The Effect of Epidural-Spinal Anesthesia on Labor Outcome and Satisfaction in Parturient Mothers: A Randomized Controlled Trial

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Abstract

Introduction: One of the health system concerns is the use of medications for pain relief during labor and its side effects. Therefore, the aim of this study was to investigate the effect of epidural-spinal anesthesia (combined anesthesia [CA]) on labor outcome and satisfaction in pregnant women.

Methods: In this randomized controlled trial study, we included 80 nulliparous women who had been admitted to Fatemieh hospital (Hamadan, Iran) during 2015-2016 due to spontaneous onset of labor. They were randomly assigned into 2 groups of 40, one group with CA versus normal vaginal delivery (NVD) group. Data were collected by using of demographic questionnaire, satisfaction questionnaire, and baby truck scales. Data were analyzed by descriptive and analytical statistics in SPSS version 16.0.

Results: Average maternal age (mean ± SD) in the CA group was 26.94 ± 4.34 and in the NVD group was 25.89 ± 5.18, respectively. There was a significant difference between the 2 groups in terms of length of second stage of labor ($P = 0.001$), headache ($P = 0.04$), and Apgar score (first minute) ($P = 0.001$). Chi-square test showed a significant difference between the 2 groups in terms of satisfaction with childbirth ($P = 0.004$).

Conclusion: In this study, labor pain relief by using the spinal-epidural anesthesia (CA) increased the labor satisfaction. Nevertheless, this approach was associated with some maternal and neonatal complications such as: headaches, length of third stage of labor, and low Apgar score. It seems that the use of this method for painless delivery requires further studies.

Keywords: Labor pain, Patient satisfaction, Analgesia, Labor, Epidural-spinal

Introduction

Pain is a natural alarm, efficient in the detection and removal of trauma from the body. Labor pain is one of the most severe pains that a woman can experience. In spite of its impact on the ongoing process of childbirth, labor pain would be traumatic for both mother and fetus if it rises in the duration and severity.¹ Labor pain is comparable with the pain of amputation and ischemic heart disease. Among the factors that affect labor pain perception and response are the number and type of deliveries, fetal size, and position of the fetus in the womb.²,³ Fear of labor pain leads to the increased secretion of catecholamines (stress hormones), subsequent reduction in the efficiency of uterine contractions, prolongation of the delivery process, reduction in blood supply to the uterus, and fetal hypoxia. These in turn may lead to the increased incidence of obstetric interventions and the increase in the likelihood of the need for emergency cesarean.⁴-⁷ Studies have shown that the fear of labor pain and also less pain in cesarean section are the main reasons for the refusal of vaginal delivery in pregnant women. Therefore, the use of labor pain relief methods is one of the key issues in promotion of reproductive health.⁸ Nowadays labor centers and hospitals use...
the pharmacological and non-pharmacological methods to reduce the labor pain. The benefits of medical methods include the rapid decline of labor pain, reduction and prevention of the negative effects of stress hormones on the uterine placental perfusion, relaxation of the pelvic muscles, and facilitation of childbirth. One of the most common medical methods is using the combination of anesthetics (combination of spinal anesthesia and epidural anesthesia). This method is used in combination with an increment of intensity of labor pain in the active phase of labor (when the cervix is open between 4 to 6 cm). Epidural-spinal anesthesia is a highly specialized technique that benefits from little use of pain-relieving and anesthesia medications, as well as high access to epidural anesthesia and continuation of anesthesia during labor. Some studies have shown that the use of combined anesthesia (CA) leads to an increase in caesarean section, prolonged second stage of labor, postpartum headache and hyperthermia, lower Apgar score, and the need to use appliances such as vacuum delivery and forceps. In contrast, some other studies have shown that using this method of analgesia does not affect birth outcomes. The aim of this study was to assess maternal and fetal outcomes in parturient mothers who underwent CA during labor.

Methods

In this randomized controlled trial during 4th November 2015 and 25th January 2016, 80 parturient mothers and their newborns were recruited in Fatemieh teaching hospital, Hamadan, Iran.

Sample Size Determination

According to the work presented by Forouzesh Fard, the average delivery duration and standard deviation of delivery duration was estimated as 173.43 ± 33.5 minutes and 138.1 ± 41.5 minutes, respectively. Based on the first type error (α = 0.05) and the second type error (β = 0.05, power 99%) and error d = 35.3, the sample size was estimated using the MedCalc software:

\[ n = \frac{1}{\alpha^2} \left( \frac{\sigma_1^2 + \sigma_2^2}{\mu_2 - \mu_1} \right)^2 = \frac{(1.96 + 1.64)^2 (33.5^2 + 41.5^2)}{35.3^2} = \frac{36864.72}{1246.09} \approx 31 \]

considering a 30% sample loss, sample size was estimated for each group as 40. In total, the final sample size was considered 80 subjects.

Randomization

In this study, 80 parturient mothers who had been admitted to Fatemieh hospital (Hamadan, Iran) due to spontaneous onset of labor were recruited and randomly assigned into 2 groups (n = 40). The participants were randomly divided into intervention and control groups, and this approach was continued until the desired sample size was recruited. Two groups were matched for age, education, employment status, gestational age, and body mass index (BMI).

Inclusion and Exclusion Criteria

Inclusion criteria were: pregnant women who had age of 18 to 35 years, singleton pregnancies, gestational age between 37–42 weeks, cephalic presentation (OA), BMI between 19.8 to 26, and normal-weight of fetus between 2500 g and 4000 g. Exclusion criteria were delivery via emergency cesarean section (CS), prolonged labor (>18 hours the duration of the first and second phases of delivery or >2 hours the second stage of labor), gestational complication such as oligohydramnios, preeclampsia, infection, hypertension, gestational diabetes or chronic diseases, active or passive smokers, history of receiving any medication during pregnancy, history of allergy to anesthesia, topical infection or sepsis at the entrance of the needle in the waist, hemorrhagic diseases, circulatory platelet loss or systemic anticoagulant diseases of the blood, brain space spasm, anatomical disorders of the spine, and low blood volume (e.g., due to massive hemorrhage, including women with childbirth problems).

Interventions

The intervention group received a CA during labor while the control group did not receive any kind of analgesia during labor (NVD).

Combined Anesthesia Process

CA process was carried out by a single experienced anesthesiologist at the hospital. At first, parturient mother’s vital signs were monitored and in order to prevent hypotension, 500 mL of Ringer was infused. Pregnant women were in sitting position and their lumbar skin was disinfected using povidone iodoine. For epidural analgesia, 18-gauge or 17-gauge Tuohy needle was inserted into the space between the vertebrae L4, L3 to be placed at the epidural space. Then, a thin needle was inserted into the spinal subarachnoid space through the lumen of the epidural needle injecting anesthetic solution containing 1.7 mL sofental and 2 mg marcaine. Afterward, spinal needle was removed and a catheter was passed into the epidural space through the lumen of the epidural needle. After removing the needle and fixing the catheter, anesthetic solution (3 mL of lidocaine 1.5% along with epinephrine) was infused. After 3-5 minutes, anesthetic solution containing 17 mg of marcaine was infused within 1 to 3 minutes.

Demographic and Basic Information

The demographic variables included maternal age, maternal education, maternal employment status, gestational age, and aerobic exercise (at least 30 minutes
of walking per day during pregnancy). Other collected information were birth weight, the length of the active phase of labor (dilatation 4 cm to full dilatation), the length of second stage of labor (full dilatation to delivery of the fetus), the length of third stage of labor (the exit of the fetus and placental removal), Apgar score (first minute and fifth minute) according to the midwife’s records, breastfeeding initiation time after birth, the volume of postpartum hemorrhage (based on the number of pads used, each considered as 10 mL blood loss), headache after delivery, and the need to use delivery aids (vacuum, forceps).

**Satisfaction Questionnaire**
Satisfaction questionnaire evaluated participants’ satisfaction about the labor process through measuring their response to intervention, tend to re-use this mode of delivery and being satisfied of this delivery method. Responding to each item was based on a 5-point Likert scale from 0 which meant “dissatisfaction” to 4 as “immense satisfaction”. This questionnaire was completed 2 hours after delivery. Infants were weighed using a digital scale (Zuhenleh model).

**Statistical Analysis**
Data were analyzed by SPSS version 16.0 using descriptive statistics (mean and standard deviation) and student’s t test, Kolmogorov-Smirnov test (for checking normality), chi-square test and Fisher exact test. In these tests the level of significance was set as \( P < 0.05 \).

**Results**
Kolmogorov-Smirnov test showed that our data followed a normal distribution for the length of active phase of labor \( (P = 0.28) \), the length of second phase \( (P = 0.45) \), the length of third stage of labor \( (P = 0.28) \), Apgar score (first minute) \( (P = 0.35) \), Apgar score (fifth minute) \( (P = 0.09) \), start time of breast-feeding after birth \( (P = 0.06) \), the volume of postpartum hemorrhage \( (P = 0.24) \), headache after delivery \( (P = 0.34) \), and the use of delivery appliances \( (P = 0.5) \). There was no significant difference in demographic characteristics between the groups as shown in Table 1. Average maternal age (mean ± SD) in the CA group was 26.94 ± 4.34 years and in the NVD group was 25.89 ± 5.18 years. Average birth weights (mean ± SD) in the CA and NVD groups were 3370 ± 472 g, 3270 ± 480 g, respectively. Independent samples t test showed that significant difference was observed between CA and NVD groups regarding maternal age \( (P = 0.08) \) and birth weight \( (P = 0.1) \). There was no significant difference between 2 groups for the duration of first stage \( (P = 0.05) \) or of the third stage of labor \( (P = 0.2) \). Independent samples t test showed that there was a significant difference between 2 groups in terms of duration of the second stage of labor \( (P = 0.001) \); as the average duration was higher in the CA group compared to the NVD group. There was no significant difference between the 2 groups in terms of initiation time of breast-feeding after birth \( (P = 0.07) \). However, there was a significant difference between the 2 groups in terms of Apgar score (first minute) \( (P = 0.001) \). A higher ratio of newborns in the CA group had Apgar score less than 7. The 2 groups had no significant difference in Apgar score (fifth minute) \( (P = 0.1, \text{Table 2}) \). The 2 groups significantly differed regarding incidence of headaches after delivery \( (P = 0.04) \). More women in the CA group had headache. The 2 groups had no significant difference in terms of volume of postpartum hemorrhage \( (P = 0.13) \). There was also no significant difference

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CA Group ( n = 40 )</th>
<th>NVD Group ( n = 40 )</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y) mean ± SD</td>
<td>26.94 ± 4.34</td>
<td>25.89 ± 5.18</td>
<td>0.20</td>
</tr>
<tr>
<td>Education (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary school</td>
<td>11 (27.5)</td>
<td>7 (17.5)</td>
<td></td>
</tr>
<tr>
<td>Undergraduate</td>
<td>21 (52.5)</td>
<td>24 (60)</td>
<td>0.60</td>
</tr>
<tr>
<td>Postgraduate</td>
<td>8 (20)</td>
<td>9 (22.5)</td>
<td></td>
</tr>
<tr>
<td>Employed (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (2.9)</td>
<td>0 (0)</td>
<td>0.20</td>
</tr>
<tr>
<td>No</td>
<td>33 (97.1)</td>
<td>34 (100)</td>
<td></td>
</tr>
<tr>
<td>Abortion and stillbirth (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5 (12.5)</td>
<td>8 (20)</td>
<td>0.50</td>
</tr>
<tr>
<td>No</td>
<td>35 (87.5)</td>
<td>32 (80)</td>
<td></td>
</tr>
<tr>
<td>Planned pregnancy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>31 (77.5)</td>
<td>34 (85)</td>
<td>0.30</td>
</tr>
<tr>
<td>No</td>
<td>9 (22.5)</td>
<td>6 (15)</td>
<td></td>
</tr>
<tr>
<td>Parity, mean ± SD</td>
<td>1.8 ± 1.0</td>
<td>1.6 ± 1.1</td>
<td>0.2</td>
</tr>
<tr>
<td>Gestational age (wk), mean ± SD</td>
<td>39.0 ± 1.4</td>
<td>39.1 ± 1.6</td>
<td>0.2</td>
</tr>
</tbody>
</table>

\*Combined Anesthesia group; \* Normal Vaginal Delivery group.
Table 2. The Effect of Combined Analgesia on Duration of Labor, Start Time of Breast-feeding and Apgar Score of Study Population

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group</th>
<th>Mean ± (SD)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First stage of labor (minute)</td>
<td>1</td>
<td>108.06 ± (67.7)</td>
<td>0.05</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>153.8 ± (118.0)</td>
<td></td>
</tr>
<tr>
<td>Second stage of labor (min)</td>
<td>1</td>
<td>83.1 ± (64.3)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>21.5 ± (14.2)</td>
<td></td>
</tr>
<tr>
<td>Third stage of labor (min)</td>
<td>1</td>
<td>8.8 ± (5.2)</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>7.3 ± (4.2)</td>
<td></td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>1</td>
<td>3170 ± (470)</td>
<td>0.40</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>3270 ± (480)</td>
<td></td>
</tr>
<tr>
<td>Start time of breast-feeding</td>
<td>1</td>
<td>35.15 ± (5.14)</td>
<td>0.07</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>30.34 ± 3.54</td>
<td></td>
</tr>
<tr>
<td>Apgar score (1st min)</td>
<td>1</td>
<td>7.82 ± (1.4)</td>
<td>0.001</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>8.8 ± (0.54)</td>
<td></td>
</tr>
<tr>
<td>Apgar score (5th min)</td>
<td>1</td>
<td>9.6 ± (0.20)</td>
<td>0.10</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>9.4 ± (0.20)</td>
<td></td>
</tr>
</tbody>
</table>

*Combined Anesthesia group; † Normal Vaginal Delivery group.

between the 2 groups for the requirements of appliances such as vacuum delivery and forceps \(P = 0.52\), while this was significant for satisfaction with the delivery method \(P = 0.004\). Twenty-eight women (60%) had immense satisfaction of delivery method in the CA group while 12 women (30%) had this level of satisfaction in deliveries in the NVD group (Table 3).

**Discussion**

CA is an anesthetic method that is performed by injection of an analgesic or topical anesthetic or both into the spinal cord immediately before or after the epidural catheter insertion, resulting in effective and rapid relief of labor pain.\(^{14}\)

In this study, CA had an impact on Apgar score (first minute), the occurrence of headache after labor, and duration of the second stage of labor. However, CA had no effect on the length of first and third stages of labor. The average time of the first stage was lower in the CA group compared with that in the NVD group, but this difference was not significant. A previous study demonstrated that the use of CA anesthesia increased the speed of cervical dilatation in nulliparous women.\(^{15}\) Labor pain can lead to the increased secretion of catecholamines and their inhibitory effects on the uterine contractions,\(^{16}\) and it can be assumed that reduction of labor pain may improve and accelerate cervical dilatation and subsequently shorten the time of the active phase.

The results of this study showed that length of the second stage of labor was prolonged in the CA group compared to the NVD group. This finding is consistent with the result of a previous study that reported a longer time of second stage of labor in the CA group compared with the NVD group.\(^{17}\) In another study, the length of the second stage of labor was not significantly different between the 2 groups.\(^{11}\) One reason may be differences in the method of anesthesia and drugs used in the 2 studies.

Our study showed that a greater number of newborns had first minute Apgar score less than 7 in the CA group compared with the NVD group. Based on the literature, the number of newborns with Apgar score below 7 was greater in the group receiving Entonox compared with the CA group during labor.\(^{18}\) In another study, first minute Apgar score was not significantly different in the 2 groups receiving spinal anesthesia and epidural anesthesia.\(^{11}\) The difference in results may be due to some associated factors such as analgesic method, features of participants, different sample sizes, and drugs used for anesthesia.

In this study, spinal-epidural anesthesia had no effect on the neonatal Apgar score (fifth minute). One study reported that there was no significant difference in Apgar score (fifth minute) in the 2 groups receiving epidural analgesia and the CA.\(^{19}\) Another study showed that there was a significant difference in Apgar score (fifth minute) in the CA group compared with vaginal delivery group.\(^{17}\) Therefore, it can be concluded that combined analgesia probably does not cause neonatal respiratory depression.

In this study, CA did not lead to atonic uterus and an increase in postpartum hemorrhage. A study demonstrated that CA does not lead to an increase in the volume of postpartum hemorrhage.\(^{17}\) These results

Table 3. The Effect of Combined Analgesia on Postpartum Hemorrhage, Need to Use Vacuum and Forceps, Headache, and Satisfaction With Delivery Method in 2 Groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CV Group*</th>
<th>NVD Group*</th>
<th>Statistical Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 40, n(%)</td>
<td>40, n(%)</td>
<td>(P = 0.13) (\chi^2 = 2.29, df = 1)</td>
</tr>
<tr>
<td>Postpartum hemorrhage</td>
<td>&lt;500 mL</td>
<td>35 (87.5)</td>
<td>36 (90)</td>
</tr>
<tr>
<td></td>
<td>&gt;500 mL</td>
<td>5 (12.5)</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Headache after labor</td>
<td>Yes</td>
<td>5 (12.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>35 (87.5)</td>
<td>40 (100)</td>
</tr>
<tr>
<td>Use of vacuum and forceps</td>
<td>Yes</td>
<td>2 (5)</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>38 (95)</td>
<td>39 (97.5)</td>
</tr>
<tr>
<td>Satisfaction</td>
<td>Very high</td>
<td>18 (45)</td>
<td>7 (17.5)</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>10 (25)</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td></td>
<td>Low</td>
<td>6 (15)</td>
<td>12 (30)</td>
</tr>
<tr>
<td></td>
<td>Very Low</td>
<td>3 (7.5)</td>
<td>8 (20)</td>
</tr>
<tr>
<td></td>
<td>Never</td>
<td>3 (7.5)</td>
<td>8 (20)</td>
</tr>
</tbody>
</table>

*Combined Anesthesia group; † Normal Vaginal Delivery group.
indicate that combined anesthetics probably do not affect the volume of postpartum hemorrhage. In this study spinal-epidural anesthesia increased the risk of headache after labor. These results are in line with a 19-year study during 1987 to 2000.20 Puncture of meningeal membrane during regional anesthesia and leads to the leakage of cerebro-spinal fluid and reduction of the volume of liquid. This reduced volume causes pressure on the pain-sensitive structures in the central nervous system.

Our study showed that the use of epidural-spinal anesthesia did not lead to an increased need for application of vacuum and forceps. Recently, the use of forceps and vacuum has been raised as a risk factor of perineal trauma and morbidity in neonates.21 The results of a study in 2011 showed that the use of vacuum and forceps was higher in the group receiving epidural anesthesia.22 Another study demonstrated that a combined approach of anesthesia did not increase the need for forceps or vacuum.23 In our study, higher ratio of parturient mothers in the CA group were immensely satisfied with the delivery method compared with the mothers in the NVD group. One study reported that the level of satisfaction with the childbirth process was much higher in epidural-spinal anesthesia group compared with non-drug pain relief group.24 In another research, level of satisfaction with the labor process was associated with relief from labor pain and lack of side effects in pregnant women.25 Since satisfaction is a complex concept and depends on the factors such as personal and social values, personal expectations, previous experience, and lifestyle,26 the researchers attend that a full assessment of satisfaction cannot be perfect according to the data. Therefore, more research is needed in this field.

Conclusion
It can be concluded that using CA method of analgesia increased the satisfaction with the delivery method. On the other hand, it was associated with some maternal and neonatal complications such as headaches, length of third stage of labor, and low Apgar score. It seems that the use of this method for painless delivery requires further studies.

Ethical approval
The study was performed according to the Declaration of Helsinki and Good Clinical Practice Guidelines, and was approved by the Ethics Committee of Research Deputy of Hamadan University of Medical Sciences, Hamadan, Iran. Trial registration code of the project was IRCT201502266888N7 (http://www.irct.ir/trial/7319). Informed consent was obtained from the participants while they were fully aware of the nature of the study.

Conflict of Interests
The authors report no conflict of interests. The authors alone are responsible for the content and writing of the paper.

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