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Comparitive Study of Bupivacaine with Fentanyl versus Bupivacaine for Epidural Labour Analgesia

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Abstract

Labour is an extremely painful process. Labour pain is of major concern since most parturients experience significant pain of extremely severe intensity. Labour pain can have deleterious effects on the mother, on the foetus and on the labour outcome. Among the current methods of obstetric analgesia, regional analgesia (the most widespread technique being epidural analgesia) offers the best effectiveness/safety ratio. We conducted this study to compare the efficacy of a mobile epidural using 0.0625% bupivacaine and 0.0002% fentanyl versus a conventional epidural using 0.125% bupivacaine for labour analgesia.

Keywords: Labour Analgesia; Bupivacaine; Fentanyl; Epidural.

Introduction

Labour is an extremely painful process. Labour pain is of major concern since most parturients experience significant pain of extremely severe intensity. Labour pain can have deleterious effects on the mother, on the foetus and on the labour outcome. Among the current methods of obstetric analgesia, regional analgesia (the most widespread technique being epidural analgesia) offers the best effectiveness/safety ratio [1]. The increased availability of epidural analgesia and the favorable experiences of women who have had painless labor with epidural block have reshaped the expectations of pregnant women entering labor [2]. Compared with other forms of pain relief, epidural analgesia is associated with the highest level of maternal satisfaction [3]. Adding an opioid to local anaesthetic solutions can provide effective analgesia with bupivacaine sparing and a reduction in motorblock [4,5]. The use of either an intermittent bolus or a continuous infusion of local anesthetic (with or without an opioid) is considered to provide similar analgesic efficacy and no measurable outcome differences [6,7]. The efficacy and duration of epidural opioid alone is considered inferior to epidural local anesthetic, but the benefits of an opioid should outweigh the side effects such as nausea, pruritus, and sedation [8,9]. An epidural opioid local anesthetic combination may enhance the duration and quality of pain relief at less intense motor blockade and contribute to the good progress of labor and vaginal delivery [3].

We conducted this study to compare the efficacy of a mobile epidural using 0.0625% bupivacaine and 0.0002% fentanyl versus a conventional epidural using 0.125% bupivacaine for labour analgesia.

Aim of the Study

To compare the efficacy of epidural analgesia using 0.0625% Bupivacaine and 0.0002% fentanyl versus an epidural using 0.125%

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Bupivacaine alone for labour analgesia.

The Following Parameters are Compared:

- Quality of analgesia (VAS)
- Duration of labour
- Motor block (Bromage score)
- Time from epidural to delivery
- Rate of operational delivery

Materials and Methods

This is a prospective randomised study conducted on Fifty parturients who were admitted to the antenatal ward and who requested pain relief during labor and who fulfilled the recruitment criteria were selected for the study. The procedure was explained to them in detail and written consent was obtained from them.

Ethical Requirement

The study was performed in accordance with the principles stated in the Declaration of Helsinki. Ethical approval of the study protocol was obtained from the Ethics Committee at the Institution before the study was undertaken.

Informed Consent

Written informed consent was obtained from each patient in the prescribed format prior to performance of any study related procedures: before physical examination, laboratory screening or any other investigational procedure and before administration of any study related medication. The patients were given full information about the nature, procedure and importance of the study.

Inclusion Criteria

- ASA Status I & II.
- Females in the age group from 18 to 30 years.
- Primigravida.
- Adequate gynaecoid pelvis.
- Cervical dilatation less than 4 cm.

Exclusion Criteria

- Patient refusal.
- Patients with pregnancy induced hypertension, heart disease, anaemia and other complications of pregnancy.
- Cervical dilatation greater than 4 cm
- Patients who received systemic opioids within 4 hours of epidural request
- Coagulopathy
- Patients with clinically significant renal, hepatic, cardiovascular, haematopoetic, pulmonary, gastrointestinal, nervous or endocrine disorders
- Patients unwilling or unable to comply with the study procedures

Study Procedures

IV access was secured but no IV fluid load was given. The patients were shifted to the operation theatre for insertion of the epidural catheter in aseptic manner. An epidural catheter was sited at the L3-L4 lumbar interspace using a standard midline technique with an 17-gauge Tuohy needle. The procedure was clearly explained to the patient. The visual analog scale was shown to them and interpretation of the scale explained in detail. Anaesthesia machine was checked and all emergency airway equipments like laryngoscopes, blades of different sizes, endotracheal tubes, LMAs, oropharyngeal airways were kept ready. An emergency drug tray containing all the emergency drugs was also kept ready.

Patient's vital parameters like heart rate, blood pressure, respiratory rate and fetal heart rate were continuously monitored during the procedure. The baseline values were recorded. The drugs to be administered epidurally were prepared and stored in a sterile container.

Procedure

With the patient in sitting position, under aseptic precaution L3-L4 interspace was identified and skin infiltration was done with 1.5 ml of 2% lignocaine. Using a 17G Tuohy needle and 'loss of resistance to air' technique the epidural space was identified. After confirmation by negative aspiration test 19G epidural catheter was inserted and 5 cms kept inside the epidural space. The catheter was tapped firmly to the back. The patient was turned to supine position. After negative aspiration of blood and CSF the initial dose of LA solution given in divided doses. A standard epidural test dose itself will result in augmentation of motor blockade. The bolus dose was given in divided doses with 5 mins interval checking for motor block after the first dose. Epidural top-ups were not given till patient complained of pain or discomfort. With the catheter in place patients were shifted to the

labour ward, where they were closely monitored till delivery.

For Group–A 0.0625% Bupivacaine with Fentanyl

15 ml of 0.0625% bupivacaine with fentanyl 30 micrograms and maintained on maternal request with bolus doses of 10ml of 0.0625% bupivacaine with fentanyl 2 micrograms/ml.

For group B – 0.125% plain Bupivacaine

15ml of 0.125% of plain bupivacaine and maintained with 10 ml bolus doses of 0.125% plain bupivacaine.

Parameters that were Compared

- Analgesia was measured using visual analogue scores (VAS) on a 100 mm line. Measurements were performed every 10 minutes until analgesia was established and at 30 min and 1 hr after the initial dose. Thereafter 2 hourly VAS were recorded until delivery.
- Motor Power was assessed using a modified Bromage score 30 mins after each top-up and at each request to get out of bed (score 0 = no weakness, able straight leg raise against resistance, 1 = not able to straight leg raise, able to flex knee, 2 = unable to flex knee, able to flex ankle, 3 = unable to move lower limb.
- Mode of delivery was recorded, as were time intervals between top-ups, duration of first and second stages of labour, and time from insertion of epidural until delivery.
- Tolerability was assessed by checking for complications like dural puncture,venous puncture, pruritus, nausea, vomiting, rigor, drowsiness, urinary retention, hypotension, respiratory depression.

Results

A total of 180 patients were screened for the study. 50 patients who fulfilled the inclusion criteria were enrolled for the study and were divided into two groups -

- *Group A*: 25 patients
- *Group B*: 25 patients

Patients were randomly allocated to groups A or B to receive either of the two study therapies–either epidural bolus administration of 0.0625% bupivacaine with 0.0002% fentanyl (Group A) or epidural bolus administration of 0.125% plain bupivacaine (Group B).

All patients in both the groups completed the study. There were no drop outs in the study. The following flow chart explains the progress of participants through the trial.

Physical Characteristics

Physical characteristics like age, height and weight were comparable in both the groups.

Age Distribution

The age distribution in both groups are shown in the Table 1 below.

Table 1: Age distribution

Age Distribution	Group - A	Group - B
< 20	9	10
20-30	16	15
Total	25	25
Mean ± SD	21.2000 ± 2.533	20.0800 ± 1.824
T-test value	1.79	
P value (Using Student T-test)	0.037	

Table 2: Weight distribution

Weight frequency	Group - A	Group - B
50-59	5	5
60-69	17	14
70-79	3	6
Mean ± SD	64.44 ± 5.58	64.68 ± 5.71
T-test value	0.15	
P value (Using Student T-test)	0.862 (Not Significant)	

Weight Distribution

The distribution of weight in both the groups are shown in Table 2. The values are similar in both groups and are statistically comparable. The Student T test done on the values revealed no statistical significance.

Height Distribution

The distribution of weight in both the groups are shown in Table 3. The values are similar in both groups and are statistically comparable. The Student T test done on the values revealed no statistical significance.

Mode of Delivery

One patient in Group A and two patients in Group B were delivered by Caesarean section. The indication for Caesarean section was failure to progress in labour. Two patients in Group B were delivered by outlet forceps delivery. The indication for forceps delivery was maternal exhaustion. All others were delivered by Labour Natural with episiotomy (Table 4).

Time from Epidural to Delivery

The time from epidural to delivery in both groups were comparable. The Student t test done on the values revealed no statistical significance (Table 5).

Duration of Labour

The total duration of labour in both groups were comparable. The duration of first and third stage of labour was comparable. Student T-test was done on duration on total and each stage of labour. The P-values were all >0.05 implying that differences were not statistically significant. Duration of the second stage of labour was significantly shorter in group A (P =0.009) (Table 6).

Table 3: Height distribution

Height frequency	Group - A	Group - B
50-59	1	3
60-69	17	16
70-79	7	6
Total	25	25
Mean ± SD	158.32 ± 4.63	156.84 ± 5.93
T-test value	0.98	
P value (Using Student T-test)	0.317 (Not Significant)	

Table 4: Mode of Delivery

Mode of Delivery	Group - A	Group - B
Labour Natural	24	21
Caesarean section	1	2
Outlet forceps	-	2
Chi-Square value	2.53333	
P value	0.28177 (Not Significant)	

Table 5: Time from epidural to delivery

Group	No. of cases	Mean time from epidural to delivery in mins	SD	Student t test P value
Group A	24	161.8750	13.578	0.900 (Not Significant)
Group B	23	166.9565	13.878	

Table 6: Duration of labour

Stage of Labour	Group - A		Group - B		T-test	P-value
	Mean (mins)	SD	Mean (mins)	SD		
First Stage	162.08	11.83	161.74	10.18	0.11	0.916
Second Stage	49.21	7.65	55.00	6.74	2.75	0.009**
Third Stage	16.67	4.08	16.96	3.91	0.25	0.805
Total	227.54	16.12	233.70	14.16	1.39	0.172

Number of Top-UPS Given

Number of top-ups given in both groups were comparable. The Chi-Square test done on the values revealed no statistical significance (Table 7).

Motor Blockade

This was assessed using the Modified Bromage Scale. The patients in group A had minimal motor blockade when compared to patients in group B. The Chi- Square test showed statistical significance with regard to motor blockade between the two groups (Table 8).

Vas Scale

The pain perceived by the patients was assessed by showing them a VAS scale which contained pictures of faces depicting pain on one end and smiling face on the other end. In between the two, there were pictures expressing intermediate emotions. The other side had a scale marked from 0 to 100. The scale had a slider which the patients move to point below the image which they felt expressed their perceived pain. The VAS score was assessed at 0, 5, 15, 30, 45, 60, 120 and 180 minutes. The initial VAS score ranged between 80 and 100 for all the patients. VAS score for pain was comparable in both groups throughout labour (Table 9).

Table 7: Number of top-ups

No. of top-ups	Group - A		Group - B	
	N	%	N	%
1	0	0	0	0
2	10	40	10	40
3	15	60	15	60
4	0	0	0	0
Chi-Square Value			0.00000	
P value			1.00000 (Not Significant)	

Table 8: Motor block- Bromage score

Bromage Scale	Group - A		Group - B	
	N	%	N	%
0	12	48	0	0
1	12	48	14	56
2	1	4	11	44
3	0	0	0	0
Chi-Square Value			20.48718	
P value			0.00004 (Significant)	

Table 9: VAS score

Time in Mins	Group - A		Group - B		Student t test
	Mean	Std Deviation	Mean	Std Deviation	P value
0	94.00	7.07	94.00	7.07	1.000
5	57.60	11.65	56.80	10.69	0.794
15	11.60	8.50	15.40	7.90	1.000
30	0.20	1.00	5.80	5.72	0.000
45	10.20	6.20	13.00	6.45	0.102
60	12.20	8.05	13.60	7.43	0.847
120	11.40	10.16	12.80	8.55	0.787
180	9.00	4.79	11.80	4.54	0.707

Table 10: Patient comfort level Comfort level

Comfort Level	Group - A		Group - B	
	N	%	N	%
1- Poor	0	0	0	0
2- Fair	0	0	15	60
3- Good	8	32	10	40
4- Excellent	0	0	0	0
Chi-Square Value			32.2222	
P value			< 0.001 (Significant)	

Patient Comfort Level

This was assessed by asking the patient how they felt at the end of the delivery. Majority of patients (68%) in group A had excellent pain relief. 32% of patients in group A had good pain relief. In group B, 60% of patients had fair pain relief and 40% of patients had good pain relief (Table 10).

Upper Sensory Level

Patients in both groups had a mean sensory level of T9. The maximum was only T11 and minimum level was T8 (Table 11).

Haemodynamic Variables

All haemodynamic variables were recorded at 0 mins (baseline), 5 mins, 15 mins, 30 mins, 45 mins, 60 mins and thereafter every 15 mins. For the purpose of statistical comparison after the first hour, only the hourly recording or that during every top-up was considered.

Maternal Pulse Rate

Pulse rate recordings were found to be comparable between the two groups. The two way ANOVA test done on the pulse rate recordings showed no statistical difference between the two groups.

Summary of ANOVA for 2X 10 factorial experiment with repeated measures on the second factor (10 times) (Table 12).

Systolic Blood Pressure

Systolic blood pressure were normal (i.e.) > 100 mm of Hg in both the groups and was not statistically significant between the groups (Table 13).

The two way ANOVA test showed no significant statistical difference between the two groups and also with time.

Diastolic Blood Pressure

The two groups had no significant difference in the diastolic blood pressure as was seen in the systolic

Table 11: Upper sensory level

Comfort Level	Group - A		Group - B	
	N	%	N	%
T6	0	0	0	0
T7	0	0	0	0
T8	5	20	6	24
T9	8	32	8	32
T10	7	28	8	32
T11	5	20	3	12

Table 12: Maternal pulse rate

Time in mins	Group - A		Group - B	
	Mean	Std Deviation	Mean	Std Deviation
0	90.26	11.14	91.44	9.57
2	92.43	9.65	93.28	9.57
5	91.48	12.11	89.36	7.20
15	91.83	9.44	89.12	7.66
30	90.87	6.20	86.40	6.03
45	90.09	6.59	85.84	4.93
60	89.74	8.10	87.60	3.61
2 hours	88.35	6.23	89.52	6.12
3 hours	88.48	9.12	89.76	2.07

Sources of variation	Sum of square	DF	Mean square	F value	P value
Between drugs	174.68	1	174.68	0.39	0.53

blood pressure. The two way ANOVA test showed no statistical difference between the two groups (Table 14).

Foetal Heart Rate

There was not much variation between the two groups and the ANOVA test did not show any statistical significance between the two groups (Table 15).

Apgar Score

APGAR score estimated at one and five minutes are tabulated in Table 16.

Complications

Hypotension (SBP <90 mm Hg or < 30% of baseline) was present in one case each in both the groups. Both cases responded to 6 mg of Ephedrine IV. Pruritus was present in one case each in both thegroups. It was only mild and reassurance was all that was needed. One patient in group B had vomiting (Table 18).

Statistical Report

Data were analysed using SPSS 11.5. Descriptive analysis for nonparametric variables was expressed in proportion and parametric variables in mean and standard deviation. The treatment difference was

Table 13: Maternal systolic blood pressure

Time in Mins	Group - A		Group - B	
	Systolic blood pressure Mean	Std Deviation	Systolic blood Pressure Mean	Std Deviation
0	116	6.455	115.84	7.116
5	113.6	9.074	114.4	8.210
15	112.4	7.141	111.12	6.685
30	112.72	7.414	111.84	7.701
45	108.88	7.096	112.4	6.481
60	112.16	7.369	111.12	6.483
2 hours	112.56	9.028	107.24	7.674
3 hours	108.36	7.658	112.40	7.000

Summary of ANOVA for 2X 9 factorial experiment with repeated measures on the second factor (9 times)

Sources of variation	Sum of square	DF	Mean square	F value	P value
Between drugs	16245	2	8122.5	5.871	0.553
With time	8415.4	7	1202.2	0.8689	0.141

Table 14: Maternal diastolic blood pressure

Time in mins	Group - A		Group - B	
	Diastolic blood pressure Mean	Std Deviation	Diastolic blood pressure Mean	Std Deviation
0	75.52	4.665	76.16	4.394
5	75.62	4.605	75.28	4.468
15	75.44	5.116	75.68	5.558
30	74.80	4.619	76.0	4.761
45	75.12	4.438	74.56	5.523
60	75.12	4.868	73.56	4.142
2 hours	76.16	4.394	76.16	4.580
3 hours	75.28	4.686	76.40	4.435

Sources of variation	Sum of square	DF	Mean square	F value	P value
Between drugs	183.6	2	918.28	0.6980	0.5141
With time	9286.9	7	1326.7	1.008	0.4656

Summary of ANOVA for 2X 9 factorial experiment with repeated measures on the second factor (9 times)

assessed using t test for independent samples for parametric variables and by Chi square test for non-parametric variables. Statistical significance was assessed using p at 0.05 cut off or 95% confidence interval (95% CI).

Discussion

A number of methods exist to provide pain relief to the labouring parturient. Of the regional techniques, epidural analgesia is considered the gold standard

Table 15: Foetal heart rate

Time in mins	Group - A		Group - B	
	mean foetal heart rate	Std Deviation	mean foetal heart rate	Std Deviation
0	142.17	8.65	142.24	15.66
5	140.87	11.08	145.28	6.29
15	138.87	7.16	151.00	6.01
30	142.26	6.16	146.00	8.10
45	145.65	7.92	142.92	4.64
60	145.22	9.74	146.72	4.58
2 hours	149.22	10.25	145.68	12.56
3 hours	144.70	12.19	152.88	5.23

Summary of ANOVA for 2X 9 factorial experiment with repeated measures on the second factor (9 times)

Sources of variation	Sum of square	DF	Mean square	F value	P value
Between drugs	945.96	1	945.96	7.3	0.08

Table 16: One minute APGAR

Comfort Level	Group - A		Group - B	
	N	%	N	%
5	0	0	0	0
6	2	2	5	20
7	11	44	6	24
8	12	48	14	56
9	0	0	0	0
10	0	0	0	0

P value by Chi square test did not show statistical difference.

Table 17: Five minute APGAR

Comfort Level	Group - A		Group - B	
	N	%	N	%
5	0	0	0	0
6	0	0	0	0
7	0	0	2	8
8	18	72	15	60
9	5	20	8	32
10	2	8	0	0

P value by Chi square test did not show statistical difference.

Table 19: Complications

Complication	Group – A	Group - B
Hypotension	1	1
Pruritus	1	1
Vomiting	0	1
Respiratory depression	0	0
Urinary retention	0	0

among all other techniques and it is the only technique which can provide a complete and convincing pain relief making labour a pleasurable experience.

In our study, we have demonstrated that with an epidural top-up technique using 0.0625% bupivacaine with fentanyl 2 microgram / ml (group A) analgesia was similar to that using 0.125% plain bupivacaine (group B), but motor power was retained allowing women to mobilize. There also appear to be beneficial effects on the progress of labour, with a clinically important reduction in the length of the second stage.

In our study, the patients in group A had minimal motor blockade when compared to patients in group B. Reduction in motor block allowing independent movement and awareness of contractions withoutpain has been shown to be popular with mothers.

Retention of pelvic floor sensation and motor function may allow appropriate coordinated pushing during the second stage, improving rotation and descent of the fetal head through the pelvis. Epidural local anaesthetic may attenuate endogenous oxytocin production reducing uterine contractility during the second stage.

Both a long second stage and instrumental delivery have associated morbidity for the mother, pose a controversial potential risk to the baby and negatively influence maternal satisfaction with the experience of labour. Although epidural analgesia produces excellent analgesia, this does not automatically produce maternal satisfaction with labour, and less effective methods of analgesia have produced higher satisfaction with scores. We demonstrated high maternal satisfaction with both epidural solutions, which was significantly greater in bupivacaine-fentanyl group.

Analgesia was established by 30 min in all women. Establishing analgesia with an epidural bolus is effective but takes longer than a combined spinal-epidural technique, which has been described widely. However, it avoids the complications of deliberate dural puncture.

The time difference between establishing spinal rather than epidural analgesia should be viewed in the context of the duration of labour and the potential complications of the spinal component of a combined technique.

The blood pressures (both systolic and diastolic) and pulse rate recorded during the analgesia in both the groups were not statistically significant. The APGAR score observed at 1 minute and 5 minutes showed no significant neonatal depression. Complications were only few, were minor and easily manageable.

Conclusion

- In our study, we have shown that establishing epidural analgesia in labour with 15ml of 0.0625% bupivacaine combined with fentanyl 30 microgram followed by top ups of 10ml of 0.0625% bupivacaine with 0.0002% fentanyl, produced similar analgesia to that obtained from the same volume of 0.125% bupivacaine alone, but motor block was minimized. This may influence the progress of labour, decreasing the duration of the second stage and produce high maternal satisfaction with the experience of labour.
- In our study, the APGAR score observed at 1 minute and 5 minutes showed no significant neonatal depression.

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