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RESEARCH ARTICLE OPEN ACCESS

30-minute versus 60-minute oxytocin incremental interval protocols for induction of labour in low parity women: a comparative study

Dina O[1], Akadri AA[2], Odelola OI[1], Durodola A[3], Osinaike B[3], Ahmed GO[4]

[1]*Department of Obstetrics and Gynaecology, State Hospital Ijebu-Ode, Ogun State, Nigeria*
[2]*Department of Obstetrics and Gynaecology, Babcock University, Ilishan-Remo, Ogun State, Nigeria*
[3]*Department of Obstetrics and Gynaecology, State Hospital Ijaiye, Ogun State, Nigeria*
[4]*Department of Obstetrics and Gynaecology, Federal Medical Centre Owo, Ondo State, Nigeria*

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Abstract
Objective: This study compared the efficacy and safety of 30-minute and 60-minute incremental protocols of oxytocin infusion for the induction of labour in women of low parity.
Methods: A hospital-based comparative cross-sectional study was carried out in two health facilities in Ogun State, Nigeria, between January 2021 and November 2022. Women admitted for induction of labour at term (n=260) were grouped and compared based on the oxytocin interval protocol used. The primary outcome of the study was successful vaginal delivery rate. Secondary outcomes included induction to onset of adequate uterine contraction interval, induction to delivery interval, uterine hyperstimulation, foetal distress and Apgar scores. Data was analysed using SPSS version 26. P value < 0.05 was considered statistically significant.
Results: Successful vaginal delivery rates were 93.8% and 96.9% for the 30-minute and 60-minute oxytocin induction protocols respectively. The mean induction–onset of adequate uterine contraction interval was significantly lower in the 30-minute group when compared to the 60-minute group (P<0.001). Uterine hyperstimulation was significantly higher among women in the 30-minute group (16; 12.3%) when compared to those in the 60-minute group (2; 1.5%) (P<0.001). The occurrence of foetal distress and Apgar scores were comparable in the two groups.
Conclusion: Both 30-minute and 60-minute oxytocin incremental interval protocols for induction of labour are associated with high success rates and a good safety profile.

Keywords: Efficacy, Induction, Labour, Oxytocin, Regimen, Safety

Plain English Summary

There is still an ongoing controversy regarding the way oxytocin is used for inducing labour in women with few previous deliveries. Some clinicians advocate increasing the rate of the oxytocin drip every 30 minutes, while others advocate increasing it every 60 minutes. This study compared the efficacy and safety of 30-minute and 60-minute incremental protocols of oxytocin drip for the induction of labour in 260 women who had not had more than two previous childbirths. One hundred and thirty women were recruited from each of two hospitals: State Hospital Ijebu-Ode (SHI) and State Hospital Abeokuta (SHA). The two hospitals served as referral centres for public and private health facilities in Ogun State, Nigeria. SHI uses the 30-

Correspondence:
Akadri, Adebayo A
Department of Obstetrics and Gynaecology
Babcock University, Ilishan-Remo
Ogun State, Nigeria
+2348023165644, bayoakadri@yahoo.com

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minute oxytocin incremental interval protocol for induction of labour, while SHA uses the 60-minute oxytocin incremental interval protocol. We found that both 30-minute and 60-minute oxytocin incremental interval protocols were associated with high rates of successful non-operative deliveries. The time to delivery was similar in both groups. In addition, both protocols were safe for both mothers and babies.

Background

Induction of labour is defined as the initiation of uterine contractions after the age of viability but before the spontaneous onset of labour by medical and /or surgical means to achieve vaginal delivery (1). Oxytocin is useful for the induction of labour because of its effectiveness in stimulating uterine contractions that are strong enough to produce cervical changes, foetal descent and eventual delivery of a live foetus, while avoiding excessive uterine activity, which could lead to maternal and foetal complications (2). Numerous regimens of oxytocin in incremental intervals have been used for the induction of labour. These vary from short incremental intervals (15-20 minutes) to long incremental intervals (30-60 minutes) (3). The American College of Obstetricians and Gynaecologists (ACOG), Society of Obstetricians and Gynaecologists of Canada (SOGC) and National Institute for Health and Care Excellence (NICE) guidelines on induction of labour have, however, recommended an incremental interval increase of not less than 30 minutes (4, 5, 6).

The current induction of labour regimen includes both high and low-dose regimens and is delivered by either continuous or pulsed infusions, with both arithmetic and geometric rates of increase in oxytocin dose. Some studies have suggested that the high-dose protocol is associated with short induction to delivery interval but may induce excessive uterine stimulation and foetal distress, while low-dose protocols seem to have a better safety profile (7, 8, 9). Other researchers have posited, however, that the prolonged induction to delivery interval associated with low-dose protocols may negatively affect birthing experience and sometimes increase the risk of foetal distress and chorioamnionitis (7, 8).

Although there are various works on dosages of oxytocin, there is no standardised, universally accepted oxytocin regimen. Many of the studies on induction protocols did not differentiate the outcomes between multiparous and nulliparous women, whereas it is common knowledge that parity may affect the outcome of the induction process. Moreover, most of these studies were conducted without using electronic foetal heart monitoring in labour, even though cardiotocography is the gold standard for foetal monitoring during induction of labour (6, 10). The previous studies on the subjects also failed to provide information on the occurrence of hyperstimulation with or without foetal heart changes (7, 9, 11). Similarly, a recent comparative study (12), and a randomised controlled trial (13) that evaluated oxytocin protocols did not include a 60-minute oxytocin incremental interval regimen. This hospital-based comparative cross-sectional study was designed to compare the efficacy and safety of 30-minute and 60-minute incremental protocols of oxytocin infusion for labour induction. In this study, labour was effectively monitored with a cardiotocograph and nulliparous women were separately sub-analysed from other women of low parity.

Methods

Study setting

This was a hospital-based comparative cross-sectional study carried out at two health facilities in Ogun State, Nigeria: State Hospital Ijebu-Ode (SHI) and State Hospital Abeokuta (SHA). These hospitals serve as referral centres for public and private health facilities in Ogun State, with delivery rates in both hospitals averaging about 1200 deliveries per year. The study was conducted between January 2021 and November 2022. SHI uses the 30-minute oxytocin incremental interval protocol for induction of labour, while SHA uses the 60-minute oxytocin incremental interval protocol.

Study population and sample size determination

The study population were women admitted at the two study centres for induction of labour at term (i.e. gestational age of 37 to 42 completed weeks). The gestational ages of the women undergoing induction of labour were ascertained by ultrasound scans done before 20 weeks of gestation. Women of low parity (0-2) with singleton live foetuses in cephalic presentations and with favourable cervices were included in the study. Women with medical conditions, and those with intrauterine growth restriction, antepartum haemorrhage and previous caesarean sections were excluded. Women who had prostaglandins for cervical ripening were also excluded.

The sample size (N) was determined by applying the formula for comparison of two means: $N = (u + v)^2 (\sigma 1^2 + \sigma 0^2)/ (\mu 1 - \mu 0)^2$. From a previous study (14), the difference in mean induction to delivery interval ($\mu 1 - \mu 0$) was 100 minutes; while standard deviations of 243.46 minutes and 197.01 minutes

were reported for 30-minute and 60-minute groups, respectively. Assuming a type 1 error of 0.05 and 95% power, the calculated sample size (N) was 127.8. However, 130 pregnant women undergoing induction of labour were recruited from each study site.

Recruitment of study participants
Patients scheduled for induction of labour who met the inclusion criteria were informed about the study, and a signed informed consent was obtained. Recruitment of pregnant women was done sequentially at the study sites until the required sample size was reached, i.e. 130 study participants from both SHI (30-minute group) and SHA (60-minute group).

Induction protocol
Women admitted for induction of labour had a cervical assessment to determine the Bishop score. Those with unfavourable cervix (Bishop score <7) were counselled for cervical ripening with trans-cervical extra-amniotic Foley catheter. A size 22 Foley catheter was passed, and the balloon was inflated with 50 millilitres of sterile water on the evening preceding the day of induction. The catheter was left overnight and expelled after an average time of about 12 hours. Induction of labour was commenced for those with Bishop Scores of 7 and above. Women with prelabour rupture of membranes at term had labour stimulation with oxytocin.

Oxytocin infusion protocol
Five units of synthetic oxytocin (Rotex^{R}) were diluted in 500 millilitres of Ringer's lactate solution and infused via intravenous giving set using a gravity-fed technique. The oxytocin infusion was started at 5mU /min (10 drops per/min) and increased by 10 drops per minute every 30 minutes (30-minute incremental protocol group) or 60 minutes (60-minute incremental protocol group), until adequate contractions was achieved or to a maximum of 30 mU/min (60 drops/minute). Foetal heart rate and uterine contractions were continually monitored using a cardiotocograph in all patients. The aim was to achieve 3 to 5 contractions in 10 minutes, lasting 40 to 60 seconds.

Data collection and analysis
Detailed data of study participants were retrieved from the available patients' records using a structured data capture sheet. The information extracted included maternal age, parity, date of last menstrual period, estimated gestational age (ascertained by early ultrasound scan), height, and weight. The Bishop score, indication for induction, mode of delivery, duration of labour and intrapartum complications such as hyperstimulation and foetal distress were also recorded in the data capture sheet.
The data were entered into the personal computer and analysed using SPSS version 26. The data were summarised using tables. Continuous variables such as maternal age, Bishop Score, gestational age, height, and weight were compared using a t-test. The chi-square was used to determine the association between obstetric variables such as mode of delivery and intrapartum complications, and the oxytocin incremental protocol. A p-value < 0.05 was considered statistically significant.

Results
A total of 260 pregnant women participated in the study. The mean maternal age (SD) was 26.9 (4.4) years with a range of 17-38 years. The mean age (SD) of the women in the 30-minute group was 27.2 (4.3) years, while that of the 60-minute group was 26.6 (4.5) years. Statistical analysis shows that the two groups were similar in their obstetric and anthropometric characteristics (Table 1).

Table 1. Characteristics of study participants

Variables	30-minute group Mean (SD)	60-minute group Mean (SD)	T-test	P-value
Maternal age (years)	27.2 (4.3)	26.6 (4.5)	1.18	0.24
Parity	1.1 (0.8)	1.0 (0.9)	0.16	0.74
Gestational age (weeks)	40.37 (1.12)	40.4 (1.0)	-0.24	0.81
Bishop score	7.9 (1.0)	8.2 (1.0)	-2.40	0.26
Height (meters)	1.6 (0.1)	1.6 (0.1)	-0.25	0.80
Weight (kilograms)	67.9 (12.3)	68.0 (16.1)	-0.07	0.95

Table 2 illustrates the indications for the induction of labour. Most of the respondents, 118 (90.8%) in the 30-minute group and 114 (88%) in the 60-minute had induction of labour on account of postdated pregnancy.

Table 2: Indications for induction of labour

Indications	30-minute Group (n=130) Frequency (%)	60-minute group (n=130) Frequency (%)
Postdated Pregnancy	114 (87.7)	118 (90.8)
Prelabour Rupture of Membranes	12 (9.2)	10 (7.7)
Unstable lie	4 (3.1)	2 (1.5)

Table 3 shows the induction interval and neonatal outcome of study participants. The mean induction start-onset of adequate uterine contraction interval was lower in the 30-minute group when compared to the 60-minute group in both nulliparous women and women of low parity. This was statistically significant (P<0.001). However, there was no statistically significant difference in the induction–vaginal delivery intervals in both 30 and 60-minute groups, for both nulliparous women and women of low parity.

The mean birth weight (SD) was 3.2 (0.8) kg and 3.3 (0.7) kg among the 30-minute and 60-minute groups, respectively. There was no statistically significant difference in mean birth weight in the two groups. The mean Apgar scores (SD) at 1-minute and 5-minute were 8.8 (1.2) and 9.6 (0.2) for the 30-minute group and 8.8 (1.0) and 9.9 (0.1) for the 60-minute group. There was no statistically significant difference in the 1st and 5th minute Apgar scores in the two groups (P=0.55; P=0.17, respectively).

Table 3: Induction interval and neonatal outcome of study participants

Variables	30-minute group (n=130) Mean (SD)	60-minute group (n=130) Mean (SD)	P-value
Induction starts - onset of contractions interval			
Nulliparous (minutes)	125 (28)	169 (51)	<0.001
Parity 1-2 (minutes)	115 (29)	167 (40)	<0.001
Induction- vaginal delivery interval			
Nulliparous (minutes)	410 (81)	413 (60)	0.84
Parity 1-2 (minutes)	358 (58)	358 (41)	0.28
Neonatal outcome			
Birth weight (Kg)	3.2 (0.8)	3.3 (0.7)	0.24
APGAR score at 1st minute	8.8 (1.2)	8.8 (1.0)	0.55
APGAR score at 5th minute	9.6 (0.2)	9.9 (0.1)	0.170

Table 4 depicts the mode of delivery and intrapartum complications of study participants. Successful vaginal delivery rates were 93.8% and 96.9% for the 30-minute and 60-minute oxytocin induction protocols respectively. The proportion of women who had a caesarean section was two times higher among women in the 30-minute incremental group (6.2%) compared to women in the 60-minute incremental interval group (3.1%). The difference was, however, not statistically significant. Overall, the delivery outcomes among nulliparas were similar in the two groups. Furthermore, all the parturient with parity 1-2 delivered through spontaneous vaginal delivery. Uterine hyperstimulation was significantly higher among women in the 30-minute group (16; 12.3%) when compared to those in the 60-minute group (2; 1.5%), (P<0.001); however, there was no statistically significant difference in the occurrence of foetal distress in the 30-minute group (11; 8.5%) compared to the 60-minute group (4; 3.1%) (P =0.06).

Table 4: Mode of delivery and intrapartum complications of study participants

Variables	30-minute group (n=130) Frequency (%)	60-minute group (n=130) Frequency (%)	P-value
Mode of Delivery			
Vaginal Delivery	122 (93.8)	126 (96.9)	0.24
Caesarean section	8 (6.2)	4 (3.1)	
Intrapartum Complications			
Uterine hyperstimulation	16 (12.3)	2 (1.5)	<0.001
Foetal distress	11 (8.5)	4 (3.1)	0.060

Discussion

This study compared the efficacy and safety of 30-minute and 60-minute oxytocin incremental interval protocols for the induction of labour among women with low parity in two tertiary health facilities in Ogun State, Nigeria. Findings from the study show that the induction to onset of uterine contractions interval was significantly shorter in the 30-minute group in both nulliparous women and women with parity of 1 or 2. However, there was no significant difference in the induction to vaginal delivery interval, mode of delivery, intrapartum complications, and neonatal outcomes in the two groups.

In this study, the induction-delivery intervals were comparable in the 30-minute and the 60-minute group. This finding is similar to results from some studies conducted on oxytocin infusion incremental interval protocols on the induction of labour (15, 16, 17), but at variance with the findings of Ade-Ojo et. al., who reported a shorter induction to delivery interval in the 60-minute group (14). In the present study, the oxytocin dose required to achieve adequate uterine contractions (i.e. 3 to 5 contractions in 10 minutes lasting 40 to 60 seconds) in both 30-minute and the 60- minute groups were similar (15 - 20mU/minute) but the 30-minute group had shorter induction - onset of adequate uterine contractions. It is also worth noting that this dose was reached earlier in the 30-minute group. This finding is similar to that of Mercer *et al* (15), who compared 20-minute with 60-minute oxytocin incremental intervals and found a significant prolongation of the time of onset of active labour in the 60-minute group. It appears that a shorter oxytocin incremental interval protocol leads to rapid build-up of oxytocin in the myometrium, thus shortening the time to onset of contractions (7, 8, 18, 19). However, the induction-delivery interval is largely dependent on the peak plasma level or steady-state plasma level of oxytocin, which is reached after 3 – 4 half-lives of steady oxytocin infusion (approximately 40 minutes) and is independent of the oxytocin incremental interval (15, 16, 18, 20).

Women in the 30-minute oxytocin induction interval group had a significantly higher risk of hyperstimulation than those in the 60-minute group. Researchers who advocate the use of long oxytocin incremental interval protocols have argued that short incremental interval protocols create a situation of repeated myocyte stimulation, thereby leading to uterine hyperstimulation with associated risk of foetal distress, increased caesarean section rate, as well as adverse neonatal outcome (7, 9). Others have, however, reported a similar caesarean section and neonatal outcome in studies comparing both protocols (8, 20, 21). The occurrence of uterine hyperstimulation following the use of oxytocin infusion has been a cause of great concern amongst clinicians because of the potential increase in maternal morbidities (such as caesarean sections and postpartum haemorrhage) and neonatal morbidity, such as asphyxia (22). Protocols for the administration of oxytocin infusion are based on the need to avoid or decrease these adverse consequences. Moreover, recent evidence suggests that discontinuing oxytocin during the active phase of labour could be associated with a reduction in moderate to severe neonatal morbidity, caesarean delivery and postpartum haemorrhage rates (23).

Findings from this study suggest that the use of a 30-minute oxytocin induction interval was not associated with a significantly increased risk of foetal distress. Similarly, there was no significant difference in the mode of delivery of women in the two groups. It should, however, be noted that the two times higher proportion of caesarean sections found among women in the 30-minute incremental group could be clinically relevant, especially in a large population of parturients.

The success rates for induction of labour were 93.8% and 96.9% for the 30-minute and 60-minute oxytocin induction protocols, respectively. This is higher than the induction success rate of 63.5% reported in a study carried out at another tertiary hospital in Ibadan, Southwest Nigeria, where a high-dose protocol with a 30-minute oxytocin induction interval was used (24). Neonatal outcomes as measured b\y Apgar scores at 1-minute and 5-minute were similar in both groups studied; adverse neonatal outcomes were infrequent, similar to findings in Ibadan (24). The high success rate may reflect good client selection for the induction of labour.

Strength and limitations

The use of cadiotocographic monitoring in labour may have helped in early detection of uterine hyperstimulation and foetal heart abnormalities, thus enhancing effective management. This study also has some limitations. One is the non-use of an oxytocin infusion pump, which is known to deliver oxytocin more accurately than the gravity-fed technique used in this study. Also, this study utilised a 5mU/minute starting oxytocin protocol, and the findings should not be extrapolated to settings where low starting dose protocols (<2mU/minute) are used. Finally, the study did not assess maternal satisfaction, which is an important factor in labour management.

Conclusion

Both 30-minute and 60-minute oxytocin incremental interval regimens for induction of labour are associated with high success rates and a good safety profile. Although the use of the 30-minute oxytocin incremental interval regimen is associated with faster onset of uterine contractions, the induction to vaginal delivery interval is similar in the two groups. The two regimens also have similar results in terms of mode of delivery, intrapartum complications, and neonatal outcomes.

List of Abbreviations

ACOG: American College of Obstetricians and Gynaecologists
NICE: National Institute for Health and Care Excellence
SD: Standard Deviation
SHI: State Hospital Ijebu-Ode
SHA: State Hospital Abeokuta
SOGC: Society of Obstetricians and Gynaecologists of Canada

Declarations

Ethics approval and consent to participate

Approval to conduct this study was obtained from the Ethics and Research Committee, State Hospital Abeokuta, Ogun State (Reference No: SHA/RES/VOI.4/185). The research was conducted following Good Clinical Practice (GCP) guidelines and in line with the Helsinki Declaration. Study participants were given full information on all aspects of the study, and a signed informed consent was obtained. It was ensured that confidentiality was not compromised. Moreover, the dataset used did not contain any direct or indirect person identifiers.

Consent for Publication

The authors hereby transfer all copyright ownership exclusively to the journal if this work is accepted and published by the journal.

Availability of Data

Data for this work are available with the authors and may be provided upon reasonable request.

Conflicts of Interest

The authors have declared no conflict of interest.

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Authors' contributions

OD conceptualised the study. OD, AAA and OIO designed the study. OD, AD, BO and AGO managed the literature search and gathered data. OD and AAA analysed the data and wrote the first draft of the manuscript. All authors read and approved the final manuscript.

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