

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20221279>

Original Research Article

A comparative study of high dose vs low dose oxytocin in the augmentation of labour

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Received: 27 February 2022

Revised: 05 April 2022

Accepted: 06 April 2022

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ABSTRACT

Background: Augmentation of labour is a practice that aims to increase the duration, frequency, and intensity of uterine contractions in order to decrease the duration of labour and reduce adverse events of maternal and fetal outcomes associated with prolonged labour. Although oxytocin is the most commonly used drug for the augmentation of labour, there is no universally accepted dosage regimen as various studies have used different regimens of oxytocin as low dose and high dose, leading to clinical heterogeneity. Hence this study was taken up to study the advantages, disadvantages and complications of a widely accepted regime for this study.

Methods: 100 patients in active labour, with inadequate uterine contractions were selected. The patients were randomly selected, allotting alternate cases for high dose and low dose oxytocin. The patients were monitored through the course of labour and compared in terms of augmentation-delivery interval, mode of delivery, maternal and fetal outcome. The findings were tabulated and statistically analyzed.

Results: Majority of the patients delivered vaginally in both groups (78% of high dose and 90% of low dose group). The mean augmentation-delivery interval was 7.20 and 7.45 hours for high dose and low dose group respectively. 12% patients in high dose group experienced maternal complications, while none were encountered in low dose group. 12% neonates from high dose group and 14% from low dose group required admission to the NICU.

Conclusions: It was concluded with moderate certainty that high dose regimen of oxytocin resulted in reduction in the duration of labour, but cesarean rate, maternal and fetal complications were more. It was concluded that neither regimen has got an absolute advantage or disadvantage over the other.

Keywords: Oxytocin, Labour, Augmentation-delivery interval, Maternal outcome, Fetal outcome

INTRODUCTION

Labour is a physiological process that leads to the expulsion of the products of conception from the uterus. Labor is induced by changes in the biochemical connective tissue as well as gradual effacement and dilatation of the uterine cervix as a result of rhythmic uterine contractions of sufficient frequency, intensity, and duration.¹ Augmentation of labour refers to enhancement of spontaneous uterine contractions that are considered inadequate because of failed cervical dilatation or fetal

descent. It is a practice that aims to increase the duration, frequency and intensity of uterine contractions, with the goal to improve the efficiency of uterine contractions in order to reduce the adverse maternal and fetal outcomes associated with prolonged duration of labour. The reasons for beginning labour augmentation may differ across settings and countries, and they may not always be supported by the best available research evidence. There is no generally accepted protocol available for augmentation of labour. The decision to augment labour is generally guided by institutional protocols and guidelines, which differ from institution to institution.

Often, in a busy labour ward, timely augmentation achieves the purpose, shortens the duration of labour pain. Thereby, reducing the load of labour monitoring of too many patients. This also helps to reduce prolonged stress to mother and fetus and ultimately reduces the rate of cesarean section. The various methods of augmentation of labour are amniotomy, and the use of pharmacological agents such as oxytocin and prostaglandins. One of the most commonly used medications in obstetrics is oxytocin for labour augmentation and induction. Worldwide, oxytocin augmentation is likely to be used by more than half of all women in labour.² During pregnancy and labour, oxytocin receptors in the uterus increase, making the uterus more sensitive to small doses of oxytocin. Starting with a low dose, the drug is titrated in an arithmetic or geometric manner. Intravenous oxytocin should ideally be administered via infusion pump. This could pose a problem in many health-care facilities, particularly in low- and middle-income countries (LMICs). Overdosage can cause uterine hyperstimulation, whereas a suboptimal dose can result in a false diagnosis of failure to progress leading to caesarean section. The risks of uncontrolled uterine hyperstimulation include foetal hypoxia and uterine rupture. In terms of oxytocin administration, published protocols vary greatly. This reflects obstetricians' lack of agreement on a standardised oxytocin regimen.³⁻⁸

Oxytocin protocols vary in: the initial dose, the time interval for increasing the dose, the increment of dose, the maximum dose. High dose vs. low dose oxytocin for augmentation of labour: some obstetricians use high dose oxytocin augmentation/ induction, but some others use low dose oxytocin. It has been seen that although high doses of oxytocin resulted in more vaginal birth and less chorioamnionitis, reduction in the length of labour and caesarean section rate, but increases the incidence of hyperstimulation and associated complications as compared with low dose of oxytocin. Various studies have used different regimens of oxytocin as high dose and low dose, leading to clinical heterogeneity. More so, studies comparing high dose and low dose regime are not too many. Hence this study has been taken up to study the role of high dose vs. low dose of oxytocin and also the advantages, disadvantages and complications of either regimen.

METHODS

This comparative study was done at a tertiary care teaching hospital- Dr. D. Y. Patil medical college and hospital, Pune, over a period of two years (September 2019 to September 2021). The sample size was 100 patients. The sample size was calculated using Winpepi software. 100 patients in labour with inadequate uterine contractions were selected and alternately allocated by simple randomisation into high dose and low dose group. 50 cases were studied in high dose oxytocin (Group A) and 50 cases in low dose oxytocin (Group B). The

inclusion criteria for the study were patients with singleton pregnancy in active phase of labour with a cervical dilatation of 4-5cm and effacement of 30% or more, patients with poor progress of labour and patients with inadequate uterine contractions. The study included both primigravidae and multiparae. Patients with non-reassuring fetal heart rate pattern, severe fetal growth restriction, severe preeclampsia or eclampsia, uncontrolled diabetes mellitus, cephalopelvic disproportion and who have undergone a previous cesarean section have been excluded from the study. Patients allotted to group A, were given high dose of oxytocin with an initial dose of 4mU/min, escalated by 4mU/min at an interval of 30 minutes till adequate uterine contractions achieved or a maximum dose of 36 mU/min was reached. The infusion rate is set using a dial-flow meter. While patients allotted to Group B were started with low dose oxytocin, which is taken as an initial dose of 2 mU/min, escalated by 2 mU/min at an interval of 30 minutes till adequate uterine contractions achieved or a maximum dose of 36 mU/min was reached.

The infusion rate is set using dial-flow meter. 5U of oxytocin that is stored at the appropriate temperature is added to 500ml of ringer lactate, which equals to 10mU in 1 ml. Titration was done setting the desired infusion rate in a dial-flow meter until adequate uterine contractions achieved. Adequate uterine contraction is defined as 3-4 contractions lasting for 45 seconds in 10 minutes. Labour was managed as per the institutional norms. The progress of labour was monitored using a partogram. Indicated cases were put on CTG monitoring. In cases of tachysystole or signs of fetal distress, oxytocin drip was discontinued, left lateral position given, O₂ inhalation given, and a plain DNS/D5 fluid started. If settled, oxytocin was restarted with careful monitoring and if not settled, patient taken up for LSCS. Augmentation-delivery interval, mode of delivery, any occurrence of PPH and neonatal outcome were recorded. Data was entered in excel sheet, tabulated and analysed. Quantitative data summarised by using mean and SD. Qualitative data summarised by using proportions. Appropriate tests of statistical significance such as Chi-square test were used.

RESULTS

The mean age of patients in high dose group was 25.04 years and in low dose group it was 24.22, with no difference in mean age between the groups ($p=0.277$). Most of the patients belonged to middle socioeconomic class in both high dose (42%) and low dose (38%) groups. Least number of patients belonged to the upper socioeconomic class in high (6%) and low (2%) dose groups. The number of primigravidae (46%) and multiparae (54%) were equally distributed in either group. Majority of participants in high dose group (56%) and low dose (50%) had Hb between 9.1 to 11gm%. 30% in high dose group and 34% in low dose group had <9 gm%. 14% high dose group patients and 16% low dose group patients

had haemoglobin above 11gm%. This indicates that majority of our patients had mild to moderate anemia. The difference between the groups was not statistically significant. As depicted in (Table 1), 48% participants in high dose group and 52% participants in low dose group were between 39 to 40.6 weeks of gestation.

Table 1: Distribution of participants based on period of gestation (n=50).

| Variable | Dose of oxytocin | | P value |
|-----------------------------|------------------|--------------|---------|
| | High dose | Low dose | |
| Period of gestation (weeks) | | | |
| 36 to 36.6 | 4 8.0% | 4 8.0% | 0.916 |
| 37 to 38.6 | 22 44.0% | 20 40.0% | |
| 39 to 40.6 | 24 48.0% | 26 52.0% | |
| Total | 50 100.0% | 50 100.0% | |

Table 2: Distribution of participants based on mode of delivery (n=50).

| Variable | Dose of oxytocin | | P value |
|------------------|------------------|--------------|---------|
| | High dose | Low dose | |
| Mode of delivery | | | |
| FTND | 39 78.0% | 45 90.0% | 0.086 |
| LSCS | 11 22.0% | 5 10.0% | |
| Total | 50 100.0% | 50 100.0% | |

Table 3: Distribution of participants based on augmentation delivery interval (n=50).

| Augmentation de interval (hours) | Dose of oxytocin | | Augmentation delivery interval (hours) |
|----------------------------------|------------------|--------------|--|
| | High dose | Low dose | |
| Mode of delivery | | | |
| ≤6 | 22 44% | 18 36.0% | 0.664 |
| 7-9 | 23 46% | 25 50.0% | |
| 10-12 | 5 10% | 7 14.0% | |
| Total | 50 100% | 50 100.0% | |

Whereas, 44% in high dose group and 40% in low dose group were between 37 to 38.6 weeks of gestation. 8% high dose group patients and 8% low dose group patients were between 36 to 36.6 weeks. The difference between the groups was not statistically significant. Distribution of participants based on mode of delivery is shown in (Table 2).

Table 4: Distribution of study participants based on maternal outcome (n=50).

| Variable | Dose of oxytocin | | P value |
|-----------------------------|------------------|------------|---------|
| | High dose | Low dose | |
| Maternal outcome | | | |
| No maternal complications | 44 88% | 50 100% | 0.027 |
| With maternal complications | 6 12% | 0 0% | |
| Total | 50 100% | 50 100% | |

Table 5: Distribution of study participants based on fetal outcome (n=50).

| Variable | Dose of oxytocin | | P value |
|---------------------------|------------------|------------|---------|
| | High dose | Low dose | |
| Fetal outcome | | | |
| No neonatal complications | 44 88% | 43 86% | 1.000 |
| NICU Admissions | 6 12% | 7 14% | |
| Total | 50 100% | 50 100% | |

Majority of the patients had full term vaginal delivery. That is, 78% high dose group patients and 90% high dose group patients had full term vaginal delivery. Whereas, 22 % high dose group patients and 10% low dose group patients delivered by caesarean section. The difference between the groups was not statistically significant (p value being 0.086).

Total 44% in high dose group and 36% in low dose group had an interval of less than 6 hours. Whereas, 46% in high dose group and 50% in low dose group had an interval between 7-9 hours. 10% in high dose group and 14% in low dose group had an augmentation delivery interval between 10-12 hours. As shown in (Table 4), among those who received high dose oxytocin, 88% had no maternal complications, while 100% patients in low dose group had no maternal complications. 12% patients in high dose group (3 post-partum hemorrhage, 3 uterine tachysystole) had complications. The difference between the groups is statistically significant (p=0.027). When neonatal complications were considered, though 1 minute and 5 minutes APGAR scores in both the groups had no statistical significance, 88% in high dose group and 86% in low dose group had no neonatal complications. This distribution is described in (Table 5).

DISCUSSION

In our study, demographic parameters were similar in both the groups without any statistically significant difference. There were 46% primigravidae and 54%

multigravidae in either group. The mean gestational age of participants in our study were 38.4 weeks and 38.7 weeks for high dose group and low dose group respectively. Assessment of anemia in this study found severe anemia of 9 gm% in 30% and 34% in the high dose and low dose group, moderate anemia (9-11gm%) in 56% and 50% and normal haemoglobin (11gm% and above) in 14% and 16% amongst high dose and low dose group respectively. It was noted that majority of the patients in both the groups were moderately anemic. Difference of anemic status between these two groups was not statistically significant (p value=0.835). High overall incidence of anemia in our study population can be attributed to poor nutrition and hygiene in our patients because of their poor socioeconomic background. We achieved vaginal delivery in 78% and 90% in high dose and low dose groups respectively. Cesarean section was required in 22% in high dose and 10% in low dose group. The difference between the two groups is of no statistical significance (p value=0.08). Overall, we achieved more vaginal delivery than cesarean delivery in both the groups in this study. In the high dose group, 11 cases required LSCS of which 45% were due to non-reassuring FHR. In the low dose group, only one (20%) out of 5 cases of cesarean delivery were due to non-reassuring FHR. This finding clearly indicates that fetal heart abnormalities are encountered more often in the high dose regime. However, indication of cesarean for non-progress of labour was 45% in high dose group and 80% in low dose group. One case in the high dose group was taken up for cesarean section for second stage arrest. However, Wei SQ et al found slightly more vaginal delivery in high dose oxytocin group. On the contrary, Ghidini et al reported similar rates of cesarean section for both high dose and low dose groups.^{9,10} The reason for a greater number of vaginal deliveries in our study, compared to cesarean section could be due to more number of multigravidae. We also excluded previous cesarean and patients with medical complications from our study which contributed to more number of vaginal deliveries. When augmentation delivery interval is considered, we achieved delivery within 6 hours in 44% vs 36%, between 7-9 hours in 46% vs 50% and between 10-12 hours in 10% vs 14% in high dose and low dose groups respectively. Mean augmentation delivery interval was 7.20 hours in high dose and 7.45 hours in low dose group. Overall, duration of labour was less in high dose group. However, without any statistically significant difference. Mean difference of decrease in labour duration in high dose group was 25 minutes, which is consistent with the study by Selin et al. Wei SQ et al stated decrease in labour duration in high dose group with mean difference of 1.54 hours, Merrill et al 2 hours, Gupta et al 2.09 hours, and Neerukonda et al 2 hours.¹²⁻¹⁴ All the studies had the common conclusion that high dose regimen of oxytocin is superior to low dose oxytocin in terms of reduction of labour duration. Ghidini et al, in a double-blinded randomised clinical trial on the subject also found significant shortening in the duration of labour in high dose regimen. Overall, it is observed that labour duration

is shortened by high dose oxytocin augmentation, in many studies as well as in the current study. However, a Cochrane Meta-analysis by Budden et al, of multiple randomised controlled trials and quasi-randomised controlled trials that compared various oxytocin regimens revealed no difference between induction to delivery interval between high dose and low dose oxytocin groups. In the present study, it was noted that while 88% of participants in the high dose group had no maternal complications, 12% i.e., 6 patients had complications, of which 3 had postpartum haemorrhage and 3 had uterine tachysystole. No patients in the low dose group had any maternal complications. Overall, augmentation of labour with high dose oxytocin do have some maternal complications, like tachysystole and postpartum hemorrhage in our study with a statistically significant value. Other complications such as uterine atony, placental abruption, chorioamnionitis and uterine rupture were not encountered in our study. The study by Selin et al found increased incidence of tachysystole in high dose group, (44% vs 33.5%). Gupta P et al, also found incidence of tachysystole was more in high dose regimen, similar to our study. However, the percentages were not statistically significant.

In the current study, in the high dose group, 88% neonates had no complications that required admission in the NICU, 12% i.e., 6 neonates were admitted to the NICU among which 3 were admitted for hyperbilirubinemia, 2 for birth asphyxia and 1 neonate was admitted for respiratory distress. In the low dose group, 86% of neonates had no complications, 14% i.e., 7 neonates were admitted to the NICU, which included 3 admissions for hyperbilirubinemia, and 4 for respiratory distress. Overall, the neonatal complications were more in low dose group in this study though the difference is not statistically significant. Ghidini et al stated that from the context of the available evidence from published randomised trials, all the trials found no significant difference in the rate of adverse neonatal outcome between low dose and high dose regimens. Tesemma et al who have conducted a study comparing perinatal outcomes in labouring mothers that received high dose versus low dose oxytocin regimen, and concluded that overall, adverse perinatal outcomes were higher in high dose group as compared to low dose group (29% vs 13.9%).¹⁶

The common adverse perinatal outcomes encountered were non-reassuring fetal heart rate patterns, need for advanced neonatal resuscitation, thick meconium-stained liquor and need for referral to NICU. Although, this finding was inconsistent with other studies that showed no significant difference on perinatal outcomes with regard to oxytocin regimen and one study by Satin et al that showed decreased risk of neonatal sepsis with high dose oxytocin.¹⁷ Overall, our study as well as most of the study found no significant difference in neonatal outcome between the two groups.

CONCLUSION

Based on the results of our study and various other studies including a cochrane review, it can be concluded that high dose oxytocin results in slight reduction in labour duration and cesarean rate, as well as similar neonatal outcome compared with low dose oxytocin. Though, maternal complications were more in high dose group. Hence, it can be concluded that high dose oxytocin has no significant advantage over low dose oxytocin in augmentation of labour.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Rudra S, Rama A, Subramanian S. A comparative study of high dose vs. low dose oxytocin in the augmentation of labour. *Int J Reprod Contracept Obstet Gynecol* 2022;11:1466-70.