

# Effect of Phloroglucinol on Active Phase of First Stage of Labour

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## ABSTRACT

**Introduction:** The problems and hazards of prolonged labour for both mother and fetus have been recognized for many years. The mother is exposed to high risk of infections, ketosis and obstructed labour while fetus faces the danger of infection, asphyxia and excessive cranial moulding.

**Objective:** The objective of this study is to compare the mean duration of active phase of first stage of labour in primigravida with and without phloroglucinol at term.

**Study Design:** Double blind randomized controlled trial.

**Setting:** This study was conducted in the Department of Obstetrics & Gynaecology Unit-1, Sir Ganga Ram Hospital, Lahore.

**Duration with Dates:** Six months from 01-01-2010 to 30-06-2010.

**Subjects and Methods:** A total of 200 primigravidas at term in active phase of first stage of labour were selected for this study. One group was given phloroglucinol at 0, ½ hour, 1 hour, 1½ hour interval 40mg intravenous (I/V) and other group was not given phloroglucinol and effects were recorded on predesigned proforma. All data pertaining to labour events, outcome that was measured in duration of first stage of labour were recorded on questionnaire.

**Results:** The mean age of the patients in phloroglucinol group was 26.1±2.6 years and in control group was 26.2±3.3 years. The mean weight of the patients in phloroglucinol group was 70.1±4.9 kg and in control group was 69.7±3.9 kg. The mean duration of pregnancy of the patients in phloroglucinol group was 38.4±1.4 weeks and in control group was 38.4±1.4 weeks. The mean duration of active phase of first stage of labour of the patients in phloroglucinol group was 282.8±23.4 minutes and in control group was 410.6±66.8 minutes.

**Conclusion:** It is concluded from this study that duration of active phase of first stage of labour is significantly shorter in patients given phloroglucinol than those who not given phloroglucinol.

**Key Words:** Active phase, first stage of labour, phloroglucinol.

## INTRODUCTION

The problem and hazards of prolonged labour for both mother and fetus have been recognized for many years. The mother is exposed to high risk of infections, ketosis and obstructed labour while fetus faces the danger of infection, asphyxia and excessive cranial moulding. O'Driscrole at National Maternity Hospital, Dublin, introduced the concept of active management of labour and this has influenced obstetricians to change their outlook regarding the management of first stage of labour.<sup>1</sup>

Active management of labour is associated with low incidence of prolonged labour and low caesarean section rate.<sup>2</sup>

Each year half million women die of childbirth. Many of these deaths are direct consequence of prolonged labour.<sup>3</sup> Morbidity like obstetric fistula is common in 3<sup>rd</sup> Pakistan and mostly due to prolonged or obstructed labour. 54.85% fistulae were due to prolonged and obstructed labour.<sup>4</sup>

Protraction of first stage of labour which is one of the components of prolonged labour, does not necessarily result in less optimal uterine contractility. Although method to increase uterine contractility such as amniotomy and use of oxytocin has been shown to increase cervical dilatation yet these methods are not without complications.<sup>5</sup>

Spasmolytics and spasmolytics mixture were administered to facilitate dilatation of cervix during delivery and to shorten the first stage of labour.<sup>5</sup> In previous literature it is seen that spasmolytics like phloroglucinol reduces mean duration of labour. Active phase of first stage of labour lasted 227.74 (13.6) and 344.26 (9.49) in phloroglucinol and control group respectively.<sup>5</sup>

An ideal antispasmodics for acceleration of cervical dilatation should have prompt and long lasting action and will have no effect on uterine

inertia. It should have minimal side effects on mother and fetus.<sup>6</sup>

Phloroglucinol is one of spasmolytic primarily used for gastrointestinal colic. The drug was then extensively used during 1970's and early 1980's for augmentation of labour.<sup>7</sup>

Phloroglucinol can significantly shorten the birth process, reducing degree of maternal pain but have no ill effect on fetal heart rate.<sup>7</sup>

Phloroglucinol can effectively improve cervical dilatation during labour and is well tolerated by both mother and new born.<sup>8</sup>

Phloroglucinol shortens the duration of labour and is non toxic to mother and fetus. It has analgesic action. So purpose of my study is to see the effect of phloroglucinol on acceleration of first stage of labour, maternal and fetal side effects so to avoid complications of prolong or protracted labour.

## MATERIAL AND METHODS

**Setting:** This study was conducted in the Department of Obstetrics & Gynaecology Unit-1, Sir Ganga Ram Hospital, Lahore.

**Study Design:** Double blind randomized controlled trial.

**Sample Size:** Sample size of 200 cases: 100 in each group is calculated with in 95% confidence level, 80% power of test and taking magnitude of phloroglucinol and control group i.e. 227.74 (13.6) and 344.26 (9.49) minutes respectively.

**Study Duration:** Six months from 01-01-2010 to 30-06-2010.

**Sampling Technique:** Non-probability purposive sampling

### Inclusion Criteria

1. Primigravida
2. Age 18-35 years.
3. Gestational age 37-40 weeks (from dating scan)
4. Singleton fetus (on USG)
5. Vertex presentation (on USG)
6. Active phase of labour (cervical dilatation 3cm with regular palpable uterine contractions).
7. Reactive cardiotocogram (average fetal heart rate 140 beats per minutes with 4-6 beats variability and at least 2 accelerations and no deceleration recorded over 40 minutes).

### Exclusion Criteria

1. Any antenatal pregnancy complication like:

- ✓ Pre-eclampsia: raised BP (140/90) and proteinuria
  - ✓ Eclampsia: raised BP, proteinuria, fits.
  - ✓ Diabetes: excluded on history and relevant investigations i.e. blood sugar level.
2. Suspected CPD (cephalopelvic disproportion) on pelvic examination.
  3. PROM (premature rupture of membrane) on speculum examination.
  4. Placenta previa on USG.
  5. Cord prolapse on pelvic and speculum examination.

### Data Collection Procedure

A total of 200 primigravidas at term in active phase of first stage of labour were selected from Sir Ganga Ram Hospital based upon inclusion criteria. Informed consent was taken regarding usage of personal information for purpose of study. Demographic information like age and addresses were obtained. Patients were randomized in double blind fashion into groups. Ninety identical paper slips (with phloroglucinol written on 100 and other 100 blank slips) were enclosed in sealed envelopes and kept in box. For each patient doctor on duty picked up the envelop from box. The envelop was then numbered corresponding to serial number of patient neither the patient nor the doctor knew the contents of envelop. One group was given phloroglucinol at 0, ½ hour, 1 hour, 1½ hour interval 40mg I/V and other group was not given phloroglucinol and effects were recorded on predesigned proforma. Half hourly monitoring of vital signs, uterine contractions, fetal heart rate were done. Labour progress was plotted on partogram. All data pertaining to labour event, outcome that was measured in duration of first stage of labour and were recorded on questionnaire. All these information was collected on specially designed proforma (attached).

### Statistical Analysis

The collected data was entered into SPSS version 16 and analyzed. Age and duration of first stage of labour (in minutes) were calculated as mean and standard deviation. Comparison between both groups (i.e. mean duration of labour) was compared by using student 't' test. P value of  $\leq 0.05$  was considered as significant.

## RESULTS

The mean age of the patients in phloroglucinol group was  $26.1 \pm 2.6$  years and in control group

was 26.2±3.3 years. In phloroglucinol group, there were 37 (37%) patients in the age range of 20-25 years, 59 (59%) patients in the age range of 26-30 years and 4 (4%) patients in the age range of 31-35 years. In control group, there were 40 (40%) patients in the age range of 20-25 years, 54 (54%) patients in the age range of 26-30 years and 6 (6%) patients in the age range of 31-35 years (Table 1).

The mean weight of the patients in phloroglucinol group was 70.1±4.9 kg and in control group was 69.7±3.9 kg. In phloroglucinol group, there were 7 (7%) patients in the weight range of 60-65 kg, 52 (52%) patients in the weight range of 66-70 kg, 31 (31%) patients in the weight range of 71-75 kg and 10 (10%) patients in the weight range of 76-80 kg. In control group, there were 12 (12%) patients in the weight range of 60-65 kg, 50 (50%) patients in the weight range of 66-70 kg, 28 (28%) patients in the weight range of 71-75 kg and 10 (10%) patients in the weight range of 76-80 kg (Table 2).

The mean duration of pregnancy of the patients in phloroglucinol group was 38.4±1.4 weeks and in control group was 38.4±1.4 weeks. In phloroglucinol group, there were 56 (56%) patients in the duration of pregnancy range of 37-38 weeks, 38 (38%) patients in the pregnancy duration range of 39-40 weeks and 6 (6%) patients in the pregnancy duration range of 41-42 weeks. In control group, there were 51 (51%) patients in the pregnancy duration range of 37-38 weeks, 43 (43%) patients in the pregnancy duration range of

39-40 weeks and 6 (6%) patients in the pregnancy duration range of 41-42 weeks (Table 3).

The mean bishop score of the patients in phloroglucinol group was 4.9±0.7 and in control group was 4.9±0.7. In phloroglucinol group, there were 23 (23%) patients had 4 bishop score, 58 (58%) patients had 5 bishop score and 19 (19%) patients had 6 bishop score. In control group, there were 31 (31%) patients had 4 bishop score, 52 (52%) patients had 5 bishop score and 17 (17%) patients had 6 bishop score (Table 4).

The mean duration of active phase of first stage of labour of patients in phloroglucinol group was 282.8±23.4 minutes and in control group was 410.6±66.8 minutes. In phloroglucinol group, there were 47 (47%) patients in the duration of labour range of 240-280 minutes, 49 (49%) patients in the duration of labour range of 281-320 minutes, 2 (2%) patients in the duration of labour range of 321-360 minutes and 2 (2%) patients in the duration of labour range of 361-400 minutes. In control group, there were 5 (5%) patients in the duration of labour range of 240-280 minutes, 7 (7%) patients in the duration of labour range of 281-320 minutes, 6 (6%) patients in the duration of labour range of 321-360 minutes, 29 (29%) patients in the duration of labour range of 361-400 minutes, 13 (13%) patients in the duration of labour range of 401-440 minutes, 23m (23%) patients in the duration of labour range of 441-480 minutes and 17 (17%) patients in the duration of labour range of 481-520 minutes (Table 5).

Table 1: Distribution of patients by age

Age (Years)	Phloroglucinol group (n=100)		Control group (n=100)	
	No.	Percentage	No.	Percentage
20-25	37	37.0	40	40.0
26-30	59	59.0	54	54.0
31-35	4	4.0	6	6.0
Mean±SD	26.1±2.6		26.2±3.3	

Key: n Number of patients SD Standard deviation

Table 2: Distribution of patients by weight

Weight (Kg)	Phloroglucinol group (n=100)		Control group (n=100)	
	No.	Percentage	No.	Percentage
60-65	7	7.0	12	12.0
66-70	52	52.0	50	50.0
71-75	31	31.0	28	28.0
76-80	10	10.0	10	10.0
Mean±SD	70.1±4.9		69.7±3.9	

Key: n Number of patients SD Standard deviation

Table 3: Distribution of patients by duration of pregnancy

Duration (Weeks)	Phloroglucinol group (n=100)		Control group (n=100)	
	No.	Percentage	No.	Percentage
37-38	56	56.0	51	51.0
39-40	38	38.0	43	43.0
41-42	6	6.0	6	6.0
Mean±SD	38.4±1.4		38.4±1.4	

**Key:** n Number of patients SD Standard deviation

Table 4: Distribution of patients by bishop score

Bishop score	Phloroglucinol group (n=100)		Control group (n=100)	
	No.	Percentage	No.	Percentage
4	23	23.0	31	31.0
5	58	58.0	52	52.0
6	19	19.0	17	17.0
Mean±SD	4.9±0.7		4.9±0.7	

**Key:** n Number of patients SD Standard deviation

Table 5: Distribution of patients by duration of active phase of first stage of labour

Duration of labour (Minutes)	Phloroglucinol group (n=100)		Control group (n=100)	
	No.	Percentage	No.	Percentage
240-280	47	47.0	5	5.0
281-320	49	49.0	7	7.0
321-360	2	2.0	6	6.0
361-400	2	2.0	29	29.0
401-440	0	0	13	13.0
441-480	0	0	23	23.0
481-520	0	0	17	17.0
Mean±SD	282.8±23.4		410.6±66.8	

t -17.5 df 99 P 0.001

**Key:** n Number of patients SD Standard deviation

## DISCUSSION

The problem and hazards of prolonged labour, both for mother and fetus have been recognized for many years. The mother is exposed to high risk of infections, ketosis and obstructed labour while fetus faces the danger of infection, asphyxia and excessive cranial moulding. O'Driscrole at National Maternity Hospital, Dublin, introduced the concept of active management of labour and this has influenced obstetricians to change their outlook regarding the management of first stage of labour.<sup>1</sup>

Active management of labour is associated with low incidence of prolonged labour and low caesarean section rate.<sup>2</sup>

Each year half million women die of childbirth. Many of these deaths are direct consequence of

prolonged labour.<sup>3</sup> Morbidity like obstetric fistula is common in Pakistan and mostly due to prolonged or obstructed labour. 54.85% fistulae were formed due to prolonged and obstructed labour.<sup>4</sup>

Protraction of first stage of labour one of the components of prolonged labour, does not necessarily result in less than optimal uterine contractility. Although method to increase uterine contractility such as amniotomy and use of oxytocin has been shown to increase cervical dilatation yet these methods are not without complications.<sup>5</sup>

Spasmolytics and spasmolytics mixture were administered to facilitate dilatation of cervix during delivery and to shorten first stage of labour. In previous literature it is seen that spasmolytics

like phloroglucinol reduces mean duration of labour. Active phase of first stage of labour lasted 227.74 (13.6) and 344.26 (9.49) in phloroglucinol and control group respectively.<sup>5</sup>

Phloroglucinol can effectively improve cervical dilatation during labour and is well tolerated by both mother and new born.<sup>8</sup>

In our study the mean age of the patients in phloroglucinol group was 26.1±2.6 years and in control group was 26.2±3.3 years. As compared with the study of Tabassum et al<sup>5</sup> the mean age of the patients in phloroglucinol group was 26.4±6.1 years and in placebo group was 25.8±5.4 years, which is comparable with our study.

In our study the mean weight of the patients in phloroglucinol group was 70.1±4.9 kg and in control group was 69.7±3.9 kg. As compared with the study of Tabassum et al<sup>5</sup> the mean weight of the patients in phloroglucinol group was 66.8±4.5 kg and in placebo group was 69.1±3.7 kg, which is comparable with our study.

In our study the mean duration of pregnancy of the patients in phloroglucinol group was 38.4±1.4 weeks and in control group was 38.4±1.4 weeks. As compared with the study of Tabassum et al<sup>5</sup> the mean duration of pregnancy of patients in phloroglucinol group was 38.6±1.3 weeks and in placebo group was 38.7±1.4 weeks, which is comparable with our study.

In our study the mean duration of labour of the patients in phloroglucinol group was 282.8±23.4 hours and in control group was 410.6±66.8 hours. The difference was statistically significant (p=0.001). As compared with the study of Tabassum et al<sup>5</sup> the mean duration of active phase of first stage of labour in phloroglucinol group was 227.74±13.60 minutes and in placebo group was 344.26±9.49 minutes. The difference was also statistically significant (p=0.001), which is comparable with our study.

In another study conducted by Hao et al<sup>8</sup> who conducted his study to determine the effect of spasfon on course of labour and found that mean duration of labour was 186 minutes.

Phloroglucinol is one of spasmolytic primarily used for gastrointestinal colic the drug was extensively used during 1970's and early 1980's for augmentation of labour. Phloroglucinol can significantly shorten the birth process, reducing degree of maternal pain but have no effect on fetal heart rate.<sup>7</sup>

On the above discussion it is concluded, that duration of active phase of first stage of labour is shorter in patients given phloroglucinol than those who not given phloroglucinol.

## CONCLUSION

It is concluded from this study that duration of active phase of first stage of labour is significantly shorter in patients given phloroglucinol than those who not given phloroglucinol.

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