

ARTIGO ORIGINAL

Combined spinal-epidural anesthesia and non-pharmacological methods of pain relief during normal childbirth and maternal satisfaction: a randomized clinical trial

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SUMMARY

Objective: The objective of this study was to compare maternal satisfaction with childbirth according to whether or not combined spinal-epidural anesthesia (CSE) of pain relief was used during labor. **Methods:** A randomized, open clinical trial was performed with 70 pregnant women, 35 of whom received CSE anesthesia while 35 received only non-pharmacological forms of pain relief during labor. The variables evaluated were visual analogue scale (VAS) pain score, maternal satisfaction with the technique of pain relief used during childbirth and with delivery, the patient's intention to request the same technique in a subsequent delivery, and loss of control during delivery. **Results:** VAS pain score decreased significantly in patients receiving CSE during vaginal delivery. Furthermore, maternal satisfaction with the technique of pain relief and with delivery was higher in the CSE group, and around 97% of the patients would repeat the same technique at future deliveries compared to 82.4% of the women in the group using only non-pharmacological methods. With respect to the women's impressions of their control during delivery, approximately half the women in both groups felt that they had lost control at some point during the process. **Conclusion:** The use of CSE was associated with a significant reduction in VAS pain scores during delivery and with greater maternal satisfaction with the pain relief method and with the childbirth process.

Keywords: Labor pain; labor, obstetric; patient satisfaction; analgesia, obstetrical.

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RESUMO

Anestesia combinada e métodos não farmacológicos para alívio da dor durante o trabalho de parto e satisfação materna: ensaio clínico randomizado

Objetivos: Comparar a satisfação materna com o processo do nascimento de acordo com a realização ou não de métodos farmacológicos para alívio da dor do trabalho de parto. **Métodos:** Realizou-se um ensaio clínico randomizado com 70 parturientes, 35 das quais receberam anestesia combinada (raquidiana e peridural associadas) e 35 receberam métodos não farmacológicos para alívio da dor durante o parto vaginal. As variáveis estudadas foram: escores de dor pela Escala Visual Analógica (EVA), satisfação materna com a técnica analgésica e com o parto, desejo de repetir a técnica analgésica em parto posterior e perda do controle sobre o parto. A análise estatística foi realizada no programa Epi-Info 3.5.3, com base na intenção de tratar. **Resultados:** Pacientes recebendo anestesia combinada (AC) durante o parto vaginal experimentaram uma diminuição significativa dos escores da EVA e maior satisfação materna com a técnica analgésica e com o parto. A maioria das parturientes, cerca de 97% do grupo da anestesia combinada, repetiu a técnica em partos futuros, contra 82,4% do grupo dos métodos não farmacológicos. No que diz respeito ao sentimento de controle do parto, aproximadamente metade das parturientes dos dois grupos sentiu que em algum momento do parto perdeu o controle deste, não havendo diferença significativa entre os grupos. **Conclusão:** O uso da AC está associado a uma significante diminuição dos escores da dor durante o parto, e maior satisfação materna com a técnica analgésica e com o parto.

Unitermos: Parto normal; dor do parto; satisfação do paciente; analgesia peridural.

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INTRODUCTION

Recent decades have heralded the introduction of new practices and technologies in the obstetric care of women during normal childbirth; however, some concerns have been raised regarding the abusive use of these innovations. The “medical” model of childbirth has been questioned, with emphasis now being given to the advantages of the holistic or social model of care in low-risk deliveries¹⁻³.

In 1996, the World Health Organization (WHO)⁴ reevaluated the scientific-based evidence on healthcare practices at normal childbirth, placing greater emphasis on the humanization of care. One aspect closely related to the humanization of childbirth concerns the evaluation of maternal satisfaction with the process. Maternal satisfaction is an endpoint that has to be taken into consideration when evaluating quality and when planning a maternal and child healthcare service⁵⁻⁹.

Many authors believe that dissatisfaction with delivery is closely related to pain and to the pain relief method used, whether neuroaxial anesthesia or an alternative form of analgesia⁵. Therefore, negative experiences at childbirth such as anger, fear and intense pain are determining factors in the psychological adjustment of women in the postpartum¹⁰⁻¹².

Bearing in mind the impact that satisfaction with childbirth has on the woman's consequent psychological adjustment, especially with respect to her relationship with her baby, the objective of the present study was to compare maternal satisfaction with childbirth in accordance with whether or not pharmacological methods of pain relief were given at delivery.

METHODS

An open, prospective, randomized, controlled clinical trial was conducted to compare a group of women who received combined spinal-epidural (CSE) anesthesia with another group of women who were given non-pharmacological methods of pain relief during delivery. The study population consisted of 70 pregnant women admitted to the pre-delivery room between February and May 2010. The study was previously approved by the institution's Internal Review Board under approval #1107 and registered at Clinical Trials under #NCT00992524. This is a secondary analysis of a clinical trial, whose main objective was to evaluate the association between combined analgesia and an increase in intrapartum maternal temperature¹³.

Patients were only included in the study after careful evaluation by the obstetrician, after assuring that they fulfilled all the inclusion criteria and that none of the exclusion criteria were present, and after having agreed to participate in the study by signing the informed consent form. Pregnant women carrying a single, full-term fetus in cephalic presentation, with cervical dilatation of

3-6 cm, were included in the study. Women with a high-risk pregnancy (presence of meconium, prematurity, acute fetal distress) and those with an indication for an immediate Cesarean section were excluded from the study. Since this was a secondary analysis, the sample size was calculated based on the main project. Nevertheless, considering the data found, the sample was sufficiently large to show statistically significant differences in the major variables evaluated.

The variables studied were visual analogue scale (VAS) pain scores during labor, maternal satisfaction with the pain relief technique and with delivery, desire to use the same pain relief method at a future delivery and loss of control during delivery.

Randomization was performed using a table of random numbers generated by the Random Allocation computer software program, version 1.0 (2004). Prior to initiating anesthesia or not, VAS pain score, blood pressure, heart rate and respiratory rate were evaluated in all patients. Auscultation of the fetal heart was performed using Doppler ultrasonography, with fetal heartbeat being recorded prior to, during and following a contraction.

All the women, despite the group to which they had been randomized, received continuous support during delivery provided by a doula or trained layperson, and Swiss exercise balls, massage and music therapy were provided during delivery^{9,14}. The women were encouraged to move around and were permitted to walk about freely. In the cases in which CSE was to be given, the women were taken to the surgical theater where all the anesthetic procedures were carried out. All the women were monitored every hour, with VAS pain score, blood pressure, heart rate and respiration rate recorded. Dynamic monitoring of the uterus and fetal heart rate was performed in accordance with the guidelines established in this institute and in compliance with the recommendations of the World Health Organization (WHO) for low-risk pregnancies: auscultation every 30 minutes during labor and every 5 minutes or after each contraction in the expulsive phase^{4,15}.

Pain intensity was evaluated using a visual analogue scale (VAS)¹⁶, which consists of a two-sided rule with a 10 cm vertical or horizontal line linking two points, at one extreme indicating a total absence of pain and at the other the worst pain imaginable. The women were required to mark a spot on the line corresponding to the intensity of their pain at that particular time on a possible scale of 0 to 10.

After delivery, in the immediate postpartum, the patients were asked about their satisfaction with delivery and with the pain relief technique used, whether they would repeat the same technique in a future delivery, and their feelings about whether they were in control during delivery. This last item was defined as “being out of control” and was associated with the women having

insufficient control of their own body processes, described as exhaustion and impotence in relation to the progress of the delivery process¹⁷.

The questions related to maternal satisfaction with delivery and with the technique used were answered on a Likert-type scale¹⁸ ranging from 1 to 5 (very satisfied, satisfied, not very satisfied, unsatisfied and very unsatisfied). With respect to the women's feelings regarding their control during delivery and whether they would repeat the same pain relief technique on a future occasion, answers were dichotomized into yes/no.

STATISTICAL ANALYSIS

Data analysis was performed using the Epi-Info program, version 3.5.3. Initially, bivariate analysis was conducted to compare the characteristics of each group and to identify any differences that could constitute biases for the study objectives. Measures of central tendency and dispersion were used (means and standard deviations, and when pertinent medians and interquartile intervals).

Next, analysis was performed to test the association between the independent variable (pain relief at delivery: yes or no) and the dependent variables. This analysis was performed on an intention-to-treat basis, i.e. the patients were analyzed as belonging to the original group to which they had been allocated at randomization despite any changes that may have been made in their planned management during labor¹⁹.

The following categorical variables were described using 2 × 2 contingency tables: maternal satisfaction with delivery and with the pain relief technique received, loss of control during delivery and whether the woman would request the same pain relief technique again at a future delivery. Yates' chi-square test was used, as well as Fisher's exact test when indicated (one of the expected values < 5). For the purpose of analysis, the categorical variables of maternal satisfaction with delivery and with the pain relief technique were dichotomized into: satisfied (for responses of very satisfied or satisfied) and

unsatisfied (for responses of not very satisfied, unsatisfied or very unsatisfied). Risk ratios and their corresponding 95% confidence intervals (95%CI) were calculated as a measurement of the relative risk of various outcomes in accordance with whether or not CSE was given. A standard risk of 1.0 was attributed to the reference category (use of non-pharmacological methods).

With respect to VAS pain score, the median was adopted as the measure of central tendency and the Mann-Whitney non-parametric test was used in the statistical analysis to compare the pain score in the two groups hourly. The MedCalc software program version 11.6.6.0 was used to construct the curve of the VAS pain scores throughout labor. A significance level of 5% was adopted.

RESULTS

A total of 88 pregnant women were screened for inclusion in the study; however, only 72 fulfilled all the inclusion and exclusion criteria and were invited to participate in the study. Two women refused to participate, resulting in a final sample of 70 women, who were then randomized into two groups: 35 to the CSE group and 35 to the group that received only non-pharmacological methods of pain relief. There were no post-randomization losses. In one patient randomized to the pharmacological group, pain never reached an intensity that would justify the use of this technique. This patient remained calm throughout labor and reported only very mild pain right up to the delivery of her baby. One patient in the non-pharmacological group reported unbearable pain and requested CSE. Following implementation of this technique, her pain disappeared and she remained pain-free until the birth of her baby.

Analysis of patients' baseline characteristics (age, parity, gestational age, VAS pain score and cervical dilatation at randomization) showed that the two groups were homogenous, with no statistically significant differences between them (Table 1). Figure 1 summarizes the median VAS pain scores over the six timed measurements. Pain scores were similar in both groups at baseline ($p = 0.43$).

Table 1 – Characteristics of the women at admission to the study according to whether pharmacological or non-pharmacological methods of pain relief were given

Variables	Pharmacological method n = 35	Non-pharmacological methods n = 35	p-value
Age (years) (Mean/SD)	22.57 (2.13)	21.65 (2.46)	0.10*
Parity (median/%)	0 (68.6%)	0 (68.6%)	0.80**
Visual analogue scale pain score (median, p = 25-75)	8 (8-10)	9 (8-10)	0.43**
Gestational age (weeks) (Mean/SD)	39.1 (0.63)	39.3 (0.63)	0.19*
Cervical dilatation (median, p = 25-75)	5 (5-6)	5 (5-6)	0.88**

*Student's *t*-test ; **Mann-Whitney test.

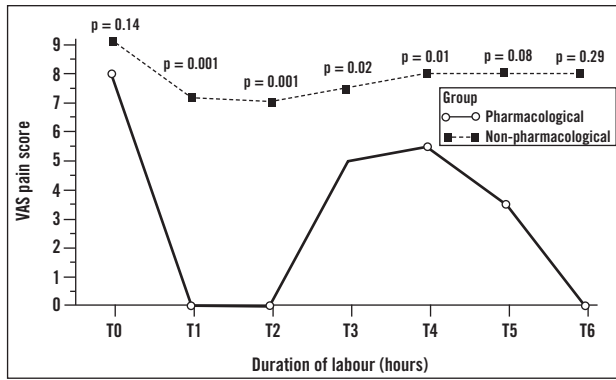


Figure 1 – Curve of the Visual Analogue Scale pain score according to group. T0 = value at randomization. p-values for comparisons between the pharmacological and non-pharmacological methods are statistically significant at the respective moments up to the 5th hour of labor (*Mann-Whitney).

Nevertheless, from the first hour of labor onwards, a significant reduction occurred in VAS pain scores in the CSE group and this statistically significant difference persisted until the fifth hour of labor after which there was no longer any difference.

When questioned regarding their satisfaction with the pain relief technique, 34 of the women in the CSE group (97.1%) reported that they were satisfied with the technique compared with 24 (68.6%) in the group using non-pharmacological methods (p = 0.001). With respect to satisfaction with delivery, 33 of the women in the CSE group (94.3%) and 24 of those in the non-pharmacological group (71.4%) stated that they were satisfied with

delivery (p = 0.01). Furthermore, the majority of the women in the CSE group (97.1%) stated that they would use the same technique at a future delivery compared to 82.4% in the non-pharmacological methods group (p = 0.04). Concerning the women’s feelings about their control during delivery, approximately half the women in both groups felt at some point during delivery that they had lost control of the process. There was no statistically significant difference between the two groups in this respect (p = 0.63) (Table 2).

Of the 70 women who participated in the study there was no statistically significant difference between the two groups with respect to Cesarean section, duration of the expulsion period, the need for oxytocin and instrumental delivery. On the other hand, the first stage of labor was significantly shorter (median 180 minutes) in the group submitted to CSE. In relation to neonatal results, median 5-minute Apgar score was the same in both groups; no statistically significant difference was found in the incidence of nonreassuring fetal heart rate; and no newborn infant had umbilical cord blood pH < 7.2 mmHg.

DISCUSSION

In the present study, a significant reduction was found in VAS pain scores in the group of women using pharmacological methods from the first hour of labor onwards. Maternal satisfaction was also found to be higher, both with the pain relief technique and with delivery, in the group using CSE. In addition, around 97% of the women in the CSE group would repeat the same technique in future deliveries compared to 82.4% in the non-pharmacological

Table 2 – Satisfaction with the pain relief technique and with delivery, feelings regarding control at delivery and whether the woman would repeat the same technique at a future delivery, in women using combined analgesia compared to non-pharmacological methods of pain relief

Groups variables	Combined analgesia (n = 35)	Non-pharmacological methods (n = 35)	RR	95%CI	p-value
Maternal satisfaction with the technique					
Yes	34 (97.1)	24 (68.6)	1.4	1.12-1.78	0.001*
No	1 (2.9%)	11 (31.4%)			
Maternal satisfaction with delivery (n/%)					
Yes	33 (94.3%)	25 (71.4%)	1.32	(1.05-1.65)	0.01*
No	2 (5.7%)	10 (28.6%)			
Whether the woman would repeat the same technique in a future delivery (n/%)					
Yes	34 (97.1%)	28 (82.4%)	1.17	(0.99-1.39)	0.04*
No	1 (2.9%)	6 (17.6%)			
Loss of control at delivery (n/%)					
Yes	14 (40%)	17 (48.6%)	0.82	(0.48-1.39)	0.2**
No	21 (60%)	18 (51.4%)			

NNT for satisfaction with the technique and delivery = 4, NNT for repeat the same technique in future delivery = 6; *, Fisher’s exact test; **, Yates’ chi-square test.

methods group. On the other hand, with respect to the women's feelings regarding control during delivery, approximately half the women in both groups felt that at some point during delivery they had lost control of the process, and there was no statistically significant difference between the groups.

Combined spinal-epidural (CSE) anesthesia involves injection of an analgesic or local anesthetic drug, or both, into the intrathecal space immediately before or after epidural catheter placement. A number of variations in this technique have been described²⁰. Nevertheless, it is known that, despite these variations, this technique results in an immediate and significant reduction in pain during labor²⁰. This is confirmed in the present study by the significant reduction in VAS pain scores in the group submitted to CSE. In corroboration with these findings, some studies have suggested that this technique promotes faster and more effective pain relief compared to other forms of analgesia, including non-pharmacological methods²¹.

The rapid and effective reduction in pain, as reflected in the lower VAS pain scores in the CSE group, may explain the higher maternal satisfaction with the technique compared to non-pharmacological methods. Nevertheless, contradicting these results, most scientific evidence suggests that satisfaction with the pain relief technique is more closely associated with a lack of availability or delay in implementing analgesia irrespective of whether the method used is neuroaxial or an alternative method^{22,23}. This finding was made clear in a recent systematic review in which, while CSE was associated with faster pain relief, maternal satisfaction was no higher than that registered with epidural anesthesia²¹.

With respect to maternal satisfaction with delivery, some authors have reported that the factors that most affect satisfaction at childbirth are: personal expectations, a good relationship with the obstetric team, trust in the obstetric team, continuous care, adequate support and the possibility of being involved in and being able to consent to the decisions being made⁸. Therefore, it is believed that satisfaction with delivery may be achieved if comfort and tranquility are assured in the management of labor, despite the technique used for pain relief²³. In addition, pain relief is believed to represent only one of the components of maternal satisfaction with the experience of childbirth, and complete analgesia (pain score < 2 on a scale of 0-10) may not be one of the most important aspects involved in patient satisfaction⁸.

In contradiction with this hypothesis, the results of the present study suggest that providing CSE for pain relief during labor is associated with a higher degree of maternal satisfaction with childbirth. On the other hand, in agreement with the results of the present study, some authors believe that pain relief is an important issue for women in labor and the level of pain experienced, as well as the

effectiveness of the pain relief method, may affect a woman's satisfaction with childbirth and may result in immediate and long-term emotional and psychological repercussions²⁴. The type of pain relief used during labor may even exert an effect on breastfeeding and on the mother-child interaction³.

Furthermore, in a country in which many women prefer a Cesarean section to vaginal delivery based on the idea that an elective Cesarean section guarantees painless childbirth, the performance of an analgesic technique capable of assuring complete pain relief may be associated with a better quality of care and, consequently, with greater maternal satisfaction. It should be emphasized, therefore, that prenatal care of good quality, in which women are well informed about childbirth and about the different forms of pain relief available, is fundamental in guaranteeing their participation in the decision-making process.

With respect to feelings of control regarding delivery, evidence suggests that this is affected mainly by the quality of the information on childbirth provided to women during their prenatal care and by women's ability to participate in making decisions during labor¹⁸. This may explain the high rate of feelings of loss of control in the women in this study, since, despite receiving comprehensive support during childbirth, most of these women received no specific information on the delivery process during prenatal care. On the other hand, some authors believe that loss of control during delivery is closely related to the woman's experiences during the process. If her experience of giving birth was not that of a healthy woman in labor or if she experienced intense pain associated with prolonged labor, this may have been understood as having been ill¹⁸. Nevertheless, this question was not evaluated as it did not constitute one of the objectives of the present study.

It should be emphasized that there is no scientific evidence suggesting the superiority of one technique over another. With the humanization of the care provided at childbirth, it has become increasingly necessary to adopt a form of management that, in addition to promoting healthy deliveries and births, also assures the well-being of the pregnant woman. Therefore, women should be informed with respect to the potential beneficial or adverse effects of all the procedures adopted during childbirth to ensure that they are able to make a free, well-informed choice.

Satisfaction is a complex concept related to various factors such as lifestyle, acquired experiences, future expectations and individual and social values. For this reason, various investigators consider that personal satisfaction cannot be completely evaluated based only on numerical data^{25,26}. There are various instruments with which to evaluate maternal satisfaction, including the "Maternity

Services Assessment Questionnaire” (MSAQ), which evaluates aspects from the postpartum and neonatal periods, and the “Patient Satisfaction with Maternity Services Instrument” (PSI), which deals with technical-professional and relationship aspects. Additionally, there is the “Women’s Experience of Maternity Care”, also known as the “Mason Survey”, which evaluates aspects from the antenatal, delivery and post-natal periods and following the patient’s release from hospital. All these questionnaires result in scores that facilitate an objective analysis²⁷. Further studies should therefore be conducted to determine the patient’s view on the positive and negative aspects of maternal and child healthcare in order to improve humanization of the process.

Consequently, we believe that one of the major challenges facing obstetricians and anesthesiologists in determining the type of analgesia that should be used is to respect the principles of humanization of healthcare at childbirth. These principles are based on respecting the patient’s autonomy, recognizing that she has the right to conduct her own delivery and leaving to the woman herself the choice of how and with whom she wishes to give birth. It is up to the woman herself to decide whether or not she needs to be submitted to analgesic procedures for pain relief in labor, as is the choice of which technique she would prefer and whether or not it is a pharmacological technique.

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