ONLINE FIRST

ORIGINAL ARTICLE

Effect of Phloroglucinol on Shortening the Duration of Active Phase of Labor: A Randomized Controlled Trial

Tahira Riaz[1*], Sadaf Shafique[2], Zahra Wasim[3], Sana Riaz[4], Huma Shehzadi[5], Areej Riaz[6]

[1]*Classified Gynecologist, Department of Obstetrics & Gynecology, CMH, Attock, Pakistan.*
[2]*Classified Gynecologist, Department of Obstetrics & Gynecology, CMH, Gujranwala, Pakistan.*
[3]*Classified Gynecologist, Department of Obstetrics & Gynecology, CMH, Rawalpindi, Pakistan.*
[4]*Resident, Department of Obstetrics & Gynecology, CMH, Quetta, Pakistan*
[5]*Registrar, Department of Obstetrics & Gynecology, Pak Emirates Military Hospital, Rawalpindi, Pakistan*
[6]*Medical Officer, Almustafa Trust, King Edward Medical University, Lahore, Pakistan*
Correspondence: *riaztahira3@gmail.com*
doi: 10.22442/jlumhs.2026.01395

ABSTRACT

OBJECTIVE: To determine the effect of phloroglucinol on shortening the duration of active phase of labor (APL).

METHODOLOGY: This randomized controlled trial was conducted at the Department of Obstetrics & Gynecology, CMH Attock, from January to June 2025. Pregnant women aged 18–35 years with gestation ≥37 weeks were randomly allocated to either the phloroglucinol (n=67) or placebo group (n=67). Phloroglucinol was given as an 80 mg intravenous stat infusion with Ringer's lactate. APL was defined as ≥4 cm cervical dilatation with regular uterine contractions. Duration of the 1st stage was measured from diagnosis of labor to full cervical dilatation. Data analysis was performed using IBM-SPSS version 26.0. P-value < 0.05 was considered significant.

RESULTS: In a total of 134 women, the mean age and gestational age were 27.89±4.29 years and 38.95±0.33 weeks, respectively. APL was significantly shorter in the phloroglucinol group (4.56±0.81 vs 5.19±1.72 hours, p=0.008). Apgar scores were notably higher in the phloroglucinol group at both 1 min (7.90±0.53 and 8.93±0.27, p=0.008) and 5 min (7.07±0.61 and 7.87±0.34, p<0.001). The cesarean section (CS) rate was lower in the phloroglucinol group (p=0.014), and the rate of vaginal deliveries was higher with phloroglucinol (76.1%) compared to the placebo (52.2%). No maternal or neonatal mortality was reported in this study.

CONCLUSION: Phloroglucinol was associated with a shorter active phase of labor duration and improved short-term outcomes.

KEYWORDS: Apgar score, gestational age, labor, mortality, phloroglucinol.

Trial Registration: NCT07184099 (https://clinicaltrials.gov)

INTRODUCTION

Labor lasting beyond 12 hours among primigravidas and 8 hours in multigravidas is described as prolonged labor. There is substantial evidence that acquiring and properly applying knowledge on the management of labor can significantly reduce the risk of adverse outcomes of prolonged and obstructed labor (POL) [1,2]. POL are the cause of maternal mortality in 8–10% of cases[3]. These women also face high risks of infection, dystocia, postpartum hemorrhage (PPH), perineal injury, and cesarean section (CS), while the fetus is also at risk of complications[4,5]. Contemporary data have shown that around 69% of severe or less severe complications are attributed to prolonged laborx[6].

Phloroglucinol is 1,3,5-trihydroxybenzoic and a popular antispasmodic, mainly chosen for gastrointestinal colic. This drug was widely used for labor enhancement in the 1970s and early 1980s. The EPAL Trial from Cameron revealed that the span of active phase of labor (APL) in the phloroglucinol and placebo group was 183.0±35.6 min versus 316.0±52.2 min ($p=0.046$), respectively[7]. In a local study by Janjua et al. [8] the duration of the 1st stage of labor in phloroglucinol versus placebo was 230.2±53.0 min versus 345.3±50.6 min ($p<0.001$), respectively.

In contemporary obstetric practice there is a clear shift toward timely active intervention to optimize labor outcomes and reduce maternal exhaustion and obstetric complications. However, the choice of pharmacological agents to safely accelerate cervical dilatation remains inconsistent, particularly in low- and middle-income settings such as Pakistan. Although antispasmodic agents like phloroglucinol have been proposed to shorten the active phase of labor without adversely affecting uterine contractility, existing evidence is largely derived from heterogeneous populations, with limited high-quality randomized data from local clinical settings where patient characteristics, labor management protocols, and resource availability differ substantially.

Phloroglucinol is not uniformly incorporated into standard labor management protocols in many tertiary care hospitals, reflecting uncertainty regarding its efficacy and safety in routine practice.

Therefore, this study was designed to address this local evidence gap by evaluating the effect of phloroglucinol on the duration of the active phase of labor in a controlled setting, thereby providing context-specific data to inform clinical decision-making. This study was planned to determine the effect phloroglucinol on the duration of APL.

METHODOLOGY

This randomized controlled trial was conducted at the Department of Obstetrics & Gynecology, CMH, Attock, Pakistan, from January to June 2025. This clinical trial was registered as NCT07184099 (https://clinicaltrials.gov). Considering an effect size of 0.3 with a 95% confidence level and a 5% error possibility, the sample size was calculated to be 134 (67 in each group) through G*Power sample size calculator software. Inclusion criteria were pregnant females aged 18-35 years with gestational age> 37 weeks. The exclusion criteria were cephalopelvic disproportion, double-scare uterus, fetal distress, life-threatening bleeding, eclampsia, or history of heart disease. Females with known allergy to phloroglucinol were also excluded. Simple random sampling technique was adopted for sample selection. Approval from the Institutional Ethical Committee was obtained (Letter No. 0195/2024). All females were subjected to informed and written consent before their enrollment in this study.
Using a computer-generated random sequence, women were randomly allocated in a 1:1 ratio to either the phloroglucinol group (n=67) or the placebo group (n=67). Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes opened at the time of intervention. The study was double-blinded with both participants and outcome assessors unaware of group allocation. Placebo (normal saline) was prepared in identical syringes. Phloroglucinol was given as an 80 mg intravenous stat dose (2 ampoules of 40 mg/4 mL each), diluted in 500 mL Ringer Lactate, and administered over 30 minutes. If < 3 contractions per 10 min interval appeared on the monitor, the woman was shifted for observation and 4-hourly monitoring. If ≥ 3 contractions in a 10-min interval and dilatation ≥ 4 cm, the woman was shifted to the delivery room. Labor was described when the women experienced regular painful uterine contractions (usually at interval of 2-4 min and lasting for 30-60 seconds or occasionally longer) that brought about effacement and dilatation of the cervix (diagnosed by per vaginal examination), and descent of the presenting part with reference from ischial spine -1, -2, -3, and +1, +2, and +3 cm above and below the ischial spine respectively. All cervical dilatation assessments were performed by trained obstetric residents using a standardized technique, and the same examiner assessed progression to minimize inter-observer variability. The 1st stage of labor was named as the diagnosis of labor to full dilatation of the cervix. Active labour was described as ≥ 4 cm cervical dilatation with regular uterine contractions (usually at intervals of 2-4 min and lasting for 30-60 seconds or occasionally longer).[9] Duration was measured from the time of diagnosis of labor until full dilatation of the cervix. Indications for cesarean section included failure to achieve adequate cervical dilatation despite adequate uterine contractions for ≥4 hours, non-reassuring fetal heart rate patterns on cardiotocography, cephalopelvic disproportion, malpresentation, and other obstetric indications as determined by the consultant obstetrician. Perinatal morbidity was documented as low Apgar score (<7 at 5 minutes), need for neonatal resuscitation, admission to neonatal intensive care unit (NICU), neonatal sepsis, birth asphyxia, or respiratory distress syndrome were also noted. A special proforma was designed to record all study data. **Figure 1** shows the CONSORT flow diagram.

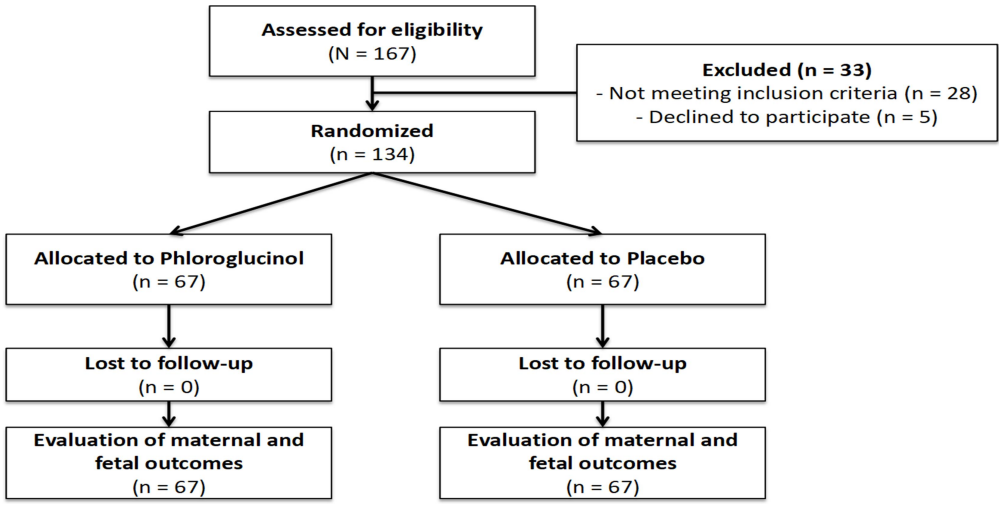

Figure 1: CONSORT flow diagram

Data were analyzed using "IBM-SPSS Statistics, version 26.0". Mean and standard deviation (SD), or median and interquartile range (IQR), were calculated for quantitative data depending on the normality distribution of the data (checked using the Shapiro-Wilk test). Frequencies and percentages were calculated for categorical data. Chi-square test or Fisher's exact test was utilized to compare categorical data, whereas independent sample t-test or Mann-Whitney U test were applied for quantitative data. Bivariate correlation analysis was performed using Pearson's correlation or Spearman's correlation. P-value<0.05 was considered significant.

RESULTS

In a total of 134 women, the mean age was 27.89±4.29 years (ranging 20-35 years. Residential status of 69 (51.5%) women was rural. The mean Bishop score and gestational age were 6.13±0.50 and 38.95±0.33 weeks, respectively. Comparison of baseline characteristics of women in both study groups is shown in **Table I**.

Table I: Comparison of baseline characteristics (N=134)

Characteristics		Total (N=134)	Phloroglucinol group (n=67)	Placebo (n=67)	P-value
Age	18-30	92 (68.7%)	44 (65.7%)	48 (71.6%)	0.456^
	31-35	42 (31.3%)	23 (34.3%)	19 (28.4%)	
Age (years)		27.89±4.29	28.19±4.12	27.58±4.47	0.411*
Residence	Rural	69 (51.5%)	39 (58.2%)	30 (44.8%)	0.120^
	Urban	65 (48.5%)	28 (41.8%)	37 (55.2%)	
Gravidity	1-2	111 (82.8%)	58 (86.6%)	53 (79.1%)	0.252^
	>2	23 (17.2%)	9 (13.4%)	14 (20.9%)	
Bishop Score		6.13±0.50	6.09±0.54	6.18±0.46	0.304*
Gestational age		38.95±0.33	39.00±0.24	38.90±0.39	0.083*

**Independent sample t-test applied; ^Chi-square test applied*

The duration of the APL was significantly less in the phloroglucinol group (4.56±0.81 vs 5.19±1.72 hours, p=0.008). Apgar scores were notably higher in the phloroglucinol group at both 1 min (7.90±0.53 and 8.93±0.27, p=0.008) and 5 minutes (7.07±0.61 and 7.87±0.34, p<0.001). The CS rate was lower in the phloroglucinol group (19.4% vs 35.8%, p=0.014). No maternal or neonatal mortality was reported in this study (**Table II**).

Table II: Comparison of outcomes (N=134)

Characteristics		Total	Phloroglucinol group (n=67)	Placebo (n=67)	P-value
Duration of active phase of labor		4.87±1.37	4.56±0.81	5.19±1.72	0.008*
Apgar score	1-minute	7.49±0.70	7.90±0.53	7.07±0.61	0.008*
	5-minutes	8.40±0.61	8.93±0.27	7.87±0.34	<0.001*
Delivery mode	Cesarean section	37 (27.6%)	13 (19.4%)	24 (35.8%)	0.014^
	Instrumental delivery	11 (8.2%)	3 (4.5%)	8 (11.9%)	
	Vaginal delivery	86 (64.2%)	51 (76.1%)	35 (52.2%)	
Perinatal morbidity		18 (13.4%)	8 (11.9%)	10 (14.9%)	0.612^

**Independent sample t-test applied; ^Chi-square test applied*

The correlation matrix presented in **Table III** shows the relationships between various quantitative variables in the study. Significant positive correlation between gestational age and Apgar score at 1 min (r=0.176, p=0.042) was noted. A significant negative correlation existed between labor duration and Apgar score at 5 min (r=-0.265, p=0.002).

Table III: Correlation matrix analyzing quantitative variables

Quantitative variables		Quantitative variables					
		Gestational age	Labor duration	Age	Bishop Score	Apgar (1 minute)	Apgar (5-minutes)
Gestational_age	R	1	.112	-.021	-.056	.176*	.132
	P-value		.199	.811	.520	.042	.128
Labor_duration	R	.112	1	-.046	.013	-.058	-.265**
	P-value	.199		.597	.885	.504	.002
Age	r	-.021	-.046	1	.087	-.082	-.006
	P-value	.811	.597		.316	.348	.946
Bishop_Score	r	-.056	.013	.087	1	-.016	-.052
	P-value	.520	.885	.316		.858	.553
Apgar (1-minute)	r	.176*	-.058	-.082	-.016	1	.704**
	P-value	.042	.504	.348	.858		.000
Apgar (5-minute)	r	.132	-.265**	-.006	-.052	.704**	1
	P-value	.128	.002	.946	.553	.000	

Pearson's correlation applied.

DISCUSSION

This study found that the duration of the APL was significantly shorter with phloroglucinol compared to placebo. Manzoor et al.[10] reported a statistically significant reduction in the APL by approximately 2 hours in the phloroglucinol group ($p<0.001$). Rauf et al.[11] observed that the APL was shortened by almost two hours in patients receiving phloroglucinol, highlighting its potential to expedite labor progression. Nazir et al. documented that the duration of labor in the 1st stage was significantly less with phloroglucinol compared to controls. The same findings were reported by Tahir et al.[12] The reduction in labor duration can be attributed to the antispasmodic properties of phloroglucinol, which help relieve cervical spasm and facilitate cervical dilatation. The shorter duration of labor may help reduce maternal fatigue and can contribute to minimizing the odds of complications linked with prolonged labour. The ability of phloroglucinol to reduce the span of labor lies in its effects on relaxing the smooth muscles of the cervix, which further leads to more efficient cervical dilatation[13]. These effects are important during APL, where rapid and adequate cervical dilatation is essential for the time progression of labor. By minimizing cervical spasm, phloroglucinol can facilitate a smoother and faster labor process[14].

Various approaches including amniocentesis, prostaglandin analogs, and oxytocin, have been used to increase uterine contractions and minimize the length of laborx[15]. These methods often have adverse maternal and fetal effects like uterine rupture, PPH, fetal distress, and asphyxia[16,17]. Hirsch first introduced the concept of using antispasmodic drugs to shorten the 1st stage of labor in 1937[17]. Hirsch documented that the duration of labor could be reduced by 2-4 hours with the administration of an atropine-like drug. These medications alleviate cervical spasm, facilitating cervical dilation during the 1st stage of labor[18,19].

This study noted that Apgar scores were notably higher in the phloroglucinol group at both 1 min and 5 min. Parveen et al. reported that babies born in the interventional group (receiving phloroglucinol) had better Apgar scores compared to controls ($p<0.01$).[20] Higher Apgar scores in the phloroglucinol group suggest better neonatal outcomes, which may be due to the reduced stress and shorter duration of labor. The association between higher gestational age and better Apgar scores at 1 min further supported the beneficial impact of optimized labor management on neonatal health. The negative correlation between labor duration and Apgar score at 5 min indicated that prolonged labor adversely affects neonatal outcomes, emphasizing the importance of interventions like phloroglucinol to shorten labor duration. The improved Apgar scores observed in the phloroglucinol group can be attributed to the reduced duration of labo. Prolonged labor is associated with increased fetal distress, which can negatively impact neonatal outcomes.[21] By shortening labor duration, phloroglucinol helps in minimizing fetal distress, leading to better Apgar scores and overall neonatal health.

This study found a lower CS rate with phloroglucinol. Rauf et al. [11] reported that the mode of delivery was not altered with respect to the use of phloroglucinol. Still, the duration of labor was significantly less among women who were administered phloroglucinol. This study showing lower CS rate in the phloroglucinol group could be due to efficient labor management, which may have reduced the need for surgical intervention. This study supports the utilization of phloroglucinol as an effective approach to reduce the duration of labor, improve neonatal outcomes, and reduce the need for CS.

This study had several limitations which must be acknowledged. A single-centre study setting may not reflect practices in different settings of the region. Lack of blinding in outcome assessment may have introduced some bias. This study only focused on immediate labor and neonatal outcomes without long-term follow-up.

CONCLUSION

Phloroglucinol was associated with a shorter active phase of labor duration and improved short-term outcomes. By optimizing labor management strategies, healthcare providers can contribute to safer and more positive childbirth experiences for women.

Acknowledgments: The authors would like to thank Muhammad Aamir Latif (RESnTEC) for his assistance in the trial registration of this research.

Ethical Permission: CMH Attock, Pakistan, IRB approval letter No. 0195/2024.
Conflict of Interest: No conflicts of interest, as stated by the authors
Financial Disclosure / Grant Approval: No funding agency was involved in this research.
Data Sharing Statement: The corresponding author can provide the data on reasonable request. Privacy or ethical restrictions bound us from sharing the data publically.

AUTHOR CONTRIBUTION

Riaz T: Data collection and synthesis, responsible for data's integrity, proof reading, approved for final publication.
Shafique S: Conception and design, drafting, critical revisions, approved for publication.
Wasim Z: Conception and design, drafting, critical revisions, approved for publication.
Riaz S: Drafting, proof reading, critical revisions, approved for final publication.
Shehzadi H: Literature review, proof reading, critical revisions, approved for final publication.
Riaz A: Data analysis, proof reading, critical revisions, approved for final publication**.**

REFERENCES

1. Ayenew AA. Incidence, causes, and maternofetal outcomes of obstructed labor in Ethiopia: systematic review and meta-analysis. Reprod Health. 2021; 18(1): 61. doi: 10.1186/s12978-021-01103-0.
2. Yeshitila YG, Daniel B, Desta M, Kassa GM. Obstructed labor and its effect on adverse maternal and fetal outcomes in Ethiopia: A systematic review and meta-analysis. PLoS One. 2022; 17(9): e0275400. doi: 10.1371/journal.pone.0275400.
3. Organization WH. Preventing Prolonged Labour: a practical guide. The partograph. Part I: Principles and Strategy. Available at: https://iris.who.int/handle/10665/58903
4. Triebwasser JE, VanArtsdalen J, Kobernik EK, Seiler K, Langen ES. Assessing Maternal and Fetal Risks Associated with Prolonged Induction of Labor. Am J Perinatol. 2019; 36(5): 455-459. doi: 10.1055/s-0038-1675642.
5. Young C, Bhattacharya S, Woolner A, Ingram A, Smith N, Raja EA et al. Maternal and perinatal outcomes of prolonged second stage of labour: a historical cohort study of over 51,000 women. BMC Pregnancy Childbirth. 2023; 23(1): 467. doi: 10.1186/s12884-023-05733-z.
6. Huda FA, Ahmed A, Dasgupta SK, Jahan M, Ferdous J, Koblinsky M et al. Profile of maternal and foetal complications during labour and delivery among women giving birth in hospitals in Matlab and Chandpur, Bangladesh. J Health Popul Nutr. 2012; 30(2): 131-42. doi: 10.3329/jhpn.v30i2.11295.
7. Tchente CN, Nana TN, Tolefac PN, Abanda MH, Angong FTE, Tamambang RF et al. Effects of phloroglucinol on the active phase of labour (EPAL trial): a single blindedrandomized controlled trial in a tertiary hospital in sub-Sahara Africa. Pan Afr Med J. 2018 May 9; 30: 17. doi: 10.11604/pamj.2018.30.17.14728.
8. Januja M, Wajid R, Sarwar A. Role of Phloroglucinol in Reducing Duration of Active 1st Stage of Labour. Med Forum. 2024; 29(9): 84-86.
9. Samreen, Rauf B, Nazir L, Jehangir K, Kishwar N. Effectiveness of Phloroglucinol in Shortening the Active Phase of the First Stage of Labour in Term Pregnancies. J Saidu Med Coll Swat. 2024; 14(1): 35-40. doi: 10.52206/jsmc.2023.13.4.844.
10. Manzoor A, Abbasai SE, Khan S, Khan S, Saeed F, Mushtaq M. Effect of Phloroglucinol in Shortening Active Labor in Primigravidas at Term. J Soc Obstet Gynaecol Pak. 2024; 14(1): 40-44.
11. Rauf R, Begum A, Bakhtair U, Shaheen A, Ziagham A, Azra Saeed. Phloroglucinol for Acceleration of Labour: Double Blind, Randomized Controlled Trial. J Islamic Int Med Coll. 2013; 8(1): 43-47.
12. Nazir R, Bano N, Rehmatullah N. Effect of Different Doses of Phloroglucinol on 1st Stage of Labour in Term Pregnancies. J Soc Obstet Gynaecol Pak. 2021; 11(2): 112-116.
13. Tahir S, Liaqat M, Jabeen S, Rasul S. Effectiveness of Phloroglucinol to accelerate labor in Primigravidas at term: Double blind, randomized controlled trial. Pak J Med Health Sci. 2015; 9(1): 169-171.
14. Schiattarella A, Riemma G, Sisti G, Savoia F, Rapisarda A, De Franciscis P et al. Efficacy of phloroglucinol in shortening the first stage of labor: systematic review and meta-analysis of randomized controlled trials. J Matern Fetal Neonatal Med. 2022; 35(25): 7036-7042. doi: 10.1080/14767058.2021.1936488.

15. Hofmeyr GJ, Gülmezoglu AM, Pileggi C. Vaginal misoprostol for cervical ripening and induction of labour. Cochrane Database Syst Rev. 2010; 2010(10): CD000941. doi: 10.1002/14651858.CD000941.pub2.
16. Kelly AJ, Tan B. Intravenous oxytocin alone for cervical ripening and induction of labour. Cochrane Database Syst Rev. 2001; (3): CD003246. doi: 10.1002/14651858.CD003246. Update in: Cochrane Database Syst Rev. 2009 Oct 07; (4): CD003246. doi: 10.1002/14651858.CD003246.pub2.
17. Hirsch FE. Antispasmodic drugs in labour. Br Med J. 1937; 2: 559–60.
18. Yu J, Chen L, Wang X, Li X. Efficacy and Safety Analysis of Phloroglucinol in Combination with Oxytocin for the Induction of Labor in Women with Term Premature Rupture of Membranes (PROM). Comput Math Methods Med. 2022; 2022: 2617075. doi: 10.1155/2022/2617075.
19. Wu F, Chen Y, Zheng C. Efficacy of phloroglucinol for acceleration of labour: a systematic review and meta-analysis. Arch Gynecol Obstet. 2021 Aug; 304(2): 421-428. doi: 10.1007/s00404-021-06043-5.
20. Parveen T, Hussain H, Khattak NN. Effects of phloroglucinol on augmentation of labour in primigravida. J Med Sci. 2013; 21(3): 131-133.
21. Young C, Bhattacharya S, Woolner A, Ingram A, Smith N, Raja EA et al. Maternal and perinatal outcomes of prolonged second stage of labour: a historical cohort study of over 51,000 women. BMC Pregnancy Childbirth. 2023; 23(1): 467. doi: 10.1186/s12884-023-05733-z.