Section: Miscellaneous

Original Research Article

A COMPARATIVE STUDY ON EFFICACY OF 0.0625% BUPIVACAINE AND 0.0002% FENTANYL COMBINATION WITH 0.125%BUPIVACAINE ALONE FOR CONTINOUS LABOUR ANALGESIA

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ABSTRACT

Background: Labour pain is one of the most intensifying pain a women experience in her lifetime surpassing all expectations. A variety of labour analgesia options are available but neuraxial techniques such as epidural analgesia have emerged as the most acceptable world wide in managing labour pain effectively while minimizing the adverse effects in the parturients and the fetus. The aim & objective are 1. To estimate efficacy of 0.0625% bupivacaine &0.0002% fentanyl combination on Labour outcome 2. To study the effect of 0.125% bupivacaine alone on Labour outcome 3. To compare the effectiveness of 0.0625% bupivacaine & 0.0002% fentanyl combination with 0.125% bupivacaine alone on Labour.

Materials and Methods: This randomized study was undertaken in department of Anaesthesiology in collaboration with Obstetrics & Gynaecology department and the Dept. of paediatrics in Hi-Tec medical college over a period of 2 years. Sixty ASA category I parturients at term with vertex presentation of a single live foetus in the 18-35 years age group were divided into two groups randomly, one receiving 0.0625% bupivacaine with 0.0002% fentanyl (Group A) and the other 0.125% bupivacaine alone(Group B). A 12ml bolus dose of the test solution at the rate of 2-3 ml/min followed by a continuous infusion of test solution at the rate of 10 ml/hr (range 8-15 ml/hr) till complete cervical dilatation. Maternal heart rate, blood pressure, foetal heart rate, visual analogue scale (VAS) score, intensity of analgesia, duration of labour, mode of delivery, maternal outcome were assessed.

Results: No significant difference (P>0.05) were observed in haemodynamic profile, foetal heart rate, duration of labour, intensity of analgesia, mode of delivery, maternal satisfaction or neonatal outcome in both the groups. Group A required a higher infusion rate for maintenance, shorter time of onset of analgesia, lower quantity of bupivacaine, lesser incidence of motor paresis with a higher ambulation rate of 96% as compared to group B.

Conclusion: Low dose bupivacaine with the short acting fentanyl can make labour and delivery a pain free process without compromising maternal and neonatal outcome while improving maternal satisfaction by enabling ambulation and reducing motor paresis thus providing a wholesome, satisfying experience to the obstetrician, anaesthesiologist and paediatrician.

Keywords: Labour analgesia, Bupivacaine, Parturients, Epidural anaesthesia.

INTRODUCTION

Pain has the most important biological function of indicating the initiation of labour. Labour and vaginal delivery leads to tissue damage which result in pain as as well as local and neurohumoral responses. The parturient incurs marked increase in respiration, circulation, and metabolism, and other body functions are altered, which can have a deleterious impact on the fetus and newborn. Pain and reflex responses have a predominant role in these alterations of maternal function as blockade of the nociceptive pathways by regional analgesia with a local anaesthetic greatly diminishes or eliminates them. McDonald, J.S.2001.[1]

Haggard, H.W.[2] wrote, "The position of women in any civilization is an index of the advancement of that civilization; the position of the woman is gauged by the care given to her at the birth of her child." Labour pain is associated with most intense pain often worse than postherpetic neuralgia. Management of labour pain can be a satisfying experience for anaesthesiologists, obstetricians, and paediatricians.

Currently, Bupivacaine is most common local anaesthetics used in combination with low doses of an opioids such as fentanyl, sufentanyl or alfentanyl producing good sensory block and minimal motor blockade. Fentanyl or sufentanyl decreases dose requirement of local anaesthetics by one half with minimal adverse effect on maternal and fetal wellbeing.

Addition of fentanyl to 0.2% w/v plain bupivacaine failed to improve the quality of labour analgesia but with low concentration of bupivacaine, fentanyl becomes effective in clinical practice Chestnut D.H. et al.[3] Thus satisfactory analgesia is obtained using low dose of bupivacaine with opioids with minimal motor blockade.

Aims & Objectives

1. To estimate efficacy of 0.0625% bupivacaine & 0.0002% fentanyl combination on Labour outcome
2. To study the effect of 0.125% bupivacaine alone on Labour outcome
3. To compare the effectiveness of bupivacaine & fentanyl combination with bupivacaine alone on Labour.

MATERIALS AND METHODS

This randomized study was conducted in department of Anaesthesiology in collaboration with Obstetrics & Gynaecology department and the Dept. of paediatrics in Hi-Tech Medical College, Odisha from July 2015 to June 2017 after taking ethical clearance. The study population comprises 60 parturients at term with vertex presentation without any definite indication of caeserean section.

Inclusion Criteria

ASA category I parturients, at term singleton pregnancy (37-42 wks) with vertex presentation within 18-35 years age were included in this study

Exclusion Criteria

Patient who had allergy to test drugs, ASA category >II, Infection over the site of placement, Vertebral anomalies, Coagulopathy, shock & hypovolemia, cephalopelvic disproportion, twice post caesarean section, malpresentation, complicated twins, mulitiple pregnancy were exempted from the study

Data Collection

After taking written informed consent, the 60 parturients were distributed into two groups randomly. Each group comprises 30 parturients. Group A receiving 0.0625% bupivacaine with 0.0002% fentanyl combination & Group B receiving only 0.125% bupivacaine. A detailed pre anaesthetic check up was done followed by a comprehensive medical, obstetrics and gynaecological history taken, antenatal records were checked. A detailed physical and systemic particularly cardiovascular and respiratory examination was done. After preloading all parturients with 500ml Ringer's lactate, second or third space was cleaned with 5% povidone iodone, infilterated with 2% lignocaine. Under aseptic procedure an 18GTuohy needle was inserted in L3 – L4 interspace. An 20G epidural catheter was inserted cephalad, fixed with adhesive tape and patients were positioned in left lateral position. 12ml of test solution injected into the catheter at 2-3ml per min followed by continuous infusion at rate of 10ml /hr and rate was adjusted to maintain T10 dermatome level analgesia bilaterally. Maternal heart rate, blood pressure, fetal heart rate was noted. Progress of labour, cervical dilation, visual analogue scale(VAS), neonatal Apgar score, mode of delivery , duration of 1st stage & 2nd stage labour, Maternal satisfaction were recorded.

Data was collected and analysed using SPSS software and p value was obtained. P value less than 0.05 was taken as significant.

RESULTS

60 parturients on spontaneous onset of labour within 18-35years age group without any cephalopelvic disproportion participated in this study. The mean age of parturients in Group A was 23±3 years whereas in Group B was 24±3.9 years. [Table 1] Comparing maternal pulse rate, mean baseline pulse rate before induction was 83.97 and 83.17 in Group A and Group B respectively. But after induction mean pulse rate was slightly risen as compared to baseline i.e Group A 87.80 and Group B 84.80 probably due to anxiety following catherization. A similar rise is also observed in 2nd stage of labour. The systolic blood pressure of both groups were compared, mean SBP in 2 groups were close baseline i.e Group A (124.87) & Group B (124.80).However after induction and 1st stage of Labour, there was fall in SBP in both Groups.

In 2nd stage upward trend was observed in both Groups which was much higher in those not receiving epidurals. Diastolic Bp also showed similar trend as that of systolic BP in both groups. The mean fetal heart rate were 140.87 and 141.53 in GroupA & GroupB respectively. In both the Group when FHR was compared showed p value > 0.05, thus epidural doses of bupivacaine with or without fentanyl appears to have minimal effect on fetal heart rate. The time of onset of analgesia was recorded and the mean was found to be 15.67±2.771 minutes in Group A and 18.33±4.73 minutes in Group B. Visual analog score (VAS) in mm was recorded in each group before epidural, 1st stage, 2nd stage of labour. [Table 2]. The score shows good analgesia is obtained in Group A using 0.0625% bupivacaine with 0.0002% fentanyl combination as compared to 0.125% bupivacaine solution. After the initial bolus dose of 12 ml, an average infusion rate in Group A was 11.74±1.389 ml/hr and 10.36±1.091 ml/hr in Group B to maintain satisfactory analgesia upto T-10 sensory level. The mean bupivacaine requirement in group A was 41.08±10.427 mg overall, as against 79.50±28.04 mg group B. In the 0.0625% bupivacaine with fentanyl group, the mean fentanyl consumption was 131.47±33.367 µg for the entire duration from epidural initiation to delivery. Comparing the ambulation rate, 96.67% of parturients were found to walk at least once in group A compared to 46.67% in group B (P<0.001). Around 63.33% of parturients in Group B developed motor paresis in comparison to 3.33% parturient in Group A (P< 0.001). Duration of labour in 2 groups were compared. The mean duration of Labour from epidural to delivery was 291.57 min in Group A and 310.10 min in Group B. Comparing mode of delivery in 2 groups, 80% women in Group A and 60% women in Group B delivered by spontaneous vaginal delivery (SVD) [Table 3]. Neonatal Apgar score at 1min , 5 min after delivery was recorded in both groups. [Table 4]. Except 1 baby who expired in Group A, all babies had Apgar score > 7 after 5 min were pink, alert, cried after delivery, breast fed within 2hrs of delivery. Maternal satisfaction score was high i.e 90% in group A and 93.33% in Group B. [Table 5]

Table 1: Age Distribution of Parturients

Age Groups(Yrs)	Group A		Group B	
	Number	Percentage	Number	Percentage
≤20	5	16.67	8	26.67
21-25	18	60	10	33.33
26-30	7	23.33	11	36.67
31-35	0	0	1	3.33
MEAN	23		24	
S.D.	±3		±3.9	

Table 2: Visual Analogue Score (VAS) score

Time Period	Group A		Group B		P
	Mean	S.D.	Mean	S.D.	
Before epidural (baseline)	66.83	±17.195	70.5	±16.523	0.403
Epidural to full dilatation	13.36	±3.914	12.44	±3.535	0.340
2nd stage	11.229	±4.665	10.453	±5.799	0.057
Epidural to delivery	12297	±3.528	11.446	±3.230	0.334

Table 3: Mode Of Delivery

	GROUP A(n=30)	GROUP B (n=30)	P
SVD	24(80%)	18(60%)	0.09096
Instrumental delivery	3(10%)	8(26.7%)	0.095274
Caesarean section	3(10%)	4(13.3%)	1.000

Table 4: Neonatal APGAR Score

	GROUP A				GROUP B			
	1 min		5 min		1 min		5 min	
APGAR score	No.	%	No.	%	No.	%	No.	%
9-10	4	13.33	24	80	3	10	21	70
7-8	20	66.67	5	16.67	18	60	9	30
≤6	6	20	1	3.33	9	30	0	0

Table 5: Maternal Satisfaction Score

Mothers who are…	Group A		Group B	
	No.	%	No.	%
Satisfied (score 1)	27	90	28	93.33
Neutral (score 2)	2	6.67	2	6.67
Dissatisfied (score 3)	1	3.33	0	0

DISCUSSION

The mean age of parturients in Group A and Group B matched with each other. A study conducted by Elliot, R.D. in 1998 on continuous infusion of bupivacaine and fentanyl for labour analgesia, the mean age was found to be 26±5 years, 26±4 years and 27±4 years in the three groups.

The mean pulse rate was increased in both groups at 2 min and 5 min during induction, but only the mean pulse at 5 min in Group A was significantly increased (P<0.05) with respect to the baseline which may be due to anxiety. In the second stage an upward trend was noted in both groups. Between the two groups none of the mean value at any stage of labour were significantly different (p>0.05). Thus, the two groups had similar values with respect to the effect of the test solutions on pulse rate during labour. Matadial L. et al,[4] found comparable decrease in systolic/diastolic blood pressure and compensatory tachycardia in both groups receiving epidural analgesia for labour pain.

When blood pressure was measured, no significant difference was noted between the two groups at induction (P>0.05). Mean blood pressure at 5 min was 124 (±8.614) / 78.53(±5.655) in Group A and 123.20 (±8.767) / 76.93 (±5.426) Group B. In the maintenance phase of the first stage, mean systolic and diastolic BP fell by less than 5% in both groups which was significant (P<0.05) when compared to the respective baseline values. Both the groups showed same result (P>0.05). The mean systolic BP showed a rising trend in the second stage which was statistically insignificant except for the significantly raised (P<0.05) systolic BP in the later part of second stage in group A. Both the two groups had similar findings with respect to the systolic BP in the second stage (P>0.05). The diastolic BP was insignificantly elevated in the later part of second stage in the 0.0625% bupivacaine with fentanyl group, but otherwise reduced insignificantly in both groups (P>0.05 in both cases). The mean diastolic values for the later part of second stage was significantly different (P<0.05) between the two groups, as The 0.0625% bupivacaine with fentanyl group showed a slight rise and the 0.125% bupivacaine group a slight fall. In all other respects the two groups were comparable with respect to the diastolic BP. On the whole, the two groups can be said to be comparable with respect to the effect of the test solutions on blood pressure.

Hollmen A. et al,[5] observed 16.5% parturients receiving 0.5% epidural bupivacaine developed hypotension. Abboud, T.K. et al,[6] found hypotension in 13.04% parturients receiving 0.5% epidural bupivacaine. Elliot, R.D. in 1998 had to use fluid bolus to correct hypotension in only one out of seventy five parturients divided in three study groups who received 0.125% or 0.25% bupivacaine.

In the present study foetal heart rate was monitored throughout labour till delivery and the neonates were followed up to 24 hours after delivery. The mean baseline foetal heart rate was 140.87±5.575/min in group A and 141.53±4.812/min in group B. The mean FHR of the two groups during labour matched with each other. (P>0.05).

The duration of onset of analgesia was measured, the mean duration was 15.67±2.771 and 18.33±4.73 minutes in Group A & Group B respectively.. The time of onset was significantly shorter in the first group (P<0.05). Hollmen, A. et al,[5] recorded 418 parturients had rapid onset of analgesia (3-5min) using 4ml dose of 0.5% bupivacaine with or without adrenaline. In contrast, longer onset time was recorded in the present study probably due to dilute concentrations used.

Visual analogue scores (VAS) was recorded on a 100 mm line assessing the quality of analgesia. The mean VAS score in Group A & Group B before epidural analgesia was 66.83±17.19 & 70.5±16.523 respectively and the two groups VAS score were comparable with each other(P>0.05). The Comparative Obstetric Mobile Epidural Trial (COMET) Study Group UK in 2002 recorded 75, 78 and 75 initial median VAS scores in the three groups before initiation of epidural analgesia. The present study findings were concordant with COMET study in UK.

However the mean VAS score in labour was 12.297±3.528 for Group A and 11.446±3.230 for Group B. The 2 groups analgesia score matched with each other. Similarly Femandez-Guisasola, J et al,[8] in 2001 observed verbal score of 1.04±1.63 for the group receiving 0.0625% bupivacaine with fentanyl and 0.95±1.71 for the group receiving 0.1% ropivacaine with 1µg/ml fentanyl though the values were similar (P>0.05).

The mean volume of test solution used in labour was 65.73±16.684 ml in Group A and 63.60±22.434 ml in Group B, the two values being comparable (P>0.05). After the initial bolus dose of 12 ml, an average of 11.734±1.389 ml/hr of test dose in Group A and 10.36±1.091 ml/hr in Group B was required to maintain satisfactory analgesia with a sensory level upto T-10; the values were significantly higher in group A (P<0.001) probably due to higher dilution. In comparision, Fernandez-Guisasola, J., et al in 2001,[8] used 0.0625% bupivacaine with 2µg/ml fentanyl at the rate of 15 ml/hr for maintenance of analgesia. Elliott, R.D. in 1991,[7] used 0.125% and 0.25% bupivacaine at 7ml/hr for maintenance.

The mean bupivacaine requirement in group A was 36.58±7.749 mg during the first stage as compared to 68±22.156 mg in group B; 4.5±4.108 mg during the 2nd stage against 11.5±7.812 mg in the 0.125% bupivacaine group; and 41.08±10.427 mg overall, as against 79.50±28.04 mg in the 0.125% bupivacaine group. All these differences are highly significant (P<0.001 in all cases). In a similar study, James, K.S., and others in 1998[9] found the median (and interquartile range) total bupivacaine doses to be 45 (35-50) mg in the 0.1% bupivacaine with fentanyl group, and 87.5 (62.5-112.5) mg in the 0.25% bupivacaine group.

In group A the mean fentanyl consumption was 117.07±24.796µg in the first stage, 14.40±113.145 µg in the second stage, and 131.47±33.367 µg for the entire duration from epidural initiation to delivery. The median (interquartile range) fentanyl dose in the 1998 study by James, K.S,[9] was 110 (90-120) µg; the fentanyl concentration being the same as in the present study through top-upps were given intermittently instead of continuous infusion. When ambulation rates were analysed, 96.67% of parturients were found to walk at least once in group A compared to 46.67% in group B, a highly significant difference (P<0.001). In the 1998 study by James, K.S,[9] 60% of women getting 0.1% bupivacaine with 2µg/ml fentanyl walked during labour; the present study is thus comparable to this study. 63.66% of parturients (56.67% grade1 & 6.67% grade 2) (P<0.001) receiving only 0.125% bupivacaine group developed motor paresis whereas only 3.33% parturients in group A developed Grade 1motor paresis the difference being highly significant (P<0.001). Fernandez-Guisasola, J., et al in 2001,[8] found minimal motor paresis to occur in 9.8% of parturients receiving 0.0625% bupivacaine with 2 µg/ml fentanyl. Ginosar, Y. et al in 2003,[10] found that women in labour who receive epidural fentanyl require smaller doses of local anaesthetic and develop lesser motor block. In present study, the findings were similar as almost all women in group A could ambulate during labour.

The mean duration of the labour from insertion of the epidural catheter to full dilatation of the cervix was 238.33±59.253 minutes in Group A and the corresponding value for Group B was 243.83±90.437 minutes, and the values between 2 groups matched with each other (P>0.05). In comparision, the mean duration of the first stage in the 1991 Elliot study was 463±272 minutes in the 0.125% bupivacaine with fentanyl group, and 495±331 minutes in the 0.125% plain bupivacaine group. Fernandez-Guisasola et al in 2001,[8] recorded a mean duration of 401±184 minutes for the first stage of labour in the group receiving 0.0625% bupivacaine with fentanyl.

The mean duration of the second stage was 59.15±41.984 minutes in the group A and 73.63±37.575 minutes in the group B. The values were similar in the two groups (P>0.05) in this regard. In a similar study by Elliott in 1991,[7] the mean second stage duration was 95±58 minutes in group A and 91±76 minutes in group B. Likewise, the mean duration of the second stage in the study by Fernandez-Guisasola, J and others in 2001[8] in the group A was 57±47 minutes.

In the present study, 80% of women in group A and 60% in group B delivered by spontaneous vaginal delivery but the difference was not significant (P>0.05). While 10% women in Group A underwent instrumental delivery while it was 26.7% in Group B. 10% parturients in group A and 13.3% in group B underwent caesarean section for delivery, the difference was not significant (P>0.05).

Kamlnski et al found the frequency of low forceps, vaccum extraction, and mid-forceps delivery in the epidural group to be significantly higher in women receiving traditional epidural (0.25% bupivacaine) analgesia for labour. Chestnut, D.H., et al,[11] concluded that early administration of epidural analgesia did not increase the incidence of operative delivery, when compared with intravenous nalbuphine followed by late administration of epidural analgesia, in nulliparous women who were in spontaneous labour at term. Carvalho, B. et al in 2005,[12] while evaluating several regimens for "ultra-light" (0.125%) patient-controlled epidural analgesia (PCEA) with basal continuous infusion(CI) in labour observed 78% spontaneous vaginal delivery 10% instrumental (forceps or vaccum) delivery and 12% caesarean section in patients. The present study findings was concordant with the above study.

Neonatal Apgar score at 1min, 5 minwas recorded. Apgar score of 9-10 were recorded at 5 min in 80% neonates in group A and 70% neonates in group B. Apgar score were above 7 in all other neonates except the one who expired, at 5 minutes. At 1 minutes, 20% neonates in group A and 30% in group B had Apgar score less than or equal to 6, while 66.67% in the former group and 60% in the latter group had scores of 7 or 8, and 13.33% in the former group and 10% in the latter group had scores of 9 or 10. All babies with the exception of one became alert and cried soon after birth and took oral feeds within hours of delivery.

Willdeck-Lund, G. et al,[13] recorded 4.5% infants developed transitory asphyxia at birth with mothers having epidural block, but after 5 min, only 1% had an Apgar score of less than 7. This study used high concentrations of local anaesthetics in contrast to the present study. Riley, E.T. in 2003,[14] said that foetal bradycardia will not occur if the uterus is quickly relaxed and foetus properly resuscitated. In 1999, Palmer et al,[15] found similar foetal heart rate changes while comparing intrathecal fentanyl labour analgesia with traditional epidural labour analgesia.

Maternal satisfaction score was 90% and 93.3% in Group A and Group B respectively. Only one woman in group A was dissatisfied with the outcome as she had pruritus and felt too much pressure during delivery. Morgan, B.M., et al in 1982,[16] found that maternal satisfaction was not related to analgesia and many women were dissatisfied despite having pain free labour because of increased instrumentation and prolongation of labour. M.I. Bowden & M. Lewis et al 1991 studied the maternal satisfaction based on level of analgesia, side effects, and psychological states and observed that 99% patients receiving 0.1% bupivacaine with 50 µg fentanyl were satisfied.

CONCLUSION

Low dose continuous epidural lumbar analgesia has emerged as a popular method of labour analgesia in many parts of the world. The two groups were

similarly matched with respect to age, haemodynamic profile, foetal heart rate, duration of labour, intensity of analgesia, mode of delivery, maternal satisfaction and neonatal outcome.

The 0.0625% bupivacaine with 2 µg/ml fentanyl group required a higher infusion rate for maintenance ($P<0.001$), had a shorter time of onset of analgesia ($P<0.05$), required lower quantity of bupivacaine ($P<0.001$), had a lesser ($P<0.001$) incidence of motor paresis with a higher ambulation rate ($P<0.001$) of 96% as compared with the 0.125% bupivacaine group, all the differences being significant.

No serious adverse outcome that could be attributed to epidural anaesthesia was recorded in either group. Both test solutions were found to provide adequate analgesia, and appeared to be safe for both the parturient and foetus, although the 0.0625% bupivacaine with 2 µg/ml fentanyl emerged as a better choice for a 'walking' epidural.

On the whole, it can be said that dilute bupivacaine and fentanyl can be safely administered to parturients in labour without compromising the safety of the foetus.

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