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Original Research Article

Combination of epidural bupivacaine and fentanyl for labour analgesia: An observational longitudnal study

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ABSTRACT

Labour is a physiological process which is associated with most severe pain. Goal of labour analgesia should be to ensure painless labour without any side effect. Various methods have been used to alleviate pain during labour but the only consistently effective method is lumbar epidural analgesia. Since higher doses of local anaesthetics cause undesirable effects like motor block and hemodynamic changes, adjuvants like opioids are used.

The present study evaluates the clinical effectiveness of continuous lumbar epidural for vaginal delivery using 0.0625% bupivacaine with 2.5 mcg/ml of fentanyl.

Materials and Method: 91 patients admitted to Lalladed hospital govt medical college Srinagar for vaginal delivery and who were in active labour were given first loading dose of 10ml 0.25% plain bupivacaine via epidural catheter followed by continuous epidural infusion of 0.0625% bupivacaine with 2.5 mcg/ml fentanyl @ 12ml/hr. the parturients were assessed for onset and duration of analgesia, hemodynamics, sensory block, mode of delivery, and APGAR(neonatal outcome).

Results: Onset of analgesia was significantly faster(10 min). The duration of analgesia was also longer. There were no significant hemodynamic changes. No motor block was seen. 1 min and 5 min APGAR scores were comparable.

Conclusion: It was concluded that epidural labour analgesia with low dose bupivacaine (0.0625%) with fentanyl (2.5mcg/ml) given through continuous infusion technique provides good pain relief to the parturient in labour with increased maternal satisfaction without significant maternal or fetal side effects.

1. Introduction

Labour is a physiologic process which is associated with most severe pain. American College of Obstetricians and Gynaecologists (ACOG) suggested, if not contraindicated, a parturient should receive labour analgesia and under no circumstances labour pain should be left untreated.[1,2] Goal of labour analgesia should be to ensure painless labour without significant adverse effects. Pharmacological and non-pharmacological methods have been employed for labour analgesia. Labour analgesia by neuraxial technique, especially by epidural is considered gold standard.[3] Epidural analgesia offers the most reliable pain relief with the least amount of side effects for the longest period of time in labour when compared to all other forms of pharmacological methods.[4]

In our study we used Bupivacaine and Fentanyl through epidural continuous infusion. Bupivacaine is the most commonly used medication administered for epidural analgesia in labour because of its widespread availability, low cost, relatively safe profile.[5] It has a rapid onset and its duration is long lasting. Bupivacaine has also been shown to provide longer lasting analgesia than other local anaesthetics even after sensations return.[6] The addition of opioid to local anaesthetic solution can help treat missed segments, perineal pressure, and maximize efficacy and maternal satisfaction.[7] Fentanyl is a potent opioid and addition in low concentration to Bupivacaine increased its

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efficacy, safety profile and cost effectiveness.

2. Aim of the Study

The aim of the study is to observe the quality of analgesia of 0.0625% bupivacaine with fentanyl2.5 mcg/ml @ 12ml/hr in a continuous epidural infusion during labour.

3. Objectives

3.1. Primary objective

1. To observe the quality of analgesia during the labour.
2. To observe patient satisfaction.

3.2. Secondary objective

1. To observe hemodynamic changes (blood pressure, heart rate) during labour inpatients who have received epidural labour analgesia.
2. To observe for complications like nausea, vomiting, respiratory depression, pruritus, urinary retention in patients receiving epidural labour analgesia.
3. To observe and assess fetal outcome by recording APGAR score.

3.3. Inclusion criteria

1. Pregnant women primigravida and multigravida (ASA grade II) with no associated comorbidity.
2. Age 18 to 45 years.

3.4. Exclusion criteria

1. Patients refusal for labour analgesia.
2. Patients with severe preeclampsia.
3. Frank coagulopathy.
4. Patients not considered for vaginal delivery due to obstetric reasons.
5. Contraindications for epidural/spinal anaesthesia, if any.

4. Materials and Methods

This observational longitudinal study comprising the use of epidural bupivacaine 0.0625% with fentanyl 2.5 mcg/ml in combination @12ml/hr continuous infusion for labour analgesia was conducted in 91 parturients, who gave consent and hence opted for painless labour in LallaDed hospital which is an associated hospital of Government Medical College, Srinagar after obtaining permission from the Institutional Ethical committee. After taking a written informed consent, only those who fulfilled the inclusion criteria were included in this study.

As per the routine protocol of the hospital the parturient female was prepared for delivery, in addition to preparation of back to perform epidural block. The onset of active labour, degree of cervical dilatation and the adequacy of pelvis for vaginal delivery were assessed by attending obstetrician. Block was performed at cervical dilatation of 4 cms. Monitors (NIBP, pulse oximeter, ECG) and CTG were connected and base line vitals were recorded. An IV line was established on the non dominant hand with an 18 G cannula. The parturient was preloaded with 500-1000 mL 0f Ringer lactate solution. Inj. Ranitidine 50mg and Ondansetron4mg (IV) was administered to all parturients. Allequipments needed for airway management and rew before performing the block.

Epidural block was performed through a midline approach with Tuohy needle and loss of resistance technique. After negative aspiration for blood and CSF, the epidural catheter was secured. Two mL of 0.5% plain bupivacaine was given as epidural test dose followed by a loading dose of 10 mL 0.25% plain bupivacaine was given 5 min and, if women were not pain free 20min later, supplementary doses of 5mL 0.25% plain bupivacaine was given until complete analgesia was achieved. Continuous epidural infusion of 0.0625% bupivacaine containing 2.5 micrograms/mL fentanyl @12ml/hr was started and the patient was shifted back to labour room. Infusion was adjusted to maintain sensory level of block between T8 and T10 level. If the block extended above T8 the rate of infusion was reduced by 2mL/hr. Top-up boluses of 5ml 0.5% plain bupivacaine was given if the female patient complained of pain untill analgesia was achieved. Left uterine displacement was ensured throughout the labour. Frequent vaginal examination was not encouraged throughout the labour. Continuous maternal and fetal monitoring was done and epidural catheter was removed immediately after delivery, under all aseptic conditions.

4.1. Monitoring

1. Time of onset and quality of analgesia as per VAS score.
2. Monitoring of hemodynamics
3. Assessment of sensory blockade.
4. Assessment of motor blockade.
5. Complications or side-effects if any like hypotension, nausea, vomiting, respiratory depression, pruritus, urinary retention.
6. Foetal monitoring and outcome.
7. Progress of labour
8. Patient satisfaction score.

4.2. Statistical analysis

Data was entered in Microsoft excel spreadsheet. Categorical variables were summarized as frequency and percentage. Continuous variables were summarized as mean and standard deviation. Repeated measures ANOVA was be used to evaluate the change in continuous variable

within a group. Two sided p-values were reported and p value <0.05 was considered statistically significant.

5. Results

Among 91 patients included in the study, 17 (18.7%) were Primigravida and 74 (81.3%) were Multigravida.

Table 1: Distribution of study parturients according to gravidity

Type	No. of Parturient	Percentage
Primigravida	17	18.7
Multigravida	74	81.3
Total	91	100

Pain was assessed using VAS every 5 min for first 20 min and at 30 min interval thereafter throughout the process of labour. The P-value <0.001* and was statistically significant for after drug infusion. The mean VAS score of laboring parturients was 3.08 ± 1.77. For the 1st stage VAS score was 2.96 ± 2.07 and for 2nd stage VAS score was 3.19 ± 0.05. The P value was <0.001 and was statistically significant.

Table 2: Changes in VAS Score

Visual Analogue Score				
Time Interval		**Mean**	**SD**	**P-Value**
Before drug		**9.19**	**0.39**	**0.030***
	5min	5.55	0.88	
	10min	4.14	0.44	
	15min	2.29	0.56	
	20min	2.01	0.10	
	50min	2.51	0.69	
	80min	2.13	0.40	
	110min	2.08	0.31	
	140min	2.89	0.59	
After drug	170min	2.05	0.31	<0.001*
	200min	2.09	0.38	
	230min	2.12	0.42	
	260min	2.51	0.69	
	290min	2.23	0.56	
	320min	3.13	0.54	
	350min	3.20	0.53	
	380min	2.16	0.45	
	410min	3.23	0.56	

Table 3: Stage of labour (VAS score)

Stages	Mean	SD	P Value
1st stage	2.96	2.07	<0.001*
2nd stage	3.19	0.05	<0.001*

All the parturients were satisfied after delivery with 9(9.9%) cases experiencing excellent analgesia and rest 82(90.1%) experiencing good analgesia out of the 91 selected cases.

Out of all selected 91 parturients, 85(93.4%) of cases went for normal vaginal delivery with 6(6.6%) for vacuum cup assisted vaginal delivery and 0 for cesarean section. P value was (0.013)<0.05 showing statistical significance.

Table 4: Distribution of the study parturients according to Patient Satisfaction Score

Patient Satisfaction score	No. of Parturient	Percentage
1-Excellent	9	9.9
2-Good	82	90.1
3-Poor	0	0
Total	91	100

Table 5: Distribution of study parturients according to the mode of delivery

Mode	No. of Parturient	Percentage
Natural	85	93.4
Vacuum cup assisted	6	6.6
Cesarean section	0	0
Total	91	100

Fetal assessment was done with continuous CTG monitoring. There was no abnormal CTG finding throughout the labour.

Table 6: Distribution of study parturients as per CTG changes in fetus

CTG changes in labour	No. of foetus	Percentage
Loss of baseline variability	0	0
Early decelerations	0	0
Variable decelerations	0	0
Late decelerations	0	0
Tachycardia	0	0
Nil	91	100
Total	91	100

The APGAR score along with percentage and distribution of babies was within normal limits. At 1min neonates had APGAR score of 7-10 with maximum no. of babies under APGAR score 8(47.3%). However, at 5 minutes all the neonates had APGAR score of 9-10 with maximum no. of babies under APGAR score 9(94.5%) concluding that all neonates had good APGAR score.

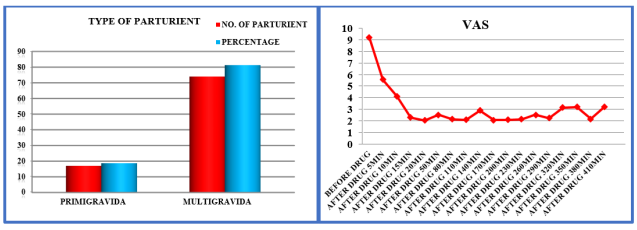
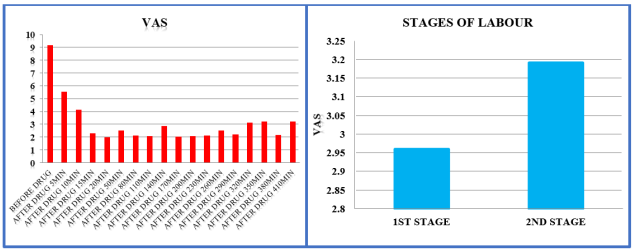
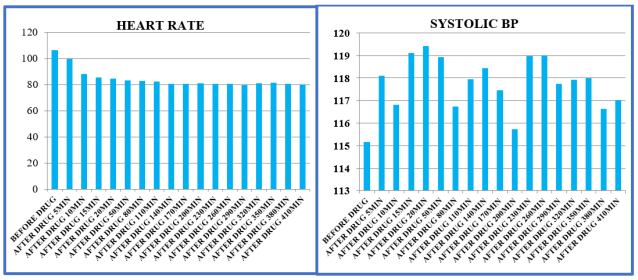
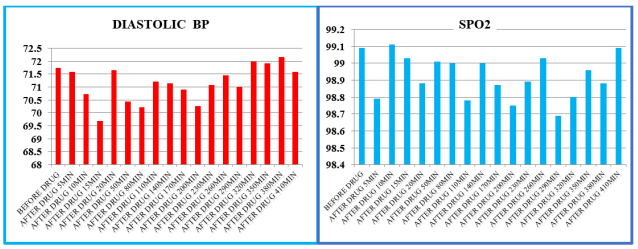


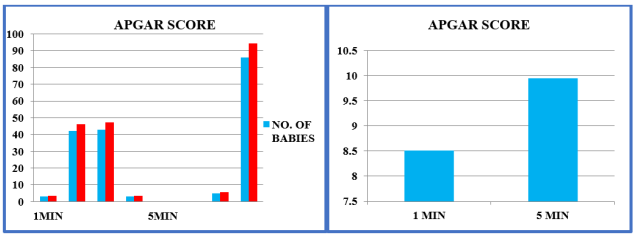
Table 7: Distribution of neonates according to 1 minute and 5 minute PGAR score changes

Time	Apgar Score	No. of babies	Percentage
	7	3	3.2
	8	42	46.2
1 min	9	43	47.3
	10	3	3.3
	Total	91	100
	7	0	0
	8	0	0
5 min	9	5	5.5
	10	86	94.5
	Total	91	100









Hemodynamic parameters that include heart rate, blood pressure and Spo2 were recorded every 5 min for first 20 min and at 30 min interval. There was no incidence of bradycardia. All the values were statistically significant at all times with the p value of <0.001 after the drug was given. In all the cases the systolic and the diastolic blood pressure remained within the normal limits, i.e. within 20% of baseline blood pressure. None of the patients suffered hypotension. All the values were statistically insignificant at all times with a p value of 0.495* for systolic blood pressure and the p value of 0.431*for diastolic blood pressure. Mean Spo_2 changes were within the normal limits. All the values were statistically insignificant at all times with the p value of 0.163. No patient complained of respiratory distress at any point of time. Mean of APGAR score at 1 minute was 8.51±0.62, with P value of <0.001* and was statistically significant and at 5 minutes was 9.95±0.23 with P value of <0.001* that was statistically significant.

6. Discussion

Labour analgesia by neuraxial technique, especially by epidural is considered as gold standard.[3] The ideal labour analgesia should be easy to administer, should provide predictable and rapid onset of analgesia, should be devoid of motor block and expulsive efforts should be preserved during the second stage of labour.

Use of low concentration local anaesthetic solution preferably blocks “C” fibres which transmit pain without causing motor block. Epidural lignocaine, chloroprocaine were used in past but bupivacaine still remains the most commonly used local anaesthetic for epidural labour analgesia.

The use of low concentrations of bupivcaine alone provides suboptimal, short lived analgesia.[8] The addition of lipid soluble opioids, fentanyl 1 to 3 mcg/mL allowed the reduction of local anaesthetic dose with associated decreased motor blockade, preserved analgesia and enhanced maternal satisfaction.[9]

In our hospital the labour analgesia was instituted as per the protocol. 10mL bolus dose of 0.25% bupivacaine followed by continuous infusion of 0.0625% bupivacaine with 2.5mcg fentanyl per mL @ 12ml/hr. we observed labour analgesia in 91 parturients of which 17(18.7%) were primiparous and 74(81.3%) were multipara (Table 1). Drug was administered at the cervical dilatation of 4cm. All parturients were preloaded with 10ml/kg of Ringer lactate before establishing the block in order to decrease the incidence of hypotension following sympathetic blockade.

We observed the quality of analgesia by using VAS score during labour analgesia and patient satisfaction at the end of delivery. We also observed other parameters like onset and duration of analgesia, sensory and motor blockade, hemodynamic parameters that includes blood pressure and heart rate, neonatal outcome by APGAR score and complications like pruritus, nausea, vomiting, respiratory depression, urinary retention and hypotension.

All parturients were observed upto 8 hrs postpartum for any complications.

6.1. Quality of analgesia

Mean baseline VAS score to pain was 9.19 with SD 0.39 and p value 0.30 that was statistically significant. After the drug was administered and infusion started, we observed that overall mean VAS score for parturient was 3.08 ± 1.7 with p value of<0.01.

6.2. Onset of analgesia

Time taken for 50% reduction in baseline VAS score (VAS<4.5) was 10 min with SD of 0.4 and p value of<0.001 (Table 2). For the first stage mean VAS score was 2.96 ± 2.07 and for the second stage mean VAS score was 3.19 ± 0.005. The p value was <0.001, that was statistically significant (Table 3). Our study was consistent with the study done by Sharma et al[10] and Kanna et al.[11] who observed that continuous epidural infusion provided a faster onset of analgesia with long lasting effect.

6.3. Patient satisfaction

After the delivery was conducted the satisfaction level of patients was recorded and graded as 1,2,3 as excellent, good, poor. Out of 91 patients 9(9.9%) expressed excellent satisfaction and rest 82(90.1%) expressed good satisfaction (Table 4). Our results are consistent with Russell et al.[12] who reported increased maternal satisfaction with low dose bupivacaine with opioid infusion and Sharma et al. who reported that all patients were fully satisfied with pain relief and were willing for labour analgesia in subsequent pregnancies.

6.4. Mode of delivery

Out of 91 parturients 85(93.4%) underwent normal vaginal delivery without any instrumentation, 6(6.6%) parturients could not bear down and had poor efforts and underwent assisted delivery with vacuum cup(Table 5). None of the patients underwent cesarean section. Our observations were comparable with Sharma et al.[10]

6.5. Fetal wellbeing

Was assessed by regular CTG monitoring. There were no CTG changes in fetus(Table 6) that is consistent with kanna et al.[11]

Neonatal outcome was observed with APGAR score at 1min and 5 min. At 1 min the APGAR score of 7-10 with maximum babies under APGAR score 8(47.3%) was observed. However at 5 min all the neonates had APGAR score of 9-10 with maximum no. of babies under the APGAR score 9(94.5%) (Table 7). Our observations are consistent with Sharma et al.[10]

Out of 91 patients 6(7.69%) complained of pruritus that was the most common side effect. None of the patients complained nausea, vomiting, urinary retention, respiratory distress or hypotension. Our observations are consistent with the observations by Sharma et al.[10]

7. Conclusion

We concluded that epidural labour analgesia with low dose bupivacaine (0.0625%) with fentanyl (2.5 mcg/ml), given through continuous infusion technique provides good pain relief to the parturients in labour with increased maternal satisfaction and without significant maternal or fetal side effects.

8. Source of Funding

None.

9. Conflict of Interest

None.

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