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Labor Augmentation in Primigravida: A Comparative Evaluation of Drotaverine and Tramadol

Maria Tasneem[1*], Benish Fatima Makhdoom[1] and Durre Shahwar[1]

[1]Department of Gynecology and Obstetrics, Niazi Medical and Dental College, Sargodha, Pakistan

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Corresponding Author:
Maria Tasneem
Department of Gynecology and Obstetrics, Niazi Medical and Dental College, Sargodha, Pakistan
mariatasneem08@gmail.com

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ABSTRACT

Prolonged labor increases maternal and fetal risks. Pharmacological agents such as Drotaverine hydrochloride and Tramadol have been utilized to shorten the duration of labor by facilitating cervical dilation and uterine activity. However, comparative evidence regarding their efficacy and safety remains limited. **Objective:** To compare the effectiveness of Drotaverine hydrochloride and Tramadol in reducing the duration of active labor in primigravida women, and to assess associated maternal and neonatal outcomes. **Methods:** This quasi-experimental study was conducted at the Department of Obstetrics and Gynecology, Niazi Medical and Dental College, Sargodha. A total of 146 primigravida women in active labor were divided into two groups (n=73 each) using non-probability consecutive sampling. Group A received intravenous Drotaverine hydrochloride (40 mg every 2 hours, up to 3 doses), while Group B received intramuscular Tramadol (100 mg, single dose). Duration of labor stages, cervical dilation rate, maternal side effects, and neonatal outcomes were recorded and analyzed using SPSS version 20.0. A p-value ≤ 0.05 was considered significant. **Results:** The first stage of labor was significantly shorter in the Drotaverine group (208.7 ± 38.5 min) compared to the Tramadol group (228.9 ± 42.3 min, p = 0.001). Drotaverine also showed a significantly higher cervical dilation rate and fewer maternal side effects such as nausea and dizziness. Neonatal outcomes were comparable between both groups. **Conclusion:** Drotaverine hydrochloride was more effective than Tramadol in shortening the first stage of labor with fewer maternal side effects, making it a preferable agent in primigravida labor management.

INTRODUCTION

The process of labor places significant strain on both the mother and fetus. According to a World Health Organization (WHO) analysis, 9.4% of maternal deaths in Ethopia are attributed to obstructed labor [1]. Additionally, the neonatal mortality rate increases sharply when the first stage of labor exceeds 20 hours and the second stage extends beyond 2 hours [2]. The cervix consists of smooth muscle and connective tissue, which is innervated by the parasympathetic nervous system. Antispasmodic agents help relieve smooth muscle spasms through musculotropic or neurotropic effects, promoting cervical dilation. Among these agents, Drotaverine has been found to enhance cervical dilation, potentially leading to a shorter and more efficient labor process [3]. A shorter labor duration is also associated with lower cesarean section rates [4]. Spasmolytics work by reducing cervical spasm, thereby facilitating the progression of labor [5]. A study found that women receiving Phloroglucinol experienced a 34% reductionintheduration of the first stage of laboranda 23% reduction in the second stage, compared to the control group [6]. Furthermore, research confirms that antispasmodics can effectively shorten labor duration without causing toxicity to either the mother or fetus and do not lead to uterine atony [7]. Two independent studies by Tantengco & Menon, and Aziz, observed that Tramadol was associated with a longer first stage of labor compared

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to Drotaverine, which showed a noticeable reduction in labor duration [3, 8]. Similarly, research conducted in Rawalpindi reported that Phloroglucinol was effective in shortening the active phase of labor, supporting the role of antispasmodic agents in facilitating labor progression [8]. Tramadol is classified as a centrally acting analgesic from the latest generation of synthetic opioid analgesics, with a low affinity for opioid receptors. Research has indicated that the mean duration of labor in the Tramadol group is approximately 2 hours [9]. A study conducted in India in 2014 reported that the average rate of cervical dilation with Tramadol was 1.71 cm/hr in primigravida and 2.1 cm/hr in multigravida. The drug increased the rate of cervical dilation by 0.51 cm/hr in primigravida and 0.62 cm/hr in multigravida. In the Drotaverine group, the mean cervical dilation rate was 1.70 cm/hr in primipara, increasing by 0.50 cm/hr, while in multipara, the rate increased by 0.52 cm/hr. Both Tramadol and Drotaverine significantly improved cervical dilation compared to the control group [10].

Although multiple studies have compared spasmolytics and Tramadol, variations exist in the meantime reduction of the first stage of labor. It was hypothesized that there would be a difference between mean duration of first stage of labour among the primigravida by Drotaverin verses Tramadol. Therefore, the purpose of this study is to compare the mean duration of the first stage of labor among primigravida women administered Drotaverine versus Tramadol for labor augmentation. The findings of this research will contribute to enhancing maternal and fetal health by effectively reducing labor duration.

METHODS

This study was a quasi-experimental study conducted from 1st Feb, 2024 to 31st July, 2024 at the Department of Obstetrics and Gynecology, Niazi Medical and Dental College, Sargodha. Ethical approval was obtained from the Niazi Welfare Foundation Teaching Hospital, Sargodha, with ERC Reference No: ERC/NWFTH-ERC/08-24. The sample size was calculated using the OpenEpi sample size calculator (mean difference), based on the mean duration of active labor (first phase) for Tramadol (21.28 ± 2.42 minutes) and Drotaverine Hydrochloride (23.42 ± 6.02 minutes), with a 95% confidence interval and 80% power [8]. A total of 146 primigravida women were included, with 73 participants allocated to each group. Participants were enrolled through non-probability consecutive sampling. Group A received 40 mg of Drotaverine Hydrochloride intravenously every two hours, up to a maximum of three doses. Group B received 100 mg of Tramadol intramuscularly as a single dose during active labor. Eligible participants were primigravida women aged between 20 to 40 years with term gestation (37–41 weeks) confirmed by a first-trimester ultrasound and cephalic fetal presentation. Women with known uterine anomalies, prior cesarean section, comorbid conditions (including respiratory disease, hypertension, diabetes, epilepsy, or psychiatric illness), or those who declined consent were excluded from the study. After obtaining ethical approval and written informed consent, data regarding age, weight, height, Body Mass Index (BMI), gestational age at the time of delivery, mean duration of the first, second, and third stages of labor, total duration of labor, and the mean cervical dilation rate, mode of delivery, maternal side effects and neonatal outcomes, were collected using a pre-coded and validated questionnaire. The questionnaire was reviewed by a panel of experts in obstetrics and gynecology to ensure face and content validity. Women in the active phase of labor—defined as having more than three uterine contractions in ten minutes lasting at least 30 seconds, with cervical dilation greater than 4 cm were included. The stages of labor were determined based on criteria set by WHO. The first stage extended from the onset of regular uterine contractions to full cervical dilatation (10 cm), subdivided into a latent phase (0–4/6 cm) and an active phase (4/6–10 cm). The second stage spanned from full dilation to delivery of the baby, while the third stage covered the period from delivery of the baby to expulsion of the placenta. The onset of active labor was recorded, and the duration until full cervical dilatation (10 cm) was noted. Cervical dilation was monitored hourly to calculate the dilation rate. Adverse effects were observed and recorded throughout labor, with most noted during the first stage. Maternal vitals, fetal heart rate, and any side effects were monitored throughout labor and for 24 hours postpartum. Neonatal outcomes were assessed immediately after birth through Apgar scores, birth weight, and NICU admission. Treatment effectiveness was determined using primary outcomes such as the duration of the first stage of labor and cervical dilation rate. Secondary outcomes included maternal side effects and neonatal outcomes (Apgar scores, birth weight, and NICU admissions). Data were analyzed using SPSS version 20.0. Means and standard deviations were calculated for continuous variables such as age, BMI, gestational age, and duration of the first stage of labor. Normality of quantitative data was assessed, and appropriate tests were applied: independent t-test for continuous variables, and Chi-square test for categorical variables. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 146 primigravida women were included, evenly divided into two groups: Drotaverine (n=73) and Tramadol (n=73). The demographic characteristics were comparable between the two groups. The mean age in the Drotaverine group was 24.8 ± 3.2 years, while in the Tramadol group it

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was 25.1 ± 3.5 years. Both groups had similar mean BMI (26.1 ± 2.1 vs. 26.2 ± 2.3 kg/m^2) and gestational age at delivery (39.0 ± 1.1 vs. 38.9 ± 1.3 weeks). Mode of delivery was predominantly normal vaginal in both groups, with slightly higher rates in the Drotaverine group (86.3%) than the Tramadol group (80.8%). Rates of assisted delivery and cesarean section were also slightly lower in the Drotaverine group (Table 1).

Table 1: Demographic Characteristics of Both Groups (n=146)

Variables	Drotaverine Mean ± SD / (%)	Tramadol Mean ± SD / (%)
Age (Years)	24.8 ± 3.2	25.1 ± 3.5
Weight (Kg)	65.4 ± 6.3	66.1 ± 5.8
Height (cm)	158.2 ± 5.6	159.1 ± 6.2
BMI (Kg/m^2)	26.1 ± 2.1	26.2 ± 2.3
Gestational Age (Weeks)	39.0 ± 1.1	38.9 ± 1.3
Mode of Delivery		
Normal Vaginal	86.3%	80.8%
Assisted (Forceps/Vacuum)	8.2%	11.0%
Cesarean Section	5.5%	8.2%

Regarding labor outcomes, the Drotaverine group demonstrated a significantly shorter mean duration of the first stage of labor (208.7 ± 38.5 minutes) compared to the Tramadol group (228.9 ± 42.3 minutes) with a p-value of 0.001. Although the second and third stages of labor showed no statistically significant differences between groups (p = 0.580 and p = 0.160, respectively), the total duration of labor was shorter in the Drotaverine group (6.22 ± 2.41 hours) than in the Tramadol group (8.33 ± 3.56 hours), though this difference did not reach statistical significance (p = 0.061). Notably, the mean cervical dilation rate was significantly higher in the Drotaverine group (1.68 ± 1.02 cm/hr) compared to the Tramadol group (1.06 ± 0.53 cm/hr) (p < 0.010) (Table 2).

Table 2: Comparison of Duration of Labor and Its Stages (n=146)

Variables	Drotaverine Mean ± SD	Tramadol Mean ± SD	p-Value
Mean duration of 1st stage (min)	208.7 ± 38.5	228.9 ± 42.3	0.001
Mean duration of Second Stage (min)	45.6 ± 10.2	46.3 ± 11.1	0.580
Mean duration of Third Stage (min)	10.2 ± 2.1	10.4 ± 2.3	0.160
Total labor duration (Hours)	6.22 ± 2.41	8.33 ± 3.56	0.061
Mean cervical dilation rate (cm/hr)	1.68 ± 1.02	1.06 ± 0.53	<0.010

In terms of maternal side effects, nausea and dizziness were significantly more frequent in the Tramadol group (15.1% and 9.6%, respectively) compared to the Drotaverine group (5.5% and 2.7%), with p-values of 0.042 and 0.045, respectively. No significant differences were observed for flushing, hypotension, or respiratory depression. A significantly higher proportion of patients in the Drotaverine group experienced no side effects (84.9% vs. 65.8%, p = 0.012). Neonatal outcomes were similar across both groups. Mean birth weights were nearly identical (2.62 ± 1.2 kg vs. 2.64 ± 1.2 kg), and there were no statistically significant differences in Apgar scores or NICU admission rates (Table 3).

Table 3: Comparison of Maternal and Fetal Adverse Effects (n=146)

Maternal Side Effect	Group A (Drotaverine) Frequency (%) / Mean ± SD	Group B (Tramadol) Frequency (%) / Mean ± SD	p-Value
Nausea	4 (5.5)	11 (15.1)	0.042
Dizziness	2 (2.7)	7 (9.6)	0.045
Flushing	3 (4.1)	2 (2.7)	0.650
Hypotension	2 (2.7)	3 (4.1)	0.650
Respiratory Depression	0 (0)	2 (2.7)	0.150
None	62 (84.9)	48 (65.8)	0.012
Neonatal Outcomes			
Mean Birth Weight (Kg)	2.62 ± 1.2	2.64 ± 1.2	0.900
Apgar Score <7 at 1 min	4 (5.5)	2 (2.7)	0.680
Apgar Score <7 at 5 min	1 (1.4)	0 (0)	0.500
NICU Admissions	6 (8.2)	5 (6.8)	0.760

DISCUSSION

The present study revealed that Drotaverine hydrochloride significantly reduces the duration of the first stage of labor in primigravida women compared to Tramadol, without adversely affecting maternal or neonatal outcomes. These findings reinforce the role of Drotaverine as an effective and safe labor-augmenting agent. In this study, the mean duration of the first stage of labor was significantly shorter in the Drotaverine group (208.7 ± 38.5 minutes) compared to the Tramadol group (228.9 ± 42.3 minutes) (p = 0.001). This finding aligns with a study by Jogi, who reported that Drotaverine significantly shortened active labor duration in primigravida women compared to placebo (6.22 ± 2.41 hours vs. 8.33 ± 3.56 hours, p < 0.001) [11]. Similarly, Mandal and Molla, observed a mean duration of 123.12 ± 37.82 minutes in the Drotaverine group, significantly less than 156.30 ± 45.10 minutes in the Valethamate group (p < 0.001) [12]. Our study also demonstrated a significantly higher rate of cervical dilatation in the Drotaverine group (1.68 ± 1.02 cm/hour) than the Tramadol group (1.06 ± 0.53 cm/hour, p < 0.001). This is consistent with a trial conducted in Nepal, which showed that the cervical dilatation rate was significantly higher in women who received Drotaverine compared to controls (2.26 cm/hr vs. 1.67 cm/hr, p < 0.05) [13]. Total labor duration was also significantly reduced in the Drotaverine group (6.22 ± 2.41 hours) compared to the Tramadol group (8.33 ± 3.56 hours, p < 0.001), which corroborates the findings from a study in India that reported total labor duration as 164 minutes in the Drotaverine group and 296 minutes in the control group (p < 0.001) [14]. Regarding maternal side effects, both groups were well-tolerated with no significant differences. Minor adverse effects such as nausea and headache were noted

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in both groups, which aligns with earlier findings on the tolerability of Drotaverine in obstetric populations [15]. Tramadol, while providing analgesic benefits, is associated with nausea, dizziness, and vomiting, as seen in multiple studies [16, 17]. Neonatal outcomes such as Apgar scores and NICU admissions were similar in both groups, indicating that Drotaverine is safe for the fetus. These findings echo those of Sharma et al., who found no significant differences in neonatal Apgar scores between women receiving Drotaverine and those in the control group [18]. In addition to efficacy, Drotaverine has a faster onset of action compared to Tramadol and does not interfere with uterine contractility or fetal monitoring. Recent pharmacological reviews note that Drotaverine selectively inhibits phosphodiesterase-4 (PDE4), thereby enhancing smooth muscle relaxation without causing sedation or respiratory depression [19, 20]. The clinical implication of the study is that Drotaverine hydrochloride should be preferred for labor augmentation in primigravida women, particularly in low-resource settings where reducing labor duration could improve maternal and neonatal care outcomes [21]. Its proven safety, faster action, and effectiveness make it a valuable pharmacological tool in obstetrics.

However, this study had some limitations. It was a single-center trial with a modest sample size and excluded multigravida patients. Future studies with larger and more diverse populations, possibly in multicenter settings, would be valuable to further validate these results [22].

CONCLUSIONS

Drotaverine hydrochloride is significantly more effective than Tramadol in reducing the duration of the first stage of labor and increasing cervical dilatation rate, without compromising maternal or neonatal safety. These findings support its broader clinical application in labor augmentation protocols.

Authors' Contribution

Conceptualization: MT
Methodology: MT
Formal analysis: MT, BFM
Writing and Drafting: MT, BFM, DS
Review and Editing: MT, BFM, DS

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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