Original Research Article

Indian Journal of Anesthesia and Analgesia
2019; 6(4) (Part - I): 1107-1111
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.6419.7

Efficacy of intrathecal Buprenorphine a Sole Method of Analgesia in Labour : A Randomized Clinical Trial

Archana Amol Gautam[1], Reji S Varghese[2]

[1]Assistant Professor, Department of Anesthesia, Krishna Institute of Medical Sciences, Karad, Maharatra 415539, India. [2]Assistant Professor, Department of Anesthesia, Pushpagiri Medical College Hospital, Thiruvalla, Kerala 689101, India.

Abstract

Background: Parturients are often not prepared for labour analgesia in advance. They demand it when they are already in labour with unbearable pain; many a times an hour or two before the delivery. This study was done to evaluate the efficacy of medicine in analgesia during labour. *Objective:* To assess the efficacy of intrathecal Buprenorphine as a sole method for analgesia in labour. *Methods:* Double blind, randomized controlled trial, 30 parturients in active labour were studied. Labour ward, Department of Obstetrics and Gynaecology, Dr. Balabhai Nanavati Hospital, Vile Parle, Mumbai, during 1st January 2006 to 31st December 2006. Epi-info 7 was used for analysis and student t-test was used. *Results:* There was no significant difference in age, weight, height and gestational age between two groups. ($p > 0.05$). There was significant change in duration of analgesia in both the groups ($p < 0.001$). Mean Pulse rate At 0 minutes and 2 minutes p value was < 0.05 – significant when compared in both groups. *Conclusion:* Addition of buprenorphine to intrathecal fentanyl and bupivacaine provides early onset and prolonged duration of analgesia during labour.

Keywords: Randomized control trial; Blinding; Labour analgesia; Intrathecal Buprenorphine.

How to cite this article:

Archana Amol Gautam, Reji S Varghese. Efficacy of intrathecal Buprenorphine a Sole Method of Analgesia in Labour: A Randomized Clinical Trial. Indian J Anesth Analg. 2019;6(4):1107-1111.

Introduction

In Indian setup, Parturients are often not prepared for labour analgesia in advance. They demand it when they are already in labour with unbearable pain; many a times an hour or two before the delivery. In such conditions, other pharmacological interventions such as intravenous narcotics or inhaled nitrous are much less effective, have short duration and many have unwanted maternal or fetal sedation as potential side effects [1]. Many studies have been done using intrathecal morphine as a sole method of analgesia in labour [2,3,4] specially in advanced labour. However, technique of intrathecal narcotics is limited in duration [5]. Fentanyl (25 mcg) lasts 1-3 hours and morphine (0.25 mg) may last 4-7 hours. Intrathecal morphine alone has a slow onset

Corresponding Author: Reji S Varghese, Assistant Professor, Department of Anesthesia, Pushpagiri Medical College Hospital, Thiruvalla, Kerala 689101, India.

E-mail: rejiabraham@pushpagiri.in

Received on 27.03.2019, **Accepted on** 04.05.2019

(40–60 min). So, it is best used in combination with fentanyl, which has a rapid onset (3-5 min). The literature supports use of intrathecal narcotics as a safe and effective alternative to epidural analgesia. Intrathecal narcotics provide a selective blockade of pain transmission without significant sympathetic or motor blockade. Literature supports the use of intrathecal buprenorphine for surgical anaesthesia as well as post-operative analgesia. Buprenorphine is 33 times more potent than morphine [6]. The onset of Buprenorphine effect occurs in about 30 minutes and duration of action is at least 8 hours. The affinity of Buprenorphine for mu receptors is 50 times greater than that of morphine and subsequent slow dissociation from these receptors' accounts for its prolonged duration of action and resistance to antagonism with naloxone. Since there is paucity of literature comparing intrathecal Buprenorphine and its quality of analgesia to other narcotics used by intrathecal route for labour analgesia. On this basis, we designed a double-blind study to evaluate efficacy and duration of intrathecal Buprenorphine for obstetric pain relief.

Material & Methods

Study Area- Labour ward, Department of Obstetrics and Gynaecology, Dr. Balabhai Nanavati Hospital, Vile Parle, Mumbai.

Study type- double blind, randomized control study

Study population- 30 parturients of the age group between 20 and 32 years who presented for full term normal delivery in the labour room

Study duration- 1st January 2006 to 31st December 2006.

Sampling technique- Purposive Sampling Technique.

Inclusion criteria- Parturients in the age group of 20 and 32 years in active labour, cervix 3 to 4 cm dilated. ASA I and II. Gravida I and II. Cephalic, Singleton pregnancy – 36 to 42 weeks.

Exclusion criteria- Age below 20 years and above 35 years. Foetal distress, fetal anomalies. Cephalopelvic dispraportion, Preecelamcia, Diabetes Mellitus, Preterm labour, Placenta previa, Heart Disease, Coagulation disorders, Socliosis, Morbid Obesity, Neurological disorders, Severe anaemia. Gross spinal deformity. Local Infection. Patients with known drug allergies were excluded.

Methodology: 30 Parturients of age group 20 to 32 years undergoing normal vaginal delivery, belonging to ASA grade I and II were considered for this study. The Parturients were randomly divided in to two groups of 15 each.

Group A: 15 Parturients of this group received 1.25 mg Bupivacaine + 12.5 mcg fentanyl.

Group B: 15 Parturients of this group received 1.25 mg Bupivacaine + 12.5 mcg fentanyl + 30 mcg Buprenorphine.

Study solution was prepared as follows.

Group A : 0.5 ml of 0.5% Bupivacaine +0.5 ml Fentanyl (diluted to 2 ml with NS).

Out of 2 ml only 1 ml solution was injected so that Bupivacaine becomes 1.25 mg (0.125%) and fentanyl 12.5 mcg.

Group B : 0.5 ml of 0.5% Bupivacaine +0.5 ml Fentanyl + 0.2 ml Buprenorphine (diluted to 2 ml with NS).

Out of 2 ml only 1 ml solution was injected so that Bupivacaine becomes 1.25 mg (0.125%), Fentanyl 12.5 mcg and Buprenorphine 30 mcg. Final concentration of Bupivacaine was 0.125% Drugs aspirated with the help of insulin syringe. All agents were introduced intrathecally and total volume of agents administered was 1 ml. Demographic variables like age, weight, height and gestation age were recorded from the case sheet.

Duration of analgesia or pain relief was taken as time after spinal injection to time of rescue analgesic administered or VAS was more than 40. Study ended at 240 minutes but duration of analgesia for episiotomy pain was considered even after delivery and data collected from sister's record.

Study tool- In order to compare the data and to draw conclusions; the mean and standard deviation of heart rate, Bromage scale and duration of analgesia were calculated.

Consent Type- Informed consent

Statistical Analysis- Data will be consolidated and entered a Microsoft Excel spreadsheet and then transferred to Epi info version (7.1.3.0. centre for disease control and prevention, Atlanta, Georgia, USA, 2013) software for analysis. student t- test was used.

Results

Table 1: Comparison of baseline characteristics of the two study groups.

Characteristics	Group A	Group B	p Value
Age (Years) (Mean + SD)	27. 73 + 6.8	27.33 + 6.3	p = 0.31
Weight (kgs) (Mean + SD)	67.0 + 12	61.8 + 10.8	p = 0.15
Height (cms) (Mean + SD)	153 + 3.3	156 + 5.1	p = 0.09
Gestational Age (Weeks) (Mean + SD)	39.6 + 1.0	39.2 + 1.3	p = 0.23

As per table 1 there was no significant difference in age, weight, height and gestational age between two groups ($p > 0.05$). Though weight, age and Gestational age was higher among Group A compared to B.

Table 2: Mean time of duration of Analgesia in Group A and Group B.

	Group A	Group B	p Value
On set of Analgesia in Minutes.	5.793 + 1.66	5.16 + 1.34	0.756
Duration of Analgesia (Minutes)	148.06 + 15.56	328.06 + 28.56	0.000

As per table 2 there was significant change in duration of analgesia in both the groups ($p<0.001$. It was 148.06 (± 15.56) minutes in group A, were as 328.06 (+ 28.56) minutes in group B. However, quality of analgesia was same in both the groups.

Table 3: Mean pulse rate between Group A and Group B

Time after Intrathecal Injection (Minutes)	Mean Pulse Rate + SD		p Value
	Group A	Group B	
T0	99.60 + 12.12	86.00 + 7.47	0.001
T2	96.66 + 13.17	87.40 + 8.07	0.028
T4	94.53 + 12.08	87.07 + 9.91	0.075
T6	89.47 + 10.37	85.80 + 9.81	0.359
T8	85.73 + 12.26	81.40 + 10.91	0.315
T10	84.00 + 14.36	81.33 + 11.51	0.663
T20	84.93 + 14.56	82.33 + 13.40	0.615
T30	86.40 + 12.88	81.73 + 8.39	0.249
T40	87.00 + 12.67	81.13 + 5.77	0.114
T60	89.20 + 10.08	80.80 + 5.95	0.010
T90	92.93 + 10.69	80.33 + 8.14	0.001
T120	93.33 + 11.51	79.53 + 8.11	0.001
T150	94.53 + 11.48	79.57 + 8.47	0.000
T180	94.93 + 9.79	78.80 + 9.58	0.000
T210	96.27+ 8.58	80.53 + 10.155	0.000
T240	103.7 + 9.16	81.80 + 9.79	0.000

Mean pulse rate was compared between Group A and Group B at different time interval after intrathecal injection. At 0 minutes and 2 minutes P value was <0.05 – significant. At 4,6,8,10,20,30 and 40 minutes after intrathecal injection, p value > 0.05 – not significant. At 60,90,120,150,180,210 and 240 minutes after intrathecal injection, p value <0.05 – significant.

As per figure 1 Mean APGAR score at 1 min and 5 minutes was higher in Group A and was found to be significant. ($p<0.05$).

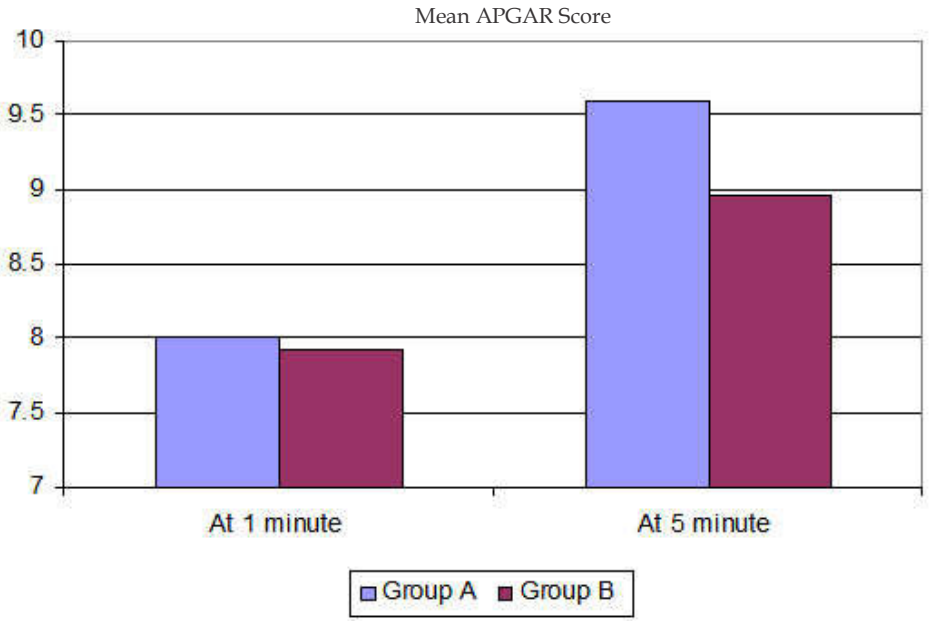

Fig. 1: Mean APGAR score

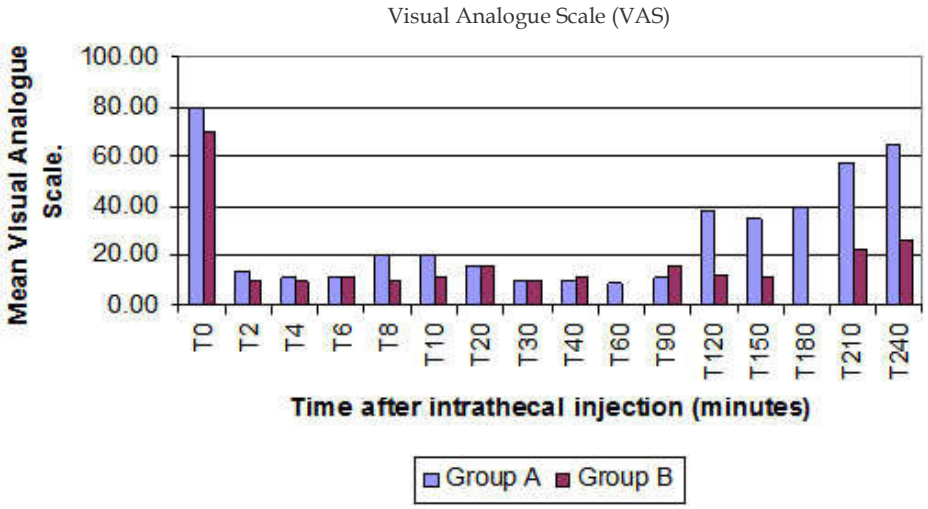

Fig. 2: Mean VAS among the groups

In figure 2 mean visual analogue scale after intrathecal injection was significantly higher in group A as compared to group B in different duration. At T_0, VAS was between 70 to 80. But within 2 minutes of intrathecal injection, VAS reduced significantly to around 20 in both the groups. VAS was between 16 to 20 in both the groups till 90 minutes of intrathecal injection.

Discussion

Intrathecal administration of opioids for labour analgesia is becoming increasingly popular because of potential savings in cost and manpower [4]. Intrathecal morphine provides prolonged analgesia, but is associated with increased risk of nausea, vomiting, pruritus and respiratory depression [7]. Short acting narcotics like fentanyl and sufentanyl have been shown to provide adequate pain relief, but of short duration [8]. Buprenorphine, a mu receptor agonist with low intrinsic activity can also be administered safely in the subarachnoid space [9]. It has a high molecular weight and lipophilicity which may prevent its rostral spread. When used intrathecally in combination with bupivacaine, it has improved the quality and duration of analgesia compared to bupivacaine alone [10]. Very few studies are done using intrathecal buprenorphine for labour analgesia. But more studies have been done using intrathecal buprenorphine for post-operative analgesia. In the present study there was no significant difference in demographic and anthropometric variables like age, height, weight and gestational age. Among the vital parameters only pulse rate was recorded in both the groups at the time intervals. As parturients were in pain, basal pulse rate was high in both the groups, but after giving intrathecal injection, within 5 to 6 minutes Pulse rate came down by 8-10 beats/ min. This was probably due to pain relief. After 90 minutes pulse rate started increasing in group A Whereas it was stable in Group B. There was no significant difference in number of partutients experiencing fall in pulse rate in both Group A and Group B. This study is consistent with the study done by Fauzia A Khan *et al.* [11]. Where it was found that there was no incidence of fall in heart rate in either groups. There was significant change in duration of analgesia in both the groups ($p < 0.001$). It was 148.06 (±15.56) minutes in group A, were as 328.06 (+28.56) minutes in group B. However, quality of analgesia was same in both the groups [4]. Parturients in Group A required rescue analgesics versus only one in Group B. This was consistant with the study done by Fauzia A Khan *et al.* [11], were the duration of sensory block was significantly longer in buprenorphine – bupivacaine group. The mean time from spinal injection to the first requirement of analgesia was 534 + 35 min in Fentanyl group and 834 ± 59 min ($p < 0.01$) in buprenorphine group. 6 patients in buprenophine group did not require any analgesic for 24 hrs (study period). There was no difference in neonatal APGAR score among the groups. However according to studies done by Zap J [12], significant differences were seen. At T_0, VAS was between 70 to 80. But with in 2 minutes of intrathecal injection, VAS reduced significantly to around 20 in both the groups. VAS was between 16 to 20 in both the groups till 90 minutes of intrathecal injection. But after that the number in group A started increasing and that of in group B was which is like the study

conducted by Lestie [1].

Conclusion

The present study was performed to evaluate the efficacy of intrathecal buprenorphine for pain relief during labour. Addition of buprenorphine to intrathecal fentanyl and bupivacaine provides early onset and prolonged duration of analgesia during labour.

Conflict of Interest- None declared

Source of Funding- None

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