Original Article

Phloroglucinol and Drotaverine in Accelerating the First Stage of Labour ; A Comparative Study

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Abstract

Objective: To compare the efficacy of phloroglucinol and drotaverine in accelerating the first stage of labour in labouring women.

Methodology: The randomized control trial study was conducted at Gynaecology and Obstetrics Department of Mardan Medical Complex Hospital from November 2017 to May 2018. A total of 100 labouring women were selected. All Women of childbearing age with cephalic presentation who reported in the first stage of labour or beginning of uterine contractions over one hour with cervical dilatation of 3 to 4 cm were included. Women with other presentations, twin pregnancy, macro or microsomic fetus and cephalopelvic disproportion were excluded. They were randomly divided into two groups (A&B). Group A was given injection phloroglucinol 40mg IV every hour, maximum three doses. Similarly group B received injection drotaverine 40mg IM every hour, the same maximum three doses.

Results: The age range in this study was 20 to 30 years in both groups. Group A had a mean age of 26.40± 1.89 years. Period of gestation was 38.02±0.97 weeks while mean parity was 0.820±1.17 in group A. In group B, mean age was 27.100± 1.98 years, period of gestation 38.460±0.88 weeks and mean parity was 1.360±1.22. Premature rupture of membrane (PROM) was seen in 9(18%) women in group A as compared to 41(82%) in group B. Efficacy was seen in 43(86%) patients in group A as compared to 35(70%) patients in group B (p-0.05).

Conclusion: It is concluded that Phloroglucinol is significantly more effective than Drotaverine (P - 0.05) in reducing the duration of the active phase of labour.

Keywords: First stage of labour, Phloroglucinol, Drotaverine, Efficacy

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Introduction

Labour or human parturition is the physiological process that results in birth of a baby, delivery of the placenta and the signal for lactation to begin. It is a very painful process.[1] Active labouring female, becomes exhausted if it becomes prolonged (> than 12 hours). This may results in the development of maternal complications such as infection and excessive bleeding while fetal complications may be fetal distress and asphyxia. [2] It is most common practice to intervene in the labouring process to shorten the duration by

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membranes rupture, drugs to speed up contractions and ongoing support. [3]

The two main features of labour are uterine contractility and cervical effacement. If the cervix remains rigid despite powerful contractions, the labour does not progress. Various techniques have been used for accelerating the process of labour in the history of obstetrics [4]. Antispasmodic drugs are the main drugs for shortening the duration of labour.[5] These drugs act either by direct relaxation of muscles or interfering with the signals transmitted by the nerves to the muscles which contract during labour. [6]

Phloroglucinol, an antispasmodic drug, can be used to relieve spasm, edema, and tension of cervical muscles in labouring patients. It can be used to improve dilatation of cervix to promote progress of labour[9] It has been observed that active phase of first stage of labour was shortened by almost two hours after administration of phloroglucinol.[10] Drotaverine hydrochloride, an analogue of papaverine with smooth muscle relaxant properties, is another drug used in labour to improve cervical dilatation and progression of labour. This drug specifically inhibits phosphodiesterase (PDE-IV) enzyme which in turn increases the intracellular concentration of cAMP and cGMP and causing relaxation of uterine smooth muscles.[10] Drotaverine hydrochloride exerts its main effect on the cervix by facilitating its dilatation. It can be used for augmentation of labour especially when cervical dilatation is 4cm or more with good uterine contractions.[11] It produces smooth muscle relaxation particularly where spasm exists.[12]

The present study is designed to compare the efficacy of Phloroglucinol and Drotaverine in the management of first stage of labour in the local population so that the beneficial effects of the study could be shared with the local obstetricians.

Methodology

This study was conducted at Gynaecology and Obstetrics Department of Mardan Medical Complex, from 20th November 2017 to 20th May 2018. All labouring women with cephalic presentation on US or vaginal examination, presenting in the first stage of labour with beginning of uterine contractions within one hour having cervical dilatation of 3 to 4 cm were included. Women with other than cephalic presentation or having twin pregnancy, macro or microsomic fetus on US, cephalopelvic disproportion on x-ray were excluded. The sample size was calculated by WHO sample size calculator, keeping 92% proportion of efficacy in Phloroglucinol group and 70.91% in the Drotaverine group with 95% confidence interval and 80% power of the test were considered. The sample was calculated as100 and randomly assigned 50 to each group. Consecutive, non probability sampling technique was adopted for the sample selection.

Both groups were followed up on regular intervals to calculate the time of first stage of labour after the first dose of drug till complete dilatation of cervix. Complete dilatation is defined as cervical dilatation of 8 cm or more. The operational definition of efficacy was, “first stage of labour less than 6 hours”. All findings of both groups were recorded including efficacy as well.

Results

During this study period we observed that the mean age in Group-A was 26.40± 1.89 years, ranging from 20 to 30 years. Period of gestation was 38.02±0.97 weeks and mean parity was 0. 82±11.Similarly in Group-B mean age was 27.10± 1.98 years, the period of gestation 38.46±0.88 weeks and mean parity was 1.36±1.22(Table-I). PROM was seen in 9(18%) in Group-A as compared to 41(82%) of women in Group-B.

Table I: Demographic Characteristics (n=100)

Demographic variable	**Group A (n=50)** Mean± SD	**Group B (n=50)** Mean± SD
Age (years)	26.40± 1.89	27.10± 1.98
Period of Gestation (weeks)	38.02±0.97	38.46±0.88
Parity	0.82±1.17	1.36±1.22

Efficacy i.e. duration of the first stage of labour less than 6 hours, was seen in 43 patients (86%) in phloroglucinol group (Group –A) as compared to 35 patients (70%) in drotaverine group (Group-B). This was statistically significant with *p*-value of 0.05 (Table II).

Table- II: Efficacy (duration of first stage of labour < than 6 hours) in both groups.

Efficacy	**Group A**	**Group B**	***P* Value**
Yes	43(86%)	35(70%)	0.05
No	7(14%)	15(30%)	

Stratification of efficacy in both groups regarding age, a period of gestation, parity and PROM was also compared (Table III). It was seen statistically significant

with regards to POG (*p*-value of 0.04) and Parity (*p*-value of 0.02)

Table III: Stratification of efficacy with respect to Age, Period of Gestation (POG), Parity & PROM in both groups (n=100)

Stratification		Groups	Efficacy (%)		P value
			Yes	No	
Age (years)	20-25	A	15 (88.2%)	2 (11.8%)	0.63
		B	9(81.8%)	2 (18.2%)	
	26-30	A	28 (84.8%)	5 (15.2%)	0.07
		B	26 (66.7%)	13 (33.3%)	
POG (weeks)	37-38	A	30 (88.2%)	4 (11.8%)	0.04
		B	16 (66.7%)	8 (33.3%)	
	>38	A	13 (81.2%)	3 (18.8%)	0.54
		B	19 (73.1%)	7 (26.9%)	
Parity	0-2	A	38 (90.5%)	4 (9.5%)	0.02
		B	29 (70.7%)	12 (29.3%)	
	>2	A	5(62.5%)	3(37.5%)	0.85
		B	6(66.7%)	3(33.3%)	
PROM	Yes	A	2(22.2%)	7(77.8%)	0.08
		B	0(0%)	12(100%)	
	No	A	41(100%)	0(0%)	0.06
		B	35 (92.1%)	3 (7.9%)	

Discussion

Compared to the efficacy of two drugs (Phloroglucinol and Drotaverine) in shortening the duration of active phase of first stage of labour. As we know that labour is a multi-factorial process that involves myometrial contraction, cervical ripening, cervical dilatation and expulsion of fetus and placenta in an orderly manner. [13] There are various mechanical and pharmacological interventions by which cervical dilatation can be facilitated. Sweeping and stretching of the cervix for releasing prostaglandins and amniotomy usually done early for augmentation and shortening the duration of labour. Prostaglandins have been used in various formulation for induction of labour specially PGE2 gel for cervical ripening.

Oxytocin is proven to induce and augment labour but has no analgesic effect. Spasmolytics and analgesics combinations are administered to facilitate dilatation of cervix during labour to shorten the first stage of labour. An ideal spasmolytic should have prompt action and no adverse effects like uterine inertia. It should also have no or minimal side effects on mother and fetus.[14] Phloroglucinol, a spasmolytic agent, used primarily for gastrointestinal colic. It has strong smooth muscle relaxing effect, especially in spasm. This relaxing effect is much pronounced in intestine and ureter while it has got no effect on the smooth muscles of blood vessels. In the uterus, it softens the lower portion and cervix without inhibiting contractions in the body. It does not interfere with labour and does not cause PPH. There has been no atropine like effects with its use as seen with other antispasmodics. It does not cause fetal adverse effects.[14] Drotaverine hydrochloride is a highly potent spasmolytic agent acting on smooth muscles by inhibiting phosphodiesterase- IV and has no anticholinergic effects. Near term, human myometrium contains a higher proportion of rolipram sensitive type-IV PDE isoforms. Drotaverine by inhibiting them increases the intracellular concentration of cAMP and cGMP resulting in smooth muscle relaxation. It does not cross the placenta and hence no fetal adverse effects seen.[15]

In this study efficacy was seen in 43(86%) patients in Phloroglucinol group while Drotaverine Group B had 35(70%) which is significant (*p*=0.05). These findings are consistent with the study conducted by Ajadi MA who concluded that total duration of first stage of labour was shorter in Phloroglucinol group.[14] Tabassum S. in their study showed that use of Phloroglucinol reduced duration of labour effectively. In their study patients receiving Phloroglucinol there was 34% reduction of first stage of labour and a mean 23% reduction in second stage of labor (*P*-0.001).[12] They also observed that the accelerated 1st stage of labour was 66% in patients randomized to Phloroglucinol. S Batool, in their study compared Phloroglucinol group with Drotaverine group for acceleration of labour. It was reported that there was 46.85 minutes (24.49%) reduction in first stage of labor in phloroglucinol group than Drotaverine group.[16]

Mean duration of 1st stage of labour in the Drotaverine group was 7.78± 3.42 hours in a study, while it was reported to be 149.78± 22.6 minutes in another study.[14] [15] Janjua M and colleagues in their comparative study also supported our findings and showed significant difference with *p*-value of 0.002.[17]

Considering the limitations in our study like small sample size and hospital-based survey, the results, however, cannot be generalized for the whole population. Studies on large scale are required to make our own criterion.

Conclusion

It has been concluded that both Phloroglucinol and Drotaverine appear to be effective in the acceleration of first stage of labour. However, Phloroglucinol was superior in efficacy.

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