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Research Article

Comparison between IV stat bolus oxytocin versus oxytocin infusion in elective cesarean section under spinal anesthesia

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ABSTRACT:

Objective: To compare the frequency of hypotension with intravenous stat bolus oxytocin versus oxytocin infusion in elective cesarean section under spinal anesthesia

Material & Methods: This Randomized control trial was carried out in Department of Anesthesiology / ICU, Sir Ganga Ram Hospital, Lahore from June January 2017 to June 2017.

Results: The mean age in bolus group was 27.96±6.35 years and in oxytocin intravenous group was 29.44±7.24 years. The ASA type I was done among 81 cases and type II was done in 79 cases. The hypotension was observed in 41(25.63%) patients. Statistically significant difference was found between the study groups i.e. p-value=0.046.

Conclusion: Bolus Oxytocin group showed significantly lower occurrence of hypotension as compared to oxytocin infusion in elective cesarean section under spinal anesthesia

MeSH Words: Cesarean Section, Anesthesia, Spinal, Oxytocin

INTRODUCTION:

One of the most frequently performed major operations in women throughout the world is cesarean section. The frequency of these operations have mounted over the past four decades to between 20% and 30% in most developed countries, up to 40% in China, and as high as 70% in some Latin American countries.[(1)] Operative morbidity includes anemia, hemorrhage, risks of transfusion, hysterectomy, and in severe cases, maternal death. Obstetric hemorrhage is the leading cause of maternal mortality worldwide, and mostly it is related to uterine atony.(2) One of the most commonly used drug as uterotonic agent is oxytocin which is administered in wide range of doses and timing patterns.(3)

Although oxytocin is used as a preventive measure, but it can paradoxically contribute to maternal morbidity and mortality peri-operatively.Transient hypotension, reflex tachycardia and an increase in cardiac output in a dose-related manner are few of the known effects of its use as intravenous bolus. Oxytocin administration is significantly associated with maternal, fetal and neonatal adverse events.(4)

Emerging knowledge about the potential harm of oxytocin during childbirth has led to a debate about the appropriate dosing of the drug. Recent studies have proposed the optimal intravenous dose that balances the risk of side effects with the benefit of preventing post caesarean section

hemorrhage as 3–5 IU after delivery of the baby, as a single prophylactic dose for all cases.(5)

However, ongoing research is establishing an evidence for use of even lower doses of oxytocin than those endorsed by current guidelines.(5-7)

A study was performed by Butwick and colleagues (2010)to determine the lowest effective bolus dose of oxytocin to produce adequate uterine tone during elective Caesarean delivery. The prevalence of hypotension was significantly higher with infusion oxytocin as compared to bolus oxytocin after 1 min of delivery (47% vs 28%, $p<0.05$, n=15 in each group), while all (100%) patients showed adequate uterine tone after 10 minutes of delivery in both groups.(5)

The rationale of our study is to compare the frequency of hypotension with intravenous stat bolus oxytocin versus oxytocin infusion during elective cesarean section under spinal anesthesia. Literature has showed that high dose of oxytocin can cause hypotension, however, the uterine tone was adequate in all patients whether oxytocin is given as stat bolus or in infusion. There is no local data available in this regard. So we want to conduct this study to confirm the evidence as well as to get local magnitudes. So that in future we may be able to recommend low dose oxytocin instead of high dose to prevent the patients from hypotension and other hemodynamic complications.

MATERIAL AND METHODS:

It was a Randomized control trial carried out in Department of Anesthesiology / ICU, Sir Ganga Ram Hospital, Lahore from June January 2017 to June 2017.The sample size of 160 cases [80 in each group] was calculated with 80% power of test, 5% level of significance and taking expected percentage of hypotension i.e. 47% with oxytocin infusion and 28% with bolus oxytocin during elective cesarean section under spinal anesthesia.[5]Data was collected by Non-Probability consecutive Sampling

Female patients of age 18-40 years, parity<4, presenting at term (gestational age>37 weeks on dating scan of antenatal record) for planned cesarean delivery under spinal anesthesia ASA class I/II were included in the study whilepatients with Known drug allergy to oxytocin (on history) and Gestational or chronic hypertension (BP≥140/90mmHg) were excluded from the study.

160 patients fulfilling selection criteria were included in the study from Operation theatre of Department of Obstetrics & Gynecology, Lahore General Hospital, Lahore after taking the ethical clearance from hospital committee (letter attached). Informed consent was taken from each patient. Demographic data (name, age, parity, gestational age, BMI, hospital registration number) was also noted. Patients were randomly allocated to two groups by using lottery method. In group A, 3unit of stat bolus oxytocin was given and in group B, 10 unit/hour oxytocin infusion was given. In pre-operative holding area, I/V cannula 18G was passed and ringer lactate was started I/V as 10ml/kg in all groups as preloading dose. Pre-operative B.P was noted. Spinal anesthesia was performed below L3 inter vertebral space with 25G spinal needle in sitting position. MAP was noted at baseline. The oxytocin dose was prepared before surgery and diluted with 0.9% normal saline containing 1 unit/ml by researcher himself. Oxytocin was administered as IV bolus over a time period of 15 second after clamping of umbilical cord. MAP will again be noted after skin closure. Hypotension was labeled if MAP≥10% decreased from baseline. All this information was collected on an especially designed Proforma.

Data was entered and analyzed in SPSS version 21.0. Quantitative variables like age, gestational age and BMI were presented in the form of mean and S.D. Qualitative variables like parity, ASA and hypotension was presented in the form of frequency and percentage. Chi-square test was used to compare the hypotension in both groups.

P-value ≤0.05 was considered as significant. Data was stratified for age, ASA, parity and BMI. Post-stratification, chi-square test was used to compare the hypotension in both groups.

RESULTS:

In this study total 160 cases were included. The mean age of the group A patients was 27.96±6.35 years and its mean value in group B was 29.44±7.24 years. The mean value of gestational age of the group A patients was 39.84±1.43 weeks and its mean value in group B was 40.04±1.46 weeks.Out of 160 patients the patients with no parity were 34 [Group A=20, Group B=14], the patients with parity one were 51 [Group A=26, Group B=25], the patients with parity two were 41 [Group A=18, Group B=23] and the patients with parity three were 34 [Group A=16, Group B=18]. The mean value of BMI of the group A patients was 23.59±3.38 kg/m^2 and its mean value in group B was 24.33±3.15 kg/m^2. Out of 160 patients the ASA type I was done among 81 cases in which 40 were from group A and 41 were from group B, similarly the ASA type II was given to 79 cases in which 40 were from group A and 39 were from group B.

The study results showed that the mean value of MAP at baseline of the group A patients was 86.26±9.56 mmHg and its mean value in group B was 85.80±8.83 mmHg. Statistically insignificant difference was found between the study groups with MAP at baseline of the patients. i. e p-value=0.751 while the mean value of MAP after delivery of the group A patients was 76.35±15.32 mmHg and its mean value in group B was 71.10±16.44 mmHg. Statistically significant difference was found between the study groups with MAP after delivery of the patients. i. e p-value=0.038 In this study the mean value of MAP percentage of the group A patients was 0.11±0.14 mmHg and its mean value in group B was 0.17±0.16 mmHg. Statistically significant difference was found between the study groups with MAP percentage of the patients. i. e p-value=0.018

In our study the hypotension was observed in 41(25.63%) patients and it was not found in 119(74.38%) patients. Among 41 hypotensive cases 15 were form group A and 26 were from group B, similarly the hypotension was not found in 119 cases in which 65 were from group A and 54 were from group B. Statistically significant difference was found between the study groups with hypotension of the patients i.e p-value=0.046. According to the results in ≤ 30 years patients the hypotension was found in 36 cases in which 15 were from group A and 21 were from group B, similarly in > 30 years patients the hypotension was found in 5 cases and all were from group B. Statistically significant difference was found between the study groups with hypotension in ≤ 30 years patients. i. e p-value=0.033.

The study results showed that in patients with primary parity, the hypotension was found in 29 cases in which 13 were from group A and 16 were from group B, similarly multiparity patients the hypotension was found in 12 cases in which 2 were from group A and 10 were from group B. statistically insignificant difference was found between the study groups with hypotension stratified by parity. i. e p-value=0.216 & 0.054 respectively.

In patients with ASA type I, the hypotension was found in 20 cases in which 6 were from group A and 14 were from group B, similarly in patients with ASA type II, the hypotension was found in 21 cases in which 9 were from group A and 12 were from group B. statistically significant difference was found between the study groups with hypotension in type I ASA patients. i. e p-value=0.046.In patients with normal BMI, the hypotension was found in 23 cases in which 12 were from group A and 11 were from group B, similarly in patients with overweight & obese BMI, the hypotension was found in 18 cases in which 3 were from group A and 15 were

fromgroup B. statistically significant difference was found between the study groups with hypotension in overweight & obese BMI patients. i. e p-value=0.011.

DISCUSSION:

This present randomized control trial was conducted at department of Anesthesiology / ICU, Lahore General Hospital, Lahore to compare the frequency of hypotension with intravenous stat bolus oxytocin versus oxytocin infusion in elective cesarean section under spinal anesthesia

Uterine atony increases the risk of obstetric hemorrhage in pregnant women undergoing cesarean sections. Oxytocin is the mainstay of treatment of uterine atony. Prophylactic routine use of oxytocin has been shown to reduce the incidence of postpartum hemorrhage by up to 40%. Larger dose of oxytocin injected rapidly is known to produce various adverse effects such as hypotension, nausea, vomiting, chest pain, headache, flushing, myocardial ischemia, ST-T segment changes, pulmonary edema, severe water intoxication, and convulsion.[8, 9]

In our study the hypotension was observed in 41(25.63%) patients in which 15 were form group A and 26 were from group B. Statistically significant difference was found between the study groups with hypotension of the patients. i. e p-value=0.046. Some of the studies are discussed below showing their results as

A recent UK survey reported that a slow intravenous bolus of 5 units oxytocin is commonly used by obstetricians and anaesthetists (86% and 92%, respectively) during cesarean section. However, safety and efficacy data are lacking to support the routine use of a 5 units bolus of oxytocin as a standard of care during elective cesarean section.[10]

One study by A. J. Butwick et al(5) presented that the prevalence of hypotension was significantly higher after 5 units oxytocin vs 0 unit at 1 min (47% vs 7%; P=0.04). UT scores were significantly lower in patients receiving 0 unit oxytocin at 2 and 3 min compared with 3 and 5 units oxytocin (P<0.05, respectively).

Previous studies have shown that bolus doses of oxytocin ≥5 units are associated with hypotension. There were no significant differences in the prevalence of hypotension or tachycardia among the study groups receiving 0.5–3 units.[11-13]

A significant fall of MAP 30 seconds after administration of a 10 IU bolus oxytocin, but a significant increase in HR and cardiac output, occurred 1 minute after 5 IU administration has been reported earlier.[11]

One trial compared the use of oxytocin bolus and placebo infusion with oxytocin bolus and 30 IU oxytocin infusion. Data showed reductions in both the use of additional uterotonic agents and major obstetric haemorrhage.[14]

Sarna and colleagues[15] studied the effect of different oxytocin infusions (total dose range=5–20 units) during elective cesarean section, and observed no differences in the incidence of adequate UT between the high- and low-dose oxytocin regimens.

Another small trial investigated the effects of a placebo bolus and oxytocin infusion compared with an oxytocin bolus and oxytocin infusion, and found no difference in the need for an additional uterotonic agent in the first 24 hours after caesarean section.[16]

On the other hand a study by Susmita Bhattacharya et al[17] concluded that in elective cesarean delivery, administration of oxytocin IV infusion is better, than the same dose administered as a bolus IV dose, to produce adequate uterine contraction and is associated with less adverse hemodynamic changes.

The limitations of our study include single centered study and relatively smaller sample size. Larger multi centered randomized control trials are needed to determine the regime for oxytocin use during cesarean sections so that the adverse effects of the drug can be minimized.

CONCLUSION:

According to our study results Bolus Oxytocin group showed significantly lower prevalence of hypotension compared to oxytocin infusion in elective cesarean section under spinal anesthesia

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TABLE1: DESCRIPTIVE STATISTICS OF BOLUS AND INFUSION GROUPS

VARIABLES	OXYTOCIN BOLUS N:80	OXYTOCIN INFUSION N:80	p-VALUE
Age	**27.96±6.35**	**29.44±7.24**	**0.59**
Gestational age	**39.84±1.43**	**40.04±1.46**	**0.67**
Parity	**1.38±1.07**	**1.56±1.03**	**0.61**
BMI	**23.60±3.38**	**24.34±3.15**	**0.76**
MAP at baseline	**86.26±9.56**	**85.80±8.84**	**0.77**
MAP after delivery	**76.35±15.33**	**71.10±16.44**	**1.00**
Hypotension Yes No	**15(18.75%) 65(81.25%)**	**26(32.5%) 54(67.5%**	**0.46**

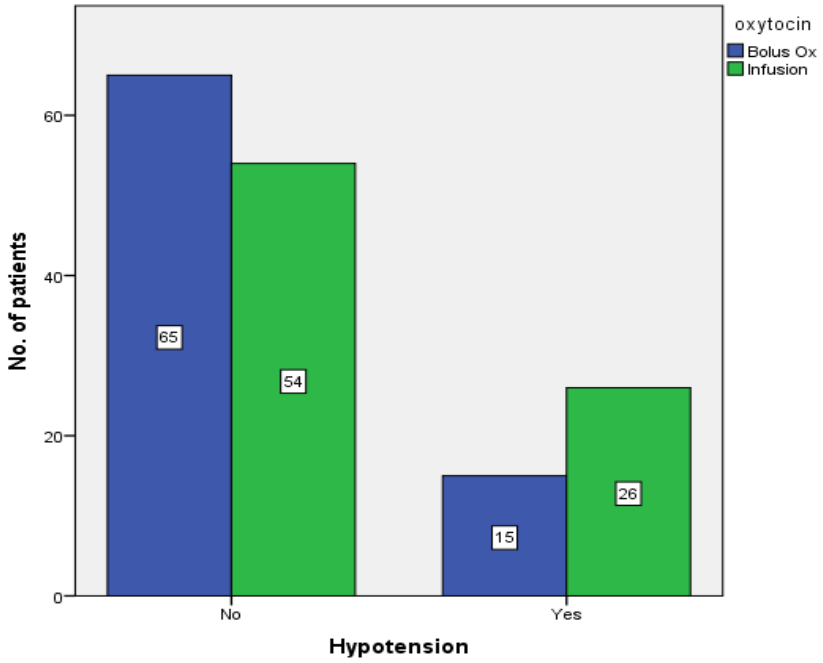

FIGURE1: FREQUENCY OF HYPOTENSION IN BOLUS AND INFUSION OXYTOCIN GROUP