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Effectiveness of Phloroglucinol in Shortening the Active Phase of the First Stage of Labour in Term Pregnancies

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ABSTRACT

Background: Labour is a normal physiological process, involving increasing myometrical contractions, cervical dilation and effacement resulting in delivery of the fetus and placenta and the initiation of the process of lactation. First Stage of labour lasts for 12-16hrs in primigravida and 6-8 hrs in multigravida. Two important characteristics of labour are uterine contractions and cervical effacement

Objectives: To determine the effectiveness of phloroglucinol in shortening the 1st stage of labour in term pregnancies.

Material and Methods: It was a double blinded randomized control trial (RCT) conducted in Obs and Gynae department of Hayatabad Medical Complex, MTI, Peshawar Pakistan, over a period of 6 months from 20th October 2022 to 20th April 2023. Patients were selected randomly for placebo and pluroghlucinol group and recorded on structured proforma. Total 375 women were selected in first stage of labour. In which 187 were given Phloroglucinol and 188 women received placebo.

Results: The mean age of patients in phloroglucinol group was 28.3 ± 4.01 and in control group was 26.6 ± 6.8 years. The mean period of gestation in Phloroglucinol group was 37.3 ± 4.0 while in control group was 38.6 ± 2.08 weeks. The mean BMI of patients in Phl group was 22.12 ± 1.4 while in control group was 21.6 2 ± 1.5. The mean duration of active phase of 1st stage of labour in Phl group was 290.4 ± 29.7 minutes while in control group was 402.4 ± 29.7 minutes.

Conclusion: Phloroglucinolhas significant effect in shortening the 1st stage of labour.

Keywords: Active phase, Labour, Phloroglucinol, Pregnancy.

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INTRODUCTION

Labour is a normal physiological process, involving increasing myometrical contractions, cervical dilation and effacement resulting in delivery of the fetus and placenta and the initiation of the process of lactation.[1,2] First Stage of labour lasts for 12-16hrs in primigravida and 6-8 hrs in multigravida.[3] Two important characteristics of labour are uterine contractions and cervical effacement .if despite of strong uterine contractions, cervix remains rigid and unaffected, this may results in cervical dystocia and the labour will be prolonged and complicated.[4] Prolonged labour has many adverse effects on mother and fetus both intrapartum and postpartum like risk of infection, obstructed labour, instrumental delivery, perineal injuries and postpartum haemorrhage while the fetus is at risk of asphyxia birth injuries, intrapartum death and early neonatal death, prolonged labour usually ends up in C-Section.[5]

Incidence of prolonged labour and its complications can be reduced by actively managing the labour process. Ruptureduterus due to obstructed labour accounts for 70% of all maternal deaths.[6] Each year a lot of women die due to direct or indirect consequences of prolonged labour.[7] Asa common practice in labour, to avoid prolonged labour, membranes are ruptured and oxytocin and prostaglandins are given to increase cervical dilation by increasing uterine contractility,[8] but all of these interventions are not free of complications. Spasmolytics have been used for cervical dilation, the anticholinergicspasmolytics used for cervical dilation was associated with nausea, vomiting and dry mouth.[1] Therefore an ideal spasmolytic was needed that is effective in dilation and effacement of cervix without interfering with uterine contractility, having no adverse effects on mother and fetus.

Non anticholinergic like phloroglucinol has relaxing effects on smooth muscles. It softens the cervix without inhibiting uterine contractions hence not interfering with uterine contractility.[9] The medicine has no adverse effect on mother such as raised BP, tachycardia, ruptureof uterus or neonatal asphyxia.[10] Phloroglucinol, a spasmoanalgesic and spasmolytic, initially used for gastrointestinal, renal and billiarycolics[11] but nowadays it has anti inflammatory and anticancer uses and is considered to be a modulator of prostaglandin release and oxidative stress.[12]

In one study, Metaanalysis of randomized control trail was done, 5 RCTS, including 487 pregnant women were analysed, a significant shortening of first and second stage of labour was achieved in phloloroglucinal group.[13] As painless and shorter labour are the dream of every mother and the aim of every obstetrician. To achieve this goal that phloroglucinol is effective and to be used during labour, the main aim of this study was to investigate the effectiveness of phloroglucinol on the first stage of labour. As we want to assess the effectiveness of phloroglucinol on the first stage of labour and its outcomes.

MATERIAL AND METHODS

It was a randomized control trail study (trial registry number: cnl_hameco_1157) of conducted in HMC,

Hayatabad Medical Complex, Peshawar, Pakistan.

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MTI, Peshawar Pakistan, Keeping in view the inclusion and exclusion criteria. After permission to the hospital ethical committee (HEC number: 923, dated 6th September 2022), all the patients were divided into two groups. The duration of study was 6 months, from 20th October 2022 to 20thApril 2023. Patients were selected randomly for placebo and pluroghlucinol group by double blind methods. A total of 375 patients were included in the study, 187 in pluroghlucinol group and 188 patients in placebo group (Figure 01).

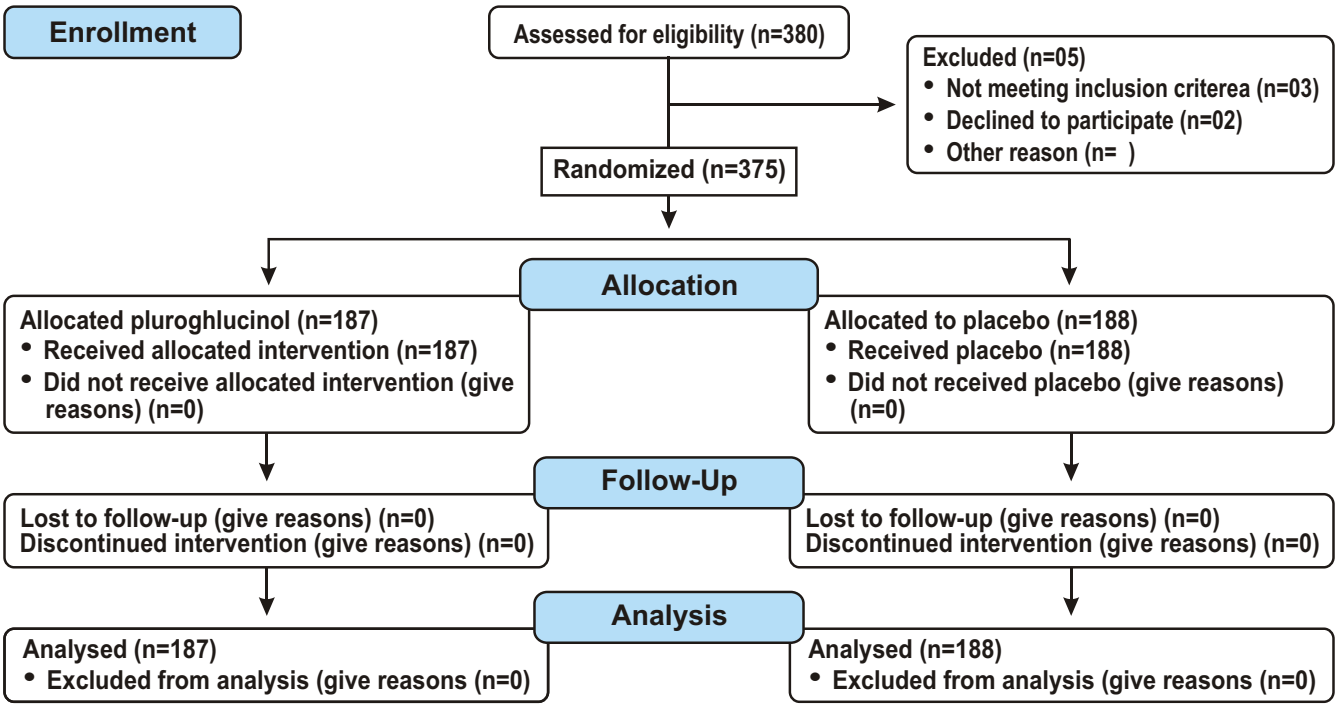


Figure 01. CONSORT Flow Chart

The sample size was calculated by using WHO sample size calculator at 95% confidence interval with the prevalence of 40% (of phloroglucinolin shortening the first stage of labour in term pregnancies).[19]

First stage of labour is defined as the time between the onset of labour and full cervix dilation. First stage of labour is defined as the time between the onset of labour and full cervix dilation. At 4cm cervical dilation patients in phloroglucinol group were given injection. Phloroglucinol 40 mg, second injection of 40mg at 1 hour after the second injection and third dose of 80 mg phloroglucinol injection after 2 hours of the first injection while the placebo group received same doses of placebo (use ringer lactate) at the same intervals Gynaecologist and anaesthesia team were fully involved while administering the doses. Exclusion criteria of the study was double scar uterus, cephalopelvic disproportion, fetal distress, life threatening bleeding, multiple pregnancies, preterm labour and women with known allergies to phloroglucinol.

A special designed Proforma was used for data collection. Labour was monitored according to labour care guide. Primary outcomes including duration of active phase of first stage of labour, mode of delivery, Apgar score, maternal and neonatal outcomes and any adverse effects were recorded. Data was entered and analyzed in SPSS version 22.0, mean and standard deviation was calculated for quantitative variables like age, Gestational age, duration of active labour, blood loss, Apgar score for both groups were measured and t-test was applied for comparison of both groups.

RESULTS

A total of 332 participants were included and analyzed in our study for results interpretation. The table 01 indicates that 332 participants had a vaginal delivery, and among them, 180 received the drug and 153 received a placebo. The mean age for drug given group (28.33±4.01) and for placebo was (26.66±6.87). There were 43 participants, who had a cesarean section, and among them, 35 received the drug and 7 received a placebo. The p-value for the mode of delivery variable is less than 0.001, indicating that there was a significant difference between the drug and placebo groups based on mode of delivery.

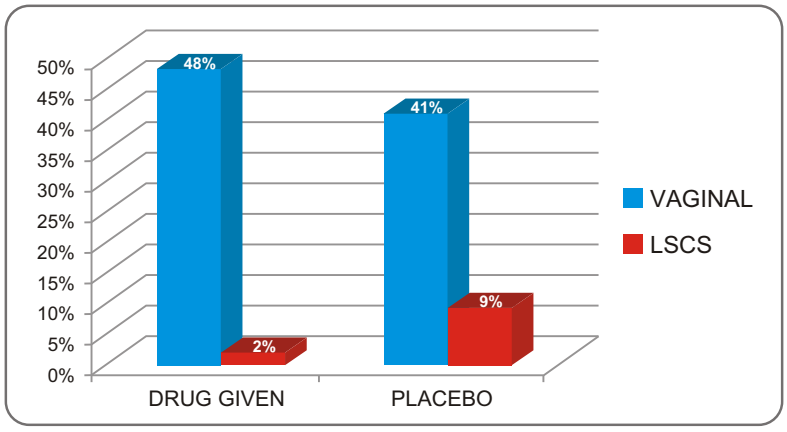


Figure 01. Comparison of the mode of delivery between treatment groups.

The table 01 titled "Labor Duration Mins" shows the distribution of participants in the study by duration of labor and treatment group. The p-value for the labor duration variable is less than 0.001, indicating that there was a significant difference between the drug and placebo groups based on labor duration. The mean labor duration was shorter for the drug given group (290.44 minutes) compared to the placebo group (402.05 minutes).

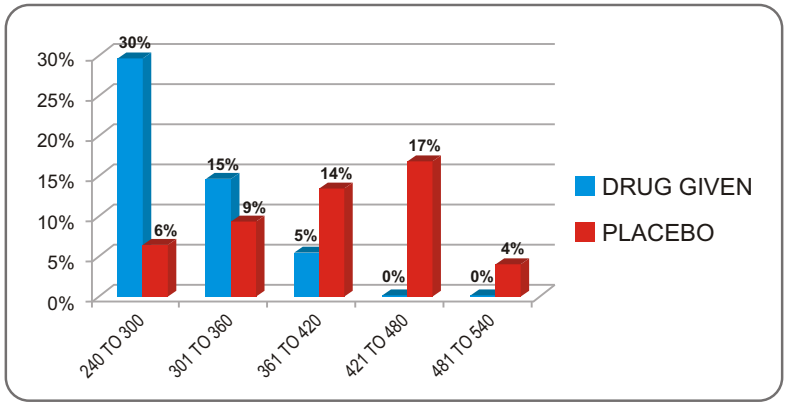


Figure 02. Distribution of study participants by the duration of labor in minutes and treatment group.

Primary PPH refers to postpartum hemorrhage that occurs within the first 24 hours after delivery. The P-value for primary PPH was 0.176, which indicates that there was no statistically significant difference between the drug and placebo groups in terms of primary PPH. The frequency of primary PPH was very low in both groups (0-1%) and the difference was not statistically significant.

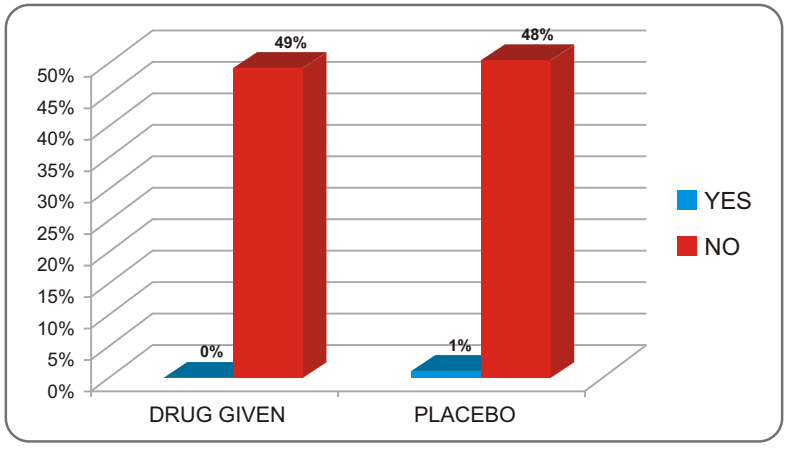


Figure 03. Comparison of the frequency of primary PPH between treatment groups.

Table 01. Statistical analysis of the PLACEBO versus DRUG GIVEN

Variables		Drug Given		Placebo		Total		P value
		n	%	n	%	n	%	
Age	18 to 28	80	21	82	22	162	43	0.936
	29 to 38	68	18	64	17	132	35	
	more than 38	39	10	42	11	81	22	
Total		187	50	188	50	375	100	
Mean±SD								
Pog	37 to 38	58	15	49	13	107	29	0.588
	39 to 40	94	25	106	28	200	53	
	41 to 42	35	9	33	9	68	18	
Total		187	50	188	50	375	100	
Mean±SD								
Mode of Delivery	180	153	48	332	41	180	89	<0.001
	7	35	2	43	9	7	11	
Total	187	188	50	375	50	187	100	
Parity	PG	119	32	121	32	240	64	
	MG	68	18	67	18	135	36	
Total		187	50	188	50	375	100	
Labor Duration Mins	240 TO 300	111	30	24	6	135	36	<0.001
	301 TO360	55	15	35	9	90	24	
	361 TO 420	20	5	51	14	71	19	
	421 TO 480	1	0	63	17	64	17	
	481 TO 540	0	0	15	4	15	4	
Total		187	50	188	50	375	100	
Mean±SD		290.44 ±29.73		402.05 ± 53.99				
Bmi	less than 18	20	5	28	7	48	13	0.676
	18 TO 25	109	29	99	26	208	55	
	more than 25	58	15	61	16	119	32	
Total		187	50	188	50	375	100	
Mean±SD		22.125 ±1.494		21.625 ±1.571				
Bishop	4	69	18	56	15	125	33	0.122
	5	103	27	112	30	215	57	
	6	15	4	20	5	35	9	
Total		187	50	188	50	375	100	
Mean±SD		4.7 ± 0.202		4.8 ±0.312				
Primary Pph	YES	1	0	4	1	5	1	0.176
	NO	186	49	184	50	370	99	
Total		187	50	188	50	375	100	

DISSCUSSION

In our study patient's age, gestational age, weight of the patients and BISHOP score were the baseline demographic and clinical features which were studied in both the control group and the interventional group. All these parameters were almost similar in both groups with a p value > 0.05, which is not significant. The primary outcome measures of this study were duration

of first stage of labour, Apgar score, mode of delivery and any complications faced by mother or baby in both groups.

In this study the duration of active phase of first stage of labour was 290.44 ± 29.73 mints in pholoroglucinol group and 402.05± 53.99 mints in placebogroup. as the difference is statistically significant (p=0.001). Same results were obtained by Janjua et al[7] where the mean duration of active phase first stage of labour in phlorogical group was 282.8 ± 23.4 mints and placebo group was 410.6 ± 66.8 mints. The difference was also statistically significant (p= 0.0001) which is comparable with our study. Same results were also shown by systemic review and Meta-analysis of randomized control trail done by Antonio schiatterella et al.[13] these results were also comparable with the results obtained by Tahira and colleagues[15] which shows shortening the duration of active phase of first stage of labour which was 183.04 mints in phloroghlucinol group and 316 mints in placebo group.

The second primary outcome measure of our study was Apgar score of the baby. In our study the babies born in phloroglucinol group had better Apgar score as like the study done Tchente et al and colleagues.[11] Another important outcome of our study was mode of delivery. In out study most of the deliveries in phloroglucinol group were normal vaginal deliveries. Same results were showed by Tahir et al[1] and Nazir et al.[11] Another major outcome of the study was postpartum complications like PPH. In our study few patients went into PPH in placebo group which is comparable with study done by Fan et al.[14] Study done in China by Jiazheng et al is in comparison with our study in terms of shortening the process of labour and improving vaginal delivery in patients who received phyloroglucinol.[15] A comparative study between drotavarineandphloroglucinol done by Salma Batool Naqvi and colleagues shared that phloroglucinol is far better in efficiency and fetal and maternal outcomes is like the results of our study[16] Same results were observed by Maham Janjua and Colleagues.[18]

CONCLUSIONS

The statistical data of our study conclude that 160mg of phloroglucinol has significantly reduced the 1st stage of labour without causing any adverse effects on both mother and baby as compared to labour without spasmolytic, with phloroglucinol.

Ethical Consideration

This study was approved by the ethical review board of Hayatabad Medical Complex, MTI, Peshawar Pakistan.

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There is no role of any funding agency in this study.

Conflict of Interest

Authors declared no conflict of interest

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DATA SHARING STATEMENT: The data that support the findings of this study are available on request from the corresponding author. The data is not publicly available due to privacy or ethical restrictions.

AUTHORS' CONTRIBUTION

The following authors fullfill authorship criteria as per ICMJE guidelines;

Samreen, Rauf B:	Substantial contribution to conception and design, drafting the manuscript, final approval, agreed to be accountable for all the work.
Nazir L:	Substantial contribution to conception and design, data acquisition, drafting the manuscript, final approval, agreed to be accountable for all the work.
Jehangir K:	Analysis and interpretation of data, drafting the manuscript, final approval, agreed to be accountable for all the work.
Kishwar N:	Analysis and interpretation of data, critical revision,final approval, agreed to be accountable for all the work.

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