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(RESEARCH ARTICLE)

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Cervical dilatation rate following augmentation of dysfunctional labour with oxytocin alone versus oxytocin and drotaverine among term nulliparas in the Rivers State University Teaching Hospital, Port Harcourt, Nigeria

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Abstract

Background: Dysfunctional labour is the commonest abnormality of the first stage of labour. It complicates 50% of nulliparous deliveries and is associated with increased perinatal morbidity and mortality. Dysfunctional labour occurs when the progress in the active phase of labour is abnormally slow (<1 cm/hr). It is largely due to ineffective uterine contractions or slow cervical dilatation. Augmentation of labour with oxytocin is the standard management of dysfunctional labour as it enhances uterine contractions. In many cases, despite good uterine contractions slow progress persists due to cervical smooth muscle spasms. Drotaverine a smooth muscle relaxant can be used to relieve cervical smooth muscle spasms.

Aim/objective: This study compared the cervical dilatation rate in term nulliparas following augmentation of dysfunctional labour with oxytocin versus oxytocin and drotaverine.

Methods: The study was a single-blinded randomized clinical trial involving 156 term nulliparous women with dysfunctional labour, who were randomized into two groups. Each group had 78 participants and received either oxytocin with a placebo or oxytocin with drotaverine. They were monitored until delivery and the cervical dilatation rates in both groups were compared. Data obtained were analysed using SPSS version 23 software. The level of significance was set at 0.05.

Results: The two groups were similar in their baseline characteristics, the mean pre-intervention cervical dilatation rate were also similar (0.53 cm/hr vs. 0.52 cm/hr, p = 0.85). Following augmentation, the cervical dilatation rate in the oxytocin-drotaverine group was significantly faster than in the oxytocin-placebo group (1.60 cm/hr vs. 1.20 cm/hr, p < 0.01).

Conclusion: The use of drotaverine with oxytocin in managing dysfunctional labour in term nulliparous women leads to a faster cervical dilatation rate.

Keywords: Dysfunctional labour; Labour augmentation; Oxytocin; Drotaverine; Nullipara

1. Introduction

Dysfunctional labour is the commonest complication of the first stage of labour [1,2]. It complicates about 50% of nulliparous and 10% of multiparous deliveries [3,4].

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Dysfunctional labour occurs when there is abnormally slow progress (<1 cm/hr) in the first stage of labour [5], and it is mainly due to abnormalities in the uterine contractions or slow cervical dilatation [4,5]. If no intervention, dysfunctional labour may degenerate into a secondary arrest of cervical dilatation or prolonged labour, which are associated with significant maternal and perinatal morbidity and mortality [4,5].

Amniotomy with oxytocin titration is the standard modality of managing dysfunctional labour as it improves uterine contractions [2,6]. At times, despite good uterine contractions slow progress persists due to cervical smooth muscle spasms, and antispasmodics can relieve these spasms [7,8]. However, antispasmodics are rarely used with oxytocin in managing dysfunctional labour.

Antispasmodics may be musculotropic or neurotropic. Musculotropic antispasmodics act directly on smooth muscles to inhibit phosphodiesterase enzyme causing a reduction in intracellular calcium and muscle tone, while neurotropic antispasmodics act indirectly by antagonising acetylcholine on the parasympathetic nerve endings supplying the muscle [7,8].

An ideal labour antispasmodic agent should have a short onset of action, a long duration of action, and no adverse effect on the mother and baby [9]. In search of an ideal labour antispasmodic agent, drotaverine a newer musculotropic antispasmodic has excellent pharmacological properties. The onset of action is about 30minutes, the duration of action is 4hours, and it has no significant adverse effect on the mother and baby [10]. Drotaverine could relieve cervical smooth muscle spasms, but it has not been used together with oxytocin in the management of dysfunctional labour.

Aim/objective

The study compared the mean cervical dilatation rate in term nulliparas with dysfunctional labour augmented with oxytocin alone versus oxytocin and drotaverine.

Study hypothesis

H01: There is no difference in the mean cervical dilatation rate in term nulliparas following augmentation of dysfunctional labour with oxytocin alone and with drotaverine

HA1: There is a difference in the mean cervical dilatation rate in term nulliparas following augmentation of dysfunctional labour with oxytocin alone and with drotaverine

2. Methodology

2.1. Study Area

The study was conducted at the labour ward of the department of Obstetrics and Gynaecology, Rivers State University Teaching Hospital (RSUTH) Port Harcourt. Rivers State is one of the thirty-six states in Nigeria located in the south-south region, and has a large reserve of crude oil and natural gas which makes it a hub of oil and gas industries. Rivers State has a population of 7,303,924 and Port Harcourt is its capital and largest city [11].

The RSUTH is the largest state-owned hospital and the only state-owned tertiary health facility in Rivers State located in Port Harcourt. It provides health care services for residents of the state and neighbouring states and also serves as a training facility for resident doctors and medical students of Rivers State University. The department has an average of 2,294 deliveries per year [12].

2.2. Study Population

The study was conducted amongst nulliparous parturients at the labour ward of the RSUTH.

2.2.1. Inclusion criteria

All booked nulliparous women at term with normal lie and presentation who went into labour spontaneously and gave consent.

2.2.2. Exclusion criteria

- Women with contraindications to vaginal delivery
- Women with multiple pregnancies, previous laparotomy, or obstetrics/medical co-morbidity

- Women who presented in advanced labour (cervical dilatation ≥7cm) and
- Women with known allergies to the intervention drugs.

2.3. Sample size determination

The sample size was calculated using the formula for comparison between two groups in a clinical trial [13].

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

Where:

Zα/2 = standard normal deviate (usually set at 1.96 for 95% confidence limit)
Zβ= 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% in a previous study = 0.93 [14]
P2= proportion of the parturient on placebo who had vaginal delivery was 76% in a previous study = 0.76 [14]

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

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

Assuming an attrition rate (AR) of 10% = 7.1
Sample size = 71 + 7.1 =78.1
A minimum sample size of 78 each was required in each study group.

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

2.4. Study design

This was a single-blinded randomized clinical trial.

2.5. Sampling Method

A multiphase random sampling was used. In the first phase, pregnant women were screened with routine history and examination, those who met the inclusion criteria were informed of the study and those who consented were recruited into the study and completed an informed consent form. In the second phase, all recruited parturients had an amniotomy done in the early active phase (4 to 5 cm cervical dilatation) and re-assessed in four hours. Those whose progress of labour was slower than 1 cm/hour were randomized into two groups by balloting and received either oxytocin with a placebo or oxytocin with drotaverine.

2.6. Study Procedure

All booked nulliparous women who were potentially eligible for the study were identified in the antenatal clinic and were informed about the study from the 35th week of gestation. When they presented in labour, history, examination and investigations were done for them as routine for women in labour. Those who met the inclusion criteria were identified and given detailed information about the study. Informed consent was obtained from those who indicated interest to participate.

The participants were evaluated as routine for women in labour and the findings were documented. An artificial rupture of foetal membranes (ARM) was done in the early active phase (4-5 cm cervical os dilatation) and the labour was monitored with a partograph.

A digital vaginal examination was repeated in four hours, women with normal labour progress of at least 1 cm/hour were excluded from the study and continued with routine care. while women with a slow cervical dilatation rate of less than 1 cm/hour were considered to have dysfunctional labour having excluded mechanical and other causes of poor

progress. They were randomized into two groups for augmentation of labour. Group A was augmented using oxytocin with a placebo while Group B was augmented using oxytocin with drotaverine.

The randomization was done by balloting. The women balloted from a set of folded pieces of paper in a box (in which either code A or B was written) until a sample size of 78 women per group was reached. The box contained 156 folded pieces of paper from the inception, code A was written in 78 of the papers and code B was also written in 78 of the papers.

Code A represents 2 ml of normal saline mixed with vitamin B-complex. This was constituted by adding 5 ml of injection vitamin B-complex into 1 litre of normal saline, from this, 2 ml was withdrawn and put in a 2 ml syringe. Code B represents 2 ml (40 mg) of drotaverine, which was also withdrawn and put into a 2 ml syringe. Both A and B were the same colour, the parturients were blinded to what each code represented.

Three drug packs were provided and stored in the labour ward refrigerator. Two of the packs were labelled either A or B. Pack A contained several 2 ml syringes, with each containing 2 mls of normal saline-vitamin B complex mixture, this served as a placebo. Pack B contained several 2 ml syringes, with each containing 2 mls (40 mg) of drotaverine. The third pack was not labelled, and it contains several ampoules of oxytocin. These packs were supplied in batches of ten drugs per day.

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

The biodata of each research participant, the intervention group, the time and cervical dilatation at the diagnosis of the active phase, and full cervical dilatation were recorded. The study spanned from 7th January 2021 to 23rd August 2021.

2.7. Data Analysis

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

Descriptive analysis was done for socio-demographic characteristics. The student t-test was used to compare the mean cervical dilatation rate in both groups. The level of significance (α) was set at 0.05.

2.8. Consort flow diagram for the study

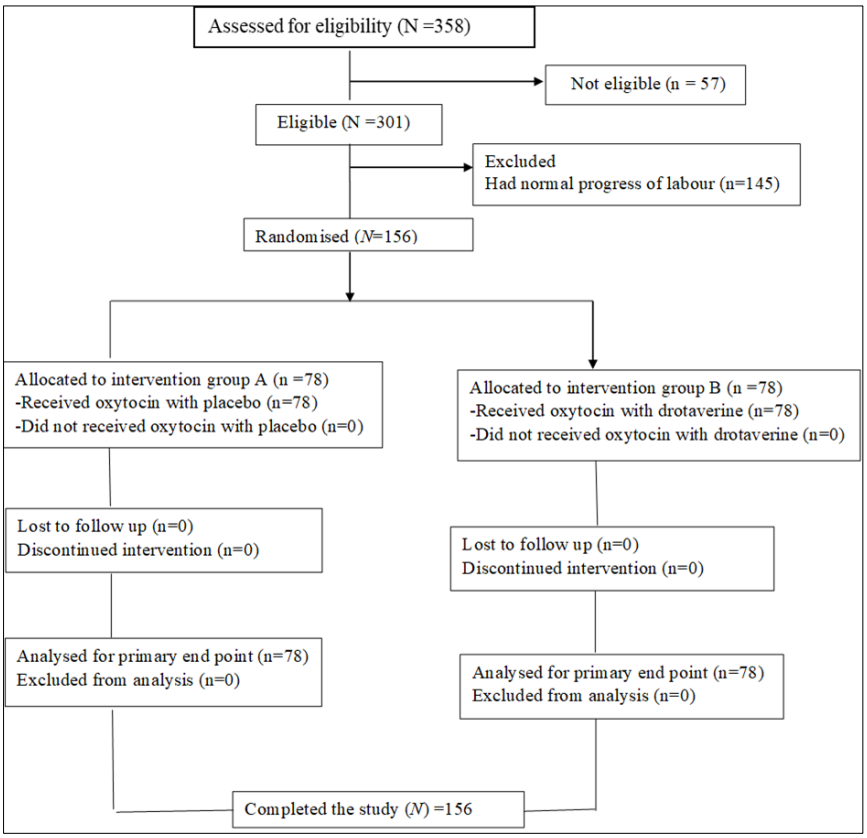

Figure 1 Consolidated Standards of Reporting Trials

3. Results

A total of 156 out of 301 eligible parturients had dysfunctional labour and participated in the study, giving an incidence of 51.8%.

Table 1 Pre-intervention Characteristics of the Study Participants

Characteristics		**Study groups (N) = 156**		**Test statistics**	**p-value**
		GROUP A (Oxytocin with Placebo) n= 78	**GROUP B (Oxytocin with Drotaverine) n=78**		
Maternal Age Range		21 - 40 years	20 - 39 years		
Mean Maternal Age		28.78 ± 6.23 years	28.23 ± 6.09 years	t (154) = 0.56	0.58
Gestational Age Range		37 - 41 weeks	37 - 41 weeks		
Mean Gestational age		38.92 ± 1.48 weeks	38.74 ± 1.45 weeks	t (154) = 0.76	0.45
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	Married	74(94.9%)	72(92.3%)	x2 (1,156) = 0.43	0.51
	Single	4(5.1%)	6(7.7%)		

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

Table 1 shows the pre-intervention characteristics of the study participants which include their socio-demographic characteristics and pre-intervention cervical dilatation rate. The mean maternal age of Group A was 28.78 years (SD = 6.23) which was similar to that of Group B which was 28.23 years (SD= 6.09) p = 0.58. The gestational ages in both groups were also similar (38.92 ± 1.48 weeks vs. 38.74 ± 1.45 weeks, p = 0.45). In Group A, majority, 41 (52.6%), had secondary education and in Group B majority, 45 (57.7%), had secondary education. There was no difference in the educational level of both groups p = 0.79. In group A, 74 (94.9%) of the parturients were married and in group B 72 (92.3%) were married. There was also no difference in the marital status of both groups (p = 0.51). The mean pre-intervention cervical dilatation rate in group A was 0.53 ± 0.24 cm/hr which was similar to that of group B 0.52 ± 0.19 cm/hr, p = 0.85. Therefore, both groups were similar in all their baseline characteristics.

Following the intervention, the mean cervical dilation rate in both groups was compared as shown in Table 2.

Table 2 Cervical dilation rate before and after intervention

Variables	**Study groups (N) = 156**		**Test statistics**	**p-value**
	GROUP A Oxytocin with placebo (n =78)	**GROUP B Oxytocin with drotaverine (n = 78)**		
Mean pre-intervention cervical dilatation rate	0.53 ± 0.24 cm/hr	0.52 ± 0.19 cm/hr	t (154) = 0.18	0.85
Mean post-intervention cervical dilatation rate	1.20 ± 0.17 cm/hr	1.60 ± 0.06 cm/hr	t (154) = 18.76	< 0.01*

*= statistically significant

3.1. Hypotheses testing

H01: There is no difference in the mean cervical dilatation rate in both groups after intervention.

$$H01: \mu 1A = \mu 1B$$

HA1: There is a difference in the mean cervical dilatation rate in both groups after intervention.

$$HA1: \mu 1A \neq \mu 1B$$

Level of significance (α) = 0.05
Mean cervical dilatation rate (±SD) in group A after intervention (x1A) =1.20 ± 0.17 cm/hr
Mean cervical dilatation rate (±SD) in group B after intervention (x1B) =1.60 ± 0.06 cm/hr
t (154) = 5.20, p<0.01

The null hypothesis was rejected at a 5% level of significance as p < 0.05. Thus, there is convincing evidence that participants in Group B had a faster cervical dilatation rate after the intervention compared to participants in Group A.

4. Discussion

Primary dysfunctional labour is a very common complication of nulliparous labour. In this study 156 out of 301 eligible nulliparous women developed dysfunctional labour which gives an incidence of 51.8% which is consistent with 50% in the general population [3,4]. The socio-demographic characteristics and pre-intervention cervical dilation rate in the study groups were similar, hence the groups were homogeneous and the differences observed can be attributed to the effect of the intervention.

The mean cervical dilatation rates in both groups were increased from less than 1 cm/hr before intervention to greater than 1 cm/hr after the intervention, with each group at least doubling its initial cervical dilation rate. This may be due to oxytocin which was common in both groups and has been shown in previous studies to cause a faster cervical dilatation rate by improving the effectiveness of uterine contractions [15-22]. However, the mean cervical dilatation rate in the oxytocin drotaverine group was 25% faster than in the oxytocin placebo group (1.6 cm/hr vs. 1.2cm/hr, p < 0.01). This implies that drotaverine may have contributed to the faster cervical dilatation rate of Group B, which was consistent with earlier studies [8, 23-25]. Dysfunctional labour results mainly from ineffective uterine contraction or slow cervical dilation. While oxytocin improves uterine contractions, cervical dilatation may still be delayed by smooth muscle spasms. Drotaverine selectively acts on the lower uterine segment and cervix to relieve spasms without affecting the upper segment or interfering with the uterine contractions [9,10,23]. This may have resulted in the faster cervical

dilatation noticed in the oxytocin-drotaverine group. Also, there may have been a synergy between oxytocin and drotaverine in enhancing the progress of labour.

This study was limited to nulliparous women at term with dysfunctional labour in RSUTH where all labour is managed according to protocol. In addition, this study did not assess side effects and maternal satisfaction. Further multi-centre studies may be needed to address this and improve the generalizability.

5. Conclusion

The study showed that the addition of drotaverine to the standard management of dysfunctional labour with oxytocin titration in term nulliparas resulted in a significantly faster cervical dilatation rate. Given these findings, the Obstetrics and Gynaecology department of RSUTH should consider adding drotaverine to the protocol for managing term nulliparas with dysfunctional labour.

Compliance with ethical standards

Acknowledgments

The authors wish to acknowledge the contributions of the interns and resident doctors who voluntarily assisted in collecting data from the participants.

Disclosure of conflict of interest

No conflict of interest statement.

Statement of ethical approval

Before the sample and data collection, the proposal was submitted to the Rivers State Health Research Ethics Committee, as the study involved human subjects. An ethical clearance letter was obtained.

Statement of informed consent

Informed written consent was obtained from all participants included in the study.

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