

## Comparative evaluation of the caesarean section rate in term nulliparas with labour dystocia following augmentation with oxytocin alone versus with oxytocin and drotaverine

Awopola Ibiebelem Jumbo <sup>1,\*</sup>, Esther Ijeoma Nonye-Enyidah <sup>1</sup>, Rose Sitonma Iwo-Amah <sup>1</sup>, Nonyenim Solomon Enyidah <sup>2</sup>, Bapakaye Ngeri <sup>1</sup>, Peacebe Sunday Abere <sup>1</sup>, Chinweowa Ohaka <sup>1</sup> and Roseline Beauty Iheagwam <sup>1</sup>

<sup>1</sup> Department of Obstetrics and Gynaecology, Rivers State University Teaching Hospital, Port-Harcourt, Nigeria.

<sup>2</sup> Department of Internal Medicine, Rivers State University, Port-Harcourt, Nigeria.

World Journal of Advanced Research and Reviews, 2023, 18(03), 1041–1050

Publication history: Received on 07 May 2023; revised on 16 June 2023; accepted on 19 June 2023

Article DOI: <https://doi.org/10.30574/wjarr.2023.18.3.1170>

### Abstract

**Background:** Labour dystocia is the commonest indication for emergency caesarean section in nulliparas, and occurs when the progress of labour is abnormally slow. Labour dystocia may be caused by abnormalities in uterine contractions, slow cervical dilatation, or mechanical disproportion between the foetal presenting part and the maternal pelvis.

Augmentation of labour with oxytocin is the traditional management for labour dystocia as it enhances uterine contractions. At times, despite good uterine contractions, dystocia persists due to cervical smooth muscle spasms or mechanical factors, thereby increasing the caesarean section rate. Drotaverine is a musculotropic antispasmodic and can relieve smooth muscle spasms.

**Aim/objective:** This study compared the caesarean section rate in term nulliparas with labour dystocia that were augmented with oxytocin and placebo versus with oxytocin and drotaverine

**Methods:** This study was a single-blinded randomized clinical trial conducted between January and August 2021. It involved 156 term nulliparous women with labour dystocia that were randomized into two groups for augmentation of labour. Each group had 78 parturients that were managed with either oxytocin with a placebo or oxytocin with drotaverine. They were monitored till delivery and the caesarean section rate in both groups was compared. Data obtained were analysed with SPSS version 23 software. The level of significance was set at 0.05,  $P < 0.05$  was statistically significant.

**Results:** The two groups were similar in their sociodemographic characteristics. In this study 21(13.5%) women had emergency caesarean section while 135(86.5%) had vaginal delivery following augmentation. The caesarean section rate in the oxytocin-placebo was similar to the oxytocin-drotaverine group (10 (12.8%) vs 11 (14.1%),  $p=0.82$ ). The majority, 14 (67%) of the caesarean sections were due to mechanical factors, 4 (19%) were due to functional dystocia and 3(14%) were due to foetal distress.

**Conclusion:** The use of drotaverine with oxytocin in managing labour dystocia did not improve the caesarean section rate as the majority of the cases had mechanical dystocia.

**Keywords:** Labour dystocia; Caesarean section; Drotaverine; Oxytocin

\* Corresponding author: Awopola Ibiebelem Jumbo

## 1. Introduction

Labour dystocia is the commonest indication for emergency caesarean section in nulliparas, and accounts for about 55% of primary caesarean section[1-3]. It occurs when the progress of labour is abnormally slow in the first or second stages of labour[3,4]. The progress of labour is assessed by the uterine contractions, cervical dilatation rate or descent of the presenting part[5].

The normal cervical dilatation rate in the first stage of labour is at least 1cm/hr and is an important determinant of the total duration of labour[5,6]. This progress in the first stage of labour becomes abnormally slow when the cervical dilatation rate is less than 1cm/hr, and this occurs mainly due to abnormalities in the uterine contractions or slow cervical dilatation[4,7].

Labour dystocia may be functional or mechanical[5]. Functional dystocia occurs due to abnormalities in uterine contractions or slow cervical dilatation and is commoner in the first stage of labour while mechanical dystocia occurs due to misfit or disproportion between the presenting part and the maternal pelvis[4,5]. Labour dystocia is commoner in nulliparas due to a high incidence of uterine inertia[6,8]. Without intervention, slow progress can degenerate into secondary arrest or prolonged labour with a significant increase in maternal and perinatal morbidity and mortality[8].

Amniotomy with oxytocin augmentation is the standard management of dystocia as it improves uterine contractions[9,10]. However, despite adequate contractions, dystocia could persist due to cervical smooth muscle spasms or mechanical factors[5,11]. Antispasmodics could relieve smooth muscle spasms but are rarely tried in persistent poor progress following augmentation with oxytocin, the usual next line of management is to resort to emergency caesarean section[3,11].

The caesarean section rate is rising globally, the recommended caesarean section rate is about 10-15% and the WHO stated that the caesarean section rate above 15% constitutes unnecessary maternal risk[12]. The incidence of caesarean section in developing countries is over 25%, with labour dystocia as the leading indication for primary caesarean section[2,13]. Mechanical factors and cervical smooth spasms are common causes of persistent poor progress despite oxytocin augmentation[5,11].

Antispasmodics can relieve smooth muscle spasms and thus may reduce the incidence of unnecessary caesarean section. Antispasmodics are classified based on their mechanism of action as neurotropic or musculotropic[14]. Neurotropic antispasmodics act indirectly on the muscarinic receptors of the nerve endings supplying the smooth muscle to inhibit acetylcholine and muscle tone, they have anti-muscarinic side effects[14]. Musculotropic antispasmodics act directly on smooth muscles to relieve muscle tone by inhibiting phosphodiesterase IV enzymes, they lack anti-muscarinic side effects[14].

An ideal antispasmodic for use in labour should have a short onset of action, a long duration of action, and no significant adverse effect on the mother or foetus[14,15]. In the search for an antispasmodic agent ideal for labour, drotaverine a novel musculotropic antispasmodic has superior pharmacokinetics[15,16]. The onset of action is 30 minutes, the duration of action is 4 hours, and it has no significant adverse effect on the mother or foetus[15,16]. When compared with other antispasmodic agents drotaverine has a minimal side effect profile[15,16]. Drotaverine has shown an excellent effect on relieving cervical smooth muscle spasms, it acts on the lower uterine segment and cervix without affecting uterine contractions[15,17].

Cervical smooth muscle spasm is one of the reasons for persistent dystocia and caesarean section despite augmentation with oxytocin. Drotaverine can relieve these spasms and perhaps reduce the caesarean section rate. However, it is scarcely used with oxytocin in literature for the management of labour dystocia.

### *Aim/objective*

The study compared the caesarean section rate in term nulliparas with labour dystocia augmented with oxytocin and placebo versus with oxytocin and drotaverine

### 1.1. Study hypothesis

- $H_{01}$ : There is no difference in the caesarean section rate in term nulliparas with labour dystocia augmented with oxytocin and placebo versus with oxytocin and drotaverine.
- $H_{A1}$ : There is a difference in the caesarean section rate in term nulliparas with labour dystocia augmented with oxytocin and placebo versus with oxytocin and drotaverine.

### 1.2. Definition of research terms

- **Labour dystocia:** This is abnormally slow progress in the active phase of labour characterized by a cervical dilatation rate of <1cm/hr
- **Term:** This is a period of gestation between 37 weeks to 41 weeks +6days during which perinatal outcome is optimal. It was calculated from the first-trimester ultrasound report or the first day of the last menstrual period.
- **Nullipara:** This is a pregnant woman who has not had any live birth or delivery beyond the age of foetal viability.
- **Amniotomy:** This is an artificial rupture of the foetal membranes in labour
- **Augmentation of labour:** This is the use of chemical agents to accelerate the progress of labour
- **Antispasmodics:** These are agents used to relieve smooth muscle spasms
- **Mechanical dystocia:** This is a slow progress of labour caused by a misfit between the foetal head and the maternal pelvis. It may manifest as cephalopelvic disproportion, delayed second stage, deep transverse arrest or features of obstruction.
- **Functional dystocia:** This is a slow progress in the active phase of labour caused by abnormalities in uterine contractions or cervical dilation.
- **Cephalopelvic disproportion:** This is a misfit between the foetal head and maternal pelvis leading to slow progress in labour with worsening caput and moulding
- **Deep transverse arrest:** This is the failure of descent and rotation of the foetal head from the transverse position at or just above the ischial spines in the second stage of labour
- **Delayed second stage:** This is a second stage of labour lasting more than 3hours
- **Features of obstruction:** This is the failure of descent of the foetal head associated with marked caput and moulding
- **Secondary arrest:** This is a functional dystocia in which there is no change in cervical dilatation on two vaginal examinations done 4hours apart
- **Foetal distress:** This is a persistent abnormality in the foetal heart rate or rhythm that does not improve with intrauterine resuscitation

---

## 2. Material and methods

### 2.1. Study Area

The study was conducted at the labour ward and theatre of the Rivers State University Teaching Hospital (RSUTH) Port Harcourt. Rivers State is one of the 36 states in Nigeria and is located in the south-south region of the country. Port Harcourt is the capital and largest city. Rivers State has a huge reservoir of crude oil and natural gas making it a heart of oil and gas industries in Nigeria. The population of the state is about 7,303,924 people[18].

The RSUTH is a tertiary health facility in Port Harcourt and the largest state-owned hospital. It provides health services for residents of the state and neighbouring states, and also functions as a referral centre and centre for the training of resident doctors and medical students of Rivers State University. The hospital has an average of 2294 deliveries per year and caesarean section accounted for 38.4% of the deliveries[19,20]. One-quarter of these caesarean sections (9.6%) were due to labour dystocia in nulliparas[19,20]

### 2.2. Study Population

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

### 2.3. Inclusion criteria

All booked nulliparous women with normal lie and presentation who had spontaneous labour at term and gave consent

## 2.4. Exclusion criteria

Conditions where vaginal delivery is contraindicated Parturients with multiple gestations, a previous laparotomy, or medical/obstetric co-morbidity parturients who presented with ruptured membranes or advanced labour (cervical dilatation  $\geq 7\text{cm}$ ) and Women with allergies to either medication.

## 2.5. Sample size determination:

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

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

Where:

$Z\alpha/2$  = standard normal deviate (usually set at 1.96 for 95% confidence limit)

$Z\beta$  = power of the study (usually set at 80% = 0.84)

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

$P1$  = proportion of the women on drotaverine who had caesarean section was 7% in a previous study = 0.07.[20]

$P2$  = proportion of the women on placebo who had caesarean section was 24% in a previous study = 0.24. [20]

$$P = \frac{0.07 + 0.24}{2} = 0.155$$

$$n = \frac{2(1.96 + 0.84)^2 0.155(1 - 0.155)}{(0.07 - 0.24)^2} = 71$$

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

Sample size per group = 71 + 7.1 = 78.1

A minimum sample size of 78 each was required in each study group.

Therefore, a total of 156 women participated in the study.

## 2.6. Study design

The study was a single-blinded randomized clinical trial.

## 2.7. Sampling Method

A multiphase random sampling was utilized. In the first phase, parturients were screened with history and examination, those who were eligible were identified and informed of the study, and written informed consent was obtained from interested parturients. In the second phase, an amniotomy was done for all the parturients in the early active phase of labour (4 to 5cm cervical dilatation) and they were re-assessed in four hours. Those with poor progress in labour (<1cm/hour) were identified and randomized into two groups. Both groups received augmentation with either oxytocin and a placebo or oxytocin and drotaverine.

## 2.8. Study Procedure

All booked potentially eligible pregnant women were identified in the antenatal clinic from the 35th week of gestation and were pre-informed about the study. When they presented in labour history clinical examination and investigations were done for them as routine for women in labour. Eligible parturients were identified and provided with details of the study procedure. Informed written consent was obtained from those who demonstrated interest to participate.

The participants were evaluated as routine for women in labour and the findings were documented. An amniotomy was done for them 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 progress of labour  $\geq 1\text{cm}/\text{hour}$  were excluded from the study and continued with routine care. Women with a cervical dilatation rate of  $< 1\text{cm}/\text{hour}$  were considered to have labour dystocia and were randomized into two groups for augmentation of labour. Group A was augmented with oxytocin and placebo while Group B was augmented with oxytocin and drotaverine.

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

Three drug packs were stored in the department's refrigerator. Two of the packs were coded either A or B. Pack A contained several 2ml syringes, each containing 2mls of normal saline-vitamin B complex mixture that served as a placebo. Pack B contained several 2ml syringes containing 2mls (40mg) of drotaverine. The third pack was unlabelled and contained several ampoules of oxytocin. These packs were supplied in batches of ten daily.

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

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

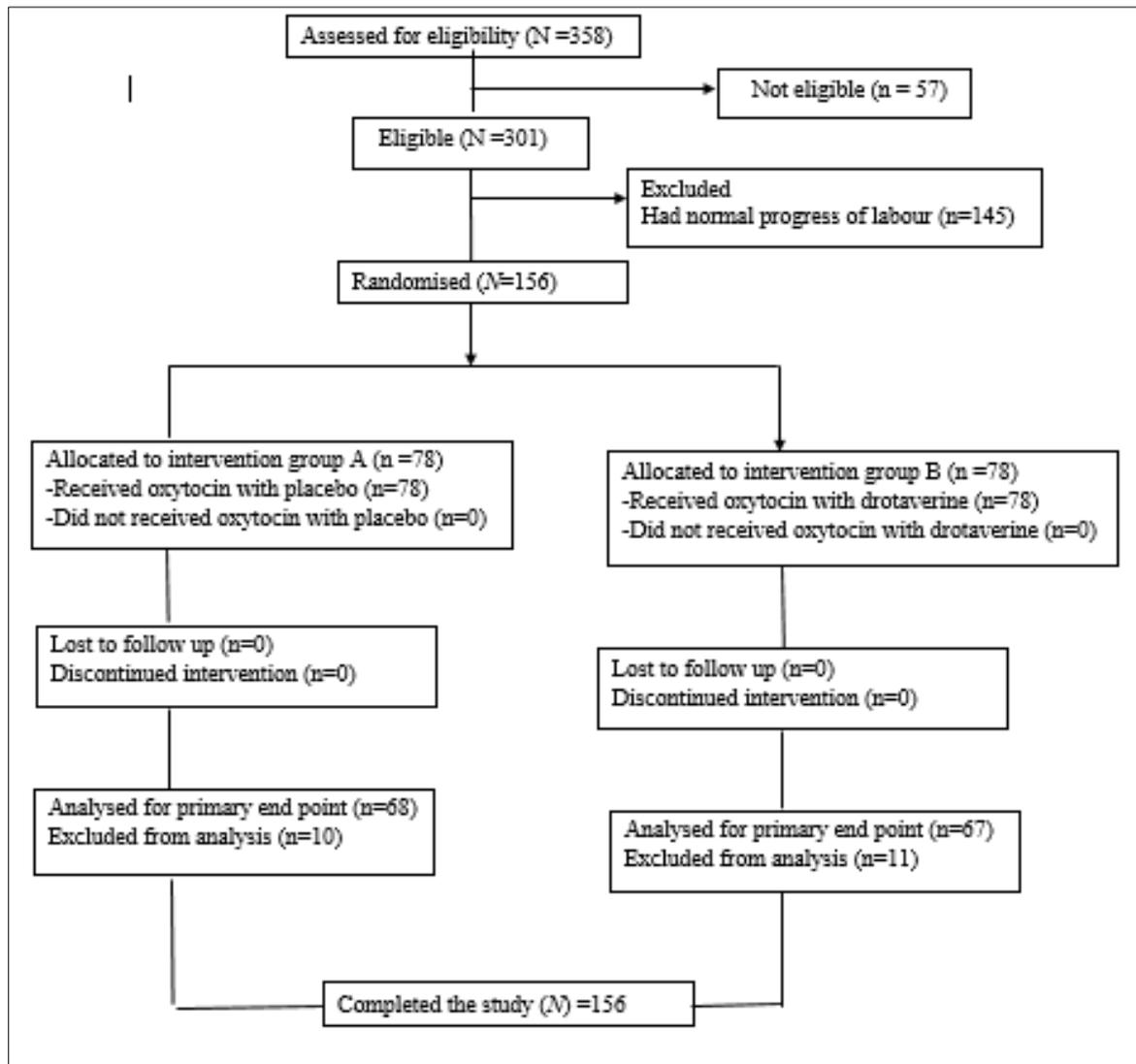
The biodata of each participant, the intervention group, the time and cervical dilatation at the diagnosis of the active phase and subsequent examination were recorded. The mode of delivery and indications for caesarean section were also recorded. The study started on 7/1/2021 and ended on 23/8/2021.

## 2.9. Data Analysis

The data obtained were 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 deviations.

Descriptive analysis was done for socio-demographic characteristics. The chi-square test was used to compare the proportion of caesarean sections in both groups, the indications for the caesarean sections in both groups were also compared using the Fischer exact test. The level of significance ( $\alpha$ ) was set at 0.05, a p-value of  $< 0.05$  was considered statistically significant.

### 2.10. Consort flow diagram for the study



**Figure 1** Consort flow diagram for the study

### 3. Results

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

Table 1 showed the socio-demographic characteristics of the study participants. The participants' age ranged between 20 and 40 years and their gestational ages were between 37 and 41 weeks. The mean maternal ages of Groups A and B were similar ( $28.78 \pm 6.23$  vs.  $28.23 \pm 6.09$  years,  $p = 0.58$ ). The gestational ages in both groups were also similar ( $38.92 \pm 1.48$  vs.  $38.74 \pm 1.45$  weeks,  $p = 0.45$ ). In Group A, the majority, 41 (52.6%) had a secondary level of education and in Group B the majority, 45 (57.7%) had a secondary level of education. There was no significant difference in the educational attainments 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 all their sociodemographic characteristics.

**Table 1** Pre-intervention Characteristics of the Study Participants

Characteristics		Study groups (N) = 156		Test statistics	p-value
		GROUP A (Oxytocin Placebo) n= 78	GROUP B (Oxytocin Drotaverine) 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
Gestational Age Range		37-41weeks	37-41weeks		
Mean Gestational age		38.92±1.48weeks	38.74±1.45weeks	t (154) = 0.76	0.45
Level of education	Primary	10 (12.8%)	8 (10.3%)	x <sup>2</sup> (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%)	x <sup>2</sup> (1,156) = 0.43	0.51
	Single	4(5.1%)	6(7.7%)		

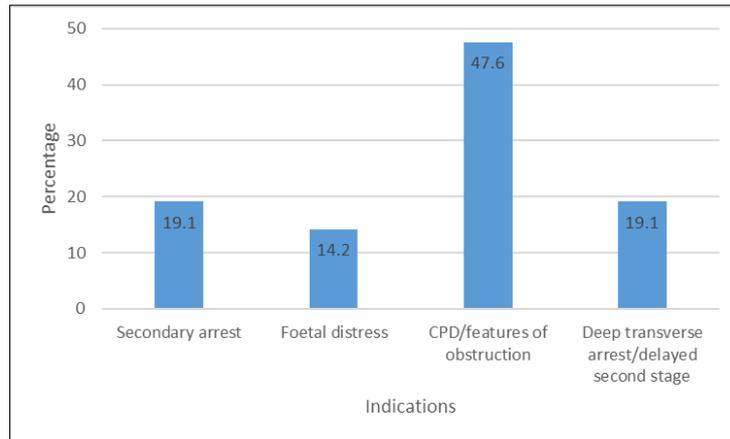
x<sup>2</sup>(a,b) = chi-square test (degree of freedom, sample size), t(a) = t-test (degree of freedom)

Following augmentation, 21 (13.5%) of the parturients had emergency caesarean section while 135 (86.5%) had vaginal deliveries. Among the caesarean sections, 10 (12.8%) were in Group A and 11 (14.1%) were in Group B there is no difference in the caesarean section rates in both groups (p=0.82) as shown in Table 2. The indications for the caesarean sections were secondary arrest (19.1%), foetal distress (14.2%) CPD/features of obstruction (47.6%) and Deep transverse arrest/delayed second stage (19.1%) as shown in figure 1. When these indications were subdivided based on the study groups as shown in Table 2, there was also no difference in the indication for caesarean section in both groups.

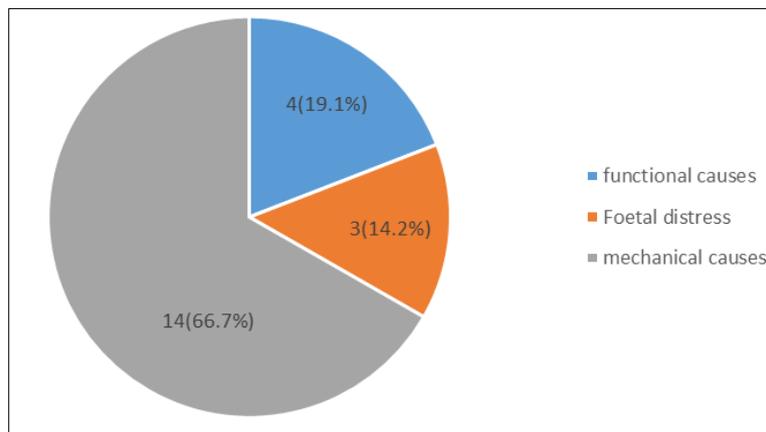
Figure 2 showed that the majority, 14 (66.7%) of the caesarean sections were due to mechanical dystocia, 4 (19.1%) were due to functional dystocia and 3(14.2%) were due to foetal distress.

**Table 2** Caesarean section rate and indications in both groups

		Study groups (N) =156		Test statistics	p-value
		Oxytocin alone n =78	Oxytocin with drotaverine n=78		
Mode of surgery	Caesarean section n=21(13.5%)	10 (12.8%)	11 (14.1%)	x <sup>2</sup> (1,156) = 0.06	0.82
	Vaginal delivery n=135 (86.5%)	68 (87.2%)	67 (85.9%)		
Indications for Caesarean Section	Secondary arrest	3(30.0%)	1(9.1%)	Fisher exact=2.6	0.52
	Foetal distress	2 (20.0%)	1(9.1%)		
	CPD/features of obstruction	4 (40.0%)	6(54.5%)		
	Deep transverse arrest/delayed second stage	1 (10.0%)	3(27.3%)		



**Figure 2** Indications for caesarean section



**Figure 3** The underlying cause of caesarean section

### 3.1. Hypotheses testing

#### 3.1.1. Caesarean section rate

H<sub>0</sub>1: There is no difference in the caesarean section rate in both groups.

$$H_{01}: P_{1A} = P_{1B}$$

H<sub>A</sub>3: There is a difference in the caesarean section rate between the two groups

$$H_{A1}: P_{1A} \neq P_{1B}$$

Level of significance ( $\alpha$ ) = 0.05

The proportion of caesarean section in Group A ( $P_{1A}$ ) = 12.8%

The proportion of caesarean section in Group B ( $P_{1B}$ ) = 14.1%

$$\chi^2(1, N= 156) = 0.06, p= 0.82$$

The null hypothesis was retained at a 5% level of significance as  $p > 0.05$ . Therefore, there is insufficient evidence to support any difference in the caesarean section rate in both groups.

#### 4. Discussion

Labour dystocia is a common complication of nulliparous deliveries[1]. In this study, 156 out of 301 eligible nulliparous parturients had labour dystocia accounting for 51.8% which is consistent with 50-55% in the general population[3,8]. The socio-demographic characteristics of both groups were similar hence the groups were homogeneous, and the differences can easily be attributed to the effect of the intervention.

Caesarean section is an essential surgical intervention to reduce maternal and perinatal morbidity and mortality when complications develop in labour. In this study, 21 (13.5%) parturients had emergency caesarean sections and n=135 (86.5%) had vaginal deliveries. The proportion of caesarean section in the oxytocin drotaverine group was similar to the oxytocin placebo group (14.1 vs. 12.8%) p=0.82. Given that oxytocin was common to both groups, the addition of drotaverine did not alter the caesarean section rate. This may be because the majority of the labour dystocia in the study were mechanical dystocia 14 (66.7%), which is the commonest type of dystocia in the sub-region[5,6] and is not amenable to antispasmodics. The findings of this study were consistent with the findings of Tile et al[17] and Ibrahim et al[22] but differed from that of Sabeen et al[23] who reported a significant reduction in the caesarean section rate. This variation may be due to the differences in population, and inclusion of both nulliparous and multiparous women in the latter study.

This study was limited to the term nulliparas with labour dystocia in RSUTH. In addition, this study did not assess maternal satisfaction, neonatal outcome and side effects of combining both drugs. Further multi-centre studies may be required to address this and improve the generalizability.

---

#### 5. Conclusion

The study showed that the addition of drotaverine to the standard management of labour dystocia with oxytocin augmentation in term nulliparas does not alter the caesarean section rate. Given these findings, there is a need to search for alternatives to reduce the rising primary caesarean rate in the sub-region.

---

#### Compliance with ethical standards

##### *Acknowledgments*

The authors wish to acknowledge the resident doctors, nurses and interns who voluntarily assisted in collecting data for the study.

##### *Disclosure of conflict of interest*

No conflict of interest.

##### *Statement of ethical approval*

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

##### *Statement of informed consent*

Individual written consent was also obtained.

---

#### References

- [1] McEwan A. Abnormal labour: an evidence-based approach. *Current Obstetrics and Gynaecology*. 2001, 11(4):245-50.
- [2] Taylor L, Long A. Abnormal labour. *Obstetrics, Gynaecology & Reproductive Medicine*. 2016, 26(3):85-8.
- [3] LeFevre NM, Krumm E, Cobb WJ. Labor dystocia in nulliparous women. *American Family Physician*. 2021, 103(2):90-6.
- [4] O'Riordan N, Robson M, McAuliffe FM. Management of poor progress in labour. *Obstetrics, Gynaecology & Reproductive Medicine*. 2021, 31(12):342-50.

- [5] Bernal AL, Norwitz ER. Normal mechanisms in labour. In: Edmonds DK, editor. *Dewhurst's Textbook of Obstetrics & Gynaecology*, 9th ed. New Jersey: John Wiley & Sons Ltd, 2012. 247–68.
- [6] Karaçam Z, Walsh D, Bugg GJ. Evolving understanding and treatment of labour dystocia. *European Journal of Obstetrics & Gynecology and Reproductive Biology*. 2014 Nov 1, 182:123-7.
- [7] Sharma D, Jain D, Sharma A. The clinical evaluation of course of labour using modified who partograph. *International Journal of Clinical Obstetrics and Gynaecology* 2022, 6(3): 45-51
- [8] El-Hamamy E, Arulkumaran S. Poor progress of labour. *Current Obstetrics & Gynaecology*. 2005, 15(1):1-8.
- [9] Nabhan A, Boulvain M. Augmentation of labour. *Best Practice and Research: Clinical Obstetrics and Gynaecology*. 2020, 67: 80–9.
- [10] ACOG Practice Bulletin No. 49: Dystocia and Augmentation of Labor. *Int J Gynecol Obstet*. 2004, 85(3):315–24.
- [11] Aziz M. Review Prolong Labour - Role of Antispasmodics and Prostaglandins. *Int J Sci Eng Res*. 2016, 7(11):123-8.
- [12] Wise J. Alarming global rise in caesarean births, figures show. *BMJ*. 2018, 363:k4319.
- [13] Betrán AP, Ye J, Moller AB, Zhang J, Gülmezoglu AM, Torloni MR. The increasing trend in caesarean section rates: global, regional and national estimates: 1990-2014. *PloS one*. 2016, 11(2):e0148343.
- [14] Rohwer AC, Khondowe O, Young T. Antispasmodics for labour. *Cochrane Database Syst Rev*. 2013, (6): CD009243.
- [15] Dhungana PR, Adhikari R, Pageni PR, Koirala A, Nepal A. A prospective study on the effectiveness of drotaverine in the acceleration of labour. *Med J Pokhara Acad Heal Sci*. 2019, 2(3):137–41.
- [16] Bolaji OO, Onyeji CO, Ogundaini AO, Olugbade TA, Ogunbona FA. Pharmacokinetics and bioavailability of drotaverine in humans. *Eur J Drug Metab Pharmacokinet*. 1996, 21(3):217–21.
- [17] Tile R, Jamkhandi S. To study the efficacy and safety of Drotaverine hydrochloride in augmentation of labour. *Obs Rev J Obstet Gynecol*. 2019, 5(1):77–82.
- [18] Demographic statistics bulletin. National Bureau of Statistics.2017
- [19] Jumbo AI, Jeremiah I, Nonye-Enyidah EI, Awoyesuku PA, Amadi SC. 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. *World Journal of Advanced Research and Reviews*. 2022, 16(3):613–620.
- [20] Jumbo AI, Nonye-Enyidah EI. A case of anencephaly in an Unbooked Primipara diagnosed at 35 weeks gestation. *World Journal of Advanced Research and Reviews*. 2021, 12(2):555-8.
- [21] Charan J, Biswas T. How to calculate sample size for different study designs in medical research. *Indian Journal of Psychological Medicine*. 2013, 35:121–6.
- [22] Ibrahim MI, Alzeeniny HA, Ellaihy MI, Salama AH, Abdellatif MA. Drotaverine to improve the progression of labour among nulliparous women. *Int J Gynecol Obstet*. 2014, 124(2):112–7.
- [23] Sabeen N, Latif F, Fazil A. Drotaverine for the acceleration of labour with reduced incidence of caesarean section and no postpartum haemorrhage. *J Fatima Jinnah Med Univ*. 2018, 10(4):51–4