Randomized Clinical Trial To Study The Effect Of Paracervical Block On Reducing Pain, Improving APGAR Score And On Accelerating The Active Phase Of Labor
Z Mehrangiz, R Sogra, A Malihe

Citation

Abstract
Aim: The Aim of the study is to ascertain the effectiveness of paracervical block in the relief of pain compared to a control group. The degree of pain relief provided by paracervical block and its effect on the fetus was studied randomly.

Material and Method: After approval by the ethics committee of the University of Hamadan Medical Science in September 1996, a randomized clinical trial with double blinding was performed.

Results and Conclusion: The degree of pain relief was complete in 90% of the study cases. The mean duration of pain relief was 26 seconds (p-value=0.486), fetal bradycardia (p=0.507). The time required in paracervical block to provide full dilatation was significantly shorter (p<0.01) in the study group than in the control group. No differences were observed in the rate of cesarean section in both groups. (P=0.310)

INTRODUCTION
Pain relief in labor presents unique problems. Labor begins without warning. Among the mammals, human birth is unique. The mother appears to require the assistance of other individuals for optimal outcome. Cervical factors play an important role in determining the progress and duration of labor. In the first stage, a paracervical block usually causes good to excellent pain relief because the pudenda nerves are not blocked (1). Yet, many women require drugs to relieve pain during labor (2-3). Recent studies do not support this view and with proper technique of paracervical block drugs might not be necessary. This is a simple and very effective procedure especially to relieve pain in the first stage of labor (3-5).

In this study, we evaluated the effectiveness of this technique to reduce elective cesarean section due to pain of labor and to reduce the psychological complications of painful labor.

MATERIAL AND METHODS
After approval by the ethics committee of the University of Hamadan Medical Sciences in September 1996, during the period 1996-1999 a total of one hundred cases of uncomplicated women of full term pregnancies in established early labor were admitted at the Fatemi hospital in Hamden City in Iran and selected for the study and randomly divided into the study group and control group.

Patients with uteroplacental insufficiency, diabetes, gestational hypertension, mal presentation, and chronic hypertension were excluded from the study. Selected patients were at stages of 4-5 cm dilatation and had contractions. Initially, the visual pain scale was performed. The patients with score 8-10 were allotted in the study. Patients were monitored every fifteen and 30 minutes. The patients received tranquillizers (promethazine 25 mg /3h/IM). After deliver, this test was repeated in the two groups (one group only received prometazine; the other group PCB and promethazine when needed ). APGAR scores of neonates after 1 and 5 minutes were recorded and all of them were revisited 6 hours later. In this study, the rate of cesarean section was reported. The real relief of pain was determined as a reduction in the analgesic scale from 8-10 to 0-2. The visual analgesic scale (VAS) was recorded for the first stage and the second stage of labor.
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We extracted data from the record including demographics, specifications of delivery, physician information on events during labor (type and amount of all analgesics used), neonatal outcomes such as weight, and 1-5 minutes APGAR. We performed statistical analyses using the statistical program SPSS. We explored bivariate relationships using chi-square tests and used 2-sided tests to compare means between the groups. We tested the use of PCB and promethazine as indicator of variables (none, 1 only, 2 or more doses) in the stepwise regression to determine potential dose response.

RESULTS
In this study, no fetal or neonatal deaths occurred. In group 1 (only promethazine) 32 cases received additional analgesia during labor, while in group II (PCB) only 2 cases received additional analgesia during the first stage of labor. Most of the women in the PCB group were painless in 60 seconds after the procedure (table 1).

**Figure 1**
Table 1: Absolute and partial distribution per case with onset of analgesia

<table>
<thead>
<tr>
<th>Time onset of analgesia</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>40 seconds</td>
<td>2</td>
<td>4.3</td>
</tr>
<tr>
<td>50</td>
<td>34</td>
<td>7.2</td>
</tr>
<tr>
<td>75</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>90</td>
<td>1</td>
<td>2.2</td>
</tr>
<tr>
<td>100</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>110</td>
<td>2</td>
<td>4.1</td>
</tr>
<tr>
<td>120</td>
<td>3</td>
<td>6.5</td>
</tr>
<tr>
<td>sum</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

In the control group, 46 (90%) of the women needed additional doses of promethazine during the first stage of labor. In the PCB group, two women (4%) needed one dose of promethazine during the first stage of labor. The range of duration of pain relief in the first stage of labor was 30 minutes in 50% women of the PCB group. The primigravidae had the largest duration of pain relief. Most of them were painless after 60 seconds.

**Figure 2**
Table 2: Mean time of pain free interval and parity

<table>
<thead>
<tr>
<th>Number of parity</th>
<th>Pain free interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>60</td>
<td>21/42</td>
</tr>
<tr>
<td>24/26</td>
<td>7/6/6</td>
</tr>
<tr>
<td>5</td>
<td>22/5</td>
</tr>
</tbody>
</table>

2% of fetuses in the PCB group and 4% in control group had distress. All of neonates had an APGAR score higher than 7 (Tables 3, 4). All of the neonates were revisited after 6 hours and were normal. The rate of cesarean sections with fetal distress in the PCB group was 2% and in the control group 4%. Most of the women in the study were primigravidae (42%).

**Figure 3**
Table 3: Neonatal outcome

<table>
<thead>
<tr>
<th>APGAR score at 5 minutes</th>
<th>PCB</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 4</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5-7</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>&gt; 7</td>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

**Figure 4**
Table 4: Effect on fetal heart rate

<table>
<thead>
<tr>
<th>Bradycardia</th>
<th>PCB</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>No effect</td>
<td>46</td>
<td>48</td>
</tr>
</tbody>
</table>

The results of the degree of pain relief are shown in table 5 and the mean labor data are listed in table 6.

**DISCUSSION**
In this study, we found that paracervical block was effective in reducing labor pain and accelerating the first stage of labor especially in primigravida.

Several studies (Chehab et al and Jina et al) found a statistically significant reduction in the injection delivery interval. (p<0.01)
The novel finding in this study was the faster pain relief in the PCBs group.

The APGAR score is not affected by PCB as shown by the study of Angel et al (1995) (11) and the study of Bracey et al. The neonatal umbilical artery pH values did not differ significantly (11). Several studies have confirmed the efficacy of this method in pain relief. Complete relief ranged from 80% - 90% (4,5,6) in this study with analgesic score test and response from the patient on the efficacy of this method in complete relief of pain of 80%. From all cases in the second stage of delivery (based on VAS and questionnaires) only 50% of patients were satisfied and needed additional pain relief.

ACKNOWLEDGMENT

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Author Information

Zamani Mehrangiz, MD
Fatemihe Hospital, Hamadan Medical University

Rabie Sogra, MD
Fatemihe Hospital, Hamadan Medical University

Arab Malihe, MD
Fatemihe Hospital, Hamadan Medical University