



Original Article

Efficacy of Phloroglucinol vs Drotaverine Hydrochloride in Shortening the Active Phase of the First Stage of Labor in Primigravidae

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ARTICLE INFO

Key Words:

labour duration, phloroglucinol, drotaverine, first stage of labour

How to Cite:

Shahid, M. ., Arif, N. ., Hamid, I. ., Arif, S. ., & Naeem, A. . (2022). Efficacy of Phloroglucinol vs Drotaverine Hydrochloride in Shortening in Primigravidae at Term the Active Phase of the First Stage of Labor: Phloroglucinol vs Drotaverine Hydrochloride in Shortening the First Stage of Labor. *Pakistan BioMedical Journal*, 5(6).
<https://doi.org/10.54393/pbmj.v5i6.571>

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Received Date: 19th June, 2022

Acceptance Date: 26th June, 2022

Published Date: 30th June, 2022

ABSTRACT

Primigravida women are those who conceive for the first time and are at high risk group for complications during childbirth. **Objective:** To compare the effectiveness of phloroglucinol i/v and drotaverine hydrochloride by measurement of the 1st stage of labor in primigravidae. **Methods:** This randomized controlled trial was held in the Obstetrics and Gynecology Department of Allama Iqbal Memorial Teaching Hospital Sialkot and The Indus hospital QF-NST Campus Lahore for six-months duration from July to December 2021. Several factors were used to determine the inclusion of primigravida females, including age range of 20- 35 years, 38-42 weeks of gestational age at LMP with single pregnancy, Uterine contractions up to 3 cm if they occur at 3-4, 10 minutes before both drugs are given, ROM, no signs of fetal and maternal distress, patient in the first stage of labour. All of the cases were divided into two groups: A and B. Group 'A' received phloroglucinol 40mg (4ml) i/v at 4 cm dilation, and the dosage was repetitive at 8 cm dilation. At 4cm dilation, Group 'B' received drotaverine 40mg i/v. The essential signs including uterine contractions and fetal heart rate were monitored every half an hour. **Results:** 80 patients were included, with 56.3% of cases in Group-A group B has 43.7% cases being between the ages of 20-35 years. There was a significant improvement in the first stage of active labour 'mean duration in Groups A and B is 160.21±4.29 minutes and 203.77±8.21 minutes, respectively. **Conclusion:** The mean active length of the 1st stage of labour in the group of phloroglucinol was substantially shorter than in the drotaverine group.

INTRODUCTION

The fetus, umbilical cord, placenta and membrane are excreted from the uterus as part of the physiologic process of conception [1,2]. It is performed by alterations in biochemical connective tissues as well as gradual dilatations and effacement of the uterine cervix as a consequence of proper frequency, duration, and intensity of uterine contractions[3,4]. Both obstetricians and active labour patients want to deliver the baby in the shortest time without jeopardizing the mother's and fetus's safety[5,6]. Following the onset of the active phase, uterine contractions increase in frequency, strength, and pace of cervix dilatation. The initial stage of the active phase of

labour is also known as the 'dilatation phase'[7,8]. Because hospitalization for childbirth is almost ubiquitous, practically all females will endure the 1st stage active period of labour in the hospital's obstetric unit[9,10]. As a result, the manner in which care is provided during this time period may impact the course of the labour and its final results. The causes of prolonged labor's first stage are multifaceted, and cervical dilation is the end result of these variables [11]. For numerous years, experts have recognized the dangers and risks of prolonged labour for both the mother and the fetus. Fetuses are at high risk for infection, including ketosis and obstructed labor, while

mothers suffer from high infection risks, including ketosis and oxygen deprivation [11]. The anti-spastic medication of choice is phloroglucinol. It is often used in obstetrics. It may decrease cervical edema and spasms, as well as lessen cervical muscular tension. As a consequence, it can be utilized to promote labour improvement and cervical dilatation progression. Drotaverine has also been shown to reduce all stages of labor [12]. In one study, the mean duration of the first phase of active delivery in patients receiving phloroglucinol was 227.74 ± 13.34 . No comparable studies have been conducted at the regional level. As a result, the purpose of this study was to compare in primigravidae at term, drotaverine vs phloroglucinol' efficacy in reducing the active period of the first stage of labour

METHODS

With the approval of the ethics committee, this randomized controlled trial was conducted in the Department of Gynecology, Allama Iqbal Memorial Teaching Hospital Sialkot and The Indus hospital QF-NST Campus Lahore for six months, from July to December 2021. In all cases, written informed permission was obtained. All women with obstetric morbidity such as gestational diabetes mellitus, polyhydramnios, pre-eclampsia, Antepartum hemorrhage (APH), medical abnormalities like renal, thyroid and heart diseases, intrauterine device (IUD) and cervical trauma were omitted from the research. All of the cases were divided into two groups: A and B. Group 'A' received phloroglucinol 40mg (4ml) i/v at 4 cm dilation, and the dosage was repetitive at 8 cm dilation. At 4cm dilation, Group 'B' received drotaverine 40mg i/v. The essential signs including uterine contractions, and fetal heart rate have been monitored every half hour. The progression of labour was charted on a partogram. On a pre-designed proforma, the primary result, which was the mean length of the first stage of active labour in both groups, was documented. SPSS version 21.0 was used to analyse the data. For both groups A and B, the mean time length of the active period of the 1st stage of labour was computed, and the *t* test was applied and $p \leq 0.05$ was regarded as significant.

RESULTS

80 patients were included, with 56.3% of cases in Group-A while 43.7% cases in Group-B, patients were in the age range of 20-35. Both groups had the same mean age of 23.85 ± 4.01 and 24.70 ± 3.11 (Table 1.)

Age	Group-A, (Phloroglucinol n=45)	Group-B, (Drotaverine n=35)	p-value
	Number of Patients (%)	Number of Patients (%)	
20-25 years	24(53.3%)	14(40.0%)	0.55
26-30 years	18(40.0%)	17(48.6%)	
31-35 years	03(6.7%)	4(11.4%)	
Total	45(100.0%)	35(100.0%)	
Mean and SD	23.85+4.01	24.70+3.11	

Table 1: The patient's distribution according to Age (n=80)

Between the gestation age 38-40 weeks, 62.2% of females in Group A and 65.7% of women were in Group B were, whereas between the gestation age 41-42 weeks, 37.8% of females in A Group and 34.3% of females were in B Group (Table 2). The first stage of active labour 'mean duration in Groups A and B is 160.21 ± 4.29 minutes and 203.77 ± 8.21 minutes, respectively (table 3).

Gestational age (in weeks)	Group-A, (Phloroglucinol n=45)	Group-B, (Drotaverine n=35)	p-value
	Number of Patients (%)	Number of Patients (%)	
38-40	28(62.2%)	23(65.7%)	0.300
41-42	17(37.8%)	12(34.3%)	
Total	45(100.0%)	35(100.0%)	

Table 2: Females division conferring to gestational age (n=80)

Mean duration	Group-A, (Phloroglucinol n=45)	Group-B, (Drotaverine n=35)	p-value
	Values in SD and mean (mints)	Values in SD and mean (mints)	
	160.21 ± 4.29	203.77 ± 8.21	0.002

Table 3: Mean duration of active phase of 1st stage of labour (n=80)

According to age groups, no significant difference was identified in either group, with p-values of 0.37 and 0.24, respectively. Between 20 and 25 years, patients were divided into three groups: (Table 4).

Age	Group-A, (Phloroglucinol n=45)	Group-B, (Drotaverine n=35)
	Values in SD and mean (mints)	Values in SD and mean (mints)
20-25	159.20 ± 2.98	201.01 ± 3.01
26-30	162.80 ± 2.70	199.14 ± 3.10
31-35	160.12 ± 3.41	202.54 ± 2.99
p-values	0.37	0.24

Table 4: Active Phase of 1st Stage of Labour Mean Duration Conferring to Age (n=80)

DISCUSSION

Prolonged labour is more common in primipara women than in multiparous women. Prolonged labour contributes considerably to maternal and foetal morbidity and death in poor countries such as Pakistan and India [13]. Ruptured uterus and prolonged labour are thought to be responsible for 70 percent of all maternal deaths and 7-15 percent of

foetal deaths [14]. In underdeveloped nations, vesicovaginal fistula, a serious consequence of prolonged labour, develops at a rate of 60-85 per one million live births. Dublin 'Driscoll, who spoke at NMH, introduced the notion of active labour management, which persuaded obstetricians to change their thoughts about the first stage of labour management. The low rate of C-sections and prolonged labour are connected to active treatment of it [15]. The Phloroglucinol chemical family includes semi-synthetic & synthetic moieties, with approximately 700 naturally occurring molecules. It is the most prevalent type of natural product that contains the fundamental component 1,3,5-trihydroxy benzene [16,17]. These chemicals have been demonstrated to have anticancer, antimicrobial, anti-inflammatory, antiallergic, neuro-regenerative, enzyme inhibitor, and anti-oxidant properties. Spasmolytic phloroglucinol (Spasfon). The goal of this study was to do comparability of the duration of the active phase of labour when phloroglucinol was administered intravenously vs drotaverine hydrochloride [18,19]. The 1st stage active phase of labour in A Group lasted 162.54+5.35 minutes and in Group-B lasted 205.64+7.35 mints, with 0.002 p-value indicating a significant variance between the two groups. The findings of the research contrast with those of Tabassum S et al, who found that the active 1st stage of labour lasted only 117.02 minutes in participants taking phloroglucinol [20,21]. Likewise, Ara B et al showed significantly shorter stages of labour length in the phloroglucinol group as 203.069±21 minutes compared to 311.12±10.89 minutes in the group of control, with 0.004 p-value. In the first stage of labour, Naqvi SB and contemporaries examined the effectiveness and safety of Phloroglucinol and drotaverine [22]. The length of the 1st stage of labour was 145.30 ±29.80 minutes in the Phloroglucinol group and 191.25 ±76.89 minutes in the drotaverine group, with a statistically significant difference ($p \leq 0.05$). These conclusions are consistent with the verdicts of this study [23]. Anjum N et al., concluded that Phloroglucinol has a positive effect on reducing the length of the 1st stage of labour, in the medicine group being 182 mins versus 315 mins in the placebo group, and that the cases given phloroglucinol had significantly shorter first and alternate stages of labour [24]. Although Singh et al found that uterine atony caused 18% of post-partum hemorrhage when spasmolytics were employed, they utilized Drotaverine hydrochloride rather than phloroglucinol. The use of Drotaverine in labour is restricted due to its statistically significant frequency [25].

CONCLUSION

Both medicines are effective for accelerating labour, however the mean active phase in the Phloroglucinol group

was much shorter than in the Drotaverine group. Additional local studies are needed to confirm these promising results.

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