving one IU oxytocin (p = 0.001). However, there was no difference in patients receiving second line rescue drugs, namely second rescue dose of oxytocin and methylergometrine. In Group B, one patient received methylergometrine at 25 minutes on obstetrician's request. More than one third (22, 37.9%) patients receiving one IU of oxytocin required additional uterotonics, out of which five patients even required second bolus dose of oxytocin; while in patients receiving five IU, six required additional bolus and one required second rescue dose (Table 2).

Keeping in view that the half-life of oxytocin is one to six minutes, 12 patients in Group A and four patients in Group B required rescue oxytocin after six minutes, which might mean that bolus oxytocin they received was adequate for initial uterine contraction, and might hint at requirement of higher infusion rates (Table 3).

The intraoperative replacement and the duration of surgery were comparable in both groups. None of the patients required blood transfusion and had post-partum haemorrhage. Estimated blood loss, values of post-operative haemoglobin and use of Inj. Mephentermine Inj. Tranexamic acid were also not significantly different in two groups. It is seen that group B had a higher initial spike in heart rate at one-minute post-oxytocin compared to group A and both groups show a gradual decline in heart rate after the initial spike (Figure 2). The differences between the groups were not statistically significant. Though the blood pressure was observed to decrease, there was also no significant hypotension noted in both the groups for the first ten minutes following the bolus dose of oxytocin (Table 5).

Following bolus dose of oxytocin, patients receiving one IU of oxytocin had significantly less incidence of facial flushing and palmar erythema with p ≤0.001 and <0.010 respectively. Headache, ECG changes and nausea were also seen in both groups which were not significant. None of the patients had vomiting or chest pain (Table 6).

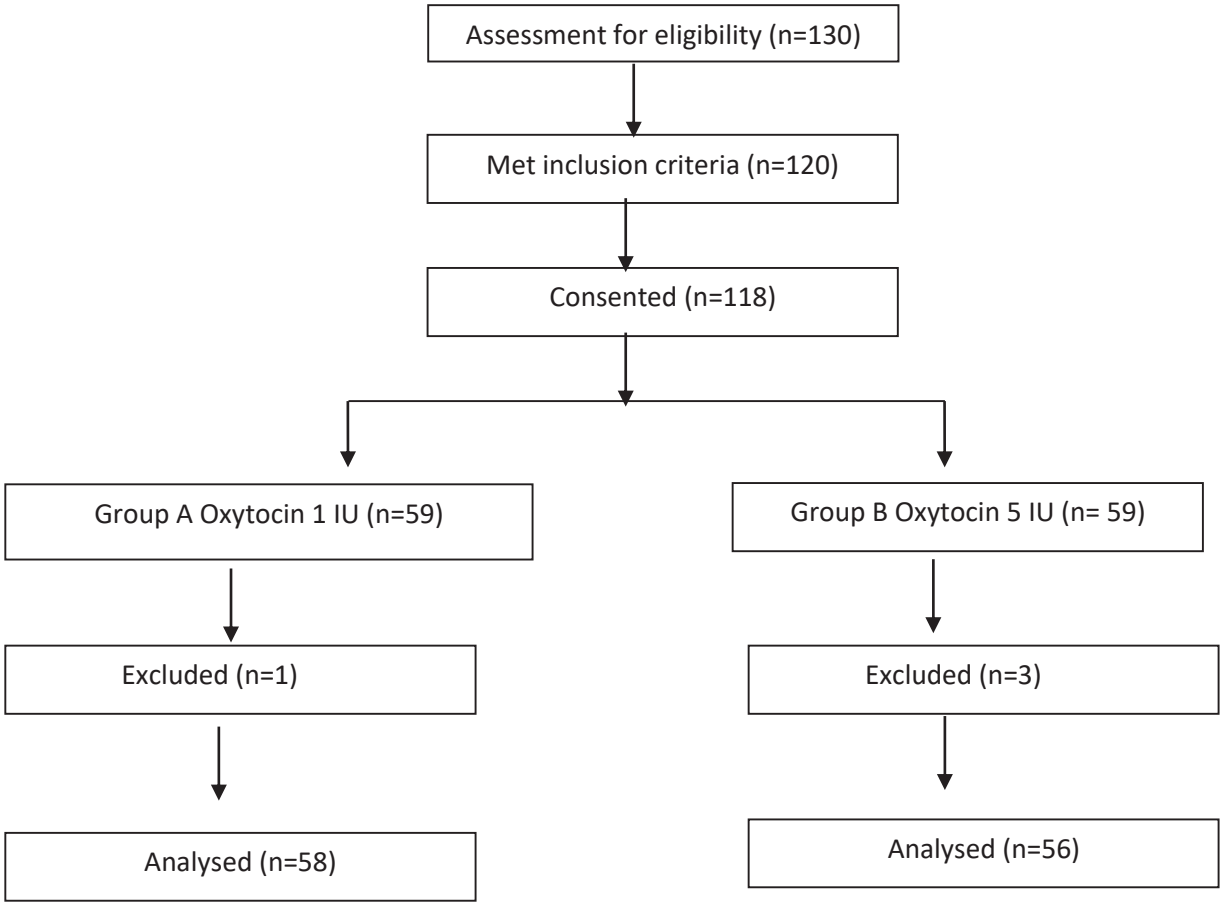

Figure 1: Consort flowchart of the study

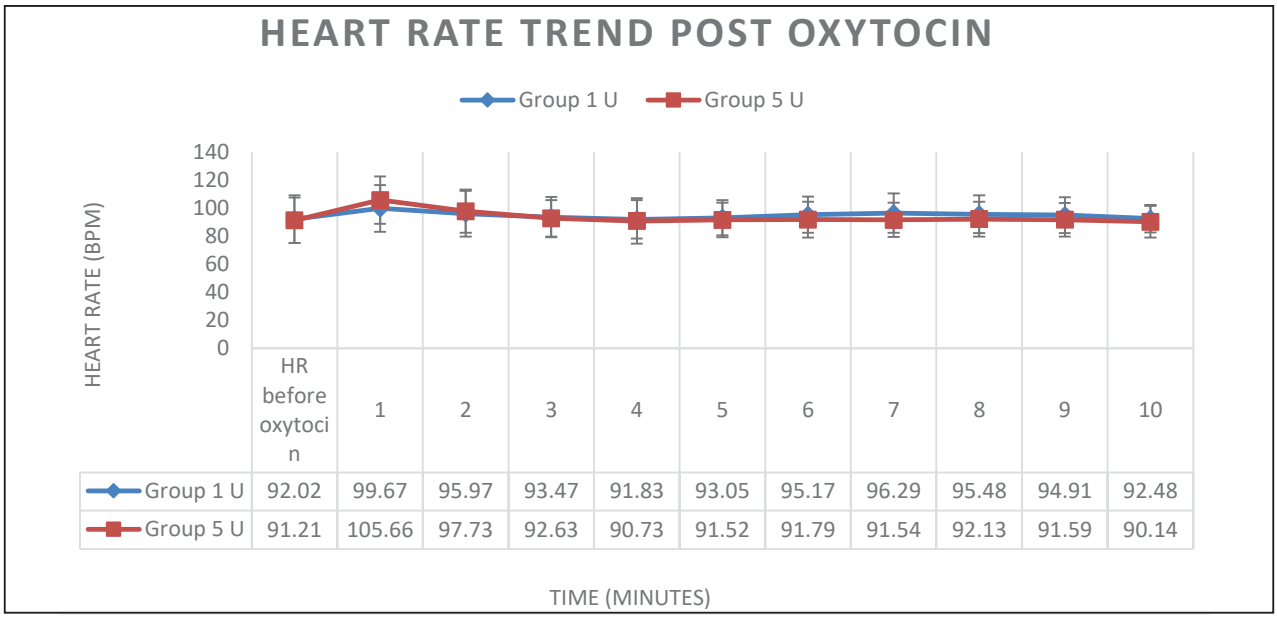

Figure 2: **Trend of heart rate following bolus dose of oxytocin for first 10 minutes**

Table 1: **Distribution of demographics and baseline characteristics among two groups**

Parameters	Oxytocin Dose		p-value	95% Confidence Interval
	Group A (1IU) (N=58)	Group B (5IU) (N=56)		
Age in years	30.53 ± 3.051	30.13 ± 4.549	0.572	(-1.023, 1.842)
Weight (kg)	69.69 ± 7.86	72.38 ± 10.52	0.125	(-6.125, 0.754)
Height (m)	1.55 ± 0.047	1.56 ± 0.041	0.075	(-0.03, 0.001)
Body mass index (kg/m2)	28.95 ± 3.29	29.42 ± 4.24	0.509	(-1.87, 0.93)
Weeks of gestation	38.43 ± 1.02	38.17 ± 1.77	0.324	(-14.93, 44.8)
Baseline haemoglobin (gm/dl)	12.6 ± 1.37	12.76 ± 1.15	0.495	(-0.63,0.31)
Preoperative baseline heart rate (beats/minute)	96.47 ± 14.1	94.09 ± 14.74	0.381	(-2.975,7.727)
Preoperative baseline mean arterial pressure (mm Hg)	92.28 ± 7.914	94.27 ± 10.51	0.256	(-5.433, 1.459)

Notes: p-value calculated as independent samples' t-test.

Table 2: **Outcomes in terms of uterine contraction in two groups**

Outcomes	Group A (1 IU) (n = 58) n (%	Group B (5 IU) (n = 56) n (%)	p-value
Primary outcome:			
Adequate uterine contraction within three minutes	54 (93.1)	55 (98.2)	0.183
Secondary outcomes:			
Adequate uterine contraction within five minutes	54 (93.1)	54 (96.43)	0.676
Adequate uterine contraction within six minutes	53 (91.38)	54 (96.43)	0.427
Adequate uterine contraction within nine minutes	48 (82.76)	54 (96.43)	0.017$
Uterine Tone Score at three minutes			
Poor: 1-2	5 (8.62)	1 (1.78)	0.10
Moderate: 3-4	52 (89.6)	55 (98.2)	0.06
Strong: 5	1 (1.72)	0	0.32
Additional uterotonic agents			

Oxytocin, 1 bolus	22 (37.9)	6 (10.71)	0.005$
Oxytocin, 2 boluses	5 (8.62)	1 (1.7)	0.114
Methylergometrine	5 (8.62)	2 (3.57)	0.262
Hot mopping	3 (5.17)	3 (5.35)	0.965
Uterine massage	29 (50)	12 (21.42)	0.001
Exteriorisation	1 (1.72)	2 (3.57)	0.513
Tranexamic acid	12 (20.6)	13 (23.2)	0.823

Notes: p-value <0.05 significant $= Fisher-exact test.

Table 3: Timing of rescue oxytocin in two groups

Group A (1IU) n=58)			Group B (5IU) (n=56)		
S. N.	First rescue dose (minutes following bolus dose)	Second rescue dose (minutes following bolus dose)	S. N.	First rescue dose (minutes following bolus dose)	Second rescue dose (minutes following bolus dose)
1.	8		1.	9	
2.	6		2.	6	
3.	25		3.	3	5
4.	12		4.	10	
5.	6	9	5.	25	
6.	9		6.	20	
7.	10				
8.	3				
9.	5				
10.	10	30			
11.	8				
12.	6				
13.	6	9			
14.	15				
15.	15				
16.	3	9			
17.	9				
18.	9				
19.	4				
20.	3	25			
21.	4				
22.	9				

Table 4: Intraoperative characteristics

Characteristics	Group A (1 IU) (n = 58)	Group B (5 IU) (n = 56)	p-value	95% Confidence Interval
Intra-venous crystalloid (millilitres)	1265.5 ± 273.5	1161.25 ± 297.6	0.054	(-1.756, 210.3)
Estimated blood loss (millilitres)	305.17 ± 81.48	306.25 ± 74.5	0.941	(-30.08, 27.92)
Post op Hb (gm/dl)	12.17 ± 1.38	12.27 ± 1.04	0.680	(-0.5, 0.36)
Duration of surgery (minutes)	45.78 ± 14.24	48.86 ± 15.94	0.279	(-8.6, 2.5)
Dose of Mephentermine used (milligram)	5.28 ± 7.003	4.56 ± 5.305	0.537	(-1.589, 3.304)

Note: p-value (independent sample t-test)

Table 5: Post oxytocin mean arterial pressure among two groups

Time following oxytocin bolus	Group A (1 IU) (n = 58)	Group B (5 IU) (n = 56)	p-value	95% Confidence Interval
Mean arterial pressure before oxytocin	85.62 ± 10.662	84.46 ± 12.171	0.572	(-2.89, 5.20)
1 min	80.78 ± 10.662	79.66 ± 12.754	0.613	(-3.24, 5.47)
2 min	83.55 ± 9.5	80.46 ± 12.18	0.133	(-0.960, 7.134)
3 min	82.71 ± 9.45	83.41 ± 10.45	0.708	(-4.41, 3.004)
4 min	83.41 ± 10.51	81.64 ± 8.685	0.412	(-5.066, 2.092)
5 min	80.43 ± 8.49	81.54 ± 9.29	0.509	(-4.405, 2.195)
6 min	78.28 ± 8.62	81.46 ± 9.97	0.070	(-6.645, 0.268)
7 min	76.41 ± 9.3	78.7 ± 9.51	0.198	(-5.77, 1.20)
8 min	75.45 ± 8.84	78.75 ± 9.5	0.056	(-6.724, 0.086)
9 min	75.53 ± 9.80	78.31 ± 9.31	0.126	(-6.347, 0.079)
10 min	75.16 ± 10.67	77.69 ± 8.60	0.169	(-6.162, 1.090)

Note: p-value calculated as independent samples' t-test.

Table 6: Adverse effects related to Oxytocin among two groups

Adverse effects	Group A (1 IU) (N = 58) n (%)	Group B (5 IU) (N = 56) n (%)	p-value
Headache	1 (1.7)	-	1.0
Facial Flushing	4 (6.8)	20 (35.7)	<0.001
Palmar erythema	32 (55.2)	44 (78.6)	0.01
ECG changes	4 (6.8)	7 (12.5)	0.35
Arrhythmia	1 (1.7)	2 (3.6)	0.61
Nausea	4 (6.8)	5 (8.9)	1.0

Notes: p-value <0.05 significant $ = Fisher-exact test

DISCUSSION

The results of this study demonstrated that one IU of oxytocin is as effective as five IU in achieving adequate uterine tone immediately after the delivery of the baby. However, the study revealed important differences in the need for additional uterotonics, uterine massage, and the incidence of adverse effects, which might have significant clinical implications.

The primary outcome of the study was the adequacy of uterine contraction within the first three minutes of oxytocin administration. Both groups (1 IU and 5 IU) achieved high rates of adequate uterine tone (93.1% and 98.2%, respectively), with no statistically significant difference (p=0.183). This finding suggests that a lower dose of oxytocin (1 IU) is equally effective as a higher dose (5 IU) in achieving uterine contractility during elective caesarean sections. This is consistent with previous studies that have shown efficacy with lower doses of oxytocin, such as 0.35 IU, in preventing uterine atony.[3] Butwick et al. also found that adequate contractility could be achieved with lesser doses of oxytocin (0.5-3 U).[5] Similar results were reported across multiple studies that evaluated the effects of two units of oxytocin in comparison to five units.[7,8] The results support the growing evidence that lower doses of oxytocin may be sufficient for routine use in elective caesarean sections, potentially reducing the risk of adverse effects associated with higher doses.[6] We also assessed uterine contractility at five, six and nine minutes following bolus oxytocin dose. Current findings also show that adequate uterine contraction was achieved in both groups at five and six minutes, with no statistically significant differences between the two groups. However, as few patients required bolus doses at six minutes, the rescue doses might have contributed to uterine contraction at that time period. The similar efficacy of these two doses at earlier time suggest that lower doses are enough in most of the clinical scenarios. This may be beneficial in settings where minimising the dose of oxytocin is desirable, like

in pregnant patients with cardiac diseases or in resource limited environments. However, at the nine minutes interval, the five IU showed a significantly higher rate of adequate uterine contraction (96.43% vs 82.76%, p = 0.017). This suggests that while one IU is equally effective in the short term, five IU oxytocin bolus may provide an advantage in sustaining uterine tone over a longer duration and maybe preferable where risk factors for postpartum haemorrhage (PPH) is present.

The half-life of oxytocin is very short; three to five minutes and in current study, we have started oxytocin infusion at three minutes, provided the uterine contraction was adequate. We found that significantly higher patients in 1 IU group required rescue doses and uterine massage at 9 minutes. This may be attributed to the lower oxytocin infusion rate used in this study (5 IU/hour), which aligns with current standard practice for all patients. In contrast, other studies have used higher infusion rates of 10 IU/hour, which likely was the reason for more effective outcomes.[9,10] Lavoie et al used even higher doses up to 18 IU/hour but they did not use bolus doses.[11] They found that those pregnant ladies who already had exposure to oxytocin required higher dose of the same post-delivery in comparison to oxytocin naïve patients. We only observed elective LSCS cases, which might have led to uterine contraction even with lower doses. While Somjit et al utilised an infusion rate of 2.5 IU/hour, the doses they compared were significantly higher, specifically five IU vs 10 IU.[7] However, given the use of lower bolus doses in this study, it may be necessary to consider increasing the infusion rate to achieve optimal outcomes. Administering a higher dose of oxytocin infusion is not without its associated risks. In an editorial by Tsen and Balki, they have highlighted the fact that continued exposure to high oxytocin in the postpartum period can lead to acute receptor desensitisation and make the myometrium less responsive to additional oxytocin.[12] The higher need for additional interventions oxytocin in the one IU group highlights the importance of individualised dosing based on patient characteristics and intraoperative findings. The oxytocin infusion was maintained for a duration of four hours, and none of them required additional uterotonics or experienced PPH during the first 24-hour postoperative period.

The analysis of haemodynamic parameters revealed that the five IU group had a higher initial spike in heart rate at 1minute post-oxytocin administration compared to the one IU group, although the difference was not statistically significant (p=0.060). Both groups showed a gradual decline in heart rate after the initial spike, with no significant differences at subsequent time points. Similarly, there were no significant differences in MAP between the groups at any time point. Though the MAP shows an initial decline, the decline was found to be similar in both groups. These findings suggest that while higher doses of oxytocin may cause transient haemodynamic changes, these effects are generally well-tolerated and do not persist over time. In contrast to this study, other studies have found significant tachycardia and hypotension in groups receiving five IU of oxytocin compared with lower doses.[5,10] Nayak et al observed tachycardia but it was statistically significant only in the first minute.[13] The reason for this might be the way hypotension has been described in the studies. Butwick et al. has taken hypotension as fall in MAP >10% of baseline blood pressure while we have taken fall more than 20% of baseline because that is what is practised in study centre. The slow administration of the boluses of oxytocin over 15 seconds might have also led to decreased incidence of side effects. Another reason for this disparity might be the lower infusion dose we used in this study, five IU/hour while most other studies have used 10 IU/hour of oxytocin infusion following the bolus dose. This study also evaluated the incidence of adverse effects associated with oxytocin administration. The five IU group had a significantly higher incidence of facial flushing (35.7% vs 6.8%, p<0.001) and palmar erythema (78.6% vs 55.2%, p=0.010) compared to the one IU group, which might be due to the vasodilatory effects of oxytocin. These findings are consistent with previous studies that have reported dose-dependent adverse effects of oxytocin, including tachycardia, hypotension, and ECG changes.[7,14] Although the study did not find significant differences in other adverse effects such as nausea, headache, or arrhythmias, the higher incidence of vasodilatory effects (flushing and erythema) in the 5 IU group underscores the potential risks of using higher doses of oxytocin.

This study has several limitations. First, this is a single center study which may limit the generalisability of the results. Secondly, the assessment of uterine tone was subjective and dependent on the obstetrician's manual palpation, which may introduce bias. Finally, the heart rate and MAP may have been influenced by the rescue boluses of oxytocin which was given when the Uterine Tone Score was inadequate.

CONCLUSION

Intravenous one IU oxytocin is comparable to five IU for maintaining uterine contraction in the short term during elective caesarean sections, with fewer side effects.

The efficacy is time-dependent in nature, with five IU becoming advantageous only after a longer duration, albeit with an increased incidence of side effects. This can help guide clinical decision-making, allowing providers to tailor doses based on the specific clinical context and duration of required uterine tone. At the same time, this data supports the use of lower doses of oxytocin in routine practice while emphasising the importance of individualised care and readiness to escalate treatment when necessary.

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