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The Comparison of Pain Relief between Postoperative Wound Infiltration with Bupivacaine 0.5% Combined with Epinephrine after Elective Cesarean Section

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Abstract

Background: So many methods have been developed and tested to control post-surgical pain. In this study, the effect of bupivacaine-H medicine (along with epinephrine) on the post-surgical pain reduction in cesarean mothers was examined.

Materials and Methods: In a double blind randomized clinical trial study conducted in Kerman, 70 pregnant women who were eligible for elective cesarean section participated in the study as randomized into two case and control groups. In all the patients, cesarean section incision lengths were equal and bupivacaine was injected after infant delivery. In the control group, physiological serum was used as placebo instead of medicine. Pain severity was compared between two groups using Visual Analogue Scale (VAS) on 6, 12, 24 and 48 hours after operation. The results were analyzed applying SPSS-11 software and using Mann-Whitney *U* and Wilcoxon tests.

Results: Mean age of the patients was 25.36 years with standard aviation of 2.48 years and the age range of 18-28 years. A previous cesarean with relative frequency of 38.5 percent was the main cause of cesarean section in such patients. In the case group, pain severity before 24 hours was less than that in the control group. After 24 hours of the operation, the pain severity in both case and control groups were similar.

Conclusion: In general, bupivacaine injection into the cesarean incision area will cause to reduce the pain after cesarean section in the mothers and considering its minor complications, such medicine may be used as an effective pain control method in women.

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Introduction

ost-surgical pain control has been always argued as one the main problems of surgeons. There is a variety of approaches to control post-surgical pains, one of which is the use of narcotics and or non-steroidal anti-inflammatory drugs. Due to the importance of breastfeeding of mother after delivery, there is mostly lower tendency toward using narcotics; that is why most of the physicians prefer methods of analgesia before or during operation [1]. There are still many discussions on the usefulness of such methods and the value of local analgesia in the pain relief after surgery have not been so much determined. Different studies have been conducted in this field including the investigation carried out by Glene et al in which they examined the patients undergoing laparotomy operation with longitudinal incision in two groups randomly. Before closing the incision, placebo was given to one group and Ropivacaine 0.5% was injected subcutaneously and facially into the other group. The amount of the morphine dose injected to all the patients after operation was measured by pain control device. Morphine dosage for the period after operation was measured at time intervals of 0-6 hours, 6-12 hours, 12-24 hours and 24-48 hours. Pain assessment was conducted by VAS at 6, 12, 24 and 48 hours after surgery [2]. The cesarean as the most important and

common surgery for women is prevalent in different societies with a relative frequency of 10-50 percent. In some cases, gynecologists are forced to perform such operation for various reasons including underlying diseases, anatomic problems and in emergency cases, etc¹ Patricia et al reported that subcutaneous injection of diclofenac into the cesarean section incision will decrease continuously and clearly the morphine dosage after operation [3]. Bupivacaine medicine is a long-acting local analgesic which is mostly used for having local, regional and/or epidural on lumbar or sacral region. This medicine is binding to plasma proteins at a level of 95% and it has half-life of 1.5-5.5 hours. It is capable of crossing placenta and is secreted into the milk in small amounts. The amount of medicine that crosses the placenta is less than what lidocaine and mepivacaine does, and adding adrenalin will not affect the amount of this medicine which crosses the placenta. If this medicine is used along with vasoconstrictor drugs, its onset and duration of effect would increase due to reduced drug absorption from the injection site into the bloodstream. The intravenous use of this medicine is prohibited and the related serious cardiovascular complications are likely to occur [4].

Given that one of the main goals of medicine is to reduce the patients' pain and suffering, the purpose of this

study is to examine the effect of local injection of bupivacaine hydrochloride 0.5% on the post-surgical pain in the mothers undergoing cesarean section by transversal incision.

Materials and Methods

This is a double blind randomized clinical trial study conducted from July until September 2004 at Afzalipour Hospital in Kerman. To conduct the project, sample size was calculated as 35 persons in each case and control group. The criteria for the subjects to participate the study was an age range of 18-28, weight range of 60-80 kg, lack of drug addiction, undergoing merely cesarean section and provided that it is not associated with other surgical procedures under general anesthesia by one type of anesthetics; all the patient who had not even one of the above conditions were excluded from the study. Finally, 70 women eligible for study were divided randomly into two groups; this division was made without the researcher's information.

All the patients underwent a general anesthesia by a dose of 3 mg/kg thiopental and 5.1 mg/kg succinylcholine as muscle relaxant and to extend the anesthesia, N₂O 5% and halothane 0.5% and oxygen 50% were used. It was tried to make cesarean section incisions in the same size and for longer incisions, the amount of the related substance was increased proportionate to the incision length. Due to the side effects of bupivacaine on the infant's liver, it was injected to all the patients after the newborn baby delivery and at time of closing abdominal wall. Ensuring the absence of needle tip into the vein by aspiration syringe, 10 ml of bupivacaine 0.5% mixed with epinephrine 1:200000 was injected in the rectus fascia at the time of closing the abdominal wall and then 10 ml of the same substance was injected under the skin around the incision area. In the control group, the only difference was in the use of physiological saline solution (normal saline 0.9%) instead of bupivacaine, but the epinephrine mixture, rate and area of injection were exactly the same as those in the case group.

All the injections were given by the assistants studying obstetrics and gynecology and without their awareness of the type of the medicine. After the operation is finished, interns on duty who were informed in details about the research as well as the method of using VAS, gave VAS forms to the patients in order to collect next data at different daily shifts at 6th, 12th, 24th and 48th hours after operation and recorded the patients' pain rate based on their own sayings [5]. After the patients are provided with necessary advices on the method of recording the pain level, using VAS form, pain severity in two groups were compared through drawing a 10cm line one side of which indicated the lack of pain and the other side showed the maximum pain severity; marked location of the patient was measured by the ruler and the data collected by the related forms were analyzed using SPSS-11 software and non-parametric statistical tests including U-Mann Whitney, Wilcoxon Rank and Repeated Measures of one-way ANOVA. The relationship between different variables was investigated and the statistical power was also measured using Sampsi command in STATA-7 software.

Results

In this investigation, 70 pregnant women elective for cesarean section were studied. Mean of the patients' age was 25.36 years with standard aviation of 2.48 years; their age range was changeable between 18 to 28 years and more than 63% of the patients had high school and higher educations. 35 persons were in the case group and the other 35 ones were in the control group. There was no significant difference between two groups for the age average. Average operation duration was 40.2±13.7 minutes in the case group and 42.5±15.6 minutes in the control group that shows no significant difference between two groups in this respect. Furthermore, comparing the weights in two groups indicated no significant difference between the subjects' average weights. In general, 38 male and 32 female infants were born. All the deliveries were singleton and the main reason for undergoing cesarean section was prior experience of the patients (Table 1).

Table 1. Frequency distribution of patients based on educational level and indication of cesarean cephalopelvic disproportion (CPD)

Variable		N(%)
Educational level	Illiterate-secondary school	26(37.1)
	High school- Diploma	33(47.1)
	University graduation	11(15.7)
Indication of cesarean	Previous cesarean	27(38.5)
	CPD	10(14.3)
	High risk groups	9(12.9)
	Placenta previa	7(10.0)
	Breech presentation	4(5.7)
	Patient's desire	6(8.6)
	Others	7(10.0)

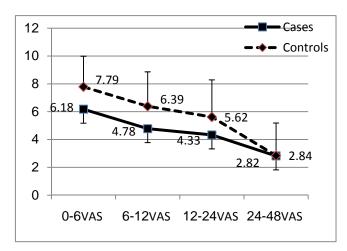
To measure the pain, VAS was used in which the patient marked on the designed scale, then using ruler, numeral value of pain was measured and recorded; the related results have been shown in table 2.

Table 2. Comparison of two for severity of pain

Time of Measure	Group 1 (Cases)	Group2 (Controls)	p-Value
6 h post operation	6.18±2.99	7.79±2.2	0.011
12 h post operation	4.78±1.9	6.39 ± 2.48	0.003
24 h post operation	4.33±2.08	5.62±2.67	0.027
48 h post operation	2.82±2.15	2.84±2.35	0.975

The results of the study related to the pain measurement of the patients were analyzed statistically using VAS scale at 6, 12, 24 and 48 hours after the injection of bupivacaine and normal saline in both case and control groups by applying Repeated Measures of ANOVA. Considering the results mentioned in the figure 1 and Table 2, it may be concluded that in the case group, average pain severity

within the periods 0-6 hours (p=0.011), 6-12 hours (p=0.030) and 12-24 hours (p=0.027) after operation was less than that in the control group and existing difference between two groups was significant. However, it was relatively similar in two groups within the period 24-48 hours after operation and there was no significant difference. Fig. 1 shows the pain reduction trend at different times of measurement. Some other variables have been also studied in this project with the results summarized as below; there were no significant difference between two case and control groups for average operation duration. A number of 11 persons in the case group had prior cesarean section experience and 16 persons in the control group had such experience too that showed an insignificant difference.



 $\textbf{Figure 1.} \ Comparison \ of two \ groups \ (case \ and \ control) \ for \ severity \ of pain \ based \ on \ the \ vas \ results \ after \ operation$

The mean for previous deliveries was 1.51 ± 0.66 in the case group and 2 ± 1.09 in the control group which showed a significant difference two means in the test (p=0.048), but multivariate test indicated the lack of a parietal relationship between the times of previous deliveries and the post-surgical pain level.

Discussion

One of the most significant challenges of surgery and obstetric and gynecological operations is to reduce postsurgical pain for which there are many different methods including non-steroidal anti-inflammatory drugs, opioid and non-opioid analgesics as well as local analgesia before and/or after operation. There has been a few studies conducted on the method of incision site analgesia up to now, and its usefulness has not been fully verified. Glenn et al concluded in their investigation that ropivacaine injection prior to the operation has no effect on the pain level and the amount of morphine dosage within 24 hours after the operation as well [2]. In the present study, the difference between the case and control groups measured at first three periods was statistically significant; these results are similar to what achieved by O'neal et al [5].

Local injection of analgesics into the operation incision area has a painlessness effect after operations [7, 8]. Systematic injection of narcotics is associated with respiratory depression, nausea and vomiting. Furthermore, it causes a slow recovery of bowel function [2, 6, 7]. Therefore, local injection of bupivacaine into the operation incision area was examined. The result of this study indicate that bupivacaine has an effective analgesic impact within the first 24 hours after operation; afterwards within an interval of 24-48 hours after operation, its painlessness effect was not significantly different from that of the control group. Most of the pain usually felt by the patients after surgery is related to the first 24 hours and it will reduce automatically within the second 24 hours; considering the bupivacaine half-life as 1.5-5.5 hours, its ineffectiveness within this period is remarkable. The results of the studies conducted in this field are different. Bupivacaine subcutaneous injection before stitching the skin in inguinal hernia surgery has reduced post-surgical pain [9].

In another investigation carried out by Pirbudakl at Gaziantep University of Turkey, a 5% mixture of bupivacaine with tramadol and tenoxicam was infiltrated into different abdominal layers during the cesarean section wall and a significant difference was found between two groups in respect of the pain level [10].

Another investigation was performed by Givens et al. in a double blind randomized study to determine the bupivacaine analgesic effect using a particular catheter on the women undergoing cesarean section. This catheter remained for 48 hours and it was connected to a patient controlled analgesia pump in recovery which injected normal saline in the control group and bupivacaine in the case group into the incision area at their own will and through themselves. This study showed that narcotics injection has been decreased in the case group. However, some variables could not be eliminated; for example, injection of normal saline and the existence of the catheter caused to stimulate the tissues around the incision area and starting the pain; this effect was not found in the group injected by bupivacaine [6, 11].

In a double blind randomized trial study carried out by Tan et al., an elective infiltration of abdominal rectus muscle opened during laparotomy surgery on the abdomen was performed by using 20cc of bupivacaine 0.5% or normal saline 0.9% in both case and control groups and it was found that the morphine dosage was reduced in the group using bupivacaine that is indicative of rectus muscle spasm which plays an important role in starting early pain after hysterectomy operation [10, 12].

In another investigation, the effect of mere bupivacaine local injection into the uterus by PCA device was compared to its effect along with diclofenac. In this study, local injection of bupivacaine had a minimal analgesic effect as compared with two-medicinal group of bupivacaine-diclofenac and morphine dosage was rather in the group with placebo [7]. In another research conducted by Patricia et al. it was reported that diclofenac subcutaneous injection into cesarean section incision, will

reduce continuously and clearly the morphine dosage after operation [3].

In general, considering the results achieved by the present project and all other similar studies, it may be concluded that the injection of bupivacaine into the cesarean section incision may cause to reduce post-surgical pain after cesarean operation in the mothers. With regard to the fact that this medicine has trivial complications, it may be used as an effective pain control in women.

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Authors' Contributions

All authors had equal role in design, work, statistical analysis and manuscript writing.

Conflict of Interest

No conflict.

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