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Original Research Article

A comparative study between high-dose versus low-dose oxytocin for labour augmentation and its maternal and fetal outcomes

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Abstract
Background: One of the most widely utilised substances toaugmentlabour is oxytocin. However, there is no universal agreement on the best dosage schedule. High-dose and low-dose oxytocin protocols differ in initiation dose and escalation rates, and their relative efficacy and safety remain debated. With rising caesarean section rates, evaluating the impact of oxytocin dosage on labour outcomes is clinically important, particularly in the Indian population.
Methods: This prospective comparative observational study was conducted in the Department of Obstetrics and Gynaecology, Durgapur Steel Plant Hospital, West Bengal, over a period of two years (2020-2022). A total of 100 term pregnant women requiring labour augmentation were enrolled and divided into two groups of 50 each. Group HD received a high-dose oxytocin regimen (starting dose 5 mU/min with 5 mU/min increments every 30 minutes), while Group LD received a low-dose regimen (starting dose 2.5 mU/min with 2.5 mU/min increments every 30 minutes). Maternal outcomes included mode of delivery, induction success, induction-to-delivery interval, and complications. Neonatal outcomes assessed were birth weight, Apgar scores, and NICU admission. Statistical analysis was performed using SPSS version 21.0.
Results: The groups were similar in terms of baseline parameters such as first Bishop score, gestational age, and maternal age. The high-dose group had a significantly higher mean Bishop score at 6 hours (8.91 vs 6.14; $p<0.01$). 72% of the high-dose group and 54% of the low-dose group experienced successful induction ($p<0.01$). Caesarean section rates were significantly lower in the high-dose group (28% vs 46%; $p<0.01$). The mean induction-to-delivery interval was significantly shorter with high-dose oxytocin (4.05 vs 9.21 hours; $p<0.01$). Maternal and neonatal complications, including postpartum haemorrhage, tachysystole, Apgar scores, and NICU admissions, were comparable between the groups.
Conclusion: With no increase in maternal or neonatal morbidity, high-dose oxytocin for labour augmentation is linked to better cervical ripening, a shorter induction-to-delivery interval, and a higher rate of successful vaginal deliver.

Keywords: Labour augmentation, oxytocin, high-dose oxytocin, low-dose oxytocin, caesarean section, induction of labour

Introduction
A common obstetric procedure when continuing pregnancy will endanger the mother, the foetus, or both is to induce labour at term with the goal of a vaginal delivery. The term "induction of labour" describes an intervention that uses medical and/or surgical techniques to artificially initiate uterine contractions, leading to gradual cervical dilation and effacement and the eventual expulsion of the foetus prior to the natural initiation of labour [1]. According to estimates, in between 5 and 25% of pregnancies, delivery is a safer alternative for the health of the mother and foetus than continuing the gestation [2].
Induction primarily aims to establish regular uterine contractions accompanied by cervical changes sufficient to initiate the active phase of labour [3]. For induction to be considered successful, it must fulfil three essential objectives: first, it should establish effective uterine contractions with progressive cervical dilatation; second, it should culminate in vaginal delivery, as induction that merely serves as a prelude to caesarean section offers limited benefit; and third, in viable pregnancies, these outcomes should be achieved with minimal discomfort and risk to both the mother and the fetus [4].

Oxytocin remains one of the most commonly used pharmacological agents for labour induction and augmentation in obstetric practice. This synthetic polypeptide hormone has been in clinical use since the 1950s, following its first synthesis in 1953 by Vincent du Vigneaud [5, 6]. Oxytocin regimens are broadly classified into high-dose and low-dose protocols based on parameters such as the initial dose, rate of dose escalation, and interval between increments [7, 8]. High-dose regimens reported in various trials typically start at 4-10 mU/min, with incremental increases of 4-7 mU/min and maximum doses ranging from 4 to 40 mU/min. In contrast, low-dose regimens usually begin at 1-4 mU/min, with incremental increases of 1-2 mU/min and maximum doses between 1 and 32 mU/min [7]. The escalation intervals across studies range from 15 to 60 minutes [4, 7-15].

Despite its widespread use, there is no global consensus on a standardized oxytocin regimen, and robust evidence supporting a single optimal dosing protocol remains lacking [8, 15].

Aims and Objectives

The aim of this study is to determine whether the administration of a high-dose oxytocin regimen reduces the likelihood of a caesarean section when compared with a low-dose oxytocin regimen. The objectives are to compare high-dose and low-dose oxytocin with respect to mode of delivery, maternal outcomes, and fetal outcomes.

Materials and Methods

Study Design

This was a comparative prospective observational study conducted in the Department of Obstetrics and Gynecology, Durgapur Steel Plant Hospital, Durgapur, West Bengal. The study included pregnant women fulfilling the predefined inclusion criteria and was carried out over a period of two years, from 2020 to 2022.

Inclusion and Exclusion Criteria

The study included primi- and multigravida women (less than gravida six) with singleton, term pregnancies in cephalic presentation, having a normal fetal heart rate, without associated medical complications, and requiring augmentation of labour, including cases with premature rupture of membranes (PROM). Women were excluded from the study if they had multiple pregnancies, cephalopelvic disproportion, malpresentation, a history of previous caesarean section, placenta previa, meconium-stained liquor, or hydramnios.

Sample Size Calculation

Sample size was calculated using following formulae:

$n= (Z\alpha/2 + Z\beta) \times PQ * 2 /d^2$

Where; n- Sample size
Zα/2 - Z value at 5% error (1.96)
Zβ - Z value at 20% (0.84)
P- (p1+p2)/ 2 Q - 1-P
P1 - Prevalence of LSCS in LD group (38.9%)
P2 - Prevalence of LSCS in HD group (27.8%)
d - Effect size (taken as 0.15)

$$n - \frac{(1.96+0.84) * 0.3 * 0.7 * 2}{(0.15)^2}$$

n- 50 (approx.) for each group

The study subjects were chosen using a consecutive non-probability sampling technique. After giving their informed consent, 100 pregnant women who met the eligibility requirements and visited our hospital's ANC-OPD were enrolled in the study. After that, the cases were split up into two groups of fifty each.

- **Group HD:** Augmentation of labor was done via high dose Oxytocin regimen
- **Group LD:** Augmentation of labor was done via low dose Oxytocin regimen

Data Collection Tools

Data were collected using a predesigned and structured proforma that included a detailed patient history, clinical examination findings, and relevant obstetric parameters. The proforma captured demographic details, obstetric history, gestational age, fetal heart rate patterns, cervical status, uterine contraction characteristics, intervention details, and labour outcomes. Monitoring tools included a stethoscope or hand-held Doppler for fetal heart rate assessment, clinical palpation of the abdomen for uterine contractions, and standard clinical instruments for measuring vital signs such as blood pressure, pulse, and temperature.

Data Collection Procedure

On admission to the labour room, each participant underwent a comprehensive initial assessment including history taking, general and systemic examination, and abdominal and vaginal examinations. Fetal heart rate was monitored every 15 minutes during the first stage of labour and every 5 minutes during the second stage. Vaginal examinations were performed at two-hour intervals after initiation of augmentation to assess cervical dilatation, effacement, station, liquor characteristics, and pelvic adequacy. Amniotomy was performed upon entry into the active phase of labour (cervical dilatation ≥4 cm) if membranes were intact. Oxytocin augmentation was initiated when uterine contractions were inadequate (<4 contractions in 10 minutes) when no cervical progress was observed one hour after amniotomy, and in cases of PROM with cervical dilatation of at least 4 cm. Participants were allocated to either high-dose or low-dose oxytocin regimens, prepared in Ringer lactate and administered via gravity-controlled infusion with incremental titration every 30 minutes until adequate uterine contractions were achieved, while carefully monitoring for tachysystole.

Statistical Analysis

A pre-designed study proforma was used to enter and record all of the data that were gathered, and the data were then assembled for analysis. Frequencies and percentages were used to express qualitative data, and the Chi-square test was used to assess associations between categorical variables. The mean±standard deviation (SD) was used to summarise quantitative variables. The unpaired t-test was used to compare quantitative data between the two research groups for variables that were normally distributed, and the Mann-Whitney U test was used for variables that did not meet the normality assumptions. Statistical significance was defined as a p-value of less than 0.05. To aid in interpretation, results were displayed graphically when appropriate. Microsoft Excel 2010 was used for graphical representation, and SPSS software version 21.0 was used for statistical analyses.

Results

Table 1: Distribution and Baseline Characteristics of Study Groups

Parameter	High Dose (n=50)	Low Dose (n=50)	p-value
Mean Age (years)	23.94±2.05	24.30±1.85	0.193 (NS)
Mean Gestational Age (weeks)	39.37±1.22	39.16±1.26	0.246 (NS)

Table 1 shows that both groups were comparable in terms of maternal age and gestational age, with no statistically significant difference, ensuring baseline homogeneity between the study groups.

Table 2: Comparison of Bishop Score at Baseline and After 6 Hours

Time	High Dose	Low Dose	p-value
Baseline Bishop Score	5.39±0.57	4.91±0.49	0.174 (NS)
Bishop Score at 6 hours	8.91±1.55	6.14±2.07	<0.01 (S)

Table 2 illustrates that while baseline Bishop scores were comparable, cervical ripening at 6 hours was significantly better in the high-dose oxytocin group.

Table 3: Mode of Delivery among Study Groups

Mode of Delivery	High Dose	Low Dose	Total
Normal Vaginal Delivery	33 (66%)	20 (40%)	53
Assisted Vaginal Delivery	3 (6%)	7 (14%)	10
Caesarean Section	14 (28%)	23 (46%)	37
p-value			<0.01 (S)

Table 3 indicates that the high-dose oxytocin group had a much lower rate of caesarean sections and a significantly greater rate of regular vaginal deliveries.

Table 4: Outcome of Labour Induction

Induction Outcome	High Dose	Low Dose	p-value
Successful	36 (72%)	27 (54%)	<0.01 (S)
Failed	14 (28%)	23 (46%)	

Table 4 demonstrates that successful induction was significantly more frequent with high-dose oxytocin compared to the low-dose regimen.

Table 5: Induction-to-Delivery Interval

Parameter	High Dose	Low Dose	p-value
Mean ITD Interval (hours)	4.05±2.75	9.21±5.34	<0.01 (S)
ITD ≤ 6 hours	32 (89%)	6 (22%)	<0.01 (S)

Table 5 illustrates that high-dose oxytocin significantly reduced the induction-to-delivery interval, with the majority delivering within 6 hours.

Table 6: Maternal Complications

Complication	High Dose	Low Dose	p-value
Any Maternal Complication	6 (12%)	7 (14%)	1.0 (NS)
Uterine Hyperstimulation	1	0	NS
Tachysystole	1	0	NS
Postpartum Hemorrhage	1	3	NS

Table 6 shows that maternal complications were infrequent and comparable between both groups, with no statistically significant difference.

Table 7: Neonatal Outcomes

Outcome	High Dose	Low Dose	p-value
Mean Birth Weight (kg)	3.07±0.93	2.71±0.81	0.21 (NS)
Mean APGAR (1 min)	8.28±0.75	8.01±0.79	0.13 (NS)
NICU Admission	2 (4%)	4 (8%)	0.67 (NS)

Neonatal outcomes, such as birth weight, APGAR scores, and NICU admission rates, were similar for high-dose and low-dose oxytocin regimens, as shown in Table 7.

Discussion

Oxytocin remains one of the most frequently used pharmacological agents for labour induction and augmentation in obstetric practice. Based on the starting dose, rate of dose escalation, and increment intervals, oxytocin regimens are broadly classified as high-dose and low-dose protocols [7, 8]. Despite its widespread use, there is no global consensus regarding the optimal oxytocin dosing regimen, and existing evidence has not conclusively recommended one protocol over the other [8, 15]. The goal of the current study was to assess the safety and effectiveness of high-dose and low-dose oxytocin regimens in an Indian population, in view of the rising rates of caesarean sections and the widespread use of oxytocin.

In the present study, both groups were comparable in baseline characteristics, including maternal age and gestational age, ensuring homogeneity between the groups. Cervical favourability at baseline, as assessed by the Bishop score, did not differ significantly between the two groups. However, after six hours of oxytocin augmentation, the Bishop score was significantly higher in the high-dose group, indicating more effective cervical ripening. Furthermore, women who received high-dose oxytocin had a much shorter induction-to-delivery period; most of them delivered within six hours. These findings suggest that high-dose oxytocin accelerates labour progression more efficiently than low-dose regimens.

Similar reductions in labour duration with high-dose oxytocin have been reported in multiple studies. Mori R *et al*. observed a significant reduction in labour length with higher oxytocin doses,[16] with findings echoed by Kenyon S *et al*. [17] and Budden A *et al*. [18] Selin L *et al*. also demonstrated shorter labours with high-dose oxytocin, though with increased tachysystole [19]. Tesemma MG *et al*. [20] Aboshama R *et al*. [21] and Son M *et al*. [22] further supported the association between higher oxytocin doses and reduced labour duration, consistent with the present study.

Regarding mode of delivery, the present study demonstrated a significantly higher rate of successful induction and normal vaginal delivery in the high-dose group, along with a lower caesarean section rate compared to the low-dose group. These findings are consistent with the observations of Xenakis EM *et al*. [23] who reported a significantly reduced caesarean section rate with high-dose oxytocin. Mori R *et al*. [16] also noted reduced caesarean rates and increased spontaneous vaginal deliveries with higher oxytocin doses. Tesemma MG *et al*. [20] similarly reported improved induction success and lower caesarean rates with high-dose regimens. However, some large trials and meta-analyses, including those by Selin L *et al*. [19] Aboshama R *et al*. [21] and Son M *et al*. [22] did not demonstrate a significant reduction in caesarean rates, highlighting ongoing variability in outcomes across different populations and study designs.

In the current study, maternal problems such as tachysystole and uterine hyperstimulation were uncommon and did not significantly differ between the two groups. Birth weight, Apgar

scores, and NICU admission rates were among the neonatal outcomes that were similar. These findings align with previous studies and meta-analyses, which reported no significant differences in maternal or neonatal morbidity between high- and low-dose oxytocin regimens [16, 18, 19, 21, 23]. High-dose oxytocin is associated with better cervical ripening, a shorter induction-to-delivery time, and a higher rate of successful vaginal delivery without an increase in mothers or neonatal complications, according to the current study. These results encourage the prudent use of high-dose oxytocin regimens for labour augmentation in appropriately selected patients.

Limitations

Despite careful planning and execution, the present study has certain limitations. Comparison of the study findings with other published literature is challenging due to variations in diagnostic criteria for dystocia, differences in oxytocin dosing intervals, and incremental regimens used across studies. Cardiotocography was not employed for continuous monitoring of uterine activity; therefore, episodes of subclinical tachysystole may have been missed. Additionally, the absence of a standardized labour care guide for monitoring may have influenced labour management. Observer bias may have been introduced because the doctors in charge of choosing the oxytocin regimen and overseeing intrapartum care were not blinded. Additionally, despite the fact that certain outcomes showed changes, others did not achieve statistical significance, possibity due to the limited sample size.

Conclusion

The present study demonstrates that high-dose oxytocin is a more effective regimen for induction of labour compared to low-dose oxytocin, as it is associated with a significantly shorter induction-to-delivery interval and better cervical ripening within six hours. The caesarean section rate was comparatively higher in the low-dose group, despite the fact that the overall mode of delivery did not differ significantly between the groups. Maternal and neonatal outcomes were comparable in both regimens, indicating that high-dose oxytocin does not increase adverse outcomes. Therefore, high-dose oxytocin may be recommended for labour induction in appropriately selected cases.

Author Contribution

Dr. Arindam Mitra (1st author) was responsible for conceptualization, investigation, case management, and overall supervision of the study. Dr. Priyanka Nath (2nd author) contributed to manuscript writing through critical review and editing. Dr. Mude Tapani (3rd author) was involved in data collection, patient management, preparation of the original draft, and literature review.

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