

Research Article**Comparison of mean duration of active 1st stage of labour
with phloroglucinol versus placebo****Maria Siddiquie, Usman Javed
and Beenish**¹House Officer, Bahawal Victoria Hospital, Bahawalpur²Medical Officer, BHU Gangran, Narowal³BHU Chauni Sulehrian, Sialkot**ABSTRACT****Objectives:** To compare the mean duration of active 1st stage of labour with phloroglucinol versus placebo**Materials & Methods:** A total of 60 cases with singleton pregnancy and in active 1st stage of uncomplicated labour, 18 to 40 years of age were included. Patients with multiple pregnancies, h/o obstetrical and surgical complications and h/o heart rhythm abnormality, heart failure and asthma were excluded. Then selected patients were placed randomly into two groups i.e. Group A (spasfon) & Group B (placebo), by using lottery method. After this, duration of the 1st stage of labour was noted in minutes from when there was 3-4 cm cervical dilatation with regular uterine contractions to complete cervical dilatation i.e. 10 cm and descent of the presenting fetal part.**Results:** The mean age of patients in group A was 27.27 ± 5.26 years and in group B was 26.87 ± 5.44 years. The mean gestational age in group A was 38.37 ± 1.40 weeks and in group B was 38.57 ± 1.38 weeks. Mean duration of 1st stage of labour in Group A (phloroglucinol group) was 230.20 ± 52.96 minutes while in Group B (placebo group) was 345.30 ± 50.57 minutes (p-value < 0.0001).**Conclusion:** This study concluded that spasfon (phloroglucinol) is effective in reducing duration of active 1st stage of labour and could be encouraged in our routine practice guidelines for acceleration of labour in these particular patients.**Keywords:** Antispasmodic, labour, acceleration, 1st stage.**INTRODUCTION**

Labour is a multifactorial process which involves myometrial contraction, cervical ripening and dilatation and the expulsion of fetus and placenta in an orderly manner. The first stage of labour in primigravida lasts about 12-16 hours and in a parous woman 6-8 hours.¹ Prolonged labour can lead to increased maternal and neonatal mortality and morbidity due to increased risks of maternal exhaustion, postpartum haemorrhage and sepsis, fetal distress and asphyxia and requires early detection and appropriate clinical response.^{2,3} The causes of prolonged labour relate to maternal age, induction of labour, prelabour rupture of

membranes, early admission to the labour ward, epidural analgesia and high levels of maternal stress hormones, but are unknown in most cases.⁴ Contractility and cervical effacement are the two main features of labour. If powerful contractions develop but the cervix remains rigid and unyielding the labour will be more complicated and prolonged.^{3,5} The concept of active management of labour was developed to assure a woman that her labour would not exceed 12 hours. The active management of labour is associated with a low incidence of prolonged labour and low Caesarian section rate.⁶

A woman who is in active labour for too long (usually set at more than 12 hours) is at risk of becoming exhausted and developing complications such as infection and excessive bleeding. The unborn baby can also be harmed, showing distress and low oxygenation (asphyxia). It is common practice to intervene in the labouring process to avoid this by rupturing membranes (breaking the waters), giving medications to speed up contractions and providing ongoing support. Antispasmodics are drugs that are usually taken to relieve cramps. They work either by direct relaxation of muscle or by interfering with the message sent by the nerves to the muscle to contract. It is thought that these drugs may help with opening the womb (dilatation of the cervix), when given during labour as a preventative or a treatment strategy.^{5,7}

Although methods to increase uterine contractility such as amniotomy and use of oxytocics have been shown to accelerate cervical dilation, yet these methods are not without complications.⁷ Spasmolytics and spasmolgesics mixtures are administered to facilitate dilatation of the cervix during delivery and to shorten first stage of labour.⁸ An ideal antispasmodic for accelerations of cervical dilations should have a prompt and long lasting action, no adverse effects on uterine contractility and be free from risk of uterine inertia. It should also have minimal side effects in the mother and foetus.^{8,9} Administering antispasmodics during labour could lead to faster and more effective dilatation of the cervix.¹⁰ Antispasmodics are drugs that relieve spasms of smooth muscle tissue and have either musculotropic or neurotropic effects. The cervix is composed of connective tissue and smooth muscle, innervated by parasympathetic nerve fibres. Smooth muscle constitutes about 15% of the cervix, which is mainly found just below the internal os.¹¹

Musculotropic antispasmodics directly relax smooth muscles. They are phosphodiesterase type IV inhibitors, structurally related to papaverine, have mild Calcium (Ca)-channel blocking effects, no anticholinergic effects and act directly on

smooth muscle cells, inhibiting spasm.¹² Neurotropic antispasmodics break the connection between the parasympathetic nerve and the smooth muscle. They are parasympatholytics acting as antagonists of acetylcholine at muscarinic receptors, thus inhibiting muscle spasm.^{10,12}

Phloroglucinol and drotaverine are commonly used pharmacological agents in labour room in many hospitals, to decrease the duration of first stage of labour in order to prevent the prolonged labour.³ In India, drotaverine hydrochloride, an antispasmodic drug, forms part of their "Programmed Labour Protocol" to decrease the pain and the duration of labour. It is used in conjunction with amniotomy, oxytocin augmentation and administration of tramadol for pain relief.¹³ Phloroglucinol has a strong relaxing effect on the smooth muscle in spasm. This relaxing effect is very pronounced in intestine and urethra and particularly zero on the smooth muscles of blood vessels. As for the uterus, it softens the lower portion and cervix without inhibiting uterine contractions in the body; hence it does not interfere with labour and does not cause bleeding after delivery. No atropine like effect has been noticed with its use as with other anti spasmotics and it is nontoxic to the fetus.¹⁴ Tabassum S et al⁸ has shown in his study the mean duration of 1st stage of labour by phloroglucinol as 227.74 ± 13.60 minutes compared to 344.26 ± 9.49 minutes in placebo group.

As prolonged labour is associated with increased maternal and neonatal mortality and morbidity due to increased risks of maternal exhaustion, postpartum haemorrhage and sepsis, fetal distress and asphyxia, so this study would help us to determine the effect of phloroglucinol in reducing duration of active 1st stage of labour in local population. And if it would be found effective in reducing duration of active 1st stage of labour then its use could be encouraged in our routine practice guidelines for acceleration of labour in these particular patients in order to

reduce perinatal mortality and morbidity of both mother and fetus.

OPERATIONAL DEFINITIONS:

- **Mean duration of Active 1st Stage of Labour:** was noted in minutes from when there was 3-4 cm cervical dilatation with regular uterine contractions to complete cervical dilation i.e. 10 cm and descent of the presenting fetal part.

MATERIAL AND METHODS

Study design: Randomized controlled trial.

Setting: Department of Obstetrics & Gynecology, Bahawal Victoria Hospital, Bahawalpur.

Sample selection:

Inclusion Criteria:

1. All cases with singleton pregnancy and in active 1st stage of uncomplicated labour as per operational definition.
2. Cases of 18-40 years of age.
3. Gestational age 36-40 weeks (assessed on LMP).
4. Females with primiparity and upto para-4.

Exclusion Criteria:

1. Multiple pregnancies.
2. Patients with para >4.
3. Any h/o obstetrical and surgical complications.
4. H/o heart rhythm abnormality, heart failure and asthma.
5. Patients not willing to participate in the study.

Data collection procedure:

After approval from local ethical committee, 60 patients admitted in the Department of Obstetrics & Gynaecology, Bahawal Victoria Hospital, Bahawalpur, fulfilling the inclusion/exclusion criteria were selected. After taking informed, written consent for participation in the study, all patients were randomized in double blind fashion in two groups. Each patient was offered to pick up a slip from total mixed up slips (half-slips will contain letter 'A' and other half slips will contain letter 'B') and she was placed in that respective

group. Group A (study group) contained 30 cases who received phloroglucinol 40mg (4ml) I/V and Group B (control group) contained 30 cases who received placebo 4ml I/V at 0 hours. Dose was repeated after 30 minutes. Neither patient nor observer knew the content of the injection. After this, duration of the 1st stage of labour (as per operational definition) was noted in both groups. All this data was recorded on a predesigned proforma which contained two parts i.e. part 1st contained the patients bio-data while part 2nd contained the study variables (Annexure-I). All the data was entered and analyzed by using SPSS version 20.0. Mean and standard deviation was calculated for age, gestational age and duration of 1st stage of labour. Frequency and percentage was calculated for parity. Comparison between the groups with respect to the mean duration of 1st stage of labour was analyzed by student 't' test. P value ≤ 0.05 was considered as statistically significant. Effect modifiers were controlled by stratification of data in terms of age, gestational age and parity. Post-stratification student 't' test was used to see their effect on mean duration of 1st stage of labour. P-value ≤ 0.05 was taken as significant.

RESULTS

Age range in this study was from 18 to 40 years with mean age of 27.07 ± 5.31 years. The mean age of patients in group A was 27.27 ± 5.26 years and in group B was 26.87 ± 5.44 years. Majority of the patients 37 (61.67%) were between 18 to 30 years of age as shown in Table I.

Mean gestational age was 38.47 ± 1.38 weeks in our study. The mean gestational age in group A was 38.37 ± 1.40 weeks and in group B was 38.57 ± 1.38 weeks. Majority of the patients 33 (55.0%) were between >38 to 40 weeks of gestation as shown in Table II. %age of patients according to parity is shown in Table III.

Mean duration of 1st stage of labour in Group A (phloroglucinol group) was 230.20 ± 52.96 minutes while in Group B (placebo group) was 345.30 ± 50.57 minutes as shown in Figure I (p-value < 0.0001). Stratification of mean duration of

1st stage of labour with respect to age groups has shown in Table IV which showed significant difference in mean duration of 1st stage of labour in all age groups among both groups. Similarly statistically significant difference was found in mean duration of 1st stage of labour in different

gestational ages among both groups as shown in Table V. Stratification of mean duration of 1st stage of labour with respect to parity in both groups has shown in Table VI which also showed statistically significant difference among them.

Table-I: Age distribution for both groups (n=60).

Age (years)	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
18-30	18	60.0	19	63.33	37	61.67
31-40	12	40.0	11	36.67	23	38.33
Mean ± SD	27.27 ± 5.26		26.87 ± 5.44		27.07 ± 5.31	

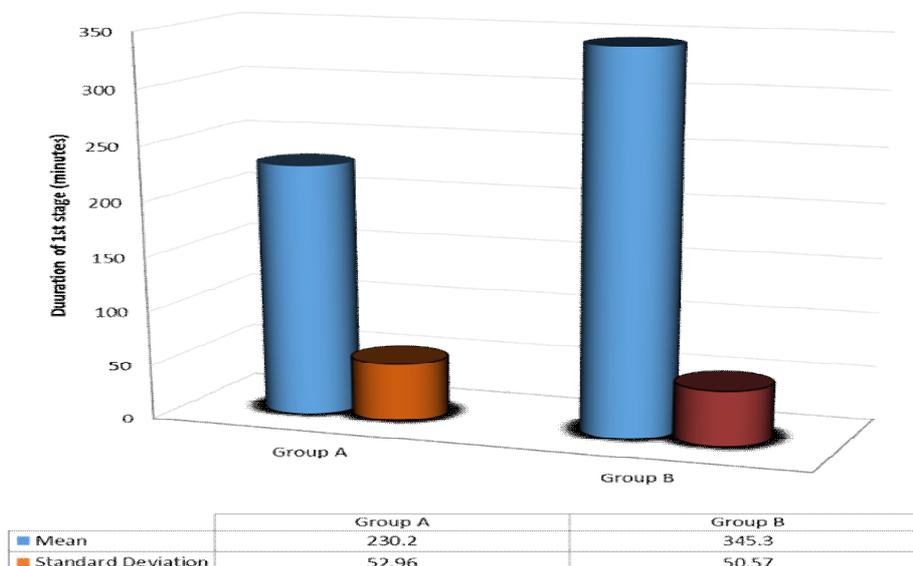
Table-II: %age of patients according to gestational age in both groups.

Gestational age (in weeks)	Group A (n=30)		Group B (n=30)		Total (n=60)	
	No. of patients	%age	No. of patients	%age	No. of patients	%age
36-38	14	46.67	13	43.33	27	45.0
>38-40	16	53.33	17	56.67	33	55.0
Mean ± SD	38.37 ± 1.40		38.57 ± 1.38		38.47 ± 1.38	

Table III: %age of patients according to parity in both groups.

Parity	Group A (n=30)		Group B (n=30)		Total (n=60)	
	Frequency	%age	Frequency	%age	Frequency	%age
Para -1	09	30.0	08	26.67	17	28.33
Para -2	11	36.67	11	36.67	22	36.67
Para -3	06	20.0	07	23.33	13	21.67
Para -4	04	13.33	04	13.33	08	13.33

Figure 1: Mean Duration of 1st Stage of labour in both groups.



P-value<0.0001 which is statistically significant

Table IV: Stratification of duration of 1st stage of labour according to age of patients in both groups.

Age of patients (years)	Group A (n=30)		Group B (n=30)		P-value
	Duration (minutes)		Duration (minutes)		
	Mean	SD	Mean	SD	
18-30	238.39	43.63	335.95	57.34	<0.0001

31-40	220.92	65.55	361.45	32.32	<0.0001
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Table V: Stratification of duration of 1st stage of labour according to gestational age in both groups.

Gestational age (weeks)	Group A (n=30)		Group B (n=30)		P-value
	Duration (minutes)		Duration (minutes)		
	Mean	SD	Mean	SD	
36-38	264.67	53.16	310.83	21.31	0.0079
>38-40	215.43	46.61	353.92	52.33	<0.0001

Table VI: Stratification of duration of 1st stage of labour according to parity in both groups.

Parity	Group A (n=30)		Group B (n=30)		P-value
	Duration (minutes)		Duration (minutes)		
	Mean	SD	Mean	SD	
Para ≤2	223.11	54.67	311.00	56.69	<0.0001
Para >2	233.24	53.28	357.77	43.00	<0.0001

DISCUSSION

In our study, mean duration of 1st stage of labour in Group A (phloroglucinol group) was 230.20 ± 52.96 minutes while in Group B (placebo group) was 345.30 ± 50.57 minutes (p-value<0.0001). TabassumS et al⁸ has shown in his study the mean duration of 1st stage of labour by phloroglucinol as 227.74 ± 13.60 minutes compared to 344.26 ± 9.49 minutes in placebo group. In another study, **Rong-kai Xet** al¹⁵ had found the mean time for the active phase in spasfon group was (3.14±0.27) h, which was significantly shorter than that in diazepam group [(3.85±0.27) h, P0.05].

Tahir S et al¹⁶ The mean duration of the first of stage labor in the control group was 311.12 minutes, compared with 203.06 minutes in the study group (P =0.004). In another study conducted by S Batool, Phloroglucinol group was compared with drotaverine group for acceleration of labor and it was reported that there is 46.85 minutes (24.49%) reduction in first stage of labor in phloroglucinol group than Drotaverine group. Short duration of active phase of labor not only reduces the duration of painful labor but also the incidence of chorioamnionitis and neonatal sepsis. Phloroglucinol is a spasmolytic, primarily used for gastrointestinal colic .it has strong relaxing effect on the smooth muscles in spasm. This relaxing effect is very much pronounced in the intestine and urethra and particularly zero on smooth muscles of blood vessels. As for uterus it

relaxes lower part of uterus and cervix without interfering with uterine contractility so it does not interfere with labour and does not cause postpartum hemorrhage.¹⁷

Hao Y et al¹⁸ in his study reported the mean time period from drug administration to full dilation of the cervix was (3.1 +/- 0.3) h in group A (sapsfon), and (4.4 +/- 0.4) h in group B (atropine) (P < 0.01). The disappearance ratio of cervical edema 2 h after drug administration in group A was 95.6%, while in group B it was 90.2% (P > 0.05); the mean dilatation of cervix between the 2 hours in group A was (4.3 +/- 0.2) cm, while in group B it was (2.5 +/- 0.3) cm (P < 0.01). There were no obvious side effects in group A. While eight women in group B complained of thirst and 22 women had increased heart rate accompanied with elevated baseline FHR, which all recovered in about 60 minutes. Vaginal delivery rate in group A was 95.7%, and 90.2% in group B (P > 0.05). There was no statistically significant difference in the color of amniotic fluid, suffocation state and weight of the newborns between the two groups (P > 0.05). There was no statistically significant difference in postpartum hemorrhage between the two groups, either (P > 0.05).

Naqvi SB et al¹ concluded that both phloroglucinol and drotaverine appears to be effective in the acceleration of labour but duration of first stage of labour was 46.85 minutes (24.49%) shorter and cervical dilatation 0.38 centimeters/ hour (15.32%) faster in

phloroglucinol group as compare to drotaverine group which was statistically significant ($p < 0.05$), no fetomaternal side effects seen in phloroglucinol group but minor side effects seen in drotaverine group. No Caesarean section was required and less number of injections required in phloroglucinol group.

Razia Ret al¹⁹ had found the mean time for the active phase in spasfon group was (183.0±35.6 minutes), which was significantly shorter than that in diazepam group [(316.0±52.2 minutes), $P=0.000$]. Anjum N et al¹²⁹ reported the mean duration of the observed active phase of 1st stage of labour in spasfon group was 183 mins and 316 mins in placebo group. The mean duration of 2nd stage of labour in spasfon group was 25.16 mins and 34.52 mins in placebo group. The mean duration of 3rd stage of labour in spasfon group was 8.72 mins and 11.1 mins in placebo group. The mean total duration of labour in spasfon group was 216.88 mins and 358.52 mins in placebo group.

Parveen T et al³ in his study concluded that the standard treatment alone compared to the augmentation with Phloroglucinol combined to standard treatment, the results were superior that is reduction in the duration of labour, no maternal or neonatal side effects, the rate of CS and AVDS was less, lesser amount of Oxytocin used. On the whole, it is concluded that spasfon (phloroglucinol) is effective in reducing duration of active 1st stage of labour and could be encouraged in our routine practice guidelines for acceleration of labour in these particular patients.

CONCLUSION

This study concluded that spasfon (phloroglucinol) is effective in reducing duration of active 1st stage of labour. So, we recommend that its use could be encouraged in our routine practice guidelines for acceleration of labour in these particular patients in order to reduce perinatal mortality and morbidity of both mother and fetus.

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