RESEARCH ARTICLE

BUPIVACAINE 0.125% VERSUS BUPIVACAINE 0.125% WITH DIFFERENT DOSES OF FENTANYL FOR EPIDURAL LABOUR ANALGESIA: A RANDOMISED DOUBLE BLIND STUDY

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ABSTRACT

Background: Epidural analgesia is the most commonly used method for labour analgesia.

Aims & Objective: To evaluate the safe dose of fentanyl added to Bupivacaine 0.125% and its effect on quality and duration of analgesia with side-effects.

Materials and Methods: Forty-five healthy nulliparous women, ASA physical status I and II with an uncomplicated pregnancy and single fetus in vertex position were given lumbar epidural analgesia. Patients in Group A (n=15) received Bupivacaine 0.125 percent; Group B (n=15) and C (n=15) received the same agents as Group A but with addition to the initial dose of 2 mcg/ml or 4 mcg/ml of fentanyl respectively. All the patients were evaluated for duration and quality of analgesia, duration of labour, method of delivery and side effects.

Results: Addition of either 2 mcg/ml or 4mcg/ml of fentanyl resulted in longer duration of analgesia (132.2 ± 12.4 minutes and 188.20 ± 18.5 minutes respectively versus 92.5 ± 10.2 minutes) and also decreased number of top up doses significantly. Quality of analgesia was better in Group B and Group C as compared to Group A. Addition of fentanyl did not affect the duration of labour, the method of delivery and fetal outcome.

Conclusion: Combination of Fentanyl 2 mcg/ml and Fentanyl 4 mcg/ml with Bupivacaine 0.125% is both and safe for providing labour analgesia via epidural route.

Key Words: Epidural Analgesia; Bupivacaine; Fentanyl

Introduction

A woman should not be denied pain relief for cultural, religions and wrong beliefs especially in developing and low socioeconomic countries. It started with introduction of inhalational agents in 1847 and intended till early decade of 20th century with use of opioids for pain relief. There are various pharmacological and non-pharmacological medication available for labor analgesia tried and adapted over years. Out of which regional analgesia/ anaesthesia techniques are most popular methods as for e.g. Epidural analgesia. Maternal request is significant justification indication for providing pain relief in labor. Epidural being the most commonly used method for labour analgesia. The combination of epidural local anaesthetics and fentanyl has been demonstrated to have benefit in analgesia and delivery.[1-4] Because fentanyl has no effects on sympathetic or motor neurons it does not lead to hemodynamic side effects like hypotension[1], it provides certain advantages over local anaesthetics, but has been shown to be inadequate as the sole agent.[2] Drawback of using low dose of local anaesthetic is chances of incomplete analgesia especially in second stage of labour. Such doses are sufficient to block the non-myelinated C-fibres in the first stage of labour, but may be inadequate to block the myelinated A-delta fibres in the second stage.[3] The present double-blind study was designed to evaluate the safe dose of fentanyl added to Bupivacaine 0.125% and its effect on quality and duration of analgesia with side-effects.

Materials and Methods

After ethical committee approval from our institution and taking informed consent, we included 45 women, ASA I or II, requesting extradural pain relief in the first stage of labour. We excluded those women in whom cervical dilatation exceeded 6cm, taking sedative and hypnotic drugs and having any contraindication for extradural pain relief technique. All women included in the study had an uncomplicated pregnancy, single foetus in vertex position and were assigned randomly to one of the following groups: Group A (n=15) received epidural Bupivacaine 0.125%, Group B (n=15) received epidural Bupivacaine 0.125% with Fentanyl 2 mcg/ml and Group C (n=15) received epidural Bupivacaine 0.125% with Fentanyl 4 mcg/ml respectively, to a total volume, in all three groups, of 12 ml.

When cervical dilatation had reached 4 cm, infusion of 500ml of lactated Ringer's solution was done followed by epidural block. The procedure was performed in left lateral

position. Epidural space was located in L2-L3 interspace by 18G Touhey needle by loss of resistance technique using 2 cc of 0.9% normal saline. The catheter was placed advancing 3cm in the epidural space. For the purpose of study, test dose was omitted. Patient was placed in supine position with left uterine displacement, and the solution was injected through the catheter, according to the randomization protocol. After the initial dose, additional doses according to initial doses of the assigned groups were administered when pain recurred, until the time of delivery. In the second stage of labour, the mother was placed in semirecumbent position. All parturients were monitored after epidural administration of epidural local anaesthetic which included patient pulse rate and systolic blood pressure, Mean arterial blood pressure, Diastolic blood pressure at 5, 10, 15, 30, 45, 60 minutes, and then every 1 hr. Duration of analgesia defined as time from initial dose to when additional analgesia requested till delivery . Hypotension defined as Systolic Blood pressure < 90 mmHg or 20% below baseline. The epidural catheter was withdrawn half hour after delivery. Assisted ambulation was permitted in patient with assistant.

Baseline pain intensity, defined as the intensity of the pain assessed just prior to the block, measured with visual analogue scale (VAS). The quality of analgesia through the labour was assessed by the following scoring system: *(i) Excellent:* When mother was completely pain free from the first or the second injection until the end of delivery. *(ii) Good:* When the mother was satisfied but some pain was experienced for a short period during labour or delivery. *(iii) Incomplete:* When the mother had significant pain relief, but experienced some pain during most of the time of labour and delivery. *(iv) Failure:* When, after the start of epidural analgesia, pain was experienced during most of the time of labour and delivery. *(v) Not possible to evaluate:* delivery by Caesarean delivery.

The peak effect was defined as the first painless contraction. Motor block of grade 0 was assessed using modified Bromage scale (0 = Able to raise the extended legs,1 = Unable to raise the extended legs, 2 = Unable to flex the knee, 3 = Unable to flex the ankle or complete motor block). Sensory level evaluated using pin prick. Mode of delivery was either normal vaginal delivery, normal vaginal delivery with episiotomy, Instrumental delivery (vacuum extraction, forceps application) or lower segment caesarean section.

Fetal outcome assessed using Apgar score at 1 minute & 5 minutes after delivery and fetal heart rate monitoring during labor. Side effects like nausea, vomiting, pruritus were noted. Pruritus score: none, minimal, (with minimal symptoms), moderate (bothersome, not requiring treatment), severe (requiring treatment). Statistical analysis was done using `ANOVA' Test.

Results

The groups were demographically similar with respect to age, weight, height, gestation, parity. Baseline pain intensity in terms of VAS was 6. Mean duration of labour in all the parturients was 628.20 ± 52.80 minutes. Peak effect for each group was 26.3 ± 4.7 minutes, 23.45 ± 5.2 minutes and 26.5 ± 3.8 minutes in Group A, Group B and Group C respectively with no statistical significance.

Hemodynamic parameters were comparable at baseline in all the three groups. Decrease in pulse rate, Diastolic blood pressure and Mean arterial pressure were statistically significant after each dose at their peak effect time in all three groups as compared to baseline with no associated bradycardia or hypotension. There was no statistical difference observed in hemodynamic parameters in between three groups at their peak effect time.

The analgesia was satisfactory in all the three groups. Duration of analgesia is prolonged and number of top up doses (Table 2) is reduced significantly in group B (p value<0.05) and C (p value<0.05) as compared to group A. There was no incidence of incomplete analgesia among group B and group C. Addition of fentanyl to Bupivacaine significantly improves the quality of analgesia (Table 3). No significant motor blockade was observed in any of the three groups with all patients being able to ambulate with assistant.

There was no significant between the groups in mode of delivery (Table 4). Duration of labour was also comparable. Only 6 parturients required lignocaine infiltration at the time of episiotomy. Itching was the only significant side effect in group C, reported in 3 patients. In 2 patients in group C, we observed neonatal respiratory depression on delivery in patients with full term pregnancy and no prolongation of labour, required intubation and ventilatory support in nursery for one day; baby discharged after 2 days. After this, the study was modified and patients in Group C received initial dose with 4 mcg/ml Fentanyl followed by top up doses containing 2 mcg/ml fentanyl. These 2 cases were excluded from the study. Fetal heart sounds during labour remained stable with no complications of fetal distress amongst all three groups. Post-delivery Apgar scores at 1st minute and 5th minute also remained greater than 7 in almost all the patients in all 3 groups with no statistical significance (Table 5).

Table-1: Population demographics (Mean ± SD)

Parameters	Group A	Group B	Group C
Age (years)	23.2 ± 1.3	22.6 ± 1.5	24.1 ± 1.2
Height (cm)	152.28 ± 5.33	153.41 ± 4.68	151.46 ± 5.23
Weight (kg)	54.30 ± 2.4	53.23 ± 2.6	53.47 ± 3.0
Gestation (weeks)	39.6 ± 1.4	38.0 ± 1.7	39.5 ± 1.2
Parity (nulliparous)	15	15	15
Cervical dilatation (cm)	4	4	4

(No significant differences between groups)

Table-2: Duration of analgesia and top up dose

Parameters	Group A	Group B	Group C
Duration of analgesia (min)	92.5 ± 10.2	132.2 ± 12.4*	188.20 ± 18.5#
No. of top up dose	6 ± 2	4 ± 2*	3 ± 1#

*p value <0.001 vs group A; #p value<0.05 vs group A and B

Table-3: Quality of analgesia

Quality	Group A	Group B	Group C
Excellent	0	96.1%*	96.1%*
Good	83.4%	3.9%	3.9%
Incomplete	16.6%	0	0
Failure	0	0	0

* p value <0.05 vs group A

Table-4: Mode of delivery

Parameters	Group A	Group B	Group C
Spontaneous	82.8%	82.2%	89.9%
Low forceps	17.1%	6.6%	10%
Vacuum	0	6.6%	0
Caesarean delivery	0	4.4%	0

Table-5: Apgar Score

Parameters	Group A	Group B	Group C
1st minute>7	97.1%	96.6%	96.6%
5th minutes>7	100%	96.6%	100%

(No significant differences between groups)

Discussion

We studied the efficacy and potency of 0.125% inj. Bupivacaine (Group A) and addition of Fentanyl (2 μgm/ml) (Group B)and Fentanyl (4 μgm/ml) (Group C) given in intermittent boluses in women going for normal labour belonging to ASA 1 and II at the time of cervical dilatation 3 to 5 cm. We had age, height, parity, BMI, weight comparable between the groups probably due to randomisation of cases in full term pregnant.

The low Bupivacaine dose used represents a negligible risk in the event of accidental intravascular administration, with a further decreased risk with addition of fentanyl, due to the lower mean dose of Bupivacaine employed. Previous study by Capogna et.al and Ferrante FM, et al[8,9] showed that addition of fentanyl to epidural solution reduces hourly requirement of local anaesthetic used by 19-31%[8,9,11]. Similar observation was seen in our study. In group C the total number of repeated doses were 3 ± 1 compared to group B in which it was 4 ± 2 and in group A in which it was 6±2 and this was statistically significant. There was statistical significance noted even amongst group B and Group A. VAS score reduced to 0 within 30 minutes, statistically significant (p< 0.05) from the baseline till the delivery of baby in all the three groups. All patients were alert and awake. All parturient were allowed assisted ambulation with motor block grade 0.

As compared to previous studies by Danilo et al. addition of either 50 or 100 mcg of fentanyl to Bupivacaine resulted in a more prolonged duration of analgesia, with a reduced number of additional doses through the labour and of the total dose of Bupivacaine administered. Similar prolongation of duration of analgesia was seen with addition of 2 mcg/ml fentanyl to 0.125% Bupivacaine by Kayacan N. et al.[10] We found similar result in our study with dose of Fentanyl 2 mcg/ml and 4 mcg/ml. In group C the duration of analgesia was 188.20 ± 18.5 minutes compared to group B in which it was 132.2 ± 2.4 minutes and in group A in which it was 92.5 ± 10.2 minutes and this was statistically significant. The duration of analgesia was prolonged statistically significant also in patients receiving 2 mcg/ml as compared to group A not receiving Fentanyl.

The incidence of instrumental delivery was 17.1%, 13.2 % and 10% in group A, group B and group C, respectively. The incidence of LSCS was 4.444% in our study group of 45 patients. Mode of delivery was not statistically different in our study and previous studies conducted by Danilo et al, Capagno et al.[8,11]

Incidence of pruritus in group C was 6.66 % with no pruritus in group A & B. There was no nausea or vomiting, hypotension or bradycardia. Maternal or neonatal respiratory depression subsequent to epidural narcotics remains a serious consideration. In contrast to study conducted by Lam et al and Danilo et al[11,14], where there was no neonatal respiratory depression with the doses of Fentanyl we used in our study; we found neonatal respiratory depression in 2 patients with use of fentanyl 4 mcg/ml in initial and top up doses . After that the top up dose was changed to addition 2 mcg/ml fentanyl to 0.125% Bupivacaine. No such further complication was observed in patients receiving Fentanyl 2 mcg/ml. All our parturients were allowed to mobilize but with assistance.

Above results shows that Inj. Fentanyl in doses used in our study, as an adjuvant to Inj. Bupivacaine in labour epidural analgesia improves the efficacy, quality & duration of analgesia with no effect on instrumental or surgical mode of delivery & no effect on fetal outcome. It also shows that Inj. Fentanyl in a dose of 50 μg significantly improves the duration of effective analgesia but it can cause slight fetal respiratory distress if delivery occurs within an hour of the last dose given. So, if the duration of labour permits, i.e. it is more than 5 hours we can use Inj. Fentanyl 50 μg as an adjuvant for the first epidural dose followed by repeat

dose of 25 µg as and when required as it significantly decreases the total number of doses given with no side effects. Otherwise 25 µg Inj. Fentanyl is also very effective and safe.

Conclusion

Hereby, we conclude from our study that, combination of Fenatnyl 2 mcg/ml and Fentanyl 4 mcg/ml with Bupivacaine 0.125% is both and safe for providing labour analgesia via epidural route.

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