# Original Research Article Comparison of high dose oxytocin with low dose oxytocin in augmentation of delayed labour

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#### Abstract

Background: Delay in the labour comprises the major factor leading to emergency intervention by caesarean section and is commonly seen in the nulliparous females. Despite the questionable efficacy of its use, as time passes, oxytocin use in labour has increased. Aims: the present clinical trial was carried out to assess the effect of high dose oxytocin against low dose oxytocin for augmentation of labour delayed on the rate of Caesarean section in nulliparous females. Methods: In 80 nulliparous females, spontaneous and instrumental vaginal births, labour duration, fever, hemorrhage, placenta removal, and sphincter injury, tachysystole, total duration of infusing oxytocin, maximum oxytocin dose, total oxytocin dose, and stoppage or reduction of oxytocin were assessed. Concerning neonatal outcomes, NICU (neonatal intensive care unit) admission and duration, metabolic acidosis, fetal distress, Apgar score of less than 4 or 7 at 5 minutes, and intrapartum thick meconium-stained amniotic fluid. The collected data were subjected to the statistical analysis and the results were formulated. The level of statistical significance was kept at the level of p < 0.05. Results: Caesarean sections were carried out in 80% (n=32) females in both low and high oxytocin groups. The main reason for C-section was the failure to progress to labour in both low oxytocin (62.5%, 25) and high oxytocin (55%, 22) groups with a nonstatistical difference. Labour duration was short for the high oxytocin group (742±207) by 24 minutes. No difference was seen in the two groups concerning the fetal outcomes concerning any assessed parameter. A significantly lower dose was used in the low oxytocin group (5.72±5.56) than the high oxytocin group (7.96±8.31) with p<0001. Maximum oxytocin dose was also statistically higher low oxytocin group (p<0001). The observation of uterine tachysystoles was higher in the high dose oxytocin group (42.5%, 17) compared to the low dose (32.5%, 13). Conclusion: High oxytocin dose can be efficiently used in managing delayed labour to avoid adverse maternal or fetal outcomes with no difference in rates of caesarean section compared to low dose oxytocin used.

Keywords: Caesarean section, nulliparous females, oxytocin dose, delayed labour.

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### Introduction

Caesarean section has increased in various countries recently with double rates in the past 10 years. This increase is more than what is recommended (5-15%). As per the data of 1998 caesarean section in India had a rate of 7.1% with the annual changes of 16.7%. These changes are among one the highest changes in any country[1]. These increases in the caesarean section are seen in both in developed as well as developing countries. This has warranted various interventions to limit caesarean sections globally without compromising fetal or maternal health. This increasing trend can be owing to uterine atony, which is the most common cause of labour dystocia[2].

Delay in the labour comprises the major factor leading to emergency intervention by caesarean section and is commonly seen in the nulliparous females. Despite the questionable efficacy of its use, as time passes, oxytocin use in labour has increased. In Obstetrics and Gynaecology, routinely administered medication for augmentation of labour is synthetic oxytocin.

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Owing to the unstructured use of Oxytocin, it can lead to negative fetal effects secondary to hyperactive uterine contractions. So, to decrease fetal effects and undesired birth outcomes, standard guidelines and protocols are made for the safe use of oxytocin and it is labeled as high-alert medication[3].

One of the physiological ways for atonic dystocia is labour augmentation using oxytocin. Augmentation of labour refers to uterine contraction stimulation in subjects where spontaneous labour onset fails to affect cervix dilatation and effacement. Titration is the only method to achieve oxytocin concentration for an individual uterus. High oxytocin dose relates to the lower rate of caesarean sections. However, safety concerns are associated with the use of high oxytocin doses. Low oxytocin doses are comparatively safe to high doses, but the efficacy of low dose oxytocin is questioned[4].

On comparing high dose and low dose oxytocin in labour augmentation, no difference concerning the rate of caesarean section was seen. However, hyperstimulation of the uterus was seen more with the high dose of oxytocin. The data concerning adequate oxytocin dose in increasing low labour progress and experience of females taking oxytocin for pain and childbirth is lacking in the literature. Less risk of caesarean sections is seen with high oxytocin doses with minimal or no adverse birth outcomes. The data supporting this fact is still questionable[5]. Hence, the present clinical trial was carried out to assess the effect of high dose oxytocin against low dose oxytocin for augmentation of labour delayed on the rate of Caesarean section in nulliparous females.

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## Materials and methods

The present study was a randomized clinical trial carried out at Department of Obstetrics and Gynaecology, GSL medical college, Rajamundary, Andhra Pradesh. The study samples comprised of 80 females that were nulliparous and pregnant with gestational age, between 37 weeks to 41 weeks, near to labour, had a normal single fetus having cephalic orientation, active labour phase (cervical dilation of at least 3mm, painful, and regular contractions of uterus), ruptured membranes, and delayed labour confirmed. The exclusion criteria for the study were subjects not understanding Hindi, subjects less than 18 years of age, allergic to oxytocin, fever, hypertension, vaginal bleeding, altered fetal heart rates, fetal growth abnormalities, fetal head, and maternal pelvis disproportions, and/or delayed labour progress. Any subject fulfilling all inclusion criteria and was taking oxytocin were excluded.

The subjects were randomly selected to participate in the study on assessment of the delayed labour which was defined and diagnosed based on the criteria that during the first labour stage: there was a delay in the 3-hour partogram action line and if during the second labour stage there was no fetal head descent for at least one hour. In delayed labour with intact membrane, amniotomy was done and subjects were assessed for one hour, and in no progress cases, oxytocin labour augmentation was progressed. After obtaining the consent, the subjects were randomly divided into two groups with

high oxytocin (33.2mg) and low oxytocin (16.6mg) in isotonic saline. Concerning high oxytocin dose, infusion started with 6.2mU/min with maximum dose reaching 40mU/min, and for low dose, infusion started with 3.2mU/min and maximum dose reaching 30mU/min. Infusion started as 10drops/min and was consistently increased until uterine contractions were noticed further with labour progress as assessed by at least 3 contractions lasting for 45 seconds in 10 minutes. Fetal heart rate, cervical dilation, and uterine contractions determined the labour progress. The study progressed after obtaining clearance from the concerned committee.

After collecting data concerning neonates and obstetrics, caesarean section rates were evaluated primarily. The study also assessed spontaneous and instrumental vaginal births, labour duration, fever, hemorrhage, placenta removal and sphincter injury, tachysystole, total duration of infusing oxytocin, maximum oxytocin dose, total oxytocin dose, and stoppage or reduction of oxytocin. Concerning neonatal outcomes, NICU (neonatal intensive care unit) admission and duration, metabolic acidosis, fetal distress, Apgar score of less than 4 or 7 at 5 minutes, and intrapartum thick meconium-stained amniotic fluid.

The collected data were subjected to the statistical analysis using SPSS 24.0 for Windows (SPSS Inc., Chicago, IL, USA) and ANOVA (analysis of variance), and the results were formulated. The level of statistical significance was kept at the level of p < 0.05.

### Results

The present clinical trial was carried out to assess the effect of high dose oxytocin against low dose oxytocin for augmentation of labour delayed on the rate of Caesarean section in 80 nulliparous females. The demographic characteristics of the study subjects as recorded at baseline are summarized in Table 1. T 1 1 D abic charactoristics of the study subject

Table 1: Demographic characteristics of the study subjects				
Characteristics	Low Oxytocin dose	High Oxytocin dose	p-value	
Gestational Age (days)	281.5±7.1	281.8±7.6	0.8557	
BMI	24.3±4.8	24.5±4.5	0.8480	
Cervical dilation at first assessment after admission	3.48±1.62	3.45±1.57	0.9332	
Cervical dilation at delayed labour	6.73±2.22	$6.62 \pm 2.19$	0.8240	
Delayed labour stage				
First	85 (n=34)	82.5 (n=33)		
Second	15 (n=6)	17.5 (n=7)		
Birth weight (gms)	3619±432	3653±444	0.7294	
Low birth weight	2.5 (n=1)	5(n=2)		
Vertex Presentation				
Anterior Occiput	87.5 (n=35)	87.5 (n=35)		
Posterior Occiput	10 (n=4)	7.5(n=3)		

The results showed that the demographic characteristics were similar and comparable for both low oxytocin and high oxytocin group with no statistical difference concerning gestational age, BMI, cervical dilations, delayed labours, birth weight, and vertex presentations with respective p-values of 0.8557, 0.8480, 0.9332, 0.8240, and 0.7249.

Concerning maternal outcomes, caesarean sections were carried out in 80% (n=32) females in both low and high oxytocin groups. The main reason for C-section was the failure to progress to labour in both low oxytocin (62.5%, 25) and high oxytocin (55%, 22) groups with a nonstatistical difference. Vaginal birth carried out spontaneously or via instruments did not differ statistically in either group with p=1.00. Labour duration was short for the high oxytocin group (742±207) by 24 minutes. However, the difference was statistically non-significant (p=0.5977). Similarly, no statistical difference was seen concerning fever, hemorrhage, and need for manual placenta removal in both groups of females (Table 2).

Table 2: Primary	y and	secon	dary	materna	outcomes
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Table 2. I I maily and secondary material outcomes				
Maternal Outcomes	Low Oxytocin dose	High Oxytocin dose	p-value	
Caesarean section	80 (n=32)	80(n=32)	1.00	
Indications for caesarean section				
Progress failure	20 (n=8)	25 (n=10)		
Fetal distress	62.5 (n=25)	55 (n=22)		
Vaginal Birth				
Spontaneous	15 (n=6)	12.5 (n=5)	1.00	
Instrumental	72.5 (n=29)	72.5 (n=29)	1.00	
Labour duration	766±198	742±207	0.5977	
Fever	2.5 (n=1)	2.5 (n=1)	1.00	
Hemorrhage	40 (n=16)	37.5 (n=15)		
Need for manual placenta removal	2.5(n=1)	5(n=2)		

No difference was seen in the two groups concerning the fetal outcomes concerning any assessed parameter. Mortality in one fetus was seen in the low oxytocin group secondary to encephalopathy and not related to oxytocin. No difference was seen for metabolic acidosis, thick meconium staining of fluid, Apgar score, NICU admission, and NICU stay with respective p-values of 0.26, 0.72, 1.00, 1.00, 0.82, and 0.54 (Table 3).

Table 5. I finiary and secondary fetal outcomes				
Fetal Outcomes	Low Oxytocin dose	High Oxytocin dose	p-value	
Mortality	2.5(n=1)	0	1.00	
Metabolic Acidosis	5 (n=2)	2.5(n=1)	0.26	
Thick meconium staining of fluid	5 (n=2)	2.5(n=1)	0.72	
Apgar score less than 4	0	0	1.00	
Apgar score less than 7	2.5(n=1)	2.5(n=1)	1.00	
NICU admission	7.5(n=3)	5(n=2)	0.82	
NICU stay	4.71±3.26	5.60±5.03	0.54	

A significantly lower dose was used in the low oxytocin group  $(5.72\pm5.56)$  than the high oxytocin group  $(7.96\pm8.31)$  with p<0001. Maximum oxytocin dose was also statistically higher low oxytocin group (p<0001). Total infusion time did not show any statistical difference (p=0.011). The observation of uterine tachysystoles was higher in the high dose oxytocin group (42.5%, 17) compared to the low dose (32.5%, 13). Fetal heart rate anomalies contributed to the primary reason for stopping or reducing the oxytocin significantly more in the high dose oxytocin group. Reduction/ stoppage was done in 50% (n=20) females in low oxytocin group and in 57.5% (n=23) females in high oxytocin group (Table 4).

Table 4: Oxytocin related study parameters				
Oxytocin Parameter	Low Oxytocin dose	High Oxytocin dose	p-value	
Total Oxytocin dose (µg)	5.72±5.56	7.96±8.31	<.0001	
Total Infusion time (in hours)	5.15±3.18	4.76±3.09	0.011	
Maximum oxytocin dose per min (µg/min)	0.029±0.021	0.047±0.036	<.0001	
Reduction/stoppage of oxytocin	50(n=20)	57.5(n=23)		
Uterine Tachysystole	32.5 (n=13)	42.5(n=17)		
Uterine Tachysystole (episode number)	2.22±1.57	2.12±1.64	0.29	
Reduction/stoppage of oxytocin (1-2 episodes)	77.5 (n=31)	75 (n=30)		
Reduction/stoppage of oxytocin (more than 3 episodes)	22.5 (n=9)	25 (n=10)		

Reduction/stoppage of oxytocin (1-2 episodes) was higher in the high oxytocin group (77.5%, 31) than low oxytocin group (75%, 30), whereas reduction/stoppage of oxytocin (3 episodes) was higher in low oxytocin group (22.5%, 9) than high oxytocin group (25%, 10).

#### Discussion

The present randomized clinical trial was conducted to assess the effect of high dose oxytocin against low dose oxytocin for augmentation of labour delayed on the rate of Caesarean section in 80 nulliparous females and it was seen that no difference in rates of Csection was seen in high oxytocin or low oxytocin group with no effect of the stage on further analysis was seen. Females who received high dose oxytocin had more uterine tachysystole and low labour duration. The results showed that the demographic characteristics were similar and comparable for both low oxytocin and high oxytocin group with no statistical difference concerning gestational age, BMI, cervical dilations, delayed labours, birth weight, and vertex presentations with respective p-values of 0.8557, 0.8480, 0.9332, 0.8240, and 0.7249. These findings were similar to the studies by Jamal A et al[6] in 2004 and Goetzl L et al[7] in 2001 where similar demographic characteristics of the study subjects were taken into consideration.

Caesarean sections were carried out in 80% (n=32) females in both low and high oxytocin groups. The main reason for C-section was the failure to progress to labour in both low oxytocin (62.5%, 25) and high oxytocin (55%, 22) groups with a non-statistical difference. Vaginal birth carried out spontaneously or via instruments did not differ statistically in either group with p=1.00. Labour duration was short for the high oxytocin group (742±207) by 24 minutes. However, the difference was statistically non-significant (p=0.5977). Similarly, no statistical difference was seen concerning fever, hemorrhage, and need for manual placenta removal in both groups of females. No difference was seen in the two groups concerning the fetal outcomes concerning any assessed parameter. Mortality in one fetus was seen in the low oxytocin group secondary to encephalopathy and not related to oxytocin. No difference was seen for metabolic acidosis, thick meconium staining of fluid, Apgar score, NICU admission, and NICU stay with respective p-values of 0.26, 0.72, 1.00, 1.00, 0.82, and 0.54. These results were in agreement with the previous studies by Kenyon N et al[8] in 2013 and Ghidini A et al[9] in 2012 where maternal and

neonatal outcomes were comparable as shown in the results of the present study.

A significantly lower dose was used in the low oxytocin group  $(5.72\pm5.56)$  than the high oxytocin group  $(7.96\pm8.31)$  with p<0001. Maximum oxytocin dose was also statistically higher low oxytocin group (p<0001). Total infusion time did not show any statistical difference (p=0.011). The observation of uterine tachysystoles was higher in the high dose oxytocin group (42.5%, 17) compared to the low dose (32.5%, 13). Fetal heart rate anomalies contributed to the primary reason for stopping or reducing the oxytocin significantly more in the high dose oxytocin group. Reduction/ stoppage was done in 50% (n=20) females in low oxytocin group and in 57.5% (n=23) females in high oxytocin group. Reduction/stoppage of oxytocin (1-2 episodes) was higher in the high oxytocin group (77.5%, 31) than low oxytocin group (75%, 30), whereas reduction/stoppage of oxytocin (3 episodes) was higher in low oxytocin group (22.5%, 9) than high oxytocin group (25%, 10). These results were following the previous works of Majoko F et al[10] in 2001 and Shu-Qin Y et al[11] in 2010 where the authors depicted comparable findings concerning oxytocin doses used.

### Conclusion

Within its limitations, the present study concludes that there was no difference in the rates of the Caesarean section for the high oxytocin or low oxytocin dose used in females with delayed labour. However, in females who received high oxytocin dose, labour duration was significantly short with more uterine tachysystole compared to low dose receiving females with no effect on maternal and fetal outcomes. Hence, high oxytocin doses can be efficiently used in managing delayed labour to avoid adverse maternal or fetal outcomes. The study had few limitations like a small sample size, geographical area bias, and lack of blinding. Hence, further blinded and randomized controlled clinical trials are needed to reach a definitive conclusion.

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