Butorphanol-bupivacaine versus Fentanyl-bupivacaine for Extradural Analgesia during Labour

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Abstract

Background: Epidural injection of a combination of local anaesthetic drugs and opioids, is known to provide good analgesia for the first and second stages of labour, with minimal risk to the mother and the foetus.

Method: 64 pregnant women were allocated to one of two groups in a double blind, randomised, prospective study design. The first group (n=32) received 15ml of 0.1% bupivacaine with 0.1 mgml⁻¹ butorphanol (1.5mg) and the second group (n=32) received 15ml of 0.1% bupivacaine with 2µgml⁻¹ of fentanyl.

Results: The times of onset and offset of analgesia were comparable. More patients of the butorphanol group were sedated but arousable. The patient satisfaction levels were good in both groups and APGAR scores were comparable.

Conclusion: Butorphanol and fentanyl when used in combination with 0.1% bupivacaine are effective, offer good patient satisfaction and are comparable in labour analgesia. Though more patients were sedated in the butorphanol group there was no maternal, foetal or neonatal adverse outcome and the drug appears to be a safe alternative to fentanyl in labour epidural analgesia.

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Key Words: Epidural analgesia; Bupivacaine; Butorphanol; Fentanyl

Introduction

The control of pain should form an integral part of the management of labour, yet pain relief in labour is a controversial subject. Pregnant women have a right to basic information about pain and its relief in labour. Labour analgesia, is rapidly catching up in the Armed Forces, and it would still be a while, before all women in labour are offered this service. Amongst the various modalities of pain relief in labour, epidurals have gained popularity. The aim of this study was to compare a relatively less utilised opioid, butorphanol with the time-tested fentanyl in epidural labour analgesia.

Method

The study was approved by our hospital ethics committee and informed consent was obtained from each patient. 64 women with American Society of Anaesthesiologists physical status I and II, between the ages of 18 and 40 years who opted for epidural labour analgesia were enrolled. Participants had singleton pregnancy of greater than 36 weeks of gestation with vertex presentation. All women were in active labour with cervical dilatation of 3 to 5 cm at the time of epidural catheter placement. The women had a pre dose Visual Analog Score (VAS) for labour pain of ≥ 30 mm measured on two occasions, when two consecutive uterine contractions occurred.

Patients with known hypersensitivity to local anaesthetics,

neurologic, neuromuscular or psychiatric disorders, blood dyscrasias, weight greater than 110 kg, height less than 144 cm, cephalopelvic disproportion, known foetal abnormalities or multiple pregnancy were excluded from the study.

Randomisation was done by the toss of a coin and patients were allocated to two groups. The first group (n=32) received 15ml of 0.1% bupivacaine with 0.1mgml⁻¹ butorphanol (1.5mg) and the second group (n=32) received 15ml of 0.1% bupivacaine with 2µgml⁻¹ of fentanyl. The patient and anaesthesiologist were blind to the drug combination, which was prepared by a trained assistant.

All patients were started on an intravenous infusion of ringer lactate. An 18 gauge epidural catheter was placed 3 to 4 cm inside the epidural space via an 18-gauge Tuohy epidural needle at the L2-3 or L3-4 level. If there was any evidence of entry into an epidural vein or cerebrospinal fluid the patient was excluded from the study. After negative aspiration, a bolus of 15 ml of either drug was given over 5 minutes. A test dose was omitted.

The efficacy of the drug was assessed using a 100 mm visual analogue scale, where 0 represented no labour pain and 100 represented the worst possible pain, at five minute intervals and during contractions for the first 20 min, at 20 minute intervals for the first hour, at 30 minute intervals for the next hour, and hourly thereafter, till the end of labour or when patient complained of pain.

The onset time was measured after 15 ml bolus of the

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epidural drug combination was administered. It was defined as the time to attain a VAS of less than 10mm. If a VAS of less than 10mm was not attained in 20 minutes, a rescue bolus of 5ml of the same drug was repeated. If there was no effect for the next 10 minutes, the patient was excluded from the study assuming a possible faulty catheter placement. The extent of the sensory block was measured using a blunted 23-gauge needle and ether swab 20 minutes after the initial epidural injection. If a rescue bolus was required, the extent of sensory block was measured after 10 minutes. The extent was measured for both right and left sides in a cephalad to caudal direction.

The offset time was measured from the onset time till the patient complained of pain of 30 mm or more on the VAS. A top up of 5 to 10ml of the same drug combination was then administered to decrease pain. The same bolus was also administered subsequently whenever the patient complained of pain of 30mm or more on the VAS.

Motor block was assessed using the modified Bromage scale of 4=no paralysis, full flexion of hips, knees and ankle, 3=inability to raise extended legs, able to move knees, 2=inability to flex knees, able to move ankles and 1=inability to move lower limb.

Motor block was assessed 20 minutes after the initial epidural dose in patients who had effective analgesia. In those who required rescue bolus, the motor block was assessed 10 minutes after the rescue bolus. Motor block was recorded on both left and right sides.

The ability of the patient to walk 20 minutes following the epidural injection was graded as: 0=no impairment, 1=unsteady gait and 2=unable to walk.

Patients were requested to grade the epidural labour analgesia provided as excellent, good, satisfactory or poor after delivery of the baby.

Hypotension was defined as a fall of the systolic arterial pressure by more than 30% from baseline measurement. Episodes of nausea and vomiting were recorded and treated with inj metoclopramide 10mg intravenously. Sedation was graded as no sedation and awake throughout labour, sedated but arousable and deeply sedated and not arousable.

Any other side effects like pruritis or giddiness were recorded. Foetal heart rate monitoring was performed throughout labour using SONICAID cardiocograph. The AGPAR scores of neonates born were recorded at 1 and 5 minutes.

Both groups were compared using the SPSS 10.0 for Windows.

Results

There were no significant differences among the groups in patients age, weight or gravidity (Table 1).

The butorphanol group had a mean onset time of 9.75 ± 5.55 minutes. The fentanyl group had a mean onset time of 12.56 ± 6.67 minutes. There was no significant difference between the times of onset in both groups. The duration of pain relief in both groups was comparable. The butorphanol

group had a mean offset time of 136.31 ± 58.07 minutes. The fentanyl group had a mean offset time of 143.63 ± 60.55 minutes. There was no significant difference between the times of offset in both the groups. There was no significant difference in the motor scores and walking ability of both groups. All patients had a motor score of 4. In all patients the sensory level of the block was between T6 and T8 dermatome level.

There was no hypotension in any patient. There was no significant difference in incidence of nausea and vomiting in the two groups. No pruritis was seen in either group. Patients of the butorphanol group were more sedated as compared to the fentanyl group (Table 2). 22 out of the 32 parturients of the butorphanol group were sedated. All patients were arousable. Two patients declined to walk 20 minutes after epidural administration in the butorphanol group, as they felt sleepy and giddy.

There were eight (12.5%) caesarian deliveries in all. Five patients in the butorphanol group and three patients of the fentanyl group had a caesarian section. Two caesarian sections in each group were for nonreassuring foetal condition. The other indication was uterine dystocia. One patient in the fentanyl group and three in the butorphanol group had dystocia (Table 3). One patient of the fentanyl group required an outlet forceps application. Analgesia was adequate for episiotomy in most parturients but a top up of 5ml of the same drug combination was used to supplement

Table 1
Maternal profile

	Butorphanol (n=32)	Fentanyl (n=32)	
Age (years)	23.97 ± 4.21	24.37 ± 3.25	NS
Parity I	22/32	23/32	NS
Weight (kg)	63.44 ± 9.14	64.53 ± 9.42	NS
Mean pain score (prior to epidural)	75.78 ± 21.29	75.16 ± 19.28	NS
ASA I physical status	28/32	29/32	NS

Value are Mean $\pm$ SD in rows; n=number of patients; NS=not significant; ASA=American Society of Anaesthesiologists

Table 2
Sedation scores of patients

	Butorphanol (n=32)	Fentanyl (n=32)
Awake throughout labour	10	27
Sedated but arousable	22	5
Deep sedation, not arousable	Nil	Nil
Total	32	32

Chi square=18.515; n=number of patients; Significant at $p < 0.001$

Table 3
Indication for caesarian section in patients

	Butorphanol (n=32)	Fentanyl (n=32)
Foetal distress	2	2
Cervical dystotia	3	1
Total	5	3

analgesia in 10 patients.

Severe foetal heart rate deceleration followed artificial rupture of membranes in two patients of each group. These patients were rushed for emergency caesarian section. The APGAR score of both groups comparable. All neonates had APGAR score of 7 or better at one minute and 9 or better at five minutes.

26 patients of the butorphanol group and 29 patients of the fentanyl group had either good or excellent analgesia (Fig 1). Five patients in the butorphanol group and three patients in the fentanyl group had satisfactory analgesia. Only one patient of the butorphanol group had poor analgesia. The patient satisfaction scores were comparable between the groups.

Discussion

Epidural analgesia is the only effective analgesia in labour [1]. The pain of labour represents severe physiological stress, which can result in maternal acidosis and hormone imbalance including catecholamine release. Stimulation of α receptors causes vasoconstriction, which may affect the maternal blood supply to the placenta while β stimulation may prolong labour. These adverse effects for the mother and the baby can be corrected by epidural analgesia [2].

The combination of epidurally administered opioids and local anaesthetics produce a more rapid onset and longer duration of analgesia [3]. Time-tested μ receptor agonists like fentanyl have been used in epidural labour analgesia alone and in combination with local anaesthetics [4-7].

The test dose was avoided in our study, as it has been argued that if injected slowly and if the dose of the bolus injection does not exceed 15mg of bupivacaine, every dose is no more than a test dose [7].

Butorphanol is a lipid soluble narcotic with weak μ receptor agonist and antagonist activity and strong κ receptor agonism. κ receptors appear to be involved in visceral pain modulation and therefore, butorphanol has been postulated to be useful in reducing labour pain which has a strong visceral component. Butorphanol administered epidurally provides excellent intra and postoperative analgesia for four to nine hours after

caesarian delivery [8,9]. Butorphanol has been successfully used in combination with bupivacaine in labour analgesia and has been found to produce effective labour analgesia. Hunt's study of a combination of 0.25% bupivacaine with 0,1,2, or 3mg of butorphanol in 40 patients with 10 patients in each group recommended 2 mg of butorphanol as the optimal dose for labour analgesia [3].

Hunt's study found the time of onset in the 1 mg butorphanol group to be 16.9 ± 3.6 minutes in the 2mg [3]. Our study showed that the time of onset in the 1.5 mg butorphanol group was 9.75 ± 5.55 minutes, but 15 ml of 0.1% bupivacaine was used in our study as compared to 10 ml of 0.25% bupivacaine in the Hunt study. The analgesic effect of the loading dose usually lasts between 60 and 90 minutes [10]. The fentanyl group had a mean offset time of 143.63 ± 60.55 minutes which was comparable to 137 ± 18.40 minutes of the 2mg group in the Hunt study.

Motor block is a dose dependent side effect of the epidural use of local anaesthetic [10]. We used a low concentration and large volume of local anaesthetic solution and found that none of the patients in either group had any motor block. All patients had a Bromage score of 4. All but two of the butorphanol group, were able to walk steadily without support 20 minutes following the loading dose, had adequate motor scores but were sleepy and felt giddy. Dysphoria was seen in two patients who had received 2 mg butorphanol in the Hunt study.

In our study, 22 of the 32 patients were sedated in the butorphanol group but all were arousable. 27 patients of the fentanyl group were awake through out labour. No other side effects were seen in either group. Foetal effects like low amplitude sinusoidal pattern on foetal heart tracing have been described with 3 mg butorphanol [3]. No such patterns were seen in our study in either group. Severe foetal heart rate decelerations followed artificial rupture of membranes in two patients of each group. Caesarian sections were performed on these patients with good neonatal outcome. In these four patients, the foetal heart tracings had shown no abnormality after administering the loading dose, during active labour and till the effect of the loading dose wore off. All neonates in our study had an APGAR score of 7 or better at one minute and 9 or better at 5 minutes.

Only eight of the 64 patients had to undergo caesarian section. The indications in four of them were for uterine dystocia and the other four for non-reassuring foetal condition. A caesarian rate of 12.5% in our study is comparable with that by Norris and Fogel of 13.4% (149/1112 patients) [11] with similar indications in the two studies. Newton and colleagues compared myometrial

Fig. 1 : Patient satisfaction scores

activity in those receiving bupivacaine/fentanyl epidural infusions with non-randomised controls receiving pethidine and reported no difference, although need for oxytocin was greater and the rate of cervical dilatation slower in the epidural group [12].

The satisfaction levels of parous women were higher compared to the nulliparous women. None of the parous patients had been given labour analgesia in their previous delivery, which could explain their higher satisfaction levels.

Conflicts of Interest

None identified

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