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Comparative difference in birth asphyxia following augmentation of poor progress of labour in term nulliparas with oxytocin alone versus with oxytocin and drotaverine at the Rivers State University Teaching Hospital

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ABSTRACT

Background: Uterine contractions during labour are associated with relative foetal hypoxia. The hypoxia becomes significant when the uterine contractions are abnormal or the labour is prolonged and can lead to fetal distress or birth asphyxia.
Prolonged labour occurs when the active phase of labour lasts more than 12 hours and could result from abnormal uterine contractions or a slow cervical dilatation rate (<1cm/hr). Amniotomy and oxytocin augmentation is the standard modality for preventing prolonged labour because it improves uterine contractions. At times, despite good uterine contractions slow progress persists due to cervical smooth muscle spasms which increase the total oxytocin usage and lead to prolonged labour, further worsening intrauterine hypoxia and resulting in foetal distress and birth asphyxia. Drotaverine a musculotropic antispasmodic can relieve smooth muscle spasms.
Aim/objective: The study compared the incidence of birth asphyxia following augmentation with oxytocin alone vs oxytocin and drotaverine for slow labour progress.
Methods: This study was a single-blinded randomized clinical trial done for eight months. It involves 156 nulliparous parturients at term with slow labour progress, who were randomized into two groups. Each group had 78 parturients who received either oxytocin with placebo or oxytocin with drotaverine. They were monitored till delivery and the incidence of birth asphyxia in both groups was compared. Data obtained were analysed using IBM SPSS version 23 software. The level of significance was set at 0.05.
Results: The two groups were similar in their socio-demographic characteristics and mode of delivery. Following augmentation, the incidence of birth asphyxia in the oxytocin-placebo was similar to the oxytocin-drotaverine group (7 (9.0%) vs. 5 (6.4%), p=0.55).
Conclusion: The addition of drotaverine to the standard management of dysfunctional labour with oxytocin titration in term nulliparas is not associated with increased adverse neonatal outcomes.

INTRODUCTION

Normal labour occurs at term and is characterised by regular painful uterine contractions and cervical dilatation that leads to the delivery of the baby and placenta[1]. During each episode of contractions, there is a reduction in the supply of oxygen to the foetus through the placenta causing foetal hypoxia[2,3]. Under normal situations a healthy baby can tolerate this hypoxia, however, when the labour becomes complicated or prolonged many foetuses may decompensate leading to foetal distress, birth asphyxia, brain damage or death[3,4].

Foetal distress and perinatal asphyxia occur following complications that arise in the first or second stage of labour. These complications could be problems with uterine contractions, cervical dilatation, cord complications, placenta abnormalities or intrauterine infections[1,5]. Problems with uterine contractions and cervical dilatations are commonest in the first stage of labour and may manifest as poor progress in labour, prolonged labour or precipitate labour[5,6].

Poor progress and prolonged labour are commoner with nulliparas while precipitate labour is more common in multiparas. Poor progress occurs when the progress of labour is abnormally slow (<1cm/hr)[5-7], and it is mainly due to abnormalities in uterine contractions or slow cervical dilatation[7,8]. Uterine contractions abnormalities may be in the form of hypotonic, hypertonic or incoordinate uterine inertia and result in a slow cervical dilatation rate of <1cm/hr. Without intervention, this could degenerate into an arrest in cervical dilatation or prolonged labour with an associated increase in perinatal morbidity and mortality[8,9].

Amniotomy and oxytocin augmentation is the traditional management for poor progress in labour as it improves the contractions and corrects the underlying uterine inertia[8,10]. At times despite good contractions, slow progress persists due to spasms in the cervical smooth muscles. This could lead toa secondary arrest in cervical dilation and prolonged labour that may worsen intrauterine hypoxia and lead to foetal decompensation and birth asphyxia[11,12]. Poor progress in labour may also increase the total volume of oxytocin used, which could result in increased side effects of oxytocin such as uterine hyperstimulation syndrome, foetal distress, water intoxication, and birth asphyxia[11-13]. Addressing the problem of cervical spasms will not only improve the management of poor progress in labour but will also reduce the volume of oxytocin used and consequently intrauterine hypoxia.

Antispasmodics are drugs used to relieve smooth muscle spasms. Antispasmodics are classified based on their mechanism of action as neurotropic or musculotropic[14]. Neurotropic antispasmodics act on the muscarinic receptors of the nerve endingsthat supply the smooth muscle to inhibit acetylcholine and muscle tone, while Musculotropic antispasmodics act directlyon smooth muscles to inhibit phosphodiesterase IV enzymes and muscle spasms. Neurotropic antispasmodics have anti-muscarinic side effects such as dry mouth, constipation, bradycardia and urinary retention, while musculotropic antispasmodics lack anti-muscarinic side effects[14].

An ideal antispasmodic agent for labour should have a short onset of action, a long duration of action, and no significant adverse effect on the mother or the foetus[15,16]. In the search for an ideal antispasmodic agent for labour, drotaverine a newer musculotropic antispasmodic has shown superior pharmacodynamics[15,17]. The onset of action is 30 minutes and the duration of action is 4 hours, it has no significant adverse effect on the mother or foetus. when compared with other antispasmodics drotaverine has a minimal side effect profile[16,17].

Drotaverine has shown an excellent effect on relieving cervical smooth muscle spasms, and it is believed to act on the lower uterine segment and cervix without affecting uterine contractions[16-18]. Despite being able to relieve cervical smooth muscle spasms, drotaverine is rarely used with oxytocin in managing poor progress in labour[13,14]. The combination of drotaverine with oxytocin in managing poor progress of labour could lead to efficient cervical dilation with uterine contraction which may reduce the total volume of oxytocin used, and therefore the risk of intrauterine hypoxia and side effects of oxytocin.

Aim/objective

To compare the incidence of birth asphyxia following augmentation of poor progressin term nulliparas with oxytocin alone versus with oxytocin and drotaverine.

Study hypothesis

$H_0$1: There is no difference in the incidence of birth asphyxia following augmentation of poor progress in term nulliparas with oxytocin alone versus with oxytocin and drotaverine.

H_A1: There is a difference in the incidence of birth asphyxia following augmentation of poor progress in term nulliparas with oxytocin alone versus with oxytocin and drotaverine.

Definition of research terms

Term: This is a gestation age between 37 weeks to 41 weeks +6 days during which delivery outcome is optimal. It was obtained from the report of the first-trimester ultrasound scan or the first day of the last menstrual period.

Poor Progress: This occurs when there is an abnormal progression of the active phase of labour characterised by a slow cervical dilatation rate of <1cm/hr.

Augmentation of labour: This is the use of drugs to accelerate the progress of labour.

Antispasmodics are drugs used to relieve smooth muscle spasms.

Secondary arrest: This occurs when the cervical dilatation does not change on two vaginal examinations done 4hours apart

Amniotomy: This is an intentional rupture of foetal membranes in labour

A nullipara is a pregnant woman that has not had a live birth or a delivery beyond 28weeks of gestation.

A parturient is a pregnant woman in labour.

Foetal distress: This is an abnormality in the foetal heart rate or rhythm that is persistent and does not improve with intrauterine resuscitation

Birth asphyxia: This is the inability of a newborn to initiate and sustain spontaneous respiration, it is diagnosed when the first minute Apgar score is <7.

METHODOLOGY

Study Area

The study was conducted in the labour ward and theatre of the Rivers State University Teaching Hospital (RSUTH). The RSUTH is a tertiary health facility located in Port Harcourt, The capital city of Rivers State, Nigeria.

Rivers State is located in the south-south region of Nigeria. It is one of the Niger Delta states and has a huge reserve of natural gas and crude oil making it a centre for the oil and gas industries. Rivers State has a population of about 7,303,924 people[19]. The RSUTH is the largest state-owned health facility, it provides health services for residents of the State and other States within its environs. It also serves as a training centre for medical students and resident doctors. The RSUTH has an average of 2294 deliveries per year[20]

Study Population

The study was conducted amongst term nulliparous women in labour and their newborns at the RSUTH.

Inclusion criteria

All booked nulliparous women at term with a longitudinal lie and cephalic presentation who had spontaneous labour and gave consent.
All newborns of consenting mothers

Exclusion criteria

Conditions in which there are contraindications to vaginal delivery

Parturients with multiple gestations, a previous laparotomy, or medical/obstetric co-morbidity. Women who presented with ruptured membranes or in advanced labour (cervical dilatation ≥7cm) and Women with known allergies to either medication.

Sample size determination:

The sample size was calculated using the formula for comparing two groups in a clinical trial[21].

Sample size per group (n) = $\frac{2(Z\alpha/2+Z\beta)^2P(1-P)}{(P1-P2)^2}$

Where:

Zα/2 = standard normal deviation (usually set at 1.96 for a 95% confidence limit)
Z_β= power of the study (usually set at 80% =0.84)

P= $\frac{P1+P2}{2}$

P1= proportion of the parturient on drotaverine who had vaginal delivery was 93% = 0.93[21]
P2= proportion of the parturient on placebo who had vaginal delivery section was 76% = 0.76[21]

P= $\frac{0.93+0.76}{2}$ = 0.845

n = $\frac{2(1.96+0.84)^2 0.845(1-0.845)}{(0.93-0.76)^2}$= 71

Assuming an attrition rate (A_R) of 10% = 7.1

Sample size = 71 + 7.1 =78.1

A minimum sample size of 78 parturients each was required in the two study groups.

Therefore, a total of 156 parturients were recruited for the study.

Study design

The study was a single-blinded randomized controlled trial

Sampling Method

In this study, a multiphase random sampling method was employed. In the first phase, the women were screened with history and examination, those who were identified to be eligible were informed of the study and written informed consent was obtained from interested parturients. In the second phase, an amniotomy was done in the early active phase of labour (4 to 5cm

cervical dilatation) for all the parturients and they were re-assessed in four hours. Those with poor progress inlabour (<1cm/hour) were identified and randomized into two groups. Both groups were augmented with either oxytocin and a placebo or oxytocin and drotaverine.

Study Procedure

All booked antenatal women who were potentially eligible for the study were identified in the antenatal clinic from the 35th week of gestation and were pre-informed about the study. When they presented in labour, they were evaluated with history examination and investigations as routine for all women in labour. Those who met the inclusion criteria were identified and provided with details of the study procedure. Informed written consent was obtained from those who indicated interest to participate.

The participants were accessed as routine for women in labour and the findings were documented. Amniotomy was done for the women in the early active phase of labour (4-5cm cervical os dilatation) and the labour was monitored on a partograph.

A digital vaginal examination was repeated in four hours, women with normal labour progress (cervical dilatation rate ≥1cm/hour) were excluded from the study and continued with routine care, while those with a cervical dilatation rate of <1cm/hour were considered to have dysfunctional labour. They were randomized into two groups for augmentation of labour. Group A was augmented using oxytocin with placebo while Group B was augmented using oxytocin with drotaverine.

The randomization was done by balloting. The study participants balloted from 156 folded pieces of paper in a box (in which either the code A or B was written) until a block size of 78 women per group was reached. Code A represented 2ml of normal saline mixed with vitamin B-complex. This was prepared by adding 5ml of vitamin B-complex injection into 1 litre of normal saline, from this mixture 2ml was withdrawn into a 2ml syringe. Code B represented 2ml (40mg) of drotaverine, which was also withdrawn into a 2ml syringe. Both A and B were of the same colour, the participants were blinded to what each code represented.

Three drug packs were supplied and stored in the department's refrigerator. Two of the packs were labeled A or B, while the third pack was not labelled. Pack A contained several 2ml syringes each containing 2mls of normal saline-vitamin B complex mixture which served as a placebo, while pack B contained several 2ml syringes containing 2mls (40mg) of drotaverine. The third pack contained several ampoules of oxytocin. These packs were supplied in batches of ten per day.

Drotaverine hydrochloride injection (40mg/2ml) manufactured by Sanofi-Aventis Zrt Hungary and oxytocin injection (10IU/ml) manufactured by Novartis Pharmaceutical Switzerland were used for the study.

Following randomization, the women received an intramuscular dose of either a placebo or drotaverine with synchronous titration of 10IU oxytocin in 1litre of normal saline (10mU/ml). The oxytocin titration was started at 15drops per minute (7.5mU/minute) and the uterine contractions were monitored. If the contractions are inadequate, the oxytocin titration was increased every 30minutes by 15 drops/minute (7.5mU/minute) until adequate uterine contractions of 3-5contractions lasting between 45-60seconds are achieved or a maximum of 60 drops per minute (30mU/minute) was reached, this was based on the departmental protocol. The labour was monitored until delivery, on apartograph, and the third stage of labour was managed actively.

The bio data of each study participant, the time and cervical dilatation at the diagnosis of the active phase and subsequent examination were recorded. The intervention group, intrauterine complications, mode of delivery, and the Apgar scores of the babies at delivery were also recorded. The study was from 7th January 2021 to 23rd August 2021.

Data Analysis

The data obtained were entered into an Excel spreadsheet and analysed using IBM SPSS version 23.0 for Windows® statistical software. Results were presented in tables and figures. categorical variables were summarised with frequencies and percentages, while numerical variables were summarized with means and standard deviations.

Descriptive analysis was done for socio-demographic characteristics. The chi-square test was used to compare the incidence of birth asphyxiain both groups. The level of significance (α) was set at 0.05, a p-value < 0.05 was considered statistically significant. The null hypothesis was rejected when p is < 0.05.

CONSORT FLOW DIAGRAM FOR THE STUDY

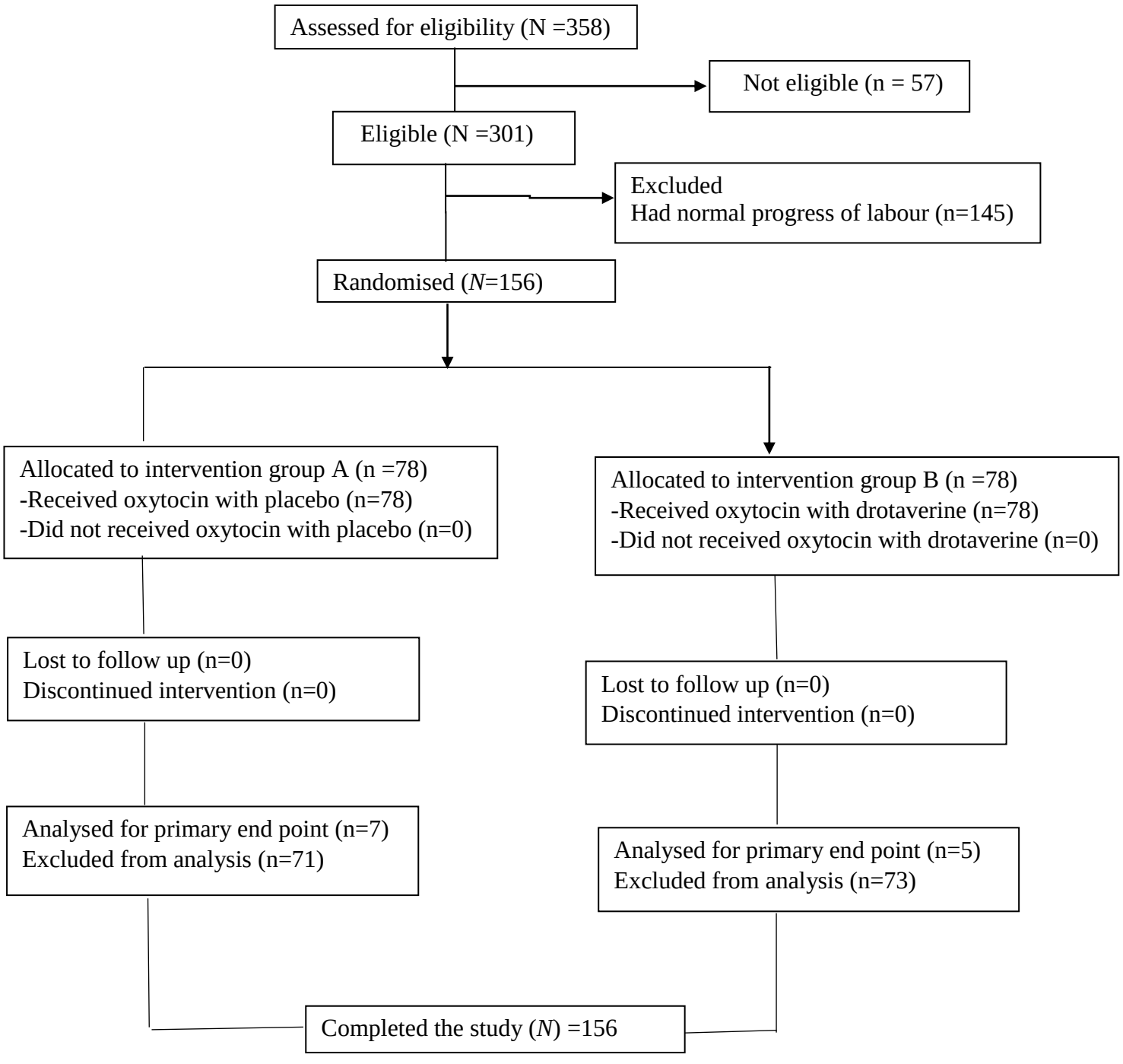

Figure 1: Consort diagram for the study

RESULTS

A total of 301 term nulliparous parturients were eligible for the study. of these, 145 had normal progress in labour while 156 had poor progress in labour as shown in Figure 1, giving an incidence of 51.8%. Parturients with poor progress were randomized into two groups of 78 each, Group A received oxytocin and a placebo while Group B received oxytocin and drotaverine.

Table 1 compared the socio-demographic characteristics of participants in both groups. The participants' age ranged between 20 and 40years and their gestational ages were between 37 and 41 weeks. The mean maternal ages of the groups were similar (28.78 ±6.23 years vs. 28.23±6.09 years, *p* = 0.58), the gestational ages were also similar (38.92 ± 1.48 vs.38.74±1.45 weeks, *p* = 0.45). The body mass index (BMI) in group A was similar to that of group B (24.68 ± 5.32 kg/m^{2}vs 24.87 ± 4.76 kg/m^2 p= 0.81). In Group A, the majority, 41 (52.6%) had a secondary level of education and in Group B the majority, 45 (57.7%) also had a secondary level of education. There was no significant difference in the educational level of both groups *p*=0.79. In Group A, 74 (94.9%) of the participants were married and in Group B 72(92.3%) were married. There was also no significant difference in the marital status of both groups (*p*= 0.51). Therefore, both groups were similar in their socio-demographic characteristics.

Table 1: Socio-demographic Characteristics of the Study Participants.

Characteristics		**Study groups (N) = 156**		**Test statistics**	**p-value**
		GROUP A (Oxyt +placebo, n= 78)	**GROUP B** (Oxyt+Drot, n=78)		
Maternal Age Range		21-40years	20-39years		
Mean Maternal Age		28.78 ±6.23years	28.23 ±6.09years	t (154) = 0.56	0.58
BMI (kg/m^2)		24.68 ± 5.32	24.87 ± 4.76	t (154) = 0.25	0.81
Mean Gestational age		38.92±1.48weeks	38.74±1.45weeks	t (154) = 0.76	0.45
Gestational Age Range		37-41weeks	37-41weeks		
Level of education	Primary	10 (12.8%)	8 (10.3%)	x2(1,156) = 0.49	0.79
	Secondary	41 (52.6%)	45 (57.7%)		
	Tertiary	27 (34.6%)	25 (32.0%)		
Marital status	Single	4(5.1%)	6(7.7%)	x2(1,156) = 0.43	0.51
	married	74(94.9%)	72(92.3%)		

x2(a,b) = chi-square test (degree of freedom, sample size), t(a) = t-test (degree of freedom)

In this study, 21(13.5%) of the participants had an emergency caesarean section, 127 (81.4%) had a vaginal delivery and 8 (5.1%) had a vacuum delivery. There was no difference in the mode of deliveries in both groups (p=0.82) as shown in Table 2.

Table 2: Mode of delivery of the Study Participants.

Mode of delivery	**GROUP A**(n= 78)	**GROUP B** (n=78)	Fisher exact test	p-value
Caesarean section n = 21(13.5%)	10 (12.8%)	11 (14.1%)	0.59	0.82
Vaginal delivery n=127 (81.4%)	63 (80.8%)	64 (82.1%)		
Vacuum delivery n= 8 (5.1%)	5(6.4%)	3(3.8%)		

Following augmentation 12 babies developed foetal distress in labour, Group A had 7 (58.3%) of the foetal distress and Group B had 5(41.7%). The majority, 9(75%) of the foetal distress occurred in the second stage of labour and predominantly had vacuum-assisted vaginal delivery, while 3 (25%) occurred in the first stage of labour and had an emergency caesarean section. In the second stage of labour, 5 (55.6%) of the foetal distress were in group A and 4 (44.4%) were in group B while in the first stage of labour, 2 (66.7%) of the foetal distress were in the Group A and 1 (33.3%) was in group B as shown in figure 1 and 2. All the babies recovered following neonatal resuscitation.

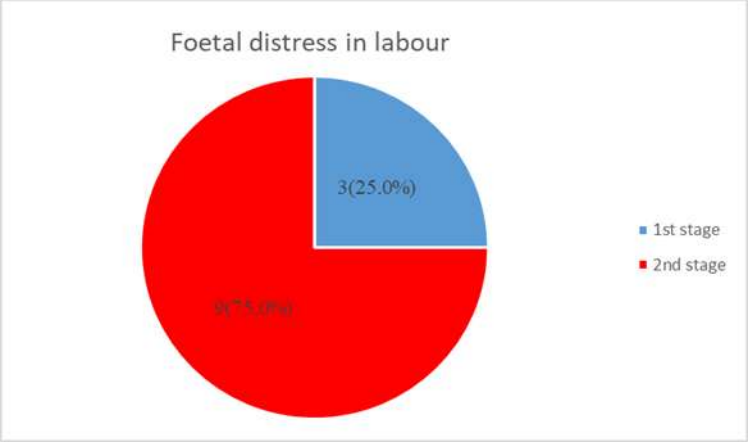

Figure 1: foetal distress in labour

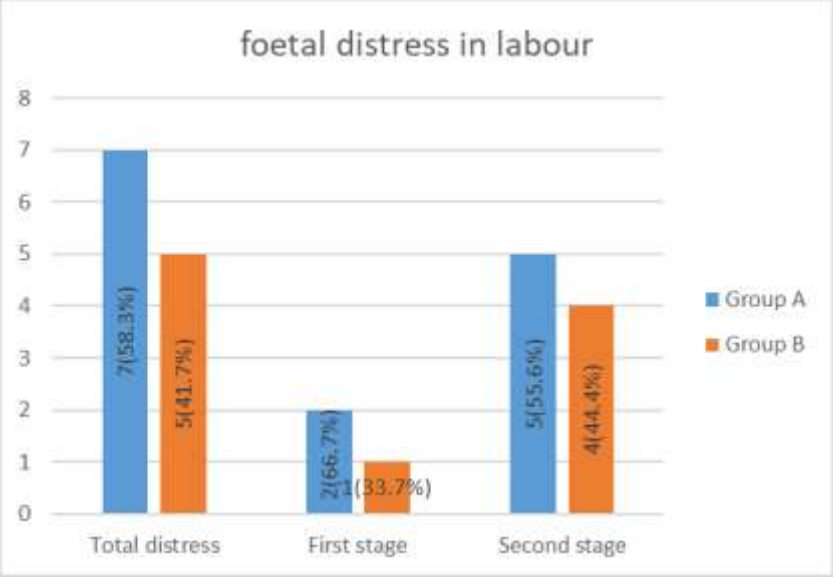

Figure 2: foetal distress in labour in the study groups

The incidence of birth asphyxia in the neonates of both groups was compared as shown in Table 3.

Table 3: neonatal asphyxiain both groups

		Study groups (N) =156		Test statistics	*p*-value
		Oxyt + placebo n =78	Oxyt +drotaverine n=78		
Birth asphyxia (first minutes Apgar score <7)	yes	7 (9.0%)	5 (6.4%)	$x^2(1,156) = 0.36$	0.55
	no	71 (91.0%)	73 (93.6%)		

HYPOTHESIS TESTING

Birth asphyxia rate

$H_0$1: There is no difference in the proportion of birth asphyxia among neonates in both groups.

$H_0$1: $P_{1A}= P_{1B}$

H_A1: There is a difference in the proportion of birth asphyxia among neonates in both groups.

H_A1: $P_{1A} \neq P_{1B}$

Level of significance (α) = 0.05

The proportion of birth asphyxia among neonates in group A (P_{1A}) = 9.0%

The proportion of birth asphyxia among neonates in group B (P_{1B}) = 6.4%

$x^2(1, N=156) = 0.361, p= 0.55$

The null hypothesis was retained at a 5% level of significance as $p> 0.05$. Hence, the evidence is inconsistent with any significant difference in the birth asphyxia rate among neonates in both groups.

DISCUSSION:

Poor progress in labour is a common complication with nulliparous deliveries[9]. In this study, 156 out of 301 eligible nulliparous parturients had poor progress in labour accounting for 51.8% of the cases and this is consistent with 50-55% in the general population[9,10]. The socio-demographic characteristics of both groups were similar and their modes of delivery were also similar. Hence the groups were homogeneous, and the differences in neonatal outcomes can be attributed to the effect of the intervention.

Foetal distress in labour is caused by intrauterine hypoxia occurring in the first or second stages of labour. This could arise from abnormalities in uterine contractions, labour progress or complication of the cord, placenta or liquor[1,5]. In this study, 3 (25%) of the foetal distress developed in the first stage and 9(75%) developed in the second stage of labour. The proportion of foetal distress in the oxytocin-drotaverine group was similar to that in the oxytocin-placebo group. Since oxytocin was common in both groups, the addition of drotaverine did not contribute to intrauterine hypoxia.

A good agent for the management of dysfunctional labour should improve the outcome of labour without compromising the neonatal outcome. In this study, 12 babies had birth asphyxia, the proportion of asphyxia in the oxytocin drotaverine group was not significantly different from the oxytocin placebo group (9.0% vs. 6.4%) p= 0.55, though there was an apparent trend towards a lower rate of birth asphyxia in the oxytocin-drotaverine group. Given that oxytocin was common in both groups, the addition of drotaverine did not worsen the neonatal outcome. This implies that drotaverine may not have a significant adverse neonatal effect which is consistent with the findings of previous studies[22-26]. The apparently lower trend in the birth asphyxia rate observed in the oxytocin-drotaverine group may be suggestive of a reduced side effect of oxytocin in this group, which may be due to reduced oxytocin requirement to effect delivery in this group due to fewer cervical spasms.

This study was limited to nulliparas at term with poor progress in labour and did not access maternal side effects. further studies are needed to assess the maternal side effects of combining oxytocin with drotaverine.

CONCLUSION

The study showed that the addition of drotaverine to the standard management of poor progress of labour with oxytocin titration in term nulliparas is not associated with increased adverse neonatal outcomes.

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Declarations

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Conflict of Interest: None declared

Ethical approval

Before the sample and data collection, ethical approval for the study was obtained from the Rivers State Health Research Ethics Committee. Individual written consent was also obtained.

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