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ORIGINAL RESEARCH

The Comparative Study Between High Dose Versus Low Dose Oxytocin for Augmentation of Labour Concerning Maternal and Fetal Outcome

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ABSTRACT

Background:Delayed labour progress is common in nulliparous women, often leading to caesarean section despite augmentation of labour with synthetic oxytocin. Background: High- or low-dose oxytocin can be used for augmentation of delayed labour, but evidence for promoting high dose is weak. Dystocia is the leading indication for primary caesarean section. Augmentation of labour with oxytocin is a frequent intervention in modern obstetric practice. Oxytocin has been demonstrated to increase the frequency and intensity of uterine contractions when spontaneous uterine contraction is inadequate and the progress of labour is slow. Oxytocin protocols can be categorized as high-dose or low-dose protocols depending on the initial dose and the amount and rate of sequential increases. Despite the frequency with which oxytocin is used in clinical practice, there is little consensus regarding the optimal dose of oxytocin for labour augmentation. This study aims to compare the efficacy and safety of high and low dose oxytocin on augmentation of labour and to study maternal and fetal morbidity and mortality.

Materials and Methods: A total of 180 pregnant women requiring augmentation of labour were randomly assigned to receive oxytocin by either a low dose protocol (3.0mU/min initially, increased by 3.0 mU/min every 30 mins) or a high dose protocol (6.0mU/min initially, increased by 6.0mU/min every 30 mins).

Results: High dose of oxytocin was associated with a significant shortening of labour 5.2hr vs 6.1hr, p= 0.0021 without a significant difference in caesarean delivery rate, and neonatal and maternal outcome.

Conclusion: The use of high dose oxytocin is associated with a significantly shorter durationof labour without any adverse fetal and maternal effects.

Keywords: High Dose Oxytocin, Low Dose Oxytocin, Augmentation of Labour, Maternal and Fetal Outcome.

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INTRODUCTION

Delayed labour progress is prevalent in nulliparous women and causes emergency caesareans (CS).[1,2] Synthetic oxytocin is one of the most commonly used obstetric medications5 and is commonly used to induce labour. Oxytocin's usefulness in treating aberrant growth has been

questioned. Despite this, oxytocin use during labour has increased over time. Unstructured use of the medication causes hyperactive uterine contractions, which can harm the foetus So oxytocin is a high-alert drug. To reduce unfavourable newborn outcomes, checklists and established methods for oxytocin use have been advocated.[1,2] C-section rates have risen over the WHO- recommended threshold of 5-15 percent in several countries, almost doubling in the last decade1. The estimated CS rates in India in 1998 were 7.1%, with a 16.7% yearly change (Stanton, 2006).[3] The growing incidence of c-sections in both rich and developing nations have led to global efforts to reduce them without compromising maternal and infant health.[4] It is the most common cause of labour dystocia, leading to an increase in caesarean sections. Oxytocin-induced labour is one physiological technique for atonic dystocia.[5] When spontaneous labour does not develop to dilation and effacement of the cervix, uterine contractions are stimulated. Tying the optimal oxytocin concentration to each uterus is the only way. High-dose oxytocin regimens have been linked to lower caesarean section rates, although safety concerns remain.[6] Low-dose oxytocin regimens are safer but not as effective.[5] Our goal was to examine the efficacy and safety of low-dose versus high-dose oxytocin regimens in labour augmentation.

Aim of the study:

- To compare the effect of high and low dose oxytocin on the augmentation oflabour.
- To study maternal and fetal morbidity and mortality.

MATERIALS & METHODS

Source of data

The study w a s conducted on 180 singleton term pregnant women admitted as patients in Govt Medical College and Hospital, Suryapet.

Period: From 1st January 2020 to January 2022.

Method of collection of data:

A total of 180 pregnant women required the augmentation of labour due to insufficient uterine contractions, even 1 hour after ARM [If membranes intact], and cervical dilatation of at least 4 cm or more. These cases were chosen at random and assigned to either a low dose or a high dose regimen. The study included an equal number of primigravida and multigravida in each group.

The following inclusion and exclusion criteria were used to select subjects.

Inclusion criteria

- Primi / multigravida [less than gravida 6]
- Singleton pregnancy
- Term gestation
- Cephalic presentation Normal fetal heart rate
- No medical complication
- Requiring augmentation of labour

Exclusion criteria

- Multiple pregnancy
- CPD
- Malpresentation

- History of previous caesarean section Placenta praevia
- Meconium-stained liquor Hydromnios.
- PROM

On admission to the labour room, an initial assessment is performed by eliciting a detailed history using a prepared questionnaire [as in proforma], followed by a clinical examination and basic investigations. General condition, BP, pulse, temperature, RS, CVS assessed, abdominal examination performed and uterine contractions, lie, presentation, and FHR evaluated Vaginal examination performed to assess cervix dilatation, membrane station, liquor colour, and pelvic adequacy.

When the patient enters the active phase of labour [cervix 4cm] and the membranes are intact, an amniotomy is performed. If uterine contractions were insufficient after 1 hour [3 contractions in 10 minutes] or there were no cervical changes for 1 hour after ARM, oxytocin augmentation was used.

Types of interventions

1) High dose – oxytocin regimen group Starting dose – 6.0 mU/min
Incremental dose – 6.0 mU/min Incremental interval - 30 min Maximum dose - 38 mU/min
2) Low dose – oxytocin regimen group
Starting dose – 3.0 mU/min Incremental dose – 3.0 mU/min Incremental interval - 30 min Maximum dose - 40 mU/min

Preparation of solution

In the high dose regimen, 5U of oxytocin was added to 500 mL of ringer lactate, and 2.5 U of oxytocin was added to 500 mL of ringer lactate in the low dose regimen. Oxytocin was titrated manually using the gravity drip method. The infusion began at 10 drops per minute. If adequate uterine contractions are not obtained by the end of the half-hour, it is increased by another 10 drops/min until adequate contractions are obtained while avoiding tachysystole. A sufficient uterine contraction is defined as three 45-second contractions in ten minutes. 5 contractions in 10 minutes were defined as uterine tachysystole.

Record of progress in labour

Partogram was used to insert data such as name, age, parity, and hospital identity.

FHR = foetal heart rate was monitored by intermittent auscultation using a stethoscope or hand- held Doppler every 15 minutes in the first stage of labour and every 5 minutes in the second stage. FHR was auscultated during and for at least 60 seconds after contraction.Cervical examinations were performed every two hours after commencing augmentation and whenever clinically warranted, with assessments of cervical effacement, dilation, membrane status, and head position completed.The membrane state was "I" if the membranes were intact, "C" if the membranes were torn, and the liquor was clear. Moulding of the head was observed during the initial examination and the subsequent vaginal examination.The most important measures of labour progress, the rate of cervix dilatation and the rate of descent of the foetal presenting part, are recorded by plotting the cervical dilatation on the left-hand side of the graph in centimetres from 0 to 10 against the elapsed time, which is plotted on the horizontal line in hours.The station of the head was determined by the descent of the head with respect to the ischial spines and the gradual rotation of the head as demonstrated by the location of the sagittal sutures and occiput concerning the quadrant of the pelvis. Station zero is located at the level of the ischial spines. The station is indicated in minus numbers if it is above the spines [-1cm, -2cm, -3cm, -4cm, -5cm] and in positive

figures if it is below the spines [+1cm, +2cm, +3cm, +4cm, -5cm+5cm].The uterine contractions were plotted on the graph beneath the cervicograph. Abdominal palpation is used to evaluate uterine activity. The inspecting hand is positioned between the umbilicus and the uterine fundus. The frequency and duration of uterineContractions are measured every 10 minutes for a total of 30 minutes.
The frequency was determined by counting the number of contractions that occurred during a 10- minute period, which was measured in seconds, and the number of blocks representing frequency was filled in by dots if the duration was less than 20 seconds, cross-hatched if it was less than 40 seconds, and blocked out if it was more than 40 seconds.Maternal outcome measures such as uterine hyperstimulation, PPH, chorioamnionitis, and uterine rupture were also documented. Chorioamnionitis was diagnosed based on maternal fever (38°C or higher) and any two of the following:
Uterine pain, foetal tachycardia, maternal tachycardia, or foul-smelling amniotic fluid.Neonatal outcomes such as birth weight, Apgar scores at 1st and 5th minutes, and NICU admissions were also documented.For continuous data, statistical analysis was performed using the student "t" test and analysis of variance. The Chi-square test was used for categorical data, and group averages were given as mean standard deviation. A "P" value of 0.05 was judged statistically significant.

RESULTS

Table 1: Demographic profile

Characteristics	**High**	**Low**	**Significance**	
			t	**P**
Age[years]	25.02±4.02	24.72±4.17	0.39	0.72
wt[kg]	62.52±6.02	61.87±5.54	0.94	0.38
Height[cm]	153.1±4.54	51.21±6.31	0.65	0.52
GA[wks]	38.6±2.5	38.09±1.21	1.13	0.27
CD[3-4cm]	47(75%)	39(65%)	X2=1.41	
CD[5-6cm]	18(25%)	22(35%)	P=0.13,NS	

There were no significant differences for any of the factors including age,weight, height and gestational age between two dosage groups. Equal no of primigravida and multigravida were distributed in the study groups. The groupswere also comparable with respect to their pre-augmentation cervical dilatation.

Table 2: Duration of Labour

Characteristics(min)	**High(n=57)**	**Low(n=53)**	**Significance**		
			t	**P**	
AFD	271.21±36.8	294.5±44.3	2.31	0.003*	S
AD	307.32±37.2	333.21±50.34	3.04	0.002*	S
2nd stage	35.4±9.4	36.6±11.09	0.72	0.76	NS
3rdstage	5.08±1.13	5.37±0.78	0.59	0.81	NS

AFD- Augmentation to full dilatation interval; AD- Augmentation to the delivery interval. When high dose oxytocin was used for labour augmentation, it was associated with a significant shortening of labour duration as demonstrated by shortened augmentation to the delivery interval [AD: High dose n307.32±37.2 min; low dose: 333.21±50.34min; p=0.002],

irrespective of parity. Time from augmentation to full dilation was also significantly shorter in the high dose group [AFD: High dose 271.21±36.8; low dose: 333.21±50.34;p=0.003].
From [Table 3], it can be concluded that a high dose oxytocin regimen is associated with shorter labour. Even though labour duration was shortened in the high dose group, there was no difference in the duration of the second and third stages of labour.

Table 3: Duration of labour in primi

Duration of labour (min)	High(n=28)	Low(n=25)	Significance		
			t	P	
AFD (min)	272.3±42.2	321.2±44.06	4.11	<0.001**	HS
AD	312.3±44.6	366.7±44.3	4.44	<0.001**	HS
2nd stage	39.9±9.6	45.4±6.3	2.4	0.02	S
3rd stage	4.79±1.03	5.08±0.95	1.07	0.29	NS

High dose augmentation group had significant shortening of augmentation tofull dilation interval [p<0.001] and augmentation to delivery interval [p<0.001] when compared between two oxytocin groups in primigravidae.
Slightly significant shortening of second stage labour was noted in high dose regimen, with no difference in duration of third stage labour.

Table 4: Duration of labour in multigravida

Duration oflabour (min)	HIGH(n=29)	LOW(n=28)	Significance		
			t	P	
AFD(min)	272.01±35.7	274.2±35.6	0.23	0.82	NS
AD	300.52±32.5	303.5±34.3	0.34	0.73	NS
2nd stage	31.7±7.7	29±8.6	1.27	0.21	NS
3rd stage	5.34±1.01	5.25±1	0.36	0.72	NS

Even though high dose oxytocin was associated with a significant reduction in labour duration [shortening of AFD, AD] in primigravidae, the difference was not significant when two dosing regimens is compared in multigravidae.
There was no difference in duration of labour, AD, AFD, second stage including the third stage of labour when high and low dose regimens are compared in multigravidae.

Table 5: Maximum Oxytocin dose

MAX Oxytocindose (mu/min)	HIGH	LOW	Significance		
			t	P	
Primi+Multi	14.23±5.12	12.23±11.36	4.23	<0.001**	HS
Primi	15.91±5.31	10.81±3.23	4.78	<0.001**	HS
Multi	13.02±4.4	11.24±2.56	1.56	0.091	NS

[Table5] represents t h e maximum oxytocin dose in high and low dose oxytocin groups. The maximum oxytocin dose was significantly high in the high dose group. When compared according to the parity, the significant difference was noted only in primigravidae, but no difference in multigravidae. In primigravidae maximum oxytocin, the dose was significantlyhigh in the high dose group [high dose:15.91±5.31 mU /min; low dose:10.81±3.23 mU/min; P<0.001, HS]. Even though maximum oxytocin dose was high

with high dose method, this was associated with significantly shorter times spent in labour and delivery.
In multigravidae, a high dose regimen was associated slightly high maximum oxytocindose compared to a low dose regimen, however, it was not significant.

Table 6: Mode of delivery

Mode of delivery	HIGH (n=90)		LOW (n=90)	
	No	%	No	%
FIND	73	88.3	68	80
Instrumental	9	6.7	10	8.3
LSCS	8	5	12	11.7

X2=3.15, p=0.37,NS

[Table6] represents the mode of delivery in high dose and low dose oxytocin groups. The mode of delivery did not differ significantly between the high dose and low dose oxytocin groups. Even though slight rise of caesarean rate in low dose groups noted, it was not significant.

Table 7: Mode of delivery according to parity

Mode ofdelivery		HIGH (n=90)		LOW(n=90)	
		No	%	No	%
FTND	Primi	53	58.88	50	55.5
	Multi	30	33.3	28	31.1
Instrumental	Primi	2	2.2	3	3.3
	Multi	2	2.2	2	2.2
LSCS	Primi	2	2.2	5	5.5
	Multi	1	31.1	2	2.2

X2=1.10, p=0.58, NS

[Table 7] shows the mode of delivery in high and low dose oxytocin groupsaccording to parity. Regardless of parity, the mode of delivery did not differ significantly between the two oxytocin groups. Low dose oxytocin regimen in primi‟s was associated with a slightly higher LSCS rate. In primi‟s high dose regimen is associated with a slightly higher spontaneous delivery rate.

Table 8: Maternal Complications

Maternal complications	HIGH		LOW	
	No	%	No	%
Tachysystole	7	7.7	3	3.3
PPH	5	5.5	2	2.2
Cervical/Vaginal tears	4	4.4	1	1.1
Chorioamnionitis	0	0	2	2.2

[Table 8], shows the impact of high dose and low dose oxytocin regimens on the maternal outcome. There was no difference in maternal complications between the two dosing regimens. Even though a high dose oxytocin regimen was associated with requirement of

high maximum oxytocin dose, it was not associated with any adverse maternal outcome. Two cases of chorioamnionitis was seen with low dose regimen group.
There were a number of other complications distributed randomly in the study, PPH, cervical tear, vaginal tear, need for blood transfusion. There was no cases of uterine rupture and precipitate labour.

Table 9: Perinatal outcome

	HIGH	**LOW**	**Significance**		
			t	**P**	
Birth wt[g]	2723.3±56	2652.5±39	0.41	0.69	NS
APGAR 1 min	5.32±0.89	5.21±0.65	0.49	0.71	NS
APGAR 5 min	8.76±0.76	8.23±0.72	1.32	0.31	NS
APGAR5 min<7	6[6.7%]	2[2.2%]	x2=1.03, p=0.31, NS		
NICU	8[8.9%]	11[12.2%]			
Neonatalsepsis	2[2.2%]	5[5.5%]			
Neonataldeaths	0	0			

Birth weight a n d Apgar score at 1 and 5 minutes did not differ between the 2groups. Apgar score at 5 min < 7 and NICU admission were similar in both groups. Three cases of neonatal sepsis and one case of neonatal sepsis in low dosegroups and high dose groups respectively occurred. There was no case of neonatal death or stillborn babies.

DISCUSSION

Our findings revealed that there was no significant difference between the study groups in terms of age, gestational age, height, weight, or cervical dilation. Our demographic characteristics pattern was similar to those found by Jamal et al, Merrill et al, and Lopez – Zeno et al.[8,9] We were unable to compare our anthropometric results to those of other studies because they were all from Western countries, and most studies did not include the height and weight criteria in their research. Pre-augmentation cervical dilatation in our study was comparable to those of Jamal et al6, and Merrill et al.[9]

Duration of labour

In our study, the duration of labour was dramatically reduced in the high dose groups. Both the augmentation to delivery interval and the duration of the second stage were reduced. All of the previous studies indicated a substantial reduction in labour duration with high dose in both multipara and nullipara, however, the reduction in labour duration in our study was only in nullipara.Despite the fact that the AD interval was shorter in the Bidgood study,[9,10] it was longer in our research. In our study, it could be due to a shortened waiting period for augmentation after functional dystocia is diagnosed (our study 1 hr, Bidgood 4 hr).
The results of multipara research could not be compared since most studies did not define the parity or were conducted on nulliparous women. In our investigation, the maximal oxytocin concentration was considerably higher in the high dose group (14.235.12 mu/min) than in the low dose group (12.2311.36 mu/min). Our findings are consistent with those of most previous research, including those of Sadler et al and Lopez-Zeno et al.[11-13]
In our investigation, the same results of a high maximum oxytocin dose in primigravida were seen in the high dose group, but this difference was not seen in multigravida. The highest oxytocin dose in primigravidae was substantially higher in the high dose group [high dose:

15.915.31 mU/min; low dose: 10.813.23 mU/min; P0.001, HS]. In our investigation, the mode of delivery did not change across groups, with no increased spontaneous births in the high dose group. There was no significant increase in caesarean section in the low dose group. These findings were comparable to those of Satin et al.[10] Increased spontaneous vaginal delivery was observed in the trial by Wei et al,[13] which could be attributed to the high maximal oxytocin dose. In contrast, in a study conducted by Xenakis et al,[1] the low dose group was related to a high caesarean rate (25.7 percent).[14] It could be due to the administration of a very low dose of oxytocin (1 mU) for augmentation. In a study conducted by Goni et al,[13] there was a rise in caesarean section and instrumental delivery with a high dose, which could be attributed to the shorter incremental interval (20 minutes) and high maximum oxytocin dose employed (64 mu/min).In our study, the spontaneous delivery rate increased substantially with high dose oxytocin while the caesarean rate decreased little. It was, however, insignificant. However, the results were comparable to those of Tabowei et al.[16] Mojoko et al discovered no variation in caesarean rate between groups.[17] The routes or modes of delivery did not differ between the two groups in our study. Our findings could not be compared to those of Xenakis because one of the maternal outcomes, tachysystole and chorioamnionitis, was the most important component examined for comparison.[14] The incidence of tachysystole in our study was 7.7 percent in the high dose group and 3.3 percent in the low dose group, which was similar to the findings of Wei et al and Jamal et al.[13,18] The effect was reversible in all cases in minutes, with no harmful maternal or foetal effects.
We can assume that the increased prevalence of tachysystole in the Merril study was owing to the use of electronic foetal monitoring, which was more sensitive to detecting tachysystole than ourstudy, which was based on clinical diagnosis.[9] It could also be because the overall neonatal outcome in our study's two study groups was similar. The lower socioeconomic status of our study population compared to other western study groups may have contributed to the lower mean birth weight of neonates in our study. Other newborn outcomes in our trial, such as NICU admission, sepsis incidence, and Apgar at 57%, were comparable to Satin et al10 results. Despite the fact that NICU admission was somewhat greater in our study than in Ghidini et al., study, there was no occurrence of infant death in our study.[19]

CONCLUSION

In this research, high dose oxytocin was employed for ineffectual spontaneous labour after membrane rupture in primigravida. High dose oxytocin for labour augmentation in primigravida resulted in 1hr shorter delivery interval and moderate second stage labour shortening. In primigravida, high oxytocin dose labour augmentation was related to shorter labour length and no evident maternal or foetal morbidity or mortality. The high dose did not affect the overall caesarean rate or mode. The high dose did not affect the total caesarean rate or method of delivery. However, the caesarean rate was slightly higher (17%) in the low dosage primigravida group (p=0.38). High dose oxytocin can be administered safely in both primigravida and multigravida.

Limitations of the study

Despite its attempts, this study has flaws. Other trials' criteria for diagnosing dystocia, dose intervals, and incriminates make comparison difficult. Our method of recording uterine contractions did not include cardiotocography. One of our study's flaws was that the oxytocin regimen and intrapartum treatment physicians were not blinded. Because of the small study group, some differences were detected in some outcomes, although not significant.

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