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Comparison of Phloroglucinol and Drotaverine in Accelerating First Stage of Labour

Tasnim Tahira, Maham Aslam, Saadia Saleem

ABSTRACT

Objective: To compare the mean duration of 1st stage of labor with phloroglucinol and drotaverine in patients with uncomplicated labour. **Study design:** Randomized controlled trial. **Settings:** Department of Obstetrics &Gynecology, Allied Hospital, Faisalabad. **Duration:** From 28th June, 2016 to 27th December, 2016. **Methodology:** 80 laboring patients with singleton pregnancy, cephalic presentation, presenting at gestational age 37-40 weeks in active phase of labour were included in the study. All the females were randomly divided into two groups. In group A, phloroglucinol 40mg IV every 60 min (Maximum of 3 doses) was given and in group B drotaverine was given 40mg IV every 60 min (Maximum of 3 doses.) Duration of 1st stage of labour was measured in minutes. **Results:** The mean age of the patients was 27.58±4.2 years and mean gestational age was 38.09±0.97 weeks. In Phloroglucinol group, mean duration of 1st stage of labour was 154.70±26.46 min and in Drotaverine group, it was 175.30±33.34 min. There was a mean difference of 20.60 minutes between both groups and the difference was statistically significant between two groups with p-value = 0.003. **Conclusion:** The phloroglucinol is better than drotaverine in patients with uncomplicated labour in terms of mean duration of 1st stage of labour.

Keywords: 1st stage of labour, Phloroglucinol, Drotaverine.

Corresponding Author
Dr. Tasnim Tahira
Associate Professor, Gynae Unit-I
Faisalabad Medical University,
Faisalabad-Pakistan
Contact: +92 300-6645192
Email: tasnimtahira192@yahoo.com

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INTRODUCTION

Labour and delivery is the focus and climax of reproductive process. Majority of women experience normal labour and delivery. The management of labour is both an art and a science. Minimizing the duration of labour without compromising fetomaternal wellbeing is a desirable outcome in all labour and delivery units.[1]

More than any other objective measurement, the duration of labour determines impact of delivery on mother, fetus and also on efficient running of a labour ward.[2] Labour lasting more than 12 hours in nulliparous women and 8 hours in multiparous women should be regarded as prolonged labour.[3]

Prolonged labour is hazardous for both mother and fetus. The mother is at risk of infection, ketosis and obstructed labour while fetus is also at risk of infection and asphyxia.[4]

The morale of most women deteriorates after 12 hours in labour. There is a greater incidence of operative vaginal deliveries, Caesarean section and fetal hypoxia.[5] Attempts to accelerate labour and there by shortening its duration without jeopardizing fetal and maternal outcome is welcomed to both mother and obstetrician.[6]

Active management of labour is a package of care, which in addition to routine amniotomy, includes strict diagnosis of labour, oxytocin for slow progress and one to one support in labour.[7] Active management of labour versus physiological, expectant management, has shown to decrease the occurrence of prolonged labour.[8] The two basic factor which determine the duration of labour are uterine contraction and cervical dilatation. If powerful contractions develop but the cervix remains rigid and unyielding the labour will be more complicated and prolonged.[6] Oxytocin, prostaglandin and amniotomy have been shown to accelerate cervical dilatation by increasing uterine contractility but these methods are not without complication.

A policy of ARM followed by intravenous infusion of oxytocin was advocated as a standard treatment for augmentation in 1968, but the success rate of this policy depends upon cervical ripeness which is calculated by Bishop scoring system. Therefore, the best intervention is one which improves cervical ripeness and establishes gradual myometrial contractility.[2]

Hirsch first described the use of antispasmodic drugs to shorten the first stage of labour in 1937. He reported that labour duration could be decreased by 2-4 hrs by using an atropine like drug.[1] These drugs relieve the cervical spasm and lead to cervical dilatation in first stage of labour.

In this era where the focus is shifting from 'wait and watch' policy to 'active intervention sooner than later' to ensure better labour outcomes these drugs used in synergy with analgesics enable modern obstetricians to make labour and delivery a safe and pleasant experience for the mother[9].

An ideal antispasmodic is one which has a long and quick action on cervical dilatation, no adverse effects on uterine contraction or uterine inertia.

Drotaverine is an isoquinoline derivative which binds to smooth muscles and change their potential and permeability. It inhibits

phosphodiesterase enzyme (PDE) which break cyclic adenine mono phosphate (cAMP) and guanine mono phosphate (cGMP) which play an important role in regulation of smooth muscles[10]. Phloroglucinol has a strong relaxing effect on the smooth muscle in spasm. 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. According to previous studies phloroglucinol shortened the duration of 1st stage of labour to 144.40 ± 30.78 minutes versus drotaverine 191.25 ± 76.89 minutes.[5]

So, our rationale was to find which drug was more effective in shortening the duration of labour by accelerating the cervical dilatation and utilize these results to recommend the suitable and safe spasmolytic for the betterment of patients in labour.

Operational definitions:

Labour: The patient will be said to be in labour when she experiences regular painful uterine contractions (usually at intervals of 2-4 minutes and lasting for 30-60 seconds or occasionally longer) that bring about effacement and dilation of the cervix (diagnosed by per vaginal examination) and descent of the presenting part (with reference from isheal spine -1, -2, -3 and +1, +2, +3 if 1, 2 & 3cm above and below the ischeal spine respectively).

First stage: The patient is said to be in first stage of labour from the diagnosis of labour to full dilatation of the cervix.

Active phase: Active phase was defined as 4 cm or > cervical dilation with regular uterine contractions (usually at intervals of 2-4 minutes and lasting for 30-60 seconds or occasionally longer). Duration will be measured from the time of diagnosis of labour (as described above) till full dilation of cervix (by repeated prevaginal examinations every 2-4 hrs).

Hypothesis: The phloroglucinol is better than drotaverine in patients with uncomplicated labour in terms of mean duration of 1st stage of labour.

METHODOLOGY

Study Design: Randomized control trial.

Setting: Labour ward of Allied Hospital, Faisalabad affiliated with Faisalabad Medical University, Faisalabad-Pakistan.

Duration: From 28th January 2016 to 27th December 2016.

Sampling Technique: Non-probability consecutive sampling.

Inclusion Criteria: All laboring females, age 20-35 years with singleton pregnancy, cephalic presentation, presenting at gestational age 37-40 weeks in active phase of labour.

Exclusion Criteria: Patient with previous uterine scar were excluded from study.

Data Collection Procedure: Approval from ethical review committee was taken. The patients presenting in labour ward who fulfill the inclusion criteria were enrolled in the study. An informed consent was taken from all the patients and/or their guardians to include the data in research work. Exclusion criteria was strictly followed.

Patients were admitted in labour ward and proper history taken, relevant examination of the patient was done. Appropriate investigations done from hospital pathology and biochemistry lab by pathologist and biochemist. Laboring patients were divided in 2 groups randomly by lottery method. Patients in group A received phloroglucinol 40mg IV every 60 min (Maximum of 3 doses). In group B received drotaverine 40mg IV every 60 min (Maximum of 3 doses).

Main outcome measure was duration of 1st stage of labour which was measured by PGR on duty.

Data Analysis Procedure: All data was analyzed by SPSS V-20. Quantitative variables like age, gestational age and duration of first stage of labour were measured by mean and standard deviation. Independent sample t-test was used to compare duration of labour between two groups. Effect modifier like age, gestational age and parity was controlled by stratification. Post stratification independent sample t-test was applied. p-value < 0.05 is taken as significant.

RESULTS

The mean age of the patients in group A and B was 27.90 and 27.25 years respectively. The mean gestational age of group A and group B was 38.05 and 38.13 weeks respectively. (Table1).

Table 1: Descriptive statistics of age & gestational age of both groups (N = 40)

Group	Age	Minimum	Maximum	Mean	Std. Deviation
A	Gestational Age	20	35	27.90	3.842
	Valid N (listwise)	37	40	38.05	.959
B	Gestational Age	20	35	27.25	4.578
	Valid N (listwise)	37	40	38.13	.992

No. of patients from 20-27 years in group A and group B was 18 (45%) and 19 (47.5%) years respectively. No. of patients form 28-35 years in group A and group B was 22 (55%) and 21 (52.5%) respectively. (Table 2)

Table 2: Distribution of age

Age Distribution (in years)	Group		Total (N)
	A	B	
20-27	18 45%	19 47.5%	37 46.25%
28-35	22 55%	21 52.5%	43 53.75%
Total	40	40	80

No. of patients with gestational age 37-38 weeks in group A and group B was 27 (67.5%) and 26 (65%) respectively. No. of patients with gestational age 38^{+1}-40 weeks in group A and group B was 13 (32.5%) and 14 (35%) respectively. (Table 3).

Table 3: Distribution of gestational age

Gestational Age Distribution (in weeks)	Group		Total (N)
	A	B	
37-38	27 67.5%	26 65%	53 66.25%
38-40	13 32.5%	14 35%	27 33.75%
Total	40	40	80

The mean duration of 1st stage in group A and group B was 154.70 min and 175.30 min respectively (Table 4).

Table 4: T-Test of total sample (N=80)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	40	154.70	26.465	4.185
	B	40	175.30	33.344	5.272

The mean duration of 1st stage in group A and group B in patients age was 20-27 years 162.33 min and 180.37 respectively (Table 5).

Table 5: T-Test of total sample with age 20-27 years (N=37)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	18	162.33	25.375	5.981
	B	19	180.37	37.844	8.682

The mean duration of 1st stage in group A and group B in patients age was 28-37 years 148.45 min and 170.71 respectively (Table 6).

Table 6: T-Test of total sample with age 28-35 years (N=43)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	22	148.45	26.244	5.595
	B	21	170.71	28.855	6.297

The mean duration of 1st stage in group A and group B at gestational age of 37-38 weeks was 153.44 & 172.35 min respectively. (Table 7)

Table 7: T-Test of Total Sample with Gestational Age 37 to 38 weeks (N=53)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	27	153.44	30.847	5.937
	B	26	172.35	35.085	6.881

The mean duration of 1st stage in group A and group B at gestational age of 37^{+1}-40 weeks was 157.31 & 180.79 min respectively. (Table 8)

Table 8: T-Test of Total Sample with Gestational Age 38+1 to 40 Years (N=27)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	13	157.31	14.273	3.959
	B	14	180.79	30.304	8.099

The mean duration of 1st stage in group A and group B in nulliparous patients was 163.65 min and 185.39 min respectively. (Table 9)

Table 9: T-Test of Nulliparous (N=35)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	17	163.65	25.517	6.189
	B	18	185.39	31.770	7.488

The mean duration of 1st stage in group A and group B in multiparous patients was 148.09 min and 167.05 min respectively. (Table 10)

Table 10: T-Test of Multiparous (N=45)

	Group	N	Mean	Std. Deviation	Std. Error Mean
Duration of 1st Stage	A	23	148.09	25.701	5.359
	B	22	167.05	33.001	7.036

Mean frequency of injection given in group A and group B was 1.58 and 2.13 respectively (Table 11).

Table 11: Frequency of Injection Given (N=80)

	Group	N	Minimum	Maximum	Mean	Std. Deviation
Injection Given Valid N (listwise)	A	40	1	3	1.58	.501
Injection Given Valid N (listwise)	B	40	1	3	2.13	.686

DISCUSSION

Labour is the process of regular uterine activity and associated cervical dilatation. More than 90% of mature babies are born after a period of labour; most deliver vaginally, either spontaneously or with operative assistance; some require emergency caesarean section. The two main reasons for emergency caesarean section during labour are 'failure to pregress' and 'fetal distress'.

Once labour has been diagnosed then progress is expected within certain time limits. The most widespread expectation for progress in labour is a rate of at least 1cm dilatation per hour which derives from the slowest 10% of women reported by Philpott.[11]

Recognition of abnormal progress in 'early' labour continues to be confounded by the problem of identifying the onset of labour. The increasing use of active management by obstetricians interested in improving the outcome of labour management has resulted in it being considered medical 'interference' with the physiological, or 'natural', process of labour. Conservative management results in some 4-6% of women having regular and painful uterine contractions for more than the mean of eight hours, described by Friedman, before there is concern that the cervix has not dilated more than 3cm.[12]

Recognition of an abnormal latent phase requires a definition of labour which does not depend on reaching a cervical dilatation of 3cm before labour can be diagnosed. A recent study of labours managed by the observational criteria of Friedman found that some (albeit less than 5%) nulliparous women experience a latent phase of more than 20 hours. However, with active management, less than 2% of primigravidae take longer than 12 hours to deliver. Active management also reduced by almost 50% the likelihood of a ceasarean section due to dystocia (ineffective uterine activity).[12] However, despite the evidence of benefit for women, active management of labour continues to be regarded by many midwives as unnecessary 'medical' intervention and forms the basis of a perceived power struggle between some midwives and obstetricians for 'control' of labour management.

There are two interventions designed to improve the rate of progress during spontaneous labour. These are rupture of the fetal membranes and intravenous infusion of oxytocin. Both procedures are widely used as method for induction of labour and their use in spontaneous labour varies according to definitions and expectations of normal progress. Their use began with the increasing desire to find methods of correcting slow progress in order to prevent prolonged labour.

A third intervention to improve poor progress nlabour is the use of antispasmodic drugs. These drugs can aid faster rate of cervical dilatation via neurotropic and / or musculortropic effects. This study compared two antispasmodics; phloroglucinol and drotaverine. The results of this study revealed mean age of the patients was 27.58$\pm$4.2 years and mean gestational age was 38.09$\pm$0.97 weeks. In phloroglucinol group, mean duration of 1st stage of labour was 154.70$\pm$26.46 min and in Drotaverine group, it was 175.30$\pm$33.34 min. There was a mean difference of 20.60 minutes between both groups and the difference was statistically significant between two groups with p-value = 0.003. These findings are in agreement with a study conducted by Naqvi SB et al; showing that phloroglucinol is better than drotaverine in shortening 1st stage of labour. In this study both phloroglucinol and drotaverine appears to be effective in the acceleration of labour but duration of first stage of labour was 46.85 minutes (24.49%) shorter and cervical dilatation 0.38 centimeters/hour (15.32%) faster in phloroglucinol group as compare to drotaverine group which was statistically significant ($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 a smaller number of injections required in phloroglucinl group. It also has analgesic effect[5].

The present as well as other studies have shown that antispasmodics have a definite role in treating the poor progress of labour. Different studies have compared different types of antispasmodies with most of the studies comparing drotaverine with other drugs.

CONCLUSION

Considering the results of the current study comparing with other national/international studies, it is justified that "Phloroglucinol is better than drotaverine in patient with uncomplicated labour in terms of mean duration of 1st stage of labour."

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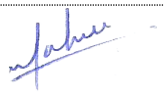
AUTHORSHIP AND CONTRIBUTION DECLARATION

AUTHORS	Contribution to The Paper	Signatures
Dr. Tasnim Tahira Associate Professor, Gynae Unit-I Faisalabad Medical University, Faisalabad	Literature Search	
Dr. Maham Aslam Women Medical Officer Allied Hospital, Faisalabad	Writing the article	
Dr. Saadia Saleem Assistant Professor, Gynae Unit-I Faisalabad Medical University, Faisalabad	Data collection and Proof Reading