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Research Article

Comparison of Patient Controlled Analgesia with Bupivacaine or Bupivacaine plus Fentanyl during Labor

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Abstract

Objective: In this study, we aimed to compare the efficacy of low dose bupivacaine vs. bupivacaine plus fentanyl, both administered via PCA, for pain relief during labor.

Materials and Methods: A total of 40 healthy pregnant women in the active phase of labor were included and randomly allocated into the two following PCA analgesia groups: 0.125% bupivacaine (Group B) and 0.125% bupivacain + 2 μg/ml fentanyl (Group BF).

Hemodynamic parameters were recorded. Fetal heart rate and uterine contractions were monitored.

Also recorded were the time of onset of analgesia, pain score, sensory and motor block levels, and adverse effects, as well as amount of solutions required by the pregnant, bolus volumes administered, total solution volume used in PCA, mode of delivery and the result of initial newborns examination. Mothers were asked to rate their level of satisfaction with analgesia after delivery.

Results: Onset of analgesia was more rapid in group BF than in group B. Subjects in Group BF had higher sedation, less pain, and less marked motor blockade than group B. The first phase of labor and total time of labor were shorter in Group BF. Volumes of solutions required by the pregnant women and of boluses given during the first phase were also lower in group BF. Satisfaction of pregnant women was higher in group BF. No significant differences were found in other variables between study groups.

Conclusion: We conclude that bupivacaine and fentanyl combination provides higher quality of analgesia and better patient satisfaction in labor than bupivacaine alone.

INTRODUCTION AND OBJECTIVE

Despite temporal and cultural differences between societies in terms of the perception of labor, pain has always been an indispensable element of this event. In the light of the experience gained with epidural anesthesia, it has been possible to achieve higher quality analgesia through reduced concentration of local anesthetics and addition of opioids. Also, methods used for this purpose has changed over time with administration of bolus doses in initial studies, with subsequent widespread use of patient-controlled and continuous analgesia strategies [1]. Similarly, patient-controlled epidural analgesia was used in the current study in order to compare low dose local anesthetic with the combination of opioid and low dose local anesthetic, and to examine their effects on maternal hemodynamics, course of labor, severity of labor pain and maternal satisfaction as well as the effects on newborn.

MATERIALS AND METHODS

Following ethics committee approval, a total of 40 nulliparous or multiparous pregnant women between 19 and 34 years of age and with an ASA I status were included in this study, after providing written and oral informed consent. Exclusion criteria included cephalopelvic disproportion, preterm labor, intrauterine growth restriction, and participant age less than 18. Fetal heart rate and uterine contractions were monitored with cardiotocography throughout the labor. After initiation of epidural analgesia, all study parameters were recorded every 5 minutes in the first 30 minute period, followed by hourly recording until completion of labor. However, only data obtained during the pre-determined time period (i.e. at baseline, and 15 minutes, 30 minutes, 1 hour, 2 hour after epidural analgesia, and also at the completion of the 1st and 2nd phase of labor). In pregnant women with normal bleeding-clotting time, prior to

the placement of an epidural catheter, an intravenous route was accessed and continuous infusion with 500 ml of lactated ringer's solution was started. An epidural catheter at intervertebral L2-3 or L3-4 space was placed while the patient was in sitting position. Pregnant women were randomly divided into two groups. The first group (Group B) received 0.125% bupivacaine (1.25 mg/ml) and the second group (Group BF) received 0.125% bupivacaine (1.25 mg/ml) + 2 µg/ml fentanyl as the study solution.

Analgesia during labor was maintained using PCEA (patient controlled epidural analgesia) using the following variables: basal infusion at a rate of 5 ml/h, 5 ml patient controlled bolus, 10 minute lock-out time. Pain was scored using the Visual Analogue Scale (VAS), where the severity of pain was marked on a 10 cm-long horizontal line with the number "0" on one end and "10" on the other end (0 and 10 corresponding to no pain and intractable pain, respectively). A VAS score of less than or equal to 3 was considered to indicate effective analgesia.

Complications such as nausea, vomiting, hypotension, bradycardia, pruritus, chills, quivering, and respiratory depression occurring during the analgesia administration and within the first 24 hours after labor were recorded. Hypotension was defined as a 20% reduction in the blood pressure or a systolic blood pressure below 90 mm Hg, and ephedrine 5 µg/ml i.v. was administered when required.

The time to first pain-free uterine contraction after administration of the drug was recorded as the analgesia onset time in both groups. Motor block levels were checked according to the Bromage scale using alcohol swabs with 15 minute intervals in the first half hour, and every half an hour thereafter. The time to complete cervical dilation (10 cm) and the time from complete cervical dilation to delivery were recorded as the 1st and 2nd phase of labor, respectively.

In both phases of the labor, the dose requested from the device by the patient, the bolus dose, and the total drug dose were recorded. The type of labor, i.e. normal, assisted (forceps or vacuum), or cesarean section, was also recorded. The newborn assessment was based on APGAR scoring system at 1 and 5 minutes. Patient monitoring was continued until two hours after delivery. The next morning after delivery, at the time of the removal of the epidural catheter, mothers were inquired about the level of satisfaction with the analgesia administered that was scored as weak, moderate, good, and excellent.

For statistical assessments Student's t test, ANOVA-post hoc Dunnett test, Mann Whitney U test, and Wilcoxon signed rank test were used. The data was expressed as mean ± standard deviation. A p value of less than 0.05 was considered as significant.

RESULTS

Pregnant women in two groups had similar demographic characteristics, age, body weight, and height (Table 1). Also, no significant differences at baseline and during the course of the labor were detected between the two groups with respect to blood pressure, maternal and fetal heart rate, and saturation (p>0.05). At the 1st phase of the labor, the time from drug administration to the onset of analgesia in Group B and Group BF was 21.1 ± 1.6 (range: 18-23) and 16.8 ± 2.7 (range: 13-23) minutes (Table 2), with a significantly shorter onset of action in group BF (p<0.001). The comparison of the groups in terms of pain severity showed that severity of pain after epidural analgesia also significantly lower in Group BF than in B (Table 3). The sensory dermatome levels at the pre-determined assessment time-points in Groups B and BF after epidural analgesia were comparable (p>0.05). Significantly higher motor block was found in Group B than in Group BF (p<0.05). In pregnant women in Group BF, a significant increase in the intensity of uterine contractions occurred from baseline to post-epidural analgesia was observed (p<0.01). However, Group B and Group BF was not significantly different in terms of the intensity of uterine contractions at baseline and after epidural analgesia (p>0.05). A comparison of the two groups at the same time-points with respect to the level of sedation showed a significantly higher sedation score in Group BF after analgesia than in Group B (p<0.001). No changes in consciousness occurred in either groups. The 1st phase of the labor was significantly shorter among pregnant women in Group BF as compared to Group B (p<0.05). The two groups were comparable in terms of the duration of the 2nd phase of the labor (p>0.05), with a similar time-to-delivery. The total duration of the labor was significantly shorter in Group BF than in Group B (p<0.05).

Table 1: Demographic Data.

	Bupivacaine (n=20)	Bupivacaine + Fentanyl (n=20)	p
Age (year)	25.2 ± 4.3	24.5 ± 4.7	0.626
Weight (kg)	73.4 ± 9.0	73.6 ± 7.1	0.954
Height (cm)	161.3 ± 4.5	162.6 ±8.2	0.537
Parity	0.6 ± 0.9	0.6 ± 0.8	0.649
Gravida	2.1 ± 1.4	2.1 ± 1.2	1.000
Serv. Dilatation (cm)	4.4 ± 0.5	4.4 ± 0.5	1.000
Serv. Efacement (%)	0.7 ±0.1	0.7 ± 0.1	0.519
Pregnancy week	39.4±1.1	39.3 ± 0.8	0.649

Table 2: Time to Onset of Analgesia in Study Groups.

	Bupivacaine	Bupivacaine+Fen	P
Effect time(min)	21.1 ± 1.6	16.8 ± 2.7###	<0.001

p<0.001, between group B and group BF

Table 3: Visual analog scale values (VAS) of the groups.

VAS	Bupivacaine	Bupivacaine+Fen	P
Baseline	8.3 ± 0.7	8.5±0.5	0.21
15. min	2.8 ± 0.7*	1.7 ± 1.1***###	<0.001
30. min	2.5 ± 0.8**	0.9 ± 0.8***###	<0.001
1. h	2.4 ± 0.8***	0.6 ± 0.8***###	<0.001
2. h	1.9 ± 0.8***	0.4 ± 0.5***###	<0.001
1. end of period	1.9 ± 0.8***	0.6 ± 0.7***###	<0.001
2. end of period	2.1 ± 0.7***	0.8 ± 0.9***###	<0.001
P	<0.001	<0.001	

*p<0.05 **p<0.01 ***p<0.001
p<0.01, between group B and group BF

Table 4: Labor methods of the groups.

Labor methods	Bupivacaine (n=20)	Bupivacaine+Fentanyl (n=20)
Normal	16 (%80)	16 (%80)
Forceps	0 (%0)	3 (%15)
Vacum	3 (%15)	1 (%5)
Caesarean	1 (%5)	0

P>0.05, between group B and group BF

The volume of drugs administered at the 1st and 2nd phase of the labor in Group B was 40.4 ± 15.7 (15.8-59.6) and 7.9 ± 7.9 (30.50-0.30) ml, respectively, with a total drug volume of 48.3 ± 18.3 (19.0-85.5) ml. In Group BF, the corresponding values were 23.8±17.8 (3.7-45.8) ml, 8.3 ± 6.4 (0.9-22.0) ml and 32.1 ± 18.7 (14.2-96.1) ml, respectively. Therefore, the volume of drugs administered at the 1st phase of labor and throughout the total duration of labor was significantly higher in Group B than in Group BF ($p<0.01$). The volume of analgesic drugs used in the 2nd phase of labor was similar across the two groups ($p>0.05$).

Women in Group BF had significantly lower number of requests and bolus doses than in Group B. The requested volume of drugs from the analgesia pump device was similar between the two groups in the 2nd phase of labor ($p>0.05$). The pain scores were also comparable between the two groups. However, there was a significant decline in the pain severity from baseline in Group BF ($p<0.001$).

The two groups were comparable with regard to APGAR scores in the newborn ($p>0.05$).

The total number of women with normal delivery was 16 (80%) in Groups B and BF. The number of women undergoing assisted delivery in Group B and Group BF was 3 (15%) and 4 (20%), respectively, and of these 3 (15%) involved the use of forceps and 1 (5%) vacuum. One woman in Group B had a cesarean delivery (5%) versus no cesarean deliveries in Group BF. The comparison of the two groups observed with respect to adverse effects such as nausea, vomiting, shivering, and pruritus during and after the procedure showed nausea in 2 patients in Group B, and pruritus in 2 patients in Group BF. Pruritus occurred after bolus administration of the drug and resolved spontaneously the next day. One patient in each group had shivering.

The satisfaction from epidural analgesia was rated as excellent, good, moderate, or weak. Proportion of patients reporting excellent, good, and moderate satisfaction in Group B was 26% (n=5), 58% (n=11), and 16% (n=3), respectively, with no patients reporting weak analgesia. The corresponding values in Group BF were 65% (n=13), 30% (n=6), and 5% (n=1), again with no patients reporting weak analgesia ($p<0.05$).

DISCUSSION

Epidural analgesia is the most common form of labor analgesia that provides an effective and safe pain relief. Use of epidural anesthesia has been associated with reduced maternal stress levels, regulation of respiratory rate and amplitude, decreased oxygen consumption, prevention of catecholamine discharge, preservation of uteroplacental blood flow, and regular uterine contractions, which lead to a more favorable condition for the fetal health [1,2].

During epidural analgesia, hypotension should be avoided. For this reason administration of 500 to 1000 ml of crystalloid infusion before or during epidural has been recommended [1], while others proposed that rapid administration of fluids just prior to epidural analgesia may lead to a temporary decrease in uterine activities [2,3]. In our study, an intravenous line was established before epidural analgesia, and 500 ml of lactated ringer's solution was given at the start of the procedure.

Despite the initial fluid loading, care was practiced to avoid from fluid overload during the labor activity. None of the pregnant women included in the study experienced hypotension requiring fluid loading and ephedrine. Similarly, no case of reduced uterine activity was noted in either group. Viscomi et al. compared continuous vs. patient controlled analgesia (PCA), and found that PCA was associated with more satisfactory results from patients' perspective [4]. They also reported reduced work-load of the healthcare personnel as well a reduced need for anesthetic agents when PCA was used. Patients generally reported that PCEA was more useful, safer, and more effective than the comparator approach [4]. Similarly, in our study epidural labor analgesia was delivered through the patient controlled analgesia method.

Vaan Steenberge et al. were the first investigators to administer 0.125% bupivacaine for epidural analgesia in 1970s [5]. Subsequent clinical studies utilized lower doses of local anesthetics and opioids. In the studies led by Polley and Capogna, the minimum effective dose of bupivacaine was explored and the lowest effective dose of local anesthetic for bupivacaine was 0.067% in the study by Polley et al. [6] and 0.093% in Capogna et al. studies [7].

Subsequently, Chestnut et al. and Fernandez et al. added fentanyl to a concentration of 0.0625%, which is considered inadequate alone, and achieved adequate level of analgesia [8-10]. These emerging data suggested that addition of opioids to local anesthetics may allow the reduction of local anesthetic dose used for labor analgesia, minimizing the risk of motor block, and prolonging the duration of analgesia [8-10].

In the current study, bupivacaine was used at a concentration of 0.125%, which has been reported to deliver adequate analgesia when used alone and which is associated with a low propensity for motor block. In one of our study groups, opioid was added to the same concentration in the setting of patient controlled epidural analgesia, and the two groups were compared with respect to their analgesic efficacy in labor. Pain severity showed a significant reduction in Group BF as compared to baseline at all assessment time-points ($p<0.001$), suggesting that 0.125 bupivacaine + fentanyl combination administered through PCEA may deliver higher quality analgesia, consistent with previous reports by Jones, Bernard, and Youngstrom [11-13]. The satisfactory analgesia and relaxation in Group BF were also in line with the previously reported reduction in catecholamine release and occurrence of regular uterine contractions, shortening the duration of labor [14,15].

Wahlin et al. performed a retrospective search on normal labors and those performed with epidural analgesia for a 5-year period before the study [15]. Two groups were defined based on the absence or presence of opioid use, and the type of labor

and duration of hospital stay were compared between these two groups. The results of the study showed combination of opioids with local anesthetics reduced the number of assisted deliveries; cesarean sections as well as the length of hospital stay [16].

Again, James observed a reduced rate of assisted deliveries when bupivacaine was combined with an opioid as compared to bupivacaine alone [17]. Our findings are somehow at odds with those of Wahlin and James. These authors found a reduced rate of assisted and operative delivery in opioid + local anesthetic combination group, while no such differences were observed in our study. Wahlin's study is a retrospective study encompassing a 5-year period, which, we believe, may necessitate confirmation of these findings with studies involving larger number of pregnant women for labor analgesia. Also there are other studies involving the use of other opioids such as the one by Selim et al. [18] in which epidural bupivacaine + fentanyl or bupivacaine + dexmedetomide showed similar efficacy. It has been well established that lowered uterine blood flow due to epidural analgesia does not result in neonatal acidosis or low APGAR scores. Similarly, APGAR scores were high and comparable in both of our study groups [18]. Akkamahadevi et al. compared bupivacaine + sulfentanyl and bupivacaine + fentanyl combinations and found high patient satisfaction and excellent labor analgesia, without any severe maternal or neonatal side effects in both groups [19]. As in our study, that study suggests that addition of an opioid to bupivacaine may lead to better outcomes. A comparison of the satisfaction level between our study groups showed significantly higher satisfaction in Group BF than in Group B. The statistical and clinical results of objective data are consistent with the subjective reports of the patients. Also, our data are in line with other publications by Jones, Bernard, and James, who reported superiority of opioid + local anesthetic combination over the use of local anesthetics alone in labor analgesia [11,12,17]. In this study the effect of low dose bupivacaine or bupivacaine + fentanyl combination administered via patient controlled epidural analgesia on a number of factors such as maternal hemodynamics, uterine contractions, labor activity, need for additional analgesics, and life quality of the newborn. Low dose bupivacaine + fentanyl administered via patient controlled epidural analgesia was associated with better quality and more effective analgesia with high patient satisfaction, suggesting that this combination represents a superior option in this setting.

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