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Original Research Article

A Randomized Comparative Clinical Study to Assess the Effect of Intrathecal Labor Analgesia on the Progress of Labor

Anil Kumar[1], Chandra Bhushan Kumar[2], Amit Kumar[3]

[1]Senior Resident, Department of Anesthesiology, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India

[2]Senior Resident, Department of Anesthesiology, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India

[3]Senior Resident, Department of Anesthesiology, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India

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Corresponding Author: Dr. Amit Kumar
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Abstract

Aim: The aim of the present study was to assess the effect of intrathecal labor analgesia on the progress of labor was compared between fentanyl 25µg alone and fentanyl 20µg plus bupivacaine 2.5mg.

Methods: The present study was single-center, interventional, randomized study, conducted in labour room & operation theater of Obstetrics & Gynaecology, conducted under Department of Anaesthesiology at Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India for the period of 12 months.

Results: Baseline maternal characteristics such as age, weight, height & gestational age were comparable in both groups (p>0.05). Cervical dilation at time of entry in study (cm) on admission, Onset time of Labor Analgesia (min), Duration of Labor Analgesia (min), Oxytocin units used till completed second stage, Duration of active 1st stage / 2nd stage (min), Total Duration of labor (min), Rate of cervical dilatation (cm/h), APGAR score (At 1 & 5 min) were comparable in both groups & difference was not significant statistically (p>0.05). Other parameters such as maternal heart rate, mean arterial pressure, fetal heart rate were comparable in both groups. VAS scores at (60 min, 120 min, 180 min, 240 min, 300 min were less in group FB as compared to group F, but difference was not statistically significant. Pruritis was noted in 4 patients in group FB & 2 patients from group F, was transient in nature & managed conservatively.

Conclusion: Progress of labor, in pregnant women with intrathecal labor analgesia using fentanyl 25µg alone was comparable with fentanyl 20µg plus bupivacaine 2.5mg. Also, VAS scores at 60 min, 120 min, 180 min, 240 min, 300 min were less in fentanyl plus bupivacaine as compared to fentanyl group, but difference was not statistically significant.

Keywords: intrathecal labor analgesia, fentanyl, bupivacaine, progress of labor

Introduction

The amount of pain that has been experienced by a woman during their childbirth is marked as severe [1] and frequent and these parturient particularly in those developing countries residents have scanty or almost no options for their relief when experiencing labour pain during childbirth. There have been quite a lot of parenteral opioid and sedatives which are the most frequently prescribed agents for women during their labour in many poor resource facilities. [2] And this method of relieving pain has been shown to have little or almost nil effective on their labour pain. [3] And this analgesic effect not only provides patient's comfort but also minimizes the release of stress hormones whose actions can draw from the parturient reserves as well as depriving the oxygen of fetus and nutrients. [1]

The provision of providing effective labour analgesia is now thought to reduce the inhibitory effects of endogenous maternal catecholamine on uterine contractility, decreasing maternal acidosis and enhances intrapartum maternal well-being. There has been certain neuraxial analgesia techniques are considered to be the most effective protocols to provide pain relief during labour. The epidural analgesia is the most common and effective technique for providing pain relief during their labour. [4] Anozie et al had assessed the effects of epidural analgesia in a study sample among the Nigerian obstetricians and mentioned high costs and

lack of sufficient skills as the potent reasons for not using the epidural technique. [5] However, some clinicians might prefer spinal analgesia to epidural analgesia. This method has used some little doses of local anesthetic, mainly because it can spread directly in the spinal fluid. On the other hand, spinal analgesia needs to use a thinner needle to give a spinal block, which means making a tiny hole in the dura. Additionally, a spinal block technique can take relatively a shorter time than an epidural block. [6]

Some studies that have mentioned about the spinal analgesia not only be applied more easily but also is relatively faster, less expensive and more effective than epidural analgesia. [7] The administration of opioid drugs in neuraxial blocks, which by its classification do not affect the sympathetic activity, along with local anesthetics, is a very common technique in order to avoid negative consequences like hypotension that has been encountered in these techniques. [8] Therefore, the local anesthetic dose that can safely provide effective, long lasting labour analgesia without motor block must be effectively documented. The current study has been aimed to compare the spinal analgesia with combined local anesthetics and narcotics versus intermittent epidural analgesia to manage labour pain effectively. [8] Labor pain is one of the most painful situations a human can experience. Painful uterine contractions cause maternal hyperventilation and increased catecholamine concentration resulting in maternal, fetal hypoxemia, and adverse effects on the course of labor. Effective labor analgesia leads to better maternal and fetal outcome. Neuraxial analgesia is considered gold standard for labor pain management. [9]

It provides complete analgesia for both first and second stages of labor. Bupivacaine is being used for labor analgesia because of its least placental transfer due to high protein binding. To minimize the motor blockade caused by bupivacaine, various adjuvants are added. [10] Traditionally, fentanyl has been extensively used for this purpose. [11] Dexmedetomidine is a highly selective α [10] adrenergic receptor agonist having diverse actions such as anxiolysis, sympatholysis, analgesia, and sedation. It does not cross placenta significantly. When added to bupivacaine, it increases the duration of labor analgesia. [12] Although United States Food and Drug Administration (FDA) and Drug Controller General of India (DGCI) have not approved “off label” use of intrathecal or epidural dexmedetomidine in parturient, its use as an adjuvant to neuraxial local anesthetics is widespread. Several studies have used dexmedetomidine intravenously and epidurally in labor without any adverse effects on mother or fetus. [13-14]

The aim of the present study was to assess the effect of intrathecal labor analgesia on the progress of labor was compared between fentanyl 25µg alone and fentanyl 20µg plus bupivacaine 2.5mg.

Materials and Methods

The present study was single-center, interventional, randomized study, conducted in labour room & operation theater of Obstetrics & Gynaecology, conducted under Department of Anaesthesiology at Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India for the period of 12 months.

Inclusion criteria

• Pregnant females 20-30 years, Booked antenatal cases, primigravida, full-term, singleton pregnancies, vertex presentation , in active phase of labor with a cervical dilatation of ≥ 4 cm with normal fetal heart rate (FHR) tracings, ASA status grade I/II, Willing to participate

Exclusion Criteria

• Patients with medical disorders, Pre-existing systemic or neurological disease

• Patients with altered coagulation profile,

• Patients required caesarean section,

• Patients with any obstetrical complications,

• Severe deformity of the spine, local infection on back,

• Patient refusal

Study was explained in local language & written consent was taken. Baseline hemodynamic parameters including maternal pulse rate, non-invasive blood pressure, oxygen saturation, and respiratory rate were recorded. The stage of labor, cervical dilation, and fetal heart rate were also noted. Total 60 labouring women were enrolled for present study.

80 parturients were enrolled in present study, randomly allocated by computer generated serial numbers, in 2 groups of 40 each.

1) Group F - received an intrathecal injection of fentanyl 25 µg

2) Group BF - received intrathecal injection of fentanyl 20 µg plus 0.5% hyperbaric bupivacaine 2.5 mg (0.5 ml)

Under all aseptic precautions & with prior preparation, block was given in a left lateral position, in L3-L4 interspace, with 25 G spinal needle & drugs were given as per group allocation.

The frequency and intensity of uterine contractions, dilation and effacement of cervix, descent of presenting part, fetal heart rate, and requirement of oxytocin were assessed using partograph by attending obstetrician. APGAR scores were recorded by paediatrician. The two groups were

evaluated with regards to the progress of labor, maternal hemodynamic variations and neonatal outcome.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables was tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

Table 1: Maternal characteristics

Characteristics	Group F (mean ± SD)	Group FB (mean ± SD)
Mean age (years)	25.32 ± 4.04	22.88 ± 4.42
Mean weight (kg)	64.26 ± 8.12	66.60 ± 9.21
Mean height (cm)	158.72 ± 6.34	159.3 ± 6.24
Gestational age (weeks)	39.4 ± 0.4	39.5 ± 1.0

Baseline maternal characteristics such as age, weight, height & gestational age were comparable in both groups (p>0.05).

Table 2: General characteristics

Parameter	Group F (mean ± SD)	Group FB (mean ±SD)	P Value
Cervical dilation (cm) on admission	4.5 ± 1.2	4.3 ± 1.1	0.62
Onset time of Labor Analgesia (min)	4.82 ± 1.84	3.57 ± 1.12	0.31
Duration of Labor Analgesia (min)	222.4 ± 42.26	250.4 ± 37.43	0.11
Oxytocin units used till completed second stage	4.74 ± 2.12	5.04 ± 1.92	0.32
Duration of active 1st stage (min)	172.58 ± 32.24	168.72 ± 26.94	0.57
Duration of 2nd stage (min)	42.8 ± 11.49	44.66 ± 10.34	0.62
Total Duration of labor (min)	186.34 ± 24.86	179.53 ± 26.64	0.19
Rate of cervical dilatation (cm/h)	1.60 ± 0.52	1.52 ± 0.34	0.53
APGAR score			
At 1 min	8.70 ±1.26	8.50 ± 1.32	0.55
At 5 min	8.73 ± 0.90	8.42 ± 1.04	0.38

Cervical dilation at time of entry in study (cm) on admission, Onset time of Labor Analgesia (min), Duration of Labor Analgesia (min), Oxytocin units used till completed second stage, Duration of active 1st stage / 2nd stage (min), Total Duration of labor (min), Rate of cervical dilatation (cm/h), APGAR score (At 1 & 5 min) were comparable in both groups & difference was not significant statistically (p>0.05). Other parameters such as maternal heart rate, mean arterial pressure, fetal heart rate were comparable in both groups.

Table 3: VAS scores

VAS score	Group F (mean ± SD)	Group FB (mean ± SD)	P value
Baseline VAS	5.88 ± 1.3	6.10 ± 1.1	0.51
60 min	2.38 ± 0.52	2.56 ± 0.54	0.34
120 min	2.92 ± 0.58	2.66 ± 0.44	0.44
180 min	2.15 ± 0.62	2.12 ± 0.26	0.62
240 min	2.54 ± 0.78	2.34 ± 0.50	0.35
300 min	2.76 ± 0.64	2.36 ± 0.40	0.73

VAS scores at (60 min, 120 min, 180 min, 240 min, 300 min were less in group FB as compared to group F, but difference was not statistically significant.

Table 4: Side-effects

Side-effects	group F (n=40)	group FB (n=40)
Pruritis	2	4
Nausea and vomiting	2	2

Pruritis was noted in 4 patients in group FB & 2 patients from group F, was transient in nature & managed conservatively.

Discussion

The level of pain experienced and the effectiveness of pain relief may influence a woman's satisfaction with labour and the birth and may have immediate

and long-term emotional and psychological effects. Labour epidurals provide superior analgesia as compared to other forms of pain control during labour. [15] An ideal labour analgesic technique should provide adequate and satisfactory analgesia without any motor blockade or adverse maternal and foetal effects. Major improvements in safe delivery and efficacy of labor epidural analgesia have ensured satisfactory birth and delivery experience in parturients; however, the variable percentage of failed or inadequate analgesia ranging from 0.9% to 24% still remains a major barrier to attaining a perfect score in the maternal satisfaction scale. [16] Given the advantage of relatively shorter duration of action and lesser side effects, fentanyl is the most commonly used opioid for analgesia and decreasing awareness intraoperatively. [17] Fentanyl causes inhibition of transmitter release along with a direct postsynaptic effect, causing hyperpolarization and reduction in neuronal activity. Fentanyl added to levobupivacaine during subarachnoid block offers faster onset of sensory block, prolonged duration of sensory block, and shorter duration of motor blockade. [18] It has been well documented that a combination of opioids and local anesthetics administered intrathecally has a synergistic analgesic effect. [19]

Baseline maternal characteristics such as age, weight, height & gestational age were comparable in both groups ($p>0.05$). Cervical dilation at time of entry in study (cm) on admission, Onset time of Labor Analgesia (min), Duration of Labor Analgesia (min), Oxytocin units used till completed second stage, Duration of active 1st stage / 2nd stage (min), Total Duration of labor (min), Rate of cervical dilatation (cm/h), APGAR score (At 1 & 5 min) were comparable in both groups & difference was not significant statistically ($p>0.05$). Other parameters such as maternal heart rate, mean arterial pressure, fetal heart rate were comparable in both groups. VAS scores at (60 min, 120 min, 180 min, 240 min, 300 min were less in group FB as compared to group F, but difference was not statistically significant. Pruritis was noted in 4 patients in group FB & 2 patients from group F, was transient in nature & managed conservatively. Tomar GS et al [20] found that 2 µg/ml extradural fentanyl is better than 1 µg/ml when combined with bupivacaine in the intermittent bolus technique, as it leads to faster onset, longer duration of analgesia, higher maternal satisfaction, and lesser drug requirement of the local anesthetic with a comparable side effect profile. Paddalwar S et al [21] found that 0.125% Ropivacaine with Fentanyl 2 µg/ml produced excellent labor analgesia, which was clinically indistinguishable from a similar concentration of Bupivacaine and Fentanyl, with the advantage of less incidence of motor block and slightly longer duration of analgesia, apart from its lesser propensity to cause cardiotoxicity, when used as intermittent doses. Gowrisree K [22] concluded that single shot intrathecal analgesia using fentanyl 25 µg or fentanyl 20 µg +bupivacaine 2.5 mg, is useful when given in the active phase of the first stage of labor, had rapid onset with satisfactory pain relief in both the groups with VAS scores <4 and good maternal and fetal hemodynamics. Similar findings were noted in present study. Minimal motor block was noted in fentanyl 20 µg plus 0.5% hyperbaric bupivacaine 2.5 mg (0.5 ml) group.

Over the ages many techniques to relieve labour pain have been tried like physical, psychological and pharmacological means but none has been so efficacious and successful than the present day's technique of Combined Spinal Epidural (CSE) Analgesia. [23] Boluses of higher concentrations, as used in the earlier years, have been associated with a dense motor block resulting in reduced mobility, decreased pelvic tone and loss of the bearing-down sensations usually experienced in the second stage of labour. Tsen et al [24] demonstrated a faster rate of cervical dilation in women randomized to receive combined spinal epidural analgesia compared with those who received epidural analgesia (2.3 vs 1.3 cm/h, respectively; $P = 0.015$). The rapid onset of analgesia decreases the maternal catecholamine levels (mainly epinephrine that has been found to have tocolytic action), leading to increase uterine activity. This leads to a decrease in the duration of first stage of labor. Combined-spinal-epidural (CSE) involves a single injection of local anaesthetic or opiate or both into the cerebral spinal fluid, as well as insertion of the epidural catheter. CSE combines the advantages of spinal analgesia (faster onset of pain relief, from the time of injection and more reliable analgesia) with the advantages of epidural analgesia, such as continuing pain relief, potentially maintained throughout the entire duration of labour. [25]

Conclusion

Progress of labor, in pregnant women with intrathecal labor analgesia using fentanyl 25µg alone was comparable with fentanyl 20µg plus bupivacaine 2.5mg. Also, VAS scores at 60 min, 120 min, 180 min, 240 min, 300 min were less in fentanyl plus bupivacaine as compared to fentanyl group, but difference was not statistically significant.

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