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Original Research Article

A Comparative Study to Evaluate the Efficacy and Safety of Two Different Doses of Oxytocin Boluses in Elective Caesarean Sections

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Abstract

Introduction: Oxytocin has essentially been used to prevent uterine atony in pregnant females. However its administration should be done cautiously as it is associated with certain hemodynamic altercations. Moreover, there is associated desensitisation of its receptors. Therefore, in our study we compared changes in heart rate and mean arterial pressure that occur after administration of two different doses of 1 and 3 units of IV oxytocin bolus. Additionally, we studied the adequacy of subsequent uterine contractions and need for additional uterotonic agents along with any adverse events.

Material and Methods: Pregnant women posted for elective LSCS under spinal anaesthesia and those meeting the inclusion criteria were recruited for the study. They were randomly divided into two groups of 52 each and were given 1 unit and 3 unit of oxytocin bolus respectively followed by regular oxytocin infusion of 10units/hour by adding 20 units of drug in 500ml of 0.9% NS after delivery of baby. Hemodynamic parameters HR, SBP, DBP and MAP were recorded and compared to baseline. Uterine tone adequacy was checked at 2,5 and 15 minutes. Use of any additional uterotonic drugs and any adverse effects were noted.

Results: Better uterine tone was achieved in the group that was administered 3 units of oxytocin bolus. The need for rescue uterotonics was observed with the 1 unit bolus group and none of the participants in 3 units group required them. Hemodynamic variations in SBP, DBP, MAP and HR were observed in the 3 unit's bolus group. There was no significant difference in the adverse effects of nausea and vomiting in the two groups.

Conclusion: 3 units of oxytocin bolus followed by infusion of 10 units per hour could provide satisfactory uterine tone with minimal hemodynamic changes and adverse effects.

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Introduction

Lower segment caesarean section (LSCS) is a common major surgery performed in many countries, with an average rate of 17.2% in India. The rise in LSCS has been driven by factors such as labor pain, apprehension about the quality of life after vaginal birth, and specific timing requirements for birth. [1] However, LSCS also presents risks such as anesthetic complications, major hemorrhage, injury to the bowel and bladder, infections, long hospital stays, placenta accrete syndrome in subsequent pregnancies, and maternal mortality. [2]

The bleeding in LSCS is far greater than that during vaginal births, and 5% of all deliveries end up in Postpartum Hemorrhage (PPH), which is one of the two major causes of maternal deaths worldwide. Uterine atony, the most common cause of severe life-threatening PPH, contributes up to 25% of maternal mortalities. [3] PPH is higher in low-resource countries like Africa and Asia, making the true incidence of PPH likely substantially higher than reported. [4]

The World Health Organization strongly advocates for the use of uterotonic agents for prevention of PPH irrespective of the mode of delivery, with oxytocin being the first line drug for both prevention and treatment. [5] It promotes uterine smooth muscle contraction, which reduces blood loss from the site of placental attachment following delivery. Prophylactic usage of oxytocin has proven to decrease the frequency of PPH by up to 40%,

suggesting that for every twenty-two females given oxytocin, one case of PPH could be prevented. [6]

Various protocols guide the administration of oxytocin during caesarean sections, leading to various practices around the world. Effective uterine tone can be reached after elective LSCS by giving the smallest effective oxytocin IV bolus dose of 0.35 IU, but the required dose in labouring females during caesarean section is approximately 9 times more. Satisfactory contraction of the uterus can be achieved with small bolus doses of 0.5-3 units. [7]

It was found that the bolus and infusion doses have distinct modes of action. The former, causing detachment of placenta followed by constriction of venous sinuses, and the latter sustaining the contraction. [8] The bolus administration is often associated with preventable maternal and fetal adverse events during the peripartum period, such as hypotension, tachycardia, ST segment depression in ECG independent of anaesthesia and cardiovascular collapse. [9] Therefore the best strategy was found to use a small titrated bolus dose first followed by a regulated infusion to minimise drug-related complications and provide better outcomes. [10]

To determine the optimal bolus dose of oxytocin, we compared two different doses of 1 unit and 3 units in terms of adequacy of uterine contraction, adverse cardiovascular effects and repeated requirement of additional uterotonics.

Materials and Methods

After approval from Institutional Ethical Committee, this randomized double-blind study was conducted in the Department of Anaesthesiology at Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana, Ambala, Haryana, India, for a period of two years in 104 women. The sample size was estimated from the results of a previous study using MAP as the outcome parameter. The study included 52 patients in each group, with the inclusion criteria being ASA grade II, age between 18 to 40 years, elective LSCS under Spinal Anaesthesia, singleton pregnancy, and refusal of the patient. Patients posted for emergency LSCS, h/o allergy to oxytocin, placenta previa/accreta, polyhydramnios, multifetal pregnancy, contraindications for SAB were excluded from the study.

Pre-anaesthetic check-up was done before surgery, routine investigations were done and written informed consent taken. Overnight fasting was ensured and Ranitidine 150 mg was given as premedication the night before and on the morning of surgery. Patients were randomly allocated to two groups by picking an opaque sealed numbered envelope opened on the day of surgery and study drug was loaded by an anaesthesiologist not involved in the study. Group 1 patients received 1 unit oxytocin bolus followed by 10units/hour infusion and group 2 patients received 3 units oxytocin followed by 10 units/hour infusion.

After shifting the patient to the operation theatre, routine monitoring was started, and baseline vital parameters like HR, BP, MAP, and SpO2 were recorded. IV was secured and central neuraxial block performed using 25G Qunicke's needle with Bupivacaine (heavy) 0.5% at L2-3 or L3-4 interspace. Following delivery of the baby and clamping of the umbilical cord, oxytocin bolus was administered IV over 15 seconds as per the group division. After 5 minutes, all patients were given oxytocin infusion at 10 IU/hr by adding 20 units of drug in 500ml of NS at 250ml/hr. Parameters like BP and HR were documented immediately before and subsequently at 10, 15, 20, 25, and 30 minutes until uterus was sutured. Hypotension was defined as more than 20% fall in SBP, DBP or MAP and Tachycardia as 20% or more increase in HR.

The incidence of drug-related side effects was evaluated by symptoms reported by the female. The adequacy of contraction of the uterus was evaluated by the performing surgeon at two, five, fifteen minutes after delivery of the baby by palpating the uterus. If the tone of the uterus was not found to be satisfactory during the assessment, supplemental uterotonic therapies were used.

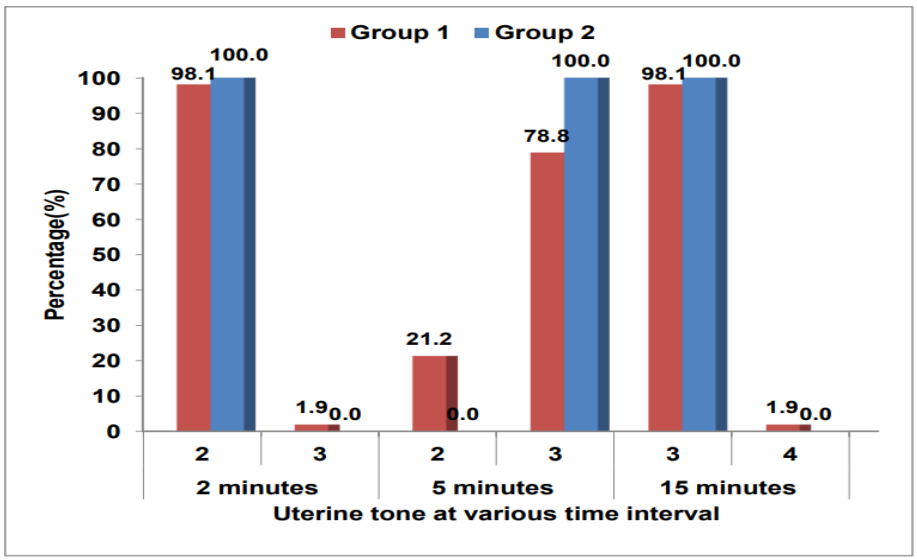
Statistical Analysis

The data obtained was entered in Microsoft excel sheet and was be statistically analysed. Qualitative variables were expressed as proportions in terms of percentage. Quantitative variables were expressed as mean, standard deviation or median and interquartile range. Association of independent and dependent variables was established using chi square test, t-test, innova test depending on variables. A probability value ('p' value) of less than or equal to 0.05 was considered as statistically significant.

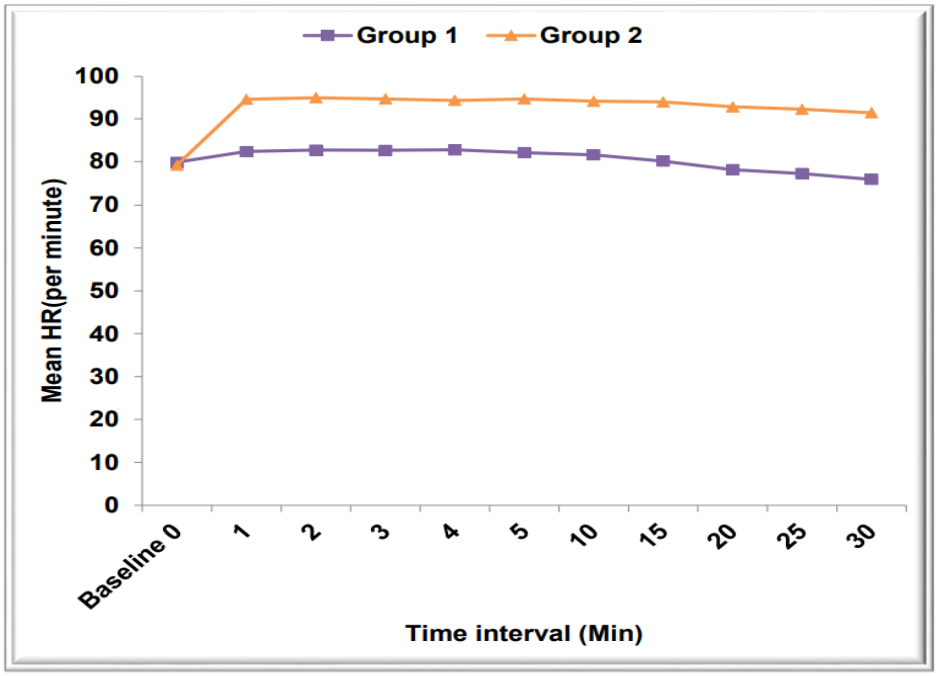
Results

The current study was conducted in the Department of Anaesthesiology, Maharishi Markandeshwar Institute of Medical Sciences and Research, Mullana. A total pf 104 pregnant females were enrolled who met the inclusion criteria and randomly allocated to two groups. Group 1 patients received 1 unit oxytocin bolus followed by infusion of 10units/hour and group 2 patients received 3 units oxytocin bolus followed by infusion of 10units/hour. Age and ASA-PS were found to be comparable between the two groups ($p>0.05$). Baseline values of HR, SBP and DBP were statistically insignificant between the two groups as shown in Table 1 ($p>0.05$). Uterine tone was similar in both groups at 2 and 15 minutes ($p>0.05$), but there was a significant difference at 5 minutes as a greater number of patients had adequate contraction in

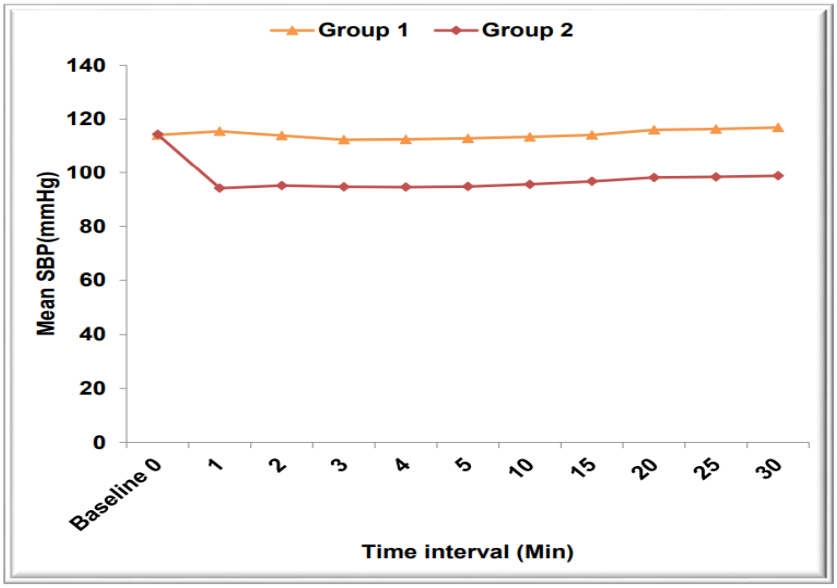
group 2 compared to group 1 (p=0.001). Upon comparison of hemodynamics, group 1 patients showed no significant fall in SBP, DBP and MAP but group 2 was observed to have a significant reduction, and the comparison was statistically significant (p<0.005). Similarly, mean HR in group 1 over various intervals did not show a significant rise, but tachycardia was observed in group 2 and difference was statistically significant. 11 patients in group 1 and none in group 2 required a rescue uterotonic medication, the difference being statistically significant (p=0.000). Surgeon satisfaction score between the two group was better in group 2 compared to group 1, which was highly significant (p=0.000). There were no significant adverse effects observed between both the groups.



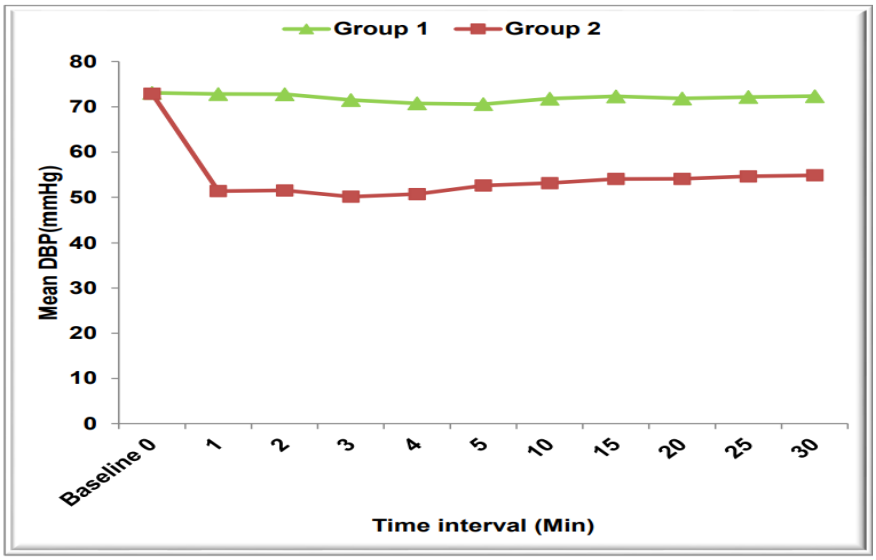
Graph 1: Comparison of uterine tone at various time intervals



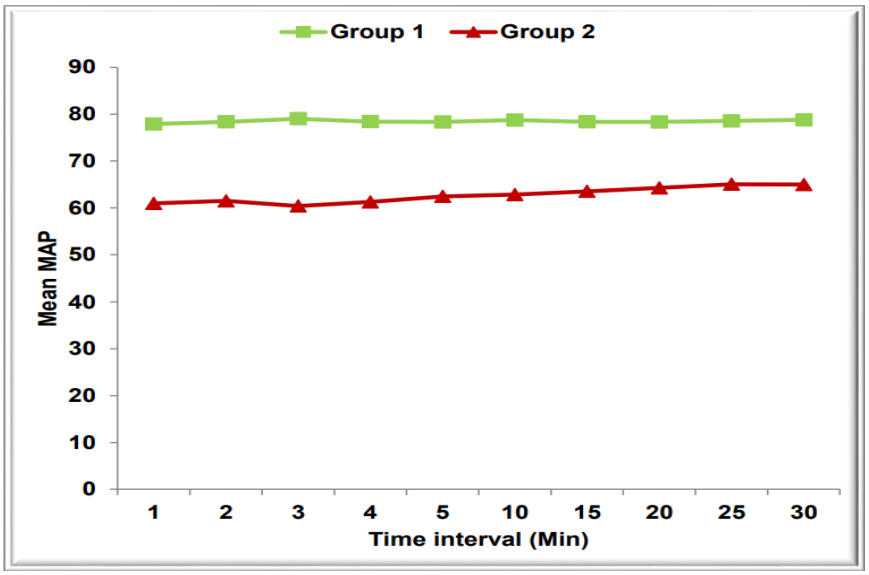
Graph 2: Comparison of maternal HR between the groups



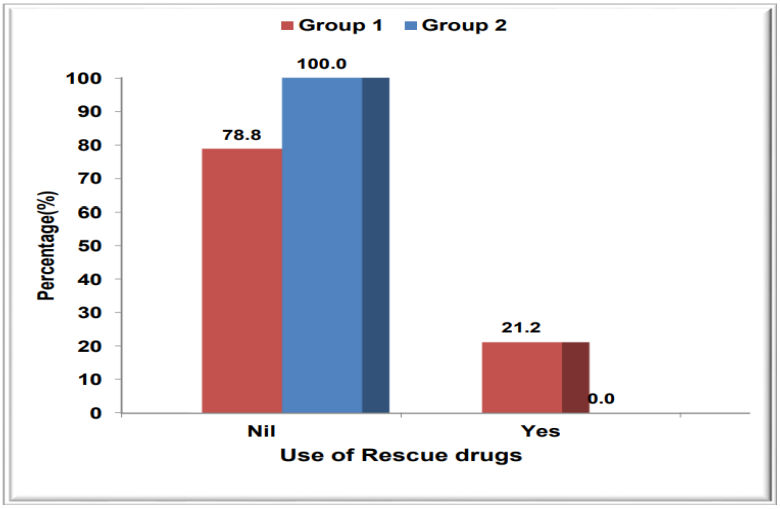
Graph 3: Comparison of maternal SBP between the groups



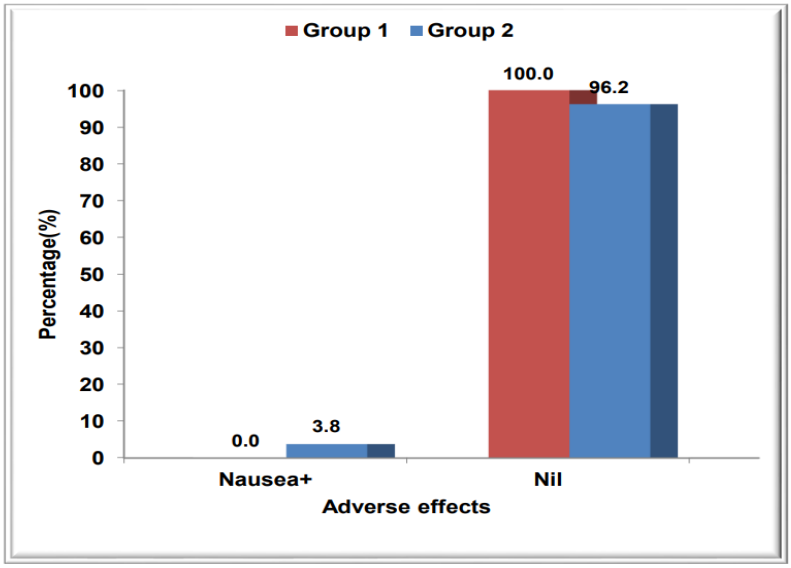
Graph 4: Comparison of maternal DBP between the groups



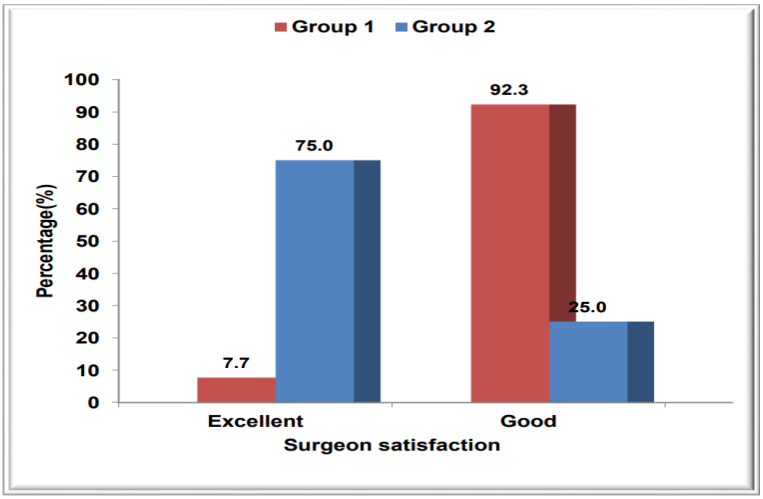
Graph 5: Comparison of MAP between the groups



Graph 6: Use of rescue drugs in both groups



Graph 7: Comparison of Adverse effects in both groups



Graph 8: Comparison of Surgeon Satisfaction Score in both groups

Discussion

Oxytocin remains the cornerstone drug for prevention of postpartum hemorrhage (PPH) during cesarean delivery. However, the optimal intravenous bolus dose that balances efficacy with minimal side effects remains debatable, particularly in the indian population. WHO has itself prioritized the need of

research for identifying optimum oxytocin dose during cesarean section. [11] Our randomised, double-blind study aimed to compare the uterotonic efficacy, need for rescue uterotonics, and hemodynamic safety of 1-unit versus 3-unit IV oxytocin bolus doses, followed by a standardised infusion of 10units/hour in 104 pregnant females undergoing elective LSCS.

In our study, 100% of patients in 3-unit group had adequate uterine tone compared to 78.8% in 1-unit group. This difference was statistically significant, and our results align with findings from Joseph et al. [12] and Bhattacharya et al. [13], both of whom found 3 units to be effective. In contrast, Butwick et al. [14] reported no significant differences between groups receiving 1, 3, and 5 units; however, this discrepancy could be due to immediate infusion start and routine use of uterine massage in their study.

Additional uterotonics were required by 21.2% of patients in the 1-unit group, while none of the patients in 3-unit group needed rescue uterotonics. This reinforces the greater efficacy of 3-unit bolus and is also consistent with previous studies such as Butwick et al. [14] Given the resource constraints in many Indian healthcare settings, avoiding additional uterotonics may be helpful to reduce complications.

Hemodynamic stability is a major concern while administering oxytocin. While both groups remained largery stable, the 3-unit bolus group showed a statistically significant decline in systolic, diastolic, and mean arterial pressure compared to 1-unit group. However, this drop was transient and did not any pharmacological intervention, suggesting that 3-unit oxytocin bolus administered slowly (over 15 seconds) is generally well-tolerated. Heart rate increased significantly in the 3-unit group, consistent with the known positive chronotropic effects of oxytocin. Similar findings were reported by Sartain et al. [15] and Bhattacharya et al. [13], who noted greater hemodynamic changes with increasing bolus doses. Earlier findings by Thomas et al. [9] and Kim et al. [16] also demonstrated dose-dependent tachycardia. However, no patient developed clinically significant arrythmias.

Only 2 patients in the 3-unit group experiences nausea, while no patients did in the 1-unit group. This low incidence is consistent with studies by Sartain et al. [15] and Carvalho et al. [17] can be explained by the lower dose of oxytocin used as well as slower rate of administration.

Several unique factors may have influenced the findings in our study. In contrast to previous studies conducted on well-nourished populations in developed countries, our study population was Indian who often have sub-optimal nutritional status and anemia, which is a potential factor to alter oxytocin requirements. Secondly, we initiated the oxytocin infusion 5 minutes after the bolus, whereas other studies start earlier.

This delay may be responsible for a more potent bolus to maintain adequate uterine tone. The routine practice of uterine exteriorization at our institute may be a factor associated with increased uterine atony and hence more need of uterotonics. [18]

This study was not short of limitations which should be considered. We did not include a 2-unit bolus group, which could have provided an intermediate dose for analysis of optimal balance between efficacy and safety. Uterine tone assessment in this study was performed by different obstetricians, which may have contributed to variable findings. Lastly, BMI was not recorded which can be a significant limitation as obesity is a known risk factor for uterine atony and increases the oxytocin requirements.

Conclusion

Through the study we reached a conclusion that three units of oxytocin bolus when followed by regular oxytocin infusion of ten units/hour leads to good uterine tone without any need of supplemental uterotonic agents with minimal hemodynamic variations and minimal side effects.

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