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EFFICAY OF PHLOROGLUCINOL IN COMPARISON TO THE PLACEBO AT THE FIRST ACTIVE STAGE OF LABOUR

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Abstract:

Objectives: *The objective of this research is the comparison of phloroglucinol to placebo in terms of mean duration of active first-stage of labour.*

Materials & Methods: *The study included sixty singletons pregnant patients having first-stage of uncomplicated labour, of (18 – 40) age group. Obstetrical/surgical complications, multiple pregnancies, heart-rhythm abnormality, asthma, and heart failure was the study's exclusion criteria. Patients were divided into group A of spasfon/phloroglucinol and B of placebo randomly through lottery method. Then we noted the time (in minutes) of first-stage labour from (3 – 4) cm cervical dilatation having uterine contractions as regular in order to complete cervical dilation (10 cm) and descent of fetal part presentation.*

Results: *The mean age was (27.2±5.2) and 26.8±5.4 years among the patients of group A and B respectively. Mean gestational age was 38.3±1.4 and 38.5±1.3 weeks among the patients of group A and B respectively. The mean duration of first-stage labour was 230.2±52.9 and 345.3±50.5 minutes among the patients of group A (Phloroglucinol) and group B (Placebo) with p-value <0.0001.*

Conclusion: *The study concludes that Phloroglucinol is comparatively more effective in the reduction of the duration of first-stage (active) labour than placebo and is recommended for the acceleration of labour among such concerned patients.*

Keywords: *Neonatal, Parous Women, Cervical Effacement, Analgesics, Labour, Contractility*

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INTRODUCTION:

Labour is described as a multi-factorial process, involving cervical dilatation and ripening, myometrial contraction, and removal of placenta and fetus in a manner of order. In primigravida, the FSOL lasts about 12 to 16 hours and 6 to 8 hours in parous women [1]. If the labour is prolonged, it can lead to increased neonatal/maternal morbidity/mortality because of post-partum haemorrhage, sepsis, maternal exhaustion, asphyxia, and fetal distress where in-time detection and treatment is necessary [2, 3]. Prolonged labour relates to epidural analgesia, high-level maternal stress-hormones, age, pre-labour ruptured membranes and labour induction but among most cases, causes are unknown [4]. The main features of labour are cervical effacement and contractility. If contractions are powerful with cervix remained rigid/unyielding, the labour will be prolonged and complicated [3, 5]. To make sure a woman doesn't exceed twelve hours' labour, active management concept has been developed. The association of active management of labour relates to reduced labour duration and rate of Caesarean section [6]. A prolonged active labour (>12 hours) causes exhaustion which leads to excessive bleeding and infection. Due to this distress, and asphyxia (low oxygen), the unborn baby can be harmed. As a common practice in labour, membranes are ruptured (water breakage) and contractions are speeded up through medication as an on-going support to avoid prolonged labour. To relieve cramps, doctors give anti-spasmodic drugs to patients which either relaxes muscles directly or interferes with nerves messages sent to muscles to contract. A thought also involves that these drugs may aid in cervix dilatation during labour as a treatment/preventive strategy [5, 7]. On the other hand, methods like the use of oxytocic and amniotomy can speed up cervical dilation but they still have complications [7]. The mixture of spasmo-analgesics and spasmolytics are used to facilitate cervix dilatation during delivery and to decrease FSOL [8]. Any ideal anti-spasmodic used to accelerate cervical dilatations must have abrupt and long-lasting action without risks of uterine inertia and adverse effects on contractility of uterine. It should not affect foetus and mother adversely as well [8, 9]. Anti-spasmodics' administration during labour leads to effective and faster cervix dilation [10]. The drugs of anti-spasmodics bring spasms to relieve of smooth muscle-tissue having either neuro-tropic or musculotropic effects. Smooth muscles and connective tissues make cervix, innervated by fibres of parasympathetic nerves. Smooth muscles makeup of 15% of the cervix, found under the internal os, relaxed by antispasmodics (Musclotropic). Musclotropic anti-spasmodics are related to papaverine (having mild Calcium-channel-blocking effects) and phosphodiesterase type (IV inhibitors), directly acting on smooth muscle cells with no anticholinergic effects, inhibiting spasm [11, 12]. Neurotropic antispasmodics breaks the smooth-muscle and para-sympathetic nerve connection acting as acetylcholine at receptors of muscarinic, preventing muscle-spasm [10, 12]. Many hospitals use drotaverine and phloroglucinol as pharmacological agents to decrease FSOL duration [3]. Hospitals in India use drotaverine hydrochloride for anti-spasmodic as their labour room protocol in order to decrease the duration/pain of labour. It is used together with oxytocin augmentation, amniotomy, and tramadol for the relief in pain [13]. During spasm of smooth muscle, phloroglucinol provides strong relaxation, as well as for urethra and intestine but zero effect on blood vessels' smooth muscle. Moreover, the lower portion and cervix of the uterus gets soften leading to uterine contractions thus reducing post-delivery bleeding. Studies did not record any atropine effect using this and it is non-toxic to the fetus [14]. Tabassum S et al. [8] shows a 227.7±13.6 minutes of FSOL with phloroglucinol comparing to placebo with 344.2±9.49 minutes. The prolonged labour leads to an increase in neonatal/maternal morbidity/mortality because of post-partum haemorrhage, sepsis, maternal exhaustion, asphyxia, and fetal distress, so this study aims to determine the effectiveness of phloroglucinol in the active FSOL duration reduction for the local population. It the outcomes are promising; the practice will be encouraged in order to reduce both mortality/morbidity of fetus and mother.

OPERATIONAL DEFINITIONS:

MD of Active FSOL: This was taken when cervical dilatation was 3 to 4cm with uterine contractions regular in order to complete cervical dilation (10cm & fetal's part descending).

MATERIAL AND METHODS:

Study design: Randomized-controlled-trial.
Setting: Dept. of Obstetrics & Gynaecology, Mayo Hospital Lahore.
Sample selection:
Inclusion Criteria:
1. Cases of singleton pregnancy with active FSOL, not complicated, according to an operational definition.
2. Patients of age 18 to 40 years.
3. GA of 36 to 40 weeks.
4. Primi-parity patients & up to para 04.

Exclusion Criteria:
1. Pregnant multiple times.
2. Patients with para > 04.

3. H/o surgical and obstetrical complications.
4. H/o asthma, abnormality of heart-rhythm, and heart failure.
5. Unwilling to participate.

Data collection procedure:
We selected sixty patients (with informed consent) who fulfilled inclusion criteria and after taking approval from the Local Ethical Committee. We divided patients into group A (study group who took 40mg or 4ml I/V phloroglucinol) and group B (control group who took 4ml I/V placebo) through lottery method. Patients took a dose at zero hours and then repeated after thirty minutes. Both observer and patient didn't know the injection content. We noted both groups' duration of the FSOL then. We used a two-part (1st bio-data, 2nd study variables) pre-designed proforma to record data. We analyzed data through SPSS V.20.0. Also, recorded SD and mean for GA, FSOL duration, and age. To calculate parity, we used percentage and frequency. We used student 't' test to analyse MD of FSOL and compared the groups. Statistically significant P-value of ≤0.05 was considered. We used data stratification in terms of GA, parity and age to control effect-modifiers. To check modifiers effect on MD of FSOL, we used student 't' test after stratification taking ≤0.050 of p-value as significant.

RESULTS:

The study included patients with 18-40 years having a mean age was 27.0±5.3 years. The mean age in group A and B was 27.2±5.2 and 26.8±5.4 years respectively. The age range of 18-30 years had 61.67 (37) patients as the majority. We recorded 38.47±1.3 weeks as mean GA. The mean GA in group A and B was 38.3±1.4 and 38.5±1.3 weeks respectively. The GA of >38-40 weeks was among 50% (33) patients. MD of FSOL in group A and B was MD of 1st stage of labour in Group A 230.20±52.9 and 345.3±50.5 minutes respectively with 0.0001 as a p-value. Stratification of MD of FSOL in terms of age groups, parity and GA is shown in the tables.

Table – I: Group-Wise Age Distribution

Details		Group - A (30)		Group - B (30)		Total (60)	
		Number	%	Number	%	Number	%
Age (Years)	18 - 30	18	60.00	19	63.33	37	61.67
	31 - 40	12	40.00	11	36.67	23	38.30
GA (Weeks)	36 - 38	14	43.67	13	43.33	27	45.00
	> 38	16	53.30	17	56.60	33	55.00

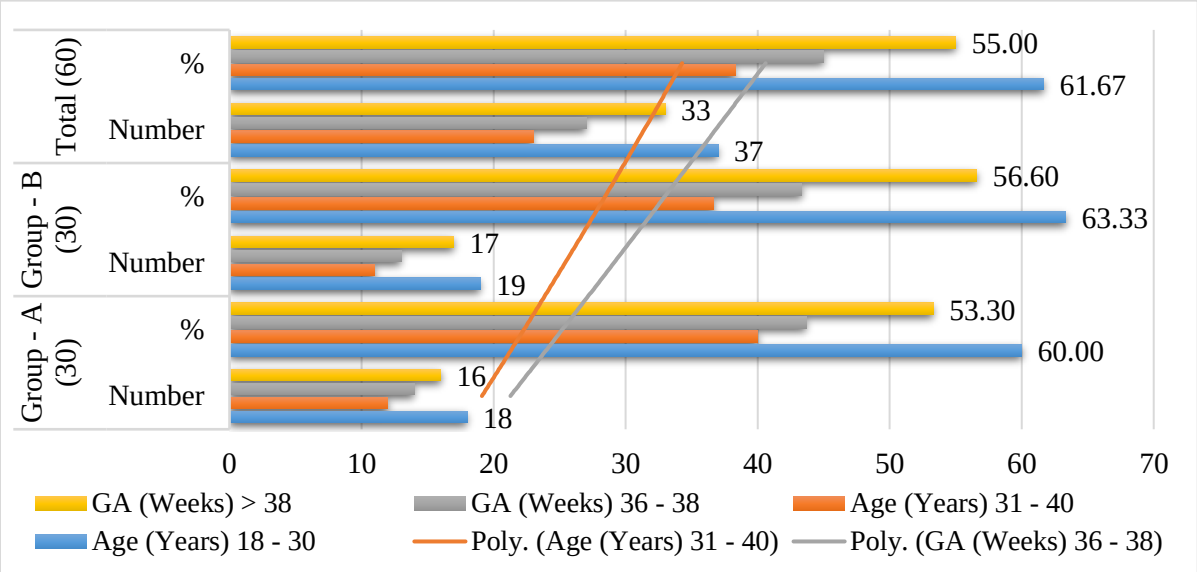


Table – II: Group-Wise Parity Stratification

Parity		Para - I	Para - II	Para - III	Para - IV
Group - A (30)	**Frequency**	9	11	6	4
	%	30.00	36.60	20.00	12.30
Group - B (30)	**Frequency**	8	11	7	4
	%	26.60	36.60	23.30	13.30
Total (60)	**Frequency**	17	22	13	8
	%	28.30	26.60	21.60	13.30

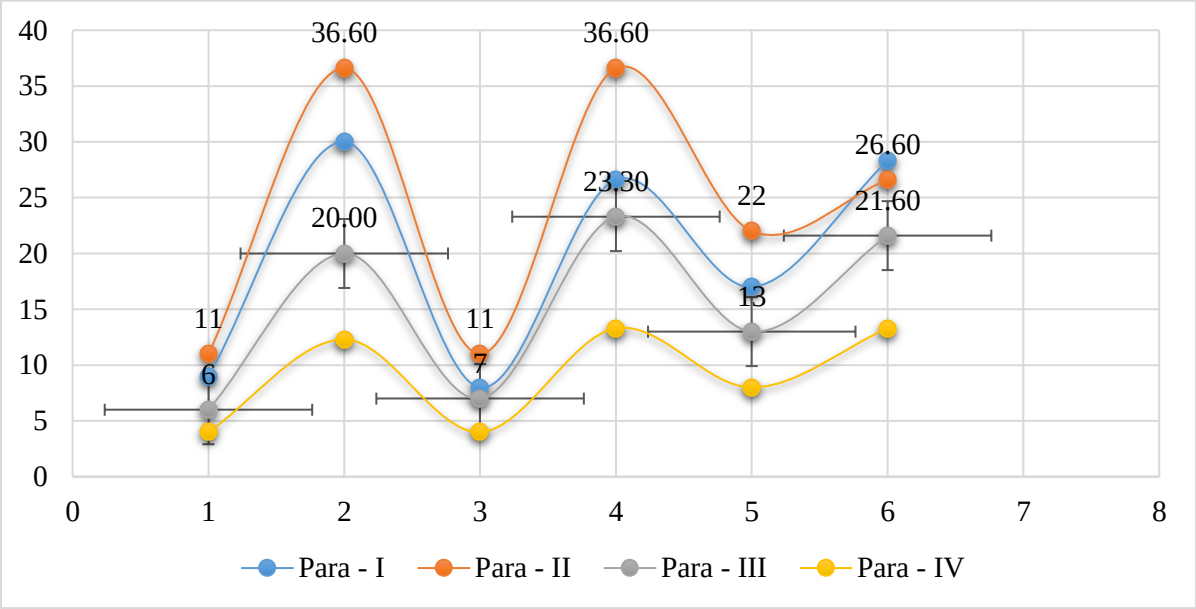


Table – III: Mean and SD Values Group-Wise

Group	Mean	±SD
Group – A	230.20	52.90
Group – B	345.30	50.50

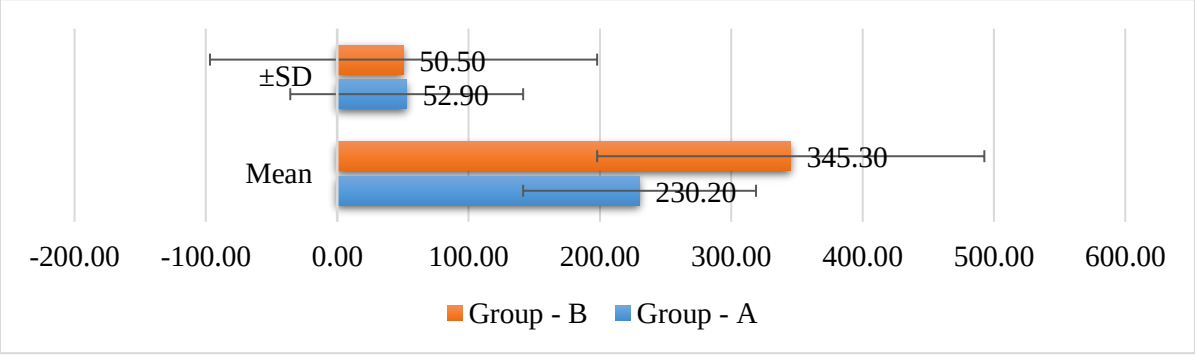
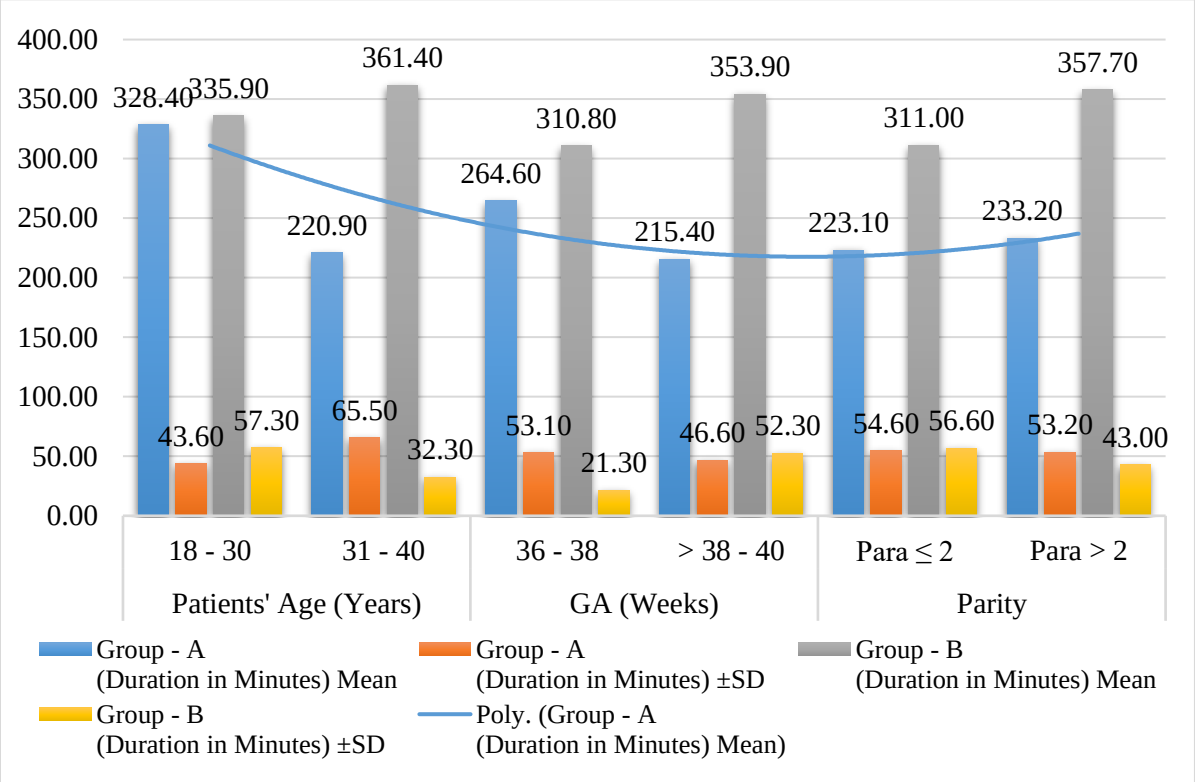


Table – IV: Stratification of duration with respect to age, parity and GA

Details		Patients' Age (Years)		GA (Weeks)		Parity	
		18 - 30	31 - 40	36 - 38	> 38 - 40	Para ≤ 2	Para > 2
Group - A (Duration in Minutes)	Mean	328.40	220.90	264.60	215.40	223.10	233.20
	±SD	43.60	65.50	53.10	46.60	54.60	53.20
Group - B (Duration in Minutes)	Mean	335.90	361.40	310.80	353.90	311.00	357.70
	±SD	57.30	32.30	21.30	52.30	56.60	43.00
P-Value		< 0.0001	< 0.0001	0.0079	< 0.0001	< 0.0001	< 0.0001



DISCUSSION:

We found MD of FSOL in Phloroglucinol (Group A) and Placebo (Group B) group as 230.2±52.9 and 345.3±50.5 minutes respectively with a p-value of <0.0001. The study of Tabassum S et al. [8] shows phloroglucinol and placebo MD of FSOL as 227.7±13.6 and 344.2±9.5 minutes respectively. Rong-Kai X et al. found 3.14±0.2 and 3.85±0.2 hours of MD of active phase among spasfon and diazepam group respectively with p-value 0.05 [15]. Tahir S et al. finds MD of FSOL as 311.1 and 203.0 minutes with p-value 0.004 for the control and study group respectively. S Batool finds a 24.5% (46.85 min) reduction in MD of FSOL using Phloroglucinol in comparison with Drotaverine [16]. A short duration of active-phase not only reduces the painful duration of labour but also neonatal sepsis and chorioamnionitis. Phloroglucinol is spasmolytic, relaxing spasm of smooth muscles is administered for gastrointestinal colic primarily. During spasm of smooth muscle, phloroglucinol provides strong relaxation, as well as for urethra and intestine but zero effect on blood vessels' smooth muscle. Moreover, the lower portion and cervix of the uterus gets soften leading to uterine contractions thus reducing post-delivery haemorrhage [17]. Hao Y et al reports MD from administrating drugs till full cervix dilation as 3.1±0.30 and 4.4±0.40 hours with p-value <0.010 among spasfon (Group-A) and atropine (Group-B) groups respectively [18]. The ratio of

cervical oedema disappearance after two hours of administrating drugs in Group-A and B was 95.60% and 90.20% having p-value>0.050 and mean cervix dilatation was 4.3±0.2 and 2.5±0.3 cm with p-value <0.010 between two hours among Group-A and B respectively. Patients from Group-A experienced no side-effects while patients from Group-B complained thirst (08), elevated baseline FHR and increased heart-rate (22) but they recovered within one hour. The vaginal-delivery rate in Group-A and B was 95.70% and 90.20% with p-value>0.050 respectively. The study neither found any significant difference statistically in post-partum haemorrhage nor in the state of suffocation, weight, and amniotic fluid's colour of the new-borns between both groups. Naqvi SB et al [1] finds 24.5% (46.8 min) shorter with 15.3% (0.38 cm/hour) faster cervical dilatation using phloroglucinol comparing to drotaverine having p-value<0.050. This study finds minor side-effects with drotaverine-group and no side-effects, the requirement of Caesarean section, and less injection requirement with phloroglucinol-group. Razia R et al. [19] found MD for active-phase to be 183.00±35.60 and 316.00±52.20 minutes with a p-value of 0.000 with Spasfon-group and Diazepam-group respectively. Anjum N et al. [19] reported MD of active FSOL in spasm-group and placebo-group to be 183.0 and 316.0 minutes, the 2nd stage was 25.1 and 34.5 minutes, and the 3rd stage was 08.7 and 11.10 minutes respectively. Total MD of labour was 216.8 and 358.5 minutes for spasfon-group and placebo-group respectively. Parveen T et al in her study concludes that using phloroglucinol with standard treatment is far effective than standard treatment alone in terms of labour duration, maternal/neonatal side-effect prevention, less rate of AVDS and CS, and lesser use of oxytocin [3]. Comparatively, Phloroglucinol (spasfon) is effective in the duration reduction of active FSOL and its use could be encouraged in routine practice-guidelines for labour acceleration in these particular patients.

CONCLUSION:

This study concludes that Phloroglucinol (spasfon) is effective in duration reduction of active FSOL so it is recommended that its use could be encouraged in routine practice-guidelines for labour acceleration to reduce morbidity and mortality of both. This study concluded that spasfon (phloroglucinol) is effective in reducing the duration of the active 1st stage of labour. So, we recommend that its use could be encouraged in our routine fetus and mother.

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