

Efficacy of Phlorogucinol in Comparison to Drotaverine Hydrochloride in Reducing Duration of Active Phase of 1st Stage of Labour in Primigravidae at Term

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Abstract

Objective: To compare the efficacy of phloroglucinol i/v and drotaverine hydrochloride by measuring the mean duration of active phase of the first stage of labour in primigravidae at term.

Place and Duration: This Randomized controlled trial was carried out at the Department of Obstetrics & Gynecology of Bahawal Victoria Hospital, Bahawalpur, with 6 months duration from September 22, 2012, to March 21, 2014.

Methodology: All the primigravida with age ranged of 18 to 35 years and gestational age of 38-42 weeks from LMP with singleton pregnancy, vertex presentation, spontaneous or induced labour, uterine contractions at 3 cm whether they were established at 3-4 in 10 minutes before administration of two drugs, rupture of membranes, no evidence of maternal or fetal distress, maternal ambulation in first stage of labour were selected for study. All the cases were divided in 2 groups Group A and group B. Patients were consecutively allowed to select the two folded slips with written group A and group B. Subsequent coming cases were placed either in group A or group B. Group 'A' was administered phloroglucinol 40mg (4ml) i/v at 4cm dilatation and dose was repeated at 8cm of dilatation. Group 'B' was administered drotaverine 40mg i/v at 4cm dilatation. Monitoring half hourly of the essential sign; contractions of the uterus and fetal heart rate have been done.

Results: A total of 100 patients were included, most cases of both groups were between 20-25 years of age as; 56% cases in Group-A and 52% in Group-B, mean age was recorded as 24.34+3.45 and 25.67+2.77 respectively, mean of active phase duration of the first stage of labour was significantly decreased as 162.54+5.35 minutes in Group-A as compare to Group-B 205.64+7.35 minutes, p-value 0.002.

Conclusion: It is concluded that the mean of active phase duration of the first stage of labour was significantly shorter in Phloroglucinol group as compared to Drotaverine group.

Keywords: Primipara, first stage of labour, phloroglucinol, drotaverine, duration of labour.

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Introduction

Labour is the physiological process of it conception production (i.e. fetus, umbilical cord, membrane, and placenta) are ejected outside of the uterus.¹ It is achieved through alteration in biochemical connective tissues and with the gradual effacements and dilatations of the uterine cervix and the result of rhythmic contractions of the uterus of sufficient occurrence, duration, and intensity.

Both obstetricians and the laboring cases would like to achieve the delivery during shorter possible duration exclusive of compromising the safety of the mother and fetus.² After the active phase originates, contractions of the uterus progressively raised in frequency, intensity and also increased the rate dilatation of cervix. The first stage of active phase sometimes called as "dilatation phase" of the labor. Because the hospitalization for the birth of child is fundamentally universal, just about all women will experience the first stage active phase of the labor within the obstetric unit of Hospital. Consequently, style of care throughout this period might influence the course of the labor and eventual outcomes of it.³ Causes of the prolonged labor's 1st stage of is multifactorial and the dilatation of cervix is the final outcome of these factors.⁴

Problems and the threats of the prolonged labour, for both maternal and the fetus, have been acknowledged for several years. Mothers are exposed to the high infection risks including ketosis and the obstructed labour, though the faces of foetus the hazards of the infection, excessive cranial moulding and the asphyxia.⁵

Phloroglucinol is choice of the anti-spastic drugs. It used extensively in the obstetrics. It may relieve the edema and spasms of the cervix and can reduce the tension of the muscles of the cervix. Accordingly, it can be utilized to progression in the cervix dilatation and promote the labour improvement.⁶ Drotaverine has also proved to shorten all stages of labour.⁷

In a local study³ mean duration of 1st stage of the active phase of labour was 227.74 ± 13.34 in patients receiving phloroglucinol while in another study by Roy A and colleagues showed durations mean of the active phase of labour in primiparous and

multiparous were 148.9 minutes.⁷ No adequate such studies have been done before at local level. Therefore, this study has been conducted to compare the efficacy of phloroglucinol with drotaverine hydrochloride in shortening the duration of active phase of the first stage of labour in primigravidae at term.

Methodology

This Randomized controlled trial was carried out at the Department of Obstetrics & Gynecology – Bahawal Victoria Hospital, Bahawalpur with 6 months duration from September 2011 to March 2012 after approval of ethical committee of BVH Bahawalpur. Written informed consent was taken from all the cases. All the primigravida with age ranged of 18 to 35 years and gestational age of 38-42 weeks from LMP with singleton pregnancy, vertex presentation, spontaneous or induced labour, uterine contractions at 3 cm whether they were established at 3-4 in 10 minutes before administration of two drugs, rupture of membranes, no evidence of maternal or fetal distress, maternal ambulation in first stage of labour were included in the study. All the women with obstetrical morbidity like polyhydromnios, APH, gestational diabetes mellitus, pre-eclampsia, eclampsia, medical comorbidities like cardiac, thyroid, renal diseases, history of cervical injury, intrauterine death and cephalopelvic disproportion were excluded from study.

All the cases were divided in 2 groups, first coming case was presented two folded slips with written group A and group B. Subsequent coming cases were placed either in group A or group B. Group 'A' was administered phloroglucinol 40mg (4ml) i/v at 4cm dilatation and dose was repeated at 8cm of dilatation. Group 'B' was administered drotaverine 40mg I/v at 4cm dilatation. Monitoring half hourly of the essential sign, contractions of the uterus and fetal heart rate have been done. Progression in the labour was plotted on partogram. The primary outcome i.e. mean duration of 1st stage of active phase of labour in both groups were recorded on a pre-designed proforma.

Data was analyzed by SPSS version 16. The mean time duration of active phase of the first stage of labour was calculated for both groups A and B and student T test was applied as a test of significance. $P < 0.05$ was considered as significant.

Results

Total of 100 cases were studied and according to age groups most of the cases in both groups were between 20-25 years of age, 56% cases in Group-A and 52% in Group-B, 26-30 years age group was found in 32% cases of Group-A, and 28% of Group-B, while only 12% women of Group-A were noted with age group of 31-35 years and 20% of Group-B. The mean age was recorded as 24.34 ± 3.45 and 25.67 ± 2.77 respectively, no significant difference was found in age groups of both groups. (Table I)

Table I: Age distribution of the patients (n=100)			
Age	Group-A (Phloroglucinol n=50)	Group-B (Drotaverine n=50)	P-value
	No. of Patients (%)	No. of Patients (%)	
20-25 years	28(56.0%)	26(52.0%)	0.547
26-30 years	16(32.0%)	14(28.0%)	
31-35 years	06(12.0%)	10(20.0%)	
Total	50(100.0%)	50(100.0%)	
Mean and S.D.	24.34 ± 3.45	25.67 ± 2.77	

No significant difference was found in both groups according to gestational age p-value 0.300. Most of the cases 68% women of Group-A and 58% women of group B were found between gestational age of 38-40 weeks, while 32% women of group A and 42% women of Group-B were seen with a gestational age of 41-42 weeks. (Table II)

Table II: Women distribution according to gestational age (n=100)			
Gestational age (in weeks)	Group-A (Phloroglucinol n=50)	Group-B (Drotaverine n=50)	P-value
	No. of Patients (%)	No. of Patients (%)	
38-40	34(68.0%)	29(58.0%)	0.300
41-42	16(32.0%)	21(42.0%)	
Total	50(100.0%)	50(100.0%)	

Mean duration of 1st stage of active phase of labour reveals 162.54 ± 5.35 minutes in Group-A and 205.64 ± 7.35 minutes in Group-B, p value was calculated as 0.002 which shows a significant difference. (Table III)

Table III: Mean duration of active phase of first stage of labour (n=100)			
Mean duration	Group-A (Phloroglucinol n=50)	Group-B (Drotaverine n=50)	P value
	Values in mean and S.D. (mins)	Values in mean and S.D. (mins)	
	162.54 ± 5.35	205.64 ± 7.35	

No significant difference was found in both groups according to age groups p-value 0.369 and 0.236 respectively. The stratification for patients age as; 160.54 ± 3.43 in Group-A and 202.41 ± 3.21 in Group-B between 20-25 years, 164.76 ± 2.65 in Group-A and 198.51 ± 3.09 in Group-B between 26-30 years and 161.65 ± 3.67 in Group-A and 204.84 ± 2.54 minutes in Group-B. (Table IV)

Table IV: Mean Duration of Active Phase of First Stage of Labour According to Age (n=100)		
Age	Group-A (Phloroglucinol n=50)	Group-B (Drotaverine n=50)
	Values in mean and S.D. (mins)	Values in mean and S.D. (mins)
20-25	160.54 ± 3.43	202.41 ± 3.21
26-30	164.76 ± 2.65	198.51 ± 3.09
31-35	161.65 ± 3.67	204.84 ± 2.54
p-values	0.369	0.236

Discussion

Primi para women more experienced prolonged labour greater often than the multiparous. In the developing countries e.g. Pakistan and India, prolonged labour contributes significantly to the mother and fetus morbidities and the mortality. Ruptured uterus and prolonged labour obstruction may interpretation for 70% of all death rates of mothers, and 7-15% of death rates of the fetus has been attributed to the labour obstruction. Vesico-vaginal fistula, severe consequences of prolonged

labour, occurs at a rate of 55-80 per 100,000 live births in developing countries.⁸

At NMH, Dublin O'Driscoll announced the concept of the active labour management and which influenced the obstetricians to improve their outlook regarding 1st stage of labour management.⁹ Active management of it is linked to the low prevalence C-section and prolonged labour.¹⁰

The compound of the Phloroglucinol comprise the family which includes semi-synthetic or synthetic moieties and > 700 compounds occurred naturally. It is the commonest class of the natural product containing of 1,3,5-trihydroxy benzene as the fundamental moiety. A vast array of activities like as anticancer, anti-microbial, anti-inflammatory anti-allergic, neuro-regenerative, enzyme inhibitor and anti-oxidant have been shown by these compounds. Phloroglucinol (Spasfon) is a spasmolytic.¹¹

This study has been conducted to compare the mean duration of active phase of the first stage of labour when given phloroglucinol i/v versus drotaverine hydrochloride. In this series reveal that the most cases of both groups were between 20-25 years of age, 56% in Group-A and 52% in Group-B, mean age was recorded as 24.34±3.45 and 25.67±2.77 respectively, mean duration of active phase of the first stage of labour reveals 162.54±5.35 minutes in Group-A and 205.64±7.35 minutes in Group-B, p-value was calculated as 0.002 which shows a significant difference. The results of the study are in contrast with Tabassum S et al³ who recorded a shorter duration of the active 1st stage of labour was 116.52 minutes in patients receiving phloroglucinol. Similarly, in another study of Ara B et al⁷ reported that the significant shorter stages of labour duration as 203.06±9.21 minutes in phloroglucinol group as compare to control as 311.12±10.89 minutes p-value-0.004.

Naqvi SB and colleagues¹² compared the safety and the efficacy of drotaverine and Phloroglucinol in the duration of 1st stage of the labour. They recorded the duration of the first stage of labour in Phloroglucinol group 144.40 ± 30.78 minutes and in drotaverine group 191.25 ± 76.89 minutes, the difference was statistically significant (p < 0.05), these findings are in agreement with the findings of this study.

In the favor of present series Anjum N et al¹³ concluded that the Phloroglucinol is the good effected in decreasing the first stage of labour duration as; the mean duration of the observed active phase of 1st stage of labour in drug group was 183 minutes and 316 minutes in placebo group and further stated that the cases administered by phloroglucinol had significant little duration of first and second stages of the labour. Though Singh et al¹⁴ mentioned that 18% of post-partum haemorrhage due to uterine atony with uses of the spasmolytics but they used the Drotaverine hydrochloride, not phloroglucinol. This prevalence statistically significant and limits utilize of Drotaverine in the labour.

The limitation of the study is that we did not include mode of delivery in our study which may further enhance the authenticity and acceptability of the drug for active management of first stage of labour. However, more trials may be done to meet this limitation.

Conclusion

It is concluded that both drugs for acceleration of labour are effective but mean of active phase was significantly shorter in Phloroglucinol group as compared to Drotaverine group. More local research is needed to these favorable findings.

References

1. Tehalia K, Sajjan R, Jyothi K, Venkatesh S, Biradar R. A comparative study of Hyoscine butylbromide versus Drotaverine hydrochloride in first stage of labor. *J Obstet Gynecol India* 2008; 58 :230-4.
2. Leah L. Albers, CNM, DrPH. The Evidence for Physiologic Management of the Active Phase of the First Stage of Labor. *J Midwifery Womens Health* 2007;52: 207-15.
3. Samina Tabassum, Bilqis Afridi, Zahid Aman. Phloroglucinol for Acceleration of labour: Double blind, randomized controlled trial. *J Pak Med Association* 2005; 55:270.
4. O'Driscoll K, Jackson RJ, Gallagher JT. Prevention of prolonged labour. *BMJ* 1969;2:477-80.
5. Francome C, Savage W, Churchill H. Caesarean birth in Britain. Middlesex University Press, London 1993.
6. Keane D. Conference on modern management of labour. Held at the Royal College of Obstetricians and Gynaecologists, London. 15th February 2002.
7. Ara B, Anwar A, Salam R. Comparison of Mean Duration of First and Second Stage of Labour in Term Primigravida with and without Phloroglucinol. *PAKISTAN JOURNAL OF MEDICAL & HEALTH SCIENCES*. 2016 Jul 1;10(3):994-7.
8. Tahzib F. Epidemiological determinants of vesicovaginal fistulas. *Br J Obstet Gynecol* 1983; 90: 387-91.

9. Himangi S, Anahita R, Vanita S, Kumud M. The efficacy of Camylofin dihydrochlorid in acceleration of labour. A randomized double blind trial. *J Bombay Hosp* 2004; 45(3):1.
10. Bohra U, Donnelly J, O'Connell M, Geary M, Mac Quillian K, Keane DP. Active mangement of labour revisited: the first primiparous labours in 2000. *J Obstet Gynaecol* 2003;23:118-20.
11. Antispasmodics and anticholinergics. In: Neeshat QM. *Pharmaguide*, 16th edition. Karachi: Pharmaguide Publishing Company; 2003; 66-70.
12. Naqvi SB, Haroon Z. Efficacy and safety of drotaverine and phloroglucinol in first stage of labour. *Pak J Surg* 2011;27(1):39-43.
13. Anjum N. Efficacy of Phloroglucinol Versus Placebo on the Duration of Labour in Term Pregnancies. *Journal of Rawalpindi Medical College*. 2013 Dec 30;17(2):238-9..
14. Singh KC, Jain P, Goel N, Saxena A. Drotaverine hydrochloride for augmentation of labour. *Int J Gynaecol Obstet* 2004;84:17-22.