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Effect of spinal anesthesia with sufentanil on length of stages I and II of labor in singleton pregnant women: a randomized controlled trial

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ABSTRACT

BACKGROUND

Labor pain is one of the most painful experiences in a women's life. One of the methods of pain relief is spinal anesthesia. The purpose of this study was to evaluate the effect of spinal anesthesia with sufentanil on the length of the first and second stages of labor in singleton pregnant women.

METHODS

A randomized clinical trial was conducted involving 56 women who had to be at least 37 weeks pregnant with a singleton pregnancy and 20 to 35 years of age, as well as seeking a spontaneous natural delivery. They were randomized into an intervention group (spinal anesthesia with sufentanil) of 28 subjects and a control group (no spinal anesthesia) of 28 subjects. Statistical analysis was performed using SPSS software program 20.0.

RESULTS

Mean duration of stage I of labor was 152.32 ± 92.01 and 187.68 ± 121.01 minutes in the intervention and control groups, respectively (p=0.34), whereas mean duration of stage II of labor in the 2 groups was 15.96 ± 14.26 and 26.43 ± 20.90 minutes, respectively (p=0.06). Twenty five percent of women in the intervention group and 35.71% of women in the control group experienced a long stage I, whereas 21.43% of women in the intervention group and 35.71% of women in the control group experienced a long stage II (p>0.05).

CONCLUSION

This study suggests that spinal anesthesia with sufentanil does not increase the duration of labor stages. It is recommended that more studies be performed in the future using larger sample sizes to allow for the drawing of solid conclusions.

Keywords: Spinal anesthesia, neuraxial analgesia, long labor, duration of labor, singleton pregnancy

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INTRODUCTION

One of a woman's most agonizing experiences is going through labor. The best treatment for reducing pain during labor is thought to be neuraxial analgesia. The most popular type of pain treatment during childbirth is epidural analgesia.[1] A self-administered questionnaire-based study on the effects of epidural anesthesia received responses from 324 Nigerian obstetricians, who mentioned high expenses and having not enough skills as the reasons for not employing the epidural approach.[2] In addition, some medical professionals prefer spinal anesthesia over epidural anesthesia. Low amounts of local anesthetic are used during the latter treatment, mostly because the drug can migrate into the spinal fluid. While still being carried out similarly as epidural anesthesia, spinal analgesia calls for a thinner needle to generate a spinal block, which entails making a tiny hole in the dura. Furthermore, the spinal block method may take less time than an epidural block.[3] According to several studies, spinal analgesia can be provided more quickly, more affordably, and more effectively than epidural analgesia.[4-6] To prevent undesirable effects such as hypotension in this procedure, it is usual practice to combine local anesthetics and opioid medications in nerve blocks that do not impact sympathetic activity.[7-9]

An elongated stage II of labor is associated with some negative outcomes including chorioamnionitis, perineal rupture, and postpartum hemorrhage. Professionals will thus be interested in any treatment that influences the course and outcome of stage II of labor.[10] A retrospective cohort study on 120 pregnant women who were divided into 2 groups, with one group receiving spinal anesthesia (n=60) and the other without spinal anesthesia (n=60), showed that the duration of stage II of labor was significantly longer in the women who received spinal anesthesia ($p=0.008$).[11]

The anesthetic drug sufentanil has high solubility, short latency and about 7 hours of action, which makes it a potential effective option for providing fast analgesia.[12] In addition, sufentanil has been reported to cause less respiratory depression than morphine and fentanyl.[13]

The analgesic properties of sufentanil have been reported previously and studies suggested its use in both spinal and epidural analgesia.[14] A study to compare the application and efficacy of ropivacaine combined with sufentanil for continuous epidural anesthesia (CEA) and combined spinal-epidural anesthesia (CSEA) in labor analgesia, showed that the use of the combination for CSEA achieved a shorter onset time and labor period ($p<0.01$).[15] Another study by Manouchehrian et al.[16] compared the effects of sufentanil and fentanyl for labor analgesia and reported a similar analgesic effect as well as longer analgesia time for sufentanil. Single-dose spinal analgesia can be useful in some cases, such as rapid delivery in primiparous and multiparous individuals and in places where the use of an epidural catheter is restricted. Since finding the best option for analgesia with the least complications is crucial, the aim of the present study was to determine whether or not spinal anesthesia using a low dose of sufentanil lengthens labor stages I and II.

Methods

Research design

This non-blinded, prospective, randomized, clinical trial was conducted in the Department of Gynaecology and Obstetrics, Amir-Al Momenin Hospital, Zabol, Iran from April 1, 2018 to April 1, 2019.

Research subjects

The study subjects were pregnant women who were sent to Amir-Al Momenin Hospital in 2019 for a natural birth and agreed to participate in the study. To be eligible for inclusion, a woman had to be at least 37 weeks pregnant with a singleton pregnancy, between 20 and 35 years old, and seeking a spontaneous natural delivery. The exclusion criteria included a history of opiate use, sensitivity to anesthesia, gestational diabetes,

gestational hypertension, and indications for cesarean delivery.

Sample size

The required sample size was estimated based on Najafi's study,[17] using a type 1 error of 0.01, a statistical power of 0.90, and a 20% possible dropout rate. The sample size for comparing the means was calculated using the formula; $n= f(\alpha, \beta) 2\sigma^2 /2\delta^2$, where δ is the true difference and σ is the standard deviation of the outcome. It was estimated that there should be 28 subjects in each of the intervention and control groups.

In the study a total of 56 pregnant women, who satisfied the requirements for entry were included. All these subjects as well as their spouses gave their written informed consent after being informed of the study's goals and conditions. Based on a table of random numbers, these participants were randomized using simple randomization into the intervention (spinal anesthesia) and the control group (no anesthesia).

Intervention

In this research, a single dosage of 2.5–5 micrograms of sufentanil was injected in the midline of the L3–L4 or L4–L5 intervertebral regions in the subarachnoid space to induce spinal anesthesia while the patient was seated in a standard operating room. Following the injection, the patient remained seated for three minutes before lying down. All procedures were performed in the sitting position under aseptic conditions by an expert anesthesiologist, who was to administer the intervention.

Outcomes measurement

Vital signs, uterine contractions, and fetal heart sounds were monitored throughout the trial in both groups every 10-15 minutes in the first stage and every 5 minutes in the second stage. The patient was dropped out of the study if any of the following conditions were met: the need for a cesarean section, anesthetic allergy, or cessation of the stages of labor. The gynecology and obstetrics resident who carried out the study kept track of the time. The lengths of the first and second stages of labor were then evaluated and recorded in the two groups, following which the data was imported into SPSS for statistical analysis. The normal length for the first stage was considered to be 10 hours in nulliparous and 5 hours in multiparous women. The corresponding lengths for the second stage were 3 and 2 hours. The patients were followed up for one month after discharge for hospital in order to be checked for any possible complications.

Data analysis

Using SPSS software version 20.0 and Student's t-test, the descriptive statistics (such as mean and standard deviation) were evaluated. Data were compared between the two groups using the t-test for quantitative variables and the chi-square test for categorical variables. A p-value less than 0.05 was regarded as significant.

Ethical clearance

The Zabol University of Medical Sciences ethics committee authorized this prospective, randomized trial (ethics approval code: IR.ZBMU.REC.1397.212). This clinical trial has been registered in the Iranian Registry of Clinical Trials (IRCT). In addition, all participants, together with their spouses, gave written consent before participating.

RESULTS

We enrolled 56 participants in the active phase of labor. Twenty eight women were assigned to the intervention group (with spinal anesthesia) and 28 to the control group (without spinal anesthesia). All 56 participants completed their enrolment to the study. No technical difficulty was found in any patient (Figure 1).

The mean age of the subjects was 26.59 ± 5.58 years in the age range of 18 to 39 years. The mean gestational age was 38.74 ± 1.17 weeks in the range of 35 to 41 weeks. Thirty-nine women (69.64%) were multiparous, while 17 were

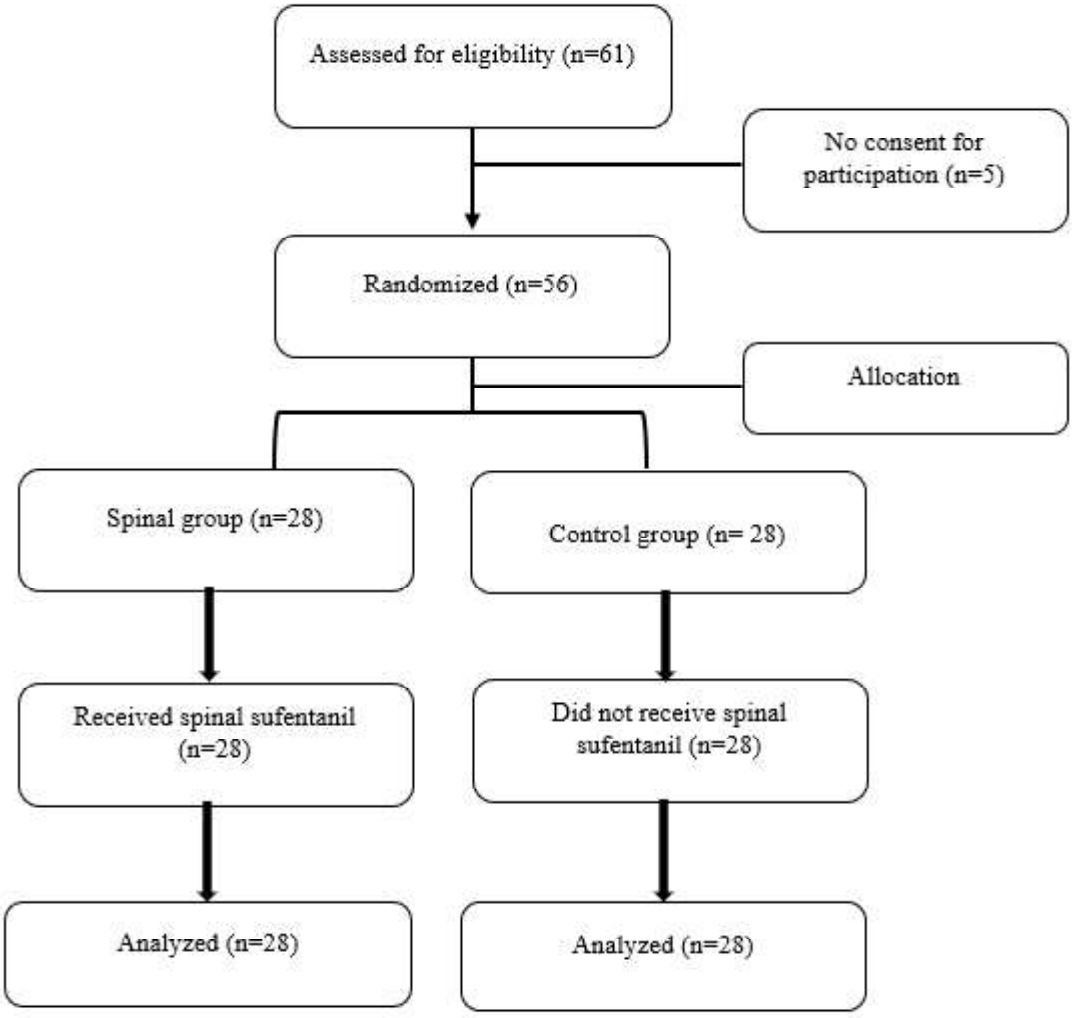

Figure 1. Flowchart of the participants

nulliparous (30.36%). There was no significant difference in any of the demographic factors between the intervention and control groups (Table 1). The mean durations of first and second stages of labor were 170.0 ± 108.0 (ranging from 35 to 480 minutes) and 21.20 ± 18.50 (ranging from 2 to 60 minutes), respectively. The mean duration of the first stage of labor was 152.32 minutes in the intervention group compared to 187.68 minutes in the control group (p=0.341), while the mean duration of the second stage was 15.96 minutes in the intervention group compared to 26.43 minutes in the control group (p=0.062), with the means showing no statistically significant difference between the two groups (Table 1).

Overall, 28.57% of women had a long second phase, whereas 30.36% of women had a long first phase. Twenty five percent of the women in the intervention group and 35.71% in the control group experienced a long first stage, while 21.43% of women in the intervention group and 35.71 % of women in the control group experienced an elongated second stage. For both stages of labor, there was no significant difference between the spinal group and the control group (Table 2).

DISCUSSION

The main finding of our study was that we observed no significant difference in the length of either of stages I and II between the group who received spinal analgesia with sufentanil and the group who did not. Sufentanil is a liposoluble opioid which has a fast onset and a low risk of hypoventilation.[18]

Table1. Demographic and clinical characteristics of subjects at base-line

Parameters	Spinal group (n=28)	Control group (n=28)	p value
Age (years)	26 ± 5.68	27.18 ± 5.52	0.431
Weight (kg)	78.6 ± 8.3	76.1 ± 7.4	0.843
Height (cm)	1.63 ± 0.05	1.59 ± 0.09	0.612
Gestational age (weeks)	38.73 ± 1.13	38.74 ± 1.23	0.871
Parity			
Nulliparous	7	10	0.743
Multiparous	21	18	
Stage I duration (min)	152.33 ± 92.01	187.68 ± 121.01	0.341
Stage II duration (min)	15.96 ± 14.26	26.42 ± 20.90	0.062
Cervical dilation before analgesia (cm)	2.3 ± 0.3	2.5 ± 0.4	0.511

*Values are expressed as mean ±_SD, except for parity as n (%); p-value was obtained from independent sample t-test; p<0.05 considered statistically significant

A study in India showed that combined spinal epidural using sufentanil and fentanyl achieved high patient satisfaction and excellent labour analgesia without serious maternal or neonatal side-effects. Sufentanil provided a significantly longer duration of labour analgesia compared with fentanyl.[19] It is suggested that spinal analgesia lengthens labor by causing the uterine muscle to generate inefficient electrical activity. This idea states that a breakdown in the transmission of contractions to the lower section of the uterus inhibits the primary genesis of uterine contractions. Other researchers reported no significant increase in the length of stages of labor by single-dose spinal analgesia with 2.5mg hyperbaric bupivacaine plus 50 µg fentanyl.[20] The heterogeneity between studies can be due to the fact that each of these studies used a specific dosage and type of medication for anesthesia. Rahmati et al.[20] in their trial used a 0.5 mL (2.5 mg) dosage of hyperbaric bupivacaine 0.5% combined with 50 µg fentanyl and suggested this combination as a safe method for spinal analgesia with no significant complication. Our results showed that the control group's mean lengths of both first and second stages were even longer than those of the spinal anesthesia group (121 ± 187.68 min vs. 92 ± 152.33 min, and 20.90 ± 26.42 min vs. 14.26 ± 15.96 min, respectively). When compared to the control group, even the prevalence of the prolonged second stage was higher in the control group, fairly close to significant levels. Zhi et al.[21] in a systematic review and meta-analysis compared the efficacy

Table 2. Comparison of the length of labor and side effects in spinal group vs. control group

Parameters	Spinal group (n=28)	Control group (n=28)	p-value
Stage I duration (min)	152.33 ± 92.01	187.68±121.01	0.341
Stage II duration (min)	15.96 ± 14.26	26.42 ± 20.90	0.062
Side effect (pruritus)	1	0	0.451
Cesarean section	0	0	-
Postpartum hemorrhage	2	3	0.523
Apgar scores at 1 min	9.68 ± 0.61	9.73 ± 0.41	0.712
Apgar scores at 5 min	9.53 ± 0.21	9.62 ± 0.56	0.832

*Values are expressed as mean ±_SD, except for side effects, cesarean section and postpartum hemorrhage as n (%)

of sufentanil and fentanyl in combined spinal-epidural analgesia and reported that sufentanil was more effective in pain management as well as in extending the analgesia time.

We only observed post-dural puncture headache in one patient which was consistent with the results of Sharpe et al.[3] which reported post-dural puncture headache as the only complication in 2.1% of spinal analgesia patients. Another study found that, especially in scenarios with limited resources, spinal anesthesia is one of the most effective methods for treating pregnant women who are extremely restless owing to pain in the later stages of labor, with a success rate of 98%.[22] They reported that a low-dose combination of 250 μg of morphine, 2.5 mg of bupivacaine, and 25 μg of fentanyl can be effective for up to 4 hours. However, due to the unpredictable nature of labor and the particular nature of the labor process, a second spinal block (fentanyl 25 μg + bupivacaine 2.5 mg) may be necessary once the first dose's effects wear off. Another recent study also reported that using opioids can extend the anesthesia time up to 2 hours or even longer.[23]

Our study had some limitations. The main one was that because of the type of injection technique needed, we could not perform a sham injection as placebo for the control group. However, we believe that this limitation did not cause differential effects on the outcomes.

Our study did not find a significant increase in labor duration among the patients who received analgesia. Since this pain control is a crucial component of labor, professionals should continue to evaluate the available data in order to develop the recommendations for labor pain management. Until then, based on our study and previous studies, the use of spinal sufentanil for anesthesia in labor seems to be a safe method that does not increase the length of labor.

CONCLUSION

This study demonstrated that spinal anesthesia with sufentanil does not increase the duration of the labor stages. It seems that the effect of this method on the duration of labor stages requires further studies.

CONFLICT OF INTEREST

All authors declare that they have no conflict on interests.

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No funding was received for conducting this study.

AUTHOR CONTRIBUTION

MY and BSM: conception and design, library searches, and assembling relevant literature, critical review of the paper, supervising the writing of the paper, and database management. KS: data collection, library searches, assembling relevant literature, writing the paper, critical review of the paper MA: data analysis. All authors have read and approved the final manuscript.

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