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Effect of Early vs. Delayed Epidural Labour Analgesia on Maternal and its Outcome.

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ABSTRACT

This study is designed to evaluate and compare the effect of early Vs delayed (≤4cm Vs > 4cm cervical dilatation) epidural analgesia on labour and its outcome. This prospective randomized study conducted at our institute on 100 terms parturient of ASA grade I and II with uncomplicated singleton pregnancy in vertex presentation. Parturient in active labour requesting painless labour included in the study. All cases divided into two groups based on cervical dilatation(Group A: ≤4cm Group B: > 4cm) 50 parturient in each group and both groups received Bupivacaine 0.5% (3 ml) + fentanyl 20 µg and N.S to make up to 10 ml and top-up the same dose. In group A two parturient (4%) delivered by outlet forceps and one parturient (2%) delivered by cesarean section, while in group B one parturient (2%) delivered by outlet forceps and one parturient (2%) delivered by cesarean section. In both groups cesarean section was done due to non- progression of labour and outlet forceps was applied for non- reassuring fetal heart rate. The p value not significant in both groups(P<0.001). Neonatal status in both group's were comparable and all neonates in both groups did not had APGAR score < 7 in 1 min and 5 min. It is not necessary to withhold epidural analgesia for labour pain when parturient is in early phase of labour (cervical dilatation ≤4cm). If there is no medical contraindication, maternal request itself should be sufficient to initiate epidural analgesia for labour pain. Our study confirms the findings of other authors, that there is no increase in rate of cesarean section, instrumental vaginal delivery or any other adverse effects in both mother and neonates, if we provide epidural analgesia in early phase of labour (cervical dilatation ≤4 cm).

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INTRODUCTION

The common belief in many maternity units is that a labouring woman is "not ready yet" for epidural analgesia, forces women to endure hours of extra pain, often while they receive less than adequate alternative methods of pain relief, such as systemic narcotics, with a concomitant increase in side effects for both themselves and their newborns. The recent Americans College of Obstetricians and Gynecologist (ACOG) guidelines is restraining use of epidural analgesia at ≤4cm of cervical dilatation is unnecessary. [4, 6] In the absence of a medical contraindication, maternal request is sufficient medical indication for pain relief during labour.

Aims and Objectives

- This study is designed to evaluate and compare the effect of early Vs delayed (≤4cm Vs > 4cm cervical dilatation) epidural analgesia on labour
- To evaluate and compare the effect of epidural analgesia on neonatal outcome
- To evaluate and compare parturient and obstetricians acceptance

METHODS AND MATERIALS

This prospective randomized study conducted at our institute on 100 terms parturient of ASA grade I and II with uncomplicated singleton pregnancy in vertex presentation. Parturient in active labour requesting painless labour included in the study. Following approval of protocol by the review committee of our institution and informed consent from all patients, they were subjected to through pre-anaesthetic evaluation to rule out any anatomical and systemic disorders. A routine pre-anaesthetic evaluation will include the past history of chronic illness and medication, drug therapy (especially corticosteroid, antihypertensive, anticoagulant, antidiabetic) drug sensitivity and past anaesthetic experience along with routine investigations. Categorial data compared two groups using chi-square test. The student t test and Mann-Whitney U test were used to analyze interval and ordinal data.

Exclusion criteria includes to study drugs, bleeding disorders, decreased platelet count, local or systemic sepsis, blood/ CSF in the epidural catheter during procedure, a history a drug abuse parturient refusal. [1,3]

All cases divided into two groups based on cervical dilatation:

- Group A: ≤4cm(n= 50)
- Group B: > 4cm (n=50)
-

All the 100 parturient will the following drug combination

Epidural bolus	Top up doses I
Bupivacaine 0.5% (3 ml) + fentanyl 20 µg and N.S to make up to 10 ml	Drug same as bolus (on demand)

Before the procedure, IV infusion with 500 ml Ringer lactate solution was started. Each parturient participating in the study was evaluated by a pain score before using a 10cm visual analogue scale (0 –no pain, 10 = worst pain imaginable). [3,4]

Parturient in both groups were placed in left lateral position and following strict aseptic precautions, a local infiltration of 2% lignocaine HCI was given and epidural space identified at L3- L4 or L4- L5 space using a loss of resistance technique to air with an 18G Toughly needle. A multiple port epidural catheter was placed 3-4 cms in epidural space and the patient was positioned in semi recumbent, 30 Left lateral position. [2,5] The epidural bolus of 10cc solution containing 15 mg (0.15%) bupivacaine and 20 mg fentanyl injected through catheter.

Following parturient were given the following instructions:

1. Pass urine every hour
2. Do not walk barefooted

Parturient were assessed 20 minutes after a bolus dose to determine the effectiveness of analgesia. Those satisfied with their analgesia continued to receive the study drug until delivery or until they request additional analgesia. Parturient experiencing inadequate analgesia at any time were given another 10ml bolus of study drug in the sitting position.

Before giving each top up, parturient was asked of pass urine. Following every top up dose parturient was monitored carefully for 10 minutes to detect any weakness or inadequate analgesia. If analgesia is inadequate top up repeated up to maximum of 10 ml at a time.

Parturient vital parameters- pulse, blood-pressure , respiratory rate , motor power grade (including Breen modified Bromage scale, straight leg raising test, trial walk and Romberg's sign), fetal heart rate, any side effects or complaints were noted at different time interval. Pain and motor block scores, block height (level), balance, ability to stand was assessed at thirty minutes or hourly after each dose. [6,8]

Pain scoring was done by using a visual an analogue score and motor scoring was done as suggested by Breen modified Bromage score, SLR, trial walk (TW) and Romberg's sign for measuring ambulation during labour. [8,9,10]

The following estimations were done:

Block level: The spread of sensory block assessed bilaterally to pinprick from the unanaesthetized to the anaesthetized zones and also by perceived temperature difference to spirit swab.

Quality of analgesia: Quality of analgesia throughout labour assessed by the following scoring system (Celleno and Capogna 1988).

- Failure, 1 – Incomplete, 2 – Good, 3 – Excellent and 4 – NPE (not possible to evaluate) need delivery by cesarean section.

Motor block assessment:

A. Breen modified Bromage score (BMB), 1993 [13]

Grade 1 – Complete block (unable to move feet or knee)
Grade 2- Almost complete block(able to move feet only)
Grade 3- partial block but able to move knees
Grade 4 – Detectable weakness of hip flexion(between scores 3 and 5)
Grade 5- no detectable weakness of hip flexion while supine (full flexion of knees)
Grade 6- Able to perform partial knee bend while standing.

B. Romberg's sign:

The parturient were asked to stand by the side of bed with her eyes closed. If she sways or tends to fall this sign was considered positive. It is a test for loss of position sense in the legs. [31,32,33]

C. Straight log raising test (SLR Sign):

When parturient is in supine position and holding the knees straight if she can lift each limb and sustain it for sometime then it was considered a negative test, strong sustained SLR test is a sensitive method of testing whether a mother can stand by her bed or ambulate with an epidural.

D. Trial walk:

All parturient were given a trial walk to assess their ability to ambulate along with the above tests.

1. Visual Analogue Score (VAS) [13,14,15]
   VAS was assessed every 15 minutes for 1 hour then whenever patient demands analgesia.
   0 cm - No pain, 10 cm- Maximum Pain
2. Verbal Pain Score (VPS) 0 Gr- No pain, 4 Gr- Maximum Pain
   The presence or absence of the oxytocin infusion and bladder catheterization in the last hour was noted. [34, 35, 36]
3. Parturient acceptance:
   Degree of pain relief or quality of analgesia (Tyagi et al 1994). Gr, 3 Excellent – with the uterine contraction patient has no sensation of pain. [28,29,30]

Gr. 2 Good – the patient was aware of uterine contractions and experienced dull ache in the back.
Gr. 1 Incomplete or fair – the patient experienced some pain or the relief was on one side only even with advancing labour with increased intensity of uterine contraction.
Gr.0 Failures or poor- there was no pain relief

4. The time of epidural bolus and further epidural top up was recorded. Walking duration (out of bed) mode of delivery, quality of maternal expulsive efforts, and maternal satisfaction score (0-10) also noted.
5. Side effects including nausea, vomiting , hypotension, hypersensitive reaction, shivering, fever, drowsiness, purities, respiratory depression, retention of urine, weakness in limbs, accidental dural puncture was assessed at 0,5,15,30,60 min then every hour, ;until complete cervical dilatation and at delivery. Neonatal assessment was done by assessing the Apgar score at 1,5 minute after delivery. [15,16,17]

DEMOGRAPHIC DATA

S.No	Parameters	Group A	Group B	P value
1.	Age in Year (Means±SD)	23.16±2.90	24.54±2.98	NS
2	Weight in Kg. (Mean±SD)	54.60± 2.81	53.96±3.10	NS
3	Height in cm (Mean ± SD)	154.74±3.05	153.24± 3.14	NS
4	Parity (no.) Primi/ Second Gravida	44/6	42/8	
5	Gestational age in wks (Mean ± SD)	37.02±0.65	37.16±0.42	NS
6.	Socio-economic status (no./%) High	17(34)	18(36)	NS
	Low	33(66)	32(64)	NS
7	Educational status (no./%)Educated	35(70)	36(72)	
	Uneducated	15(30)	14(28)	NS

On comparison of demographic data in both groups there was no statistical significance (p>0.05).

TABLE 2

S.No	Parameters	Group A(Mean±SD)	Group B(Mean±SD)	P Value
1.	Cervical dilatation at start of Epidural analgesia (cm)	2.76±0.48	4.84±0.91	<0.001
2	Station of vertex at start of Epidural analgesia	-1.08±0.45	-1.10±0.30	<0.05
3	Duration of 2nd stage of labour (min)	41.40±11.95	33.80±11.63	<0.05
4	Interval between injection of drug to 2nd stage of labour (min)	226.46±119.57	142.28±109.18	<0.05
5	Injection delivery interval (min)	267.86±123.80	176.08±114.73	<0.001
6	Timing of last top-up to delivery (min)	75.54± 47.29	73.52±35.92	NS

On comparison of both the groups, except timing of top-up to delivery all other parameters (cervical dilation and station of vertex at start of epidural, duration of 2nd stage labour, interval between start of cervical

dilatation and complete cervical dilatation and injection delivery interval) achieved statistical significance (p< 0.05).

CLINICAL DATA AND DOSE REQUIREMENT-TABLE 3

S.No	Parameters	Group A(mean ±SD)	Group B(mean ±SD)	P value
1.	Number of top-up doses	2.19±1.20	1.58±0.87	<0.05
2.	Total dose of Bupivacaine (mg)	42.90±20.33	32.40±15.26	<0.05
3	Total dose of fentanyl (µg)	56.48±28.04	43.64±21.18	<0.05

Total dose requirement of bupivacaine, fentanyl was more in group A as compared to group B(P< 0.05).

ONSET OF ANALGESIA –TABLE 4

S.No.	Time(min)	Group A No. (%)	Group BNo.(%)
1.	0-5	6(12%)	5(10%)
2	>5-15	42(84%)	45(90%)
3	>15-30	2(4%)	0
4	>30	0	0

Table IV shows that onset of analgesia was achieved within 5-15 min in maximum number of parturient (84% group A and 90% in group B). Two parturient in group A had inadequate analgesia with the first dose and required an additional dose of epidural top-up within 30 min.

EPIDURAL BLOCK CHARECTERISTICS-TABLE 5

S.No	Observation with initial bolus dose	Group A (mean ±SD)	Group B(mean ±SD)
1	Effective duration of analgesia of first bolus dose (min)	97.96 ± 46.54	80.86 ± 41.66
2	Level of Analgesia (Thoracic)	9.16 ± 1.00	9.24 ± 0.98

P-NS

The effective duration of analgesia of first bolus dose was prolonged in group A, though it did not achieve any statistical significance (P> 0.05), while the level of analgesia achieved in the thoracic dermatome was comparable in both groups (statistically not significant) .

PAIN ASSESSMENT

Visual Analogue Pain Scale (0-10)				
	Group A(n=50)		Group B(n=50)	
Time (min)	Mean	Range	Mean	Range
0	8.72	8 - 10	8.64	8 - 10
5	2.5	0 - 6	2.36	0 – 4
15	0.16	0 – 4	-	-
20	2.00	2 – 2	-	-
30	-	-	-	-
Verbal pain Score (0 4)				
Time (min)	Mean	Range	Mean	Range
0	3.6	3 – 4	3 .48	3 – 4
5	1.46	0 – 4	1.32	0 – 2
15	0 .12	0 – 3	0	0 – 0
20	2	2 – 2	-	-
30	-	-	-	-
No. of parturient who require additional analgesia. (within 30 min)				
	2		-	

Satisfactory pain relief in most parturient was achieved within 15 min both groups. Only two parturient in group A required additional analgesia within 30 min.

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Motor Power Assessment					
S. No.	Tests	Time (min)			
		0	30	60	180
1.	Grading of Motor Power BMB (Grade 6) Group A Group B	 50 50	 49 49	 49 50	 50 50
2	Romberg's Sign (negative) Group A Group B	 50 50	 49 49	 49 50	 50 50
3	SLR test (negative) Group A Group B	 50 50	 50 50	 50 50	 50 50
4	Trial Walk Group A Group B	 50 50	 49 49	 49 50	 50 50

The above table shows one parturient in both groups had a BMB score of 5 for up to 60 min in group A up to 30 min in group B but in both the groups parturient were able to do SLR and these parturient were not allowed to do Romberg's sign and trial walk till motor power was adequate.

Hemodynamic Parameters			
S.No.	Haemodynamic Data	Group A (Mean± SD)	Group B (Mean ±SD)
1	Baseline MAP mmHg	93.48±5.50	94.76±5.98
2	Lowest MAP (mmHg)	83.33	83.33
3	Baseline Heart rate (bpm)	77.74±3.19	78.12± 4.16
4	Lowest Heart rate (bpm)	73	70

P=NS

S. No.		Group A(n=50)	Group B(n = 50)
1 a. b. c.	Mode of Delivery SPND Instrumental vaginal Delivery (outlet assisted forceps) Cesarean Section	 47 (94%) 2(4%) 1(2%)	 49(96%) 1(2%) 1(2%)
2 a b C	Indication for Instrumental vaginal delivery Elective Non reassuring FHR Prolonged second stage (≥3hr)	 0 2 1	 0 2 0

In group A two parturient (4%) delivered by outlet forceps and one parturient (2%) delivered by cesarean section, while in group B one parturient (2%) delivered by outlet forceps and one parturient (2%) delivered by cesarean section. In both groups cesarean section was done due to non- progression of labour and outlet forceps was applied for non- reassuring FHR.

Neonatal Status			
S.No.	Observations	Group A (Mean ±SD)	Group B (Mean ±SD)
1	Weight of new born (Kg)	2.88 ±0.219	2.78 ± 0.15
2	APGAR score a) at 1 min	 7.92±0.34	 7.96±0.20
	b) < 7at 1 min (no.)	0	0
3	APGAR score a) at 5 min	 9.42±0.54	 9.38±0.49
	b) < 7 at 5 min (no.)	0	0
4	Foetal distress (no.)	3	1
5	Respiratory depression (Neonatal) (no.)	0	0

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Neonatal status in both group's were comparable and all neonates in both groups did not had Apgar score < 7 in 1 min and 5 min.

Paturient Acceptance and Obstetrician's Response					
		Group A		Group B	
		No.	%	No.	%
	Grade 0 Failure	0	0	0	0
	Grade 1 Incomplete	2	4%	2	4%
	Grade 2 Good	31	62%	32	64%
	Grade 3 Excellent	17	34%	16	32%
	Good	16	32%	10	20%
	Moderate	25	50%	33	66%
	Fair	6	12%	5	10%
	Poor	3	6%	2	4%

Table shows maximum number of parturients (96%) accepted the procedure with good to excellent grading and obstetrician's response (86%) was good to moderate

Maternal Side Effects			
S. No.		Group A No. (%)	Group B No. (%)
1	Nausea & Vomiting	0	1(2%)
2	Hypotension	1(2%)	1(2%)
3	Hypersensitivity reaction	0	0
4	Pruritus	0	0
5	Respiratory depression	0	0
6	Retention Urine	1(2%)	1 (2%)
7	Weakness in limbs	1(2%)	1(2%)
8	Shivering	1(2%)	0
	Total	6(12%)	4(8%)

SUMMARY AND DISCUSSION

The present study was conducted in our institute. after institutional review board approval and informed consent one hundred healthy term parturient with uncomplicated singleton pregnancy in vertex presentation of ASA I and II grade were recruited into two groups (50 each) ; with cervical dilatation ≤4cm in group A and cervical dilatation >4 cm in group B.[17,18] In both groups, the following dose was injected in the epidural space, both as a initial bolus and subsequent top-up does : Bupivacaine 0.5% 3ml + Fentanyl 20 µg with normal saline to make the solution up to 10 ml and a concentration of Bupivacaine 0.15%.

Our observation was as follows:

1. There was no significant difference in demographic data and obstetric data between the two groups ($p>0.05$).
2. The total time duration from injection of the drug to delivery was more in group A and it was 267.86 11.95 min in group A and 33.80 11.63 in group B ($p<0.05$). There was a prolongation of 2nd stage of labour in group A when compared with group B
3. The onset of analgesia were almost equal in parturient of both groups (5-15 min). There was no significant prolongation in effective duration of analgesia in both groups (requirement of first top-up does), which was 97.96 46.54 min in group A and 80.86 41.66. min in group B. ($0p<0.05$). Quality of analgesia was assessed by VAS and VPS at different time interval and was almost similar in both groups.
4. Quality of motor block:

   There was no significant difference in the degree of motor blockade in parturient between the two groups. No parturient fell down during the study, although one parturient in both group had a BMB motor grade <6 for 60 min in group A and 30 min in group B. Approximately 84% parturient in group A and 78% parturient in group B, were able to get out of bed for 25-50% off study time.

5. There was no significant difference in hemodynamic status of parturient in both group. Two parturient in group A and one parturient in group B required a single dose of vasopressor (6mg of Ephedrine hydrochlorides intravenously).
6. The incidence of spontaneous vaginal delivery in group a (94%) and group B (98%) was similar, with 4% instrumental vaginal delivery in group A and 2% instrumental vaginal delivery in group B and 2% cesarean delivery each in both the group.[20.,21,22]
7. Neonatal outcome was favourable (Apgar score >7 at 1& 5 min) in both the groups and there was no deleterious effect on neonatal outcome. [23, 24, 25]
8. In both groups preservation of maternal expulsive force made both parturient and obstetrician's to accept this procedure and express satisfaction as the incidence of side effects in both groups were almost similar.[26, 27]

CONCLUSION

To conclude it is unnecessary to withhold epidural analgesia for labour pain when parturient are in early phase of labour (cervical dilatation ≤4cm). If there is no medical contraindication, maternal request itself should be sufficient to initiate epidural analgesia for labour pain. Our study confirms the findings of other authors, that there is no increase in rate of cesarean section, instrumental vaginal delivery or any other adverse effects in both mother and neonates, if we provide epidural analgesia in early phase of labour (cervical dilatation ≤4 cm)

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