Efficacy of Phloroglucinol Versus Placebo on the Duration of Labour in Term Pregnancies

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Abstract

Background: To determine the efficacy of phloroglucinol in terms of duration of first stage of labour

Methods: In this randomized, controlled trial patients were divided into two groups as group A (phloroglucinol drug) and group B (placebo). Sixty one patients in the drug group received phloroglucinol 40mg (4ml) I/V at >3cm dilatation. Sixty one in the placebo group received distilled water 4ml I/V at >3cm dilatation. Dose was repeated after 60 min. Maximum 3 doses were given. Half hourly monitoring of vital signs, uterine contractions and fetal heart rate was done. Labour progress was plotted on partograph.

Result: Mean gestational age in both groups was 38.8 weeks. The mean duration of the observed active phase of 1st stage of labour in drug group was 183 mins and 316 mins in placebo group. The mean duration of 2nd stage of labour in drug group was 25.16 mins and 34.52 mins in placebo group. The mean duration of 3rd stage of labour in drug group was 8.72 mins and 11.1 mins in placebo group. The mean total duration of labour in drug group was 216.88 mins and 358.52 mins in placebo group.

Conclusion: Phloroglucinol is effective in reducing duration of first stage of labour

Key Words: Phloroglucinol, first stage of labour.

Introduction

The problems and hazards of prolonged labour, for mother and fetus have been recognized. The mother is exposed to high risk of infection, ketosis and obstructed labour, while the fetus faces the danger of infection, asphyxia and excessive cranial moulding. Labour lasting more than 12 hours in nulliparous women and 8 hours in multiparous women should be regarded as prolonged labour.1

Phloroglucinol, an antispastic drug, can relieve the spasm and edema of cervix and can lower the tension of cervix muscles. It can be used to improve dilatation of cervix and promote the progression of labour.2 Average duration of observed active phase of first stage of labour was shortened by almost two hours in patients who received phloroglucinol.3

Patients and Methods

This randomized controlled trial was conducted at Department of Obstetric and Gynaecology DHQ teaching hospital, from February 2009 to July 2009. All term primigravidae 18 yrs or older, having singleton fetus with cephalic presentation, in active phase of uncomplicated labour were included. Any contraindication to vaginal delivery e.g. CPD, placenta previa, Multigravida, Multiple gestation, pre-term, meconium stained liquor, CTG abnormalities and any obstetrical, surgical or severe medical complications such as heart disease or eclampsia were excluded. Patients in the drug group (A) (n=61) received phloroglucinol 40mg (4ml) I/V at >3cm dilatation. Patients in placebo group (B) (n=61) received distilled water 4ml I/V at >3cm dilatation. Dose was repeated after 60 mins. Maximum 3 doses were given. Half hourly monitoring of vital signs, uterine contractions and fetal heart rate was done. Labour progress was plotted on partograph.

Result

Majority were in age group 22-25 years (Table 1). Mean gestational age in both groups was 38.8 weeks. There were three groups of patients according to the number of doses of drug or placebo used during 1st stage of labour. Thirty seven cases (60.7%) received 1 injection, whereas 17 cases (27.8%) were given 2 injections and 7 cases (11.5%) received 3 injections during the 1st stage of labour

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Case</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-21</td>
<td>15</td>
<td>18(29.5%)</td>
<td>33(27%)</td>
</tr>
<tr>
<td>22-25</td>
<td>25(40.9%)</td>
<td>32(52.4%)</td>
<td>57(46.7%)</td>
</tr>
<tr>
<td>26-29</td>
<td>13(21.3%)</td>
<td>05(8.1%)</td>
<td>18(14.7%)</td>
</tr>
<tr>
<td>&gt;29</td>
<td>08(13.1%)</td>
<td>04(6.5%)</td>
<td>12(9.8%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of doses used</th>
<th>No (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>37(60.7)</td>
</tr>
<tr>
<td>2</td>
<td>17(27.8)</td>
</tr>
<tr>
<td>3</td>
<td>7(11.5)</td>
</tr>
</tbody>
</table>
mean total duration of labour in drug group was 216.88 mins and 358.52 mins in placebo group. (p = 0.000) The mode of delivery was not altered in 2 and 331.6 mins in control group. 8 Singh KC et al primigravidas was 148.9 mins in drotavarine group 11.1 mins (2.02) in placebo group. (p = 0.191) .The stage of labour in drug group was 8.72 mins (3.47) and regional studies have been done to study the effects of phloroglucinol on duration of labour. 6,7 and dihydrochloride, phloroglucinol trimethylether etc is advised to hasten the 1st stage of labour. 5,6 Many local Patra K, studied the effect of drotavarine on 1st stage of labour, the mean duration of 1st stage of labour in arrests labor, physicians should ensure that the cause. Before resorting to operative delivery for uterine contractions, fetal malposition, or CPD may be responsible for more than 50 % of primary cesarean deliveries. 4

Phloroglucinol accelerates the labour by relieving the spasm and edema of cervix and facilitates dilatation. 3 Use of antispasmodic agents like hyosine butylbromide, dicyclomine valethamate, camylofine dihydrochloride, phloroglucinol trimethylether etc is advised to hasten the 1st stage of labour. 5,6 Many local and regional studies have been done to study the effects of phloroglucinol on duration of labour. 6,7 Tehalia MK and Sajjan GR compared the effects of hyosine and Drotavarine in 1st stage of labour. Mean time to full cervical dilatation was significantly less in hyosine group in nulliparas (p< 0.01). 5 Roy A and Patra K, studied the effect of drotavarine on 1st stage of labour, the mean duration of 1st stage of labour in primigravidas was 148.9 mins in drotavarine group and 331.6 mins in control group. 8 Singh KC et al studied the use of drotavarine for acceleration of labour. In drotavarine group there was a mean 28% reduction in the duration of 1st stage of labour (p= 0.04). 9 Hemangi S et al evaluated camylofin dihydrochloride in active phase of labour. Mean duration of 1st stage in study group was 215 mins as compared to 334 mins in control group ( p< 0.001). 10 Yilmaz B et al found that the mean duration of active 1st stage in mepdridine group was 103 +/ - 64.5 mins in contrast to placebo was 173.9 +/ - 74.8 mins (p < 0.001). 11 Results of different studies reveal potential benefits of a reduced 1st stage time include a reduced incidence of chorioamnionitis, neonatal sepsis and puerperal sepsis, all of which are increased in women with prolonged labour. 12,13

Conclusion
In the presence of good and regular uterine contractions phloroglucinol can be used for augmentation of labour, helping the delivery to be easy and safe.

Discussions
Dystocia is common in nulliparous women and is responsible for more that 50% of primary cesarean deliveries. If labor is not progressing, inadequate uterine contractions, fetal malposition, or CPD may be the cause. Before resorting to operative delivery for arrested labor, physicians should ensure that the patient has had adequate uterine contractions for four hours, using oxytocin infusion for augmentation as needed. 4

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Table 3: Comparison of duration of labour between groups

<table>
<thead>
<tr>
<th>Stage of labour</th>
<th>Study group(min)</th>
<th>Control Group(min)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active 1st Stage</td>
<td>183.04(35.64)</td>
<td>316.09(52.29)</td>
<td>0.001</td>
</tr>
<tr>
<td>2nd Stage</td>
<td>25.16(6.21)</td>
<td>34.52(5.57)</td>
<td>0.001</td>
</tr>
<tr>
<td>3rd Stage</td>
<td>8.72(3.47)</td>
<td>11.18(2.02)</td>
<td>0.191</td>
</tr>
<tr>
<td>Duration of labour</td>
<td>216.88(38.94)</td>
<td>358.52(65.88)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

(Table 2). Duration of active 1st stage of labour was 183.04 +/- (35.64) mins in the drug group and 316.09 +/- (52.29) mins in the placebo group. There was a difference of almost 2 hours in the study and control group which was statistically significant. (p= 0.001) The mean duration of 2nd stage of labour in drug group was 25.16 mins (6.21) and 34.52 mins (5.57) in placebo group. ( p = 0.001) The mean duration of 3rd stage of labour in drug group was 8.72 mins (3.47) and 11.1 mins (2.02) in placebo group. ( p = 0.191).The mean total duration of labour in drug group was 216.88 mins and 358.52 mins in placebo group. (p = 0.000) The mode of delivery was not altered in 2 groups (Table 3).

References

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