A prospective randomised comparative study of epidural bupivacaine and levobupivacaine after single dose of intrathecal fentanyl for combined spinal epidural labour analgesia

Bhavya Reddy H A¹, Priyadharshini V C Moorthy^{2*}, Shilpa H L³, Prajwal C Gowda⁴,

Ramesh Kumar P B⁵

^{1,2}Assistant Professor, ³Associate Professor, ⁴Senior Resident, ⁵Professor & HOD, Department of Anaesthesiology and Critical Care, BGS Global Institute of Medical Sciences, Bangalore, Karnataka, INDIA. **Email:** <u>bhavyareddyha@gmail.com</u>

Abstract

Background: Pain relief in labour has always been surrounded with myths and controversies. Providing effective and safe analgesia during labour has remained an ongoing challenge. Advances in the field of labour analgesia have tread a long journey from the days of ether and chloroform in 1847 to the present day practice of comprehensive labour pain management using evidence based medicine. Neuraxial techniques were introduced for pain relief in labour in 1949. Present study was undertaken at BGS GIMS Hospital, Bangalore. It is a prospective comparative double blind study. 60 patients were enrolled, 30 in each group. Sample size was calculated from a similar previous study. Randomization was done. Group B received epidural 0.125% Bupivacaine with intrathecal fentanyl 25mcg and Group L received epidural 0.125% Levobupivacaine with intrathecal fentanyl 25mcg. All patients had IV access with 18G cannula and preloaded with 500ml RL. ECG, Pulse oximeter, NIBP were connected and vitals recorded. Resuscitative equipment and drugs were kept ready. After subarachnoid blockade, fentanyl was injected and epidural space was identified and epidural catheter was inserted and fixed. Test dose of 2% lignocaine+ adrenaline was given. Then the study drug was injected; 10ml in amount through epidural in increments of 5ml. Time was noted. Time duration till the subsequent analgesia required was recorded. Time interval between test dose of epidural analgesia and patient developing pain equivalent to VAS score >4 was recorded. Such patients were treated with subsequent incremental doses. Total number of doses and duration between successive doses was recorded. Heart rate, oxygen saturation, NIBP monitored. Fetal heart rate (FHR) was also monitored. Adverse effects were monitored and treated. Statistical analysis of data was done by Student t test, Chi square test and Fisher Exact test. Results: - Intrathecal fentanyl has rapid onset of action and was associated with increased maternal satisfaction; Initial duration of analgesia was longer in parturients who received epidural dose of levobupivacaine 0.125% compared to bupivacaine 0.125%. levobupivacaine group of patients required more top ups compared to bupivacaine. Key Words: Labour analgesia, parturient, epidural.

*Address for Correspondence:

Dr Priyadharshini V C Moorthy, Assistant Professor, Department of Anaesthesiology and Critical Care, BGS Global Institute of Medical Sciences, Bangalore, Karnataka, INDIA.

Email: maildrpvcm@gmail.com

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INTRODUCTION

Pain relief in labour analgesia has always been surrounded with myths and controversies; Advances in the field of labour analgesia have tread a long journey from days of Ether and chloroform to the present day practice of comprehensive labour pain management using evidence based medicine¹ Neuraxial techniques were introduced for pain relief in labour in 1949;² Lumbar epidural analgesia is considered the modality of choice for labour analgesia;⁽³⁾

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Combined spinal epidural blockade has been found to be the most effective method of providing analgesia during labour;⁴ According to the American College of Obstetricians and Gynaecologists, pharmacological analgesia is safe intervention to relieve pain and physical discomfort;5 CSEA consists of identification of epidural space and insertion of an epidural catheter plus the initial intentional intrathecal dose opioids, local anaesthetic or both as single procedure;6 Bupivacaine and levobupivacaine have been widely used to provide efficient epidural analgesia in labour.²,⁴ Bupivacaine is a long acting amide and has beneficial ratio of sensory to motor block in epidural labour analgesia; but risks of motor blockade and cardiotoxicity are the limitations.7 It has potential for neurotoxicity.8 Levobupivacaine has similar effects as bupivacaine but has less side effects on cardiovascular system and central nervous system. Hence it seems to be an attractive alternative to bupivacaine; Diluted solutions of local anaesthetics are used in this study to minimize the unwanted motor blockade;

MATERIALS AND METHODS

The present study is a prospective randomized comparative double blinded study conducted at BGS GIMS Hospital, Bangalore during the period of June 2019- May 2020. Institutional Ethical committee approval was obtained and informed consent was taken from all the patients; 60 patients were enrolled after meeting the inclusion and exclusion criteria; 30 in each group, sample size was calculated from previous similar study; Inclusion criteria includes maternal request for labour analgesia, ASA G I, II, primigravida patients with gestational age \geq 36 weeks, singleton vertex presentation, women in active labour with cervical dilatation < 5cms, age group of 18-30 years, height 150-170 cms. Patients with preterm gestation, multiple pregnancies, cephalopelvic disproportions, ante partum haemorrhage, previous LSCS, neurological diseases, HIV, HbSAG reactive status are excluded. A detailed preanaesthetic examination was performed; noting down vitals, condition of membranes, fetal heart rate. Randomization was done including computer generated tables;

Group B – received epidural 0.125% bupivacaine + 25 mcg intrathecal fentanyl

Group L – received epidural 0.125% levobupivacaine +25 mcg intrathecal fentanyl

Intravenous access was secured with 18G cannula for all the patients, preloaded with RL 500ml;

ECG, Pulse oximeter, NIBP connected and basal values recorded; Resuscitative equipment and drugs were kept ready; Parturient and the anaesthesiologist performing the technique were blinded to the drug; Under strict aseptic precautions and patient in sitting position, subarachnoid block was performed in L₂-L₃ or L₃- L₄ interspace with 25 G (Q) spinal needle and after confirming clear, free flow of CSF 25 mcg fentanyl was injected. Epidural space was identified and confirmed by LOR to air technique, catheter threaded in cephalad 3-4 cms and fixed; after confirming negative aspiration for blood and CSF, test dose of 3ml of 2% lignocaine + adrenaline 1: 2,00,000 was administered through the catheter to see if any intravascular placement. Heart rate more than 30 beats/ minute from baseline within 20-40 seconds is noted as positive test; if any positive test then the patient is excluded from the study. Study drug containing 10ml of 0.125% bupivacaine and 0.125% levobupivacaine was prepared and given in the increments of 5ml. The time of administering the study drug was noted, time duration till subsequent analgesia request was recorded, time interval between first dose of epidural analgesia and patient developing pain equivalent to VAS > 4 was defined as duration of analgesia was recorded and such patients were given increments of 5ml of test drug with minimum interval of 20 minutes between successive doses; Total number of epidural doses and duration between successive epidural doses was recorded; Oxygen saturation, NIBP, HR were noted before insertion and after insertion of catheter and at the time of first epidural bolus and at 5,10, 15, 20, 25, 30 minutes after first epidural bolus and every half hourly after that until delivery; FHR, cervical dilatation, any infusions like oxytocin were also noted down:

Adverse effects like hypotension, bradycardia were noted and treated;

After administration of bolus following parameters were noted;

- Pain score assessed by using visual analogue scale (VAS) 0-10, where 0- no pain and 10–worst possible pain.
- Highest level of sensory block assessed by gentle pin prick.
- Degree of motor blockade is assessed by using Bromage scale.
- Total dose of local anaesthetic administered per hour and number of additional supplements was recorded.

All these parameters were assessed at 5, 10, 15, 20, 25 and 30 minutes after the initial bolus and every half hourly thereafter.

The parturients were monitored for 2 h following delivery and the epidural catheter was removed. The following were noted.

- 1. The mode of delivery normal vaginal, instrumental vaginal, caesarean section
- 2. Assessment of Newborn Assessed for weight, and Apgar at 1 min and 5 min.
- 3. Other Associated side effects like shivering, nausea, vomiting, pruritis experienced by the patient were

categorized as none, minimal, moderate, severe

- 4. Enquiry about the symptoms related to post-dural puncture headache (PDPH) was done during the duration of hospital stay.
- 5. Parturient's satisfaction They were questioned 24 hrs after delivery regarding the procedure and their satisfaction.

OBSERVATION AND RESULTS

Table 1: Age distribution of patients studied

Age in years	Group L		Gro	oup B
	No	%	No	%
<20	1	3.3	1	3.3
20-30	29	96.7	28	93.3
>30	0	0.0	1	3.3
Total	30	100.0	30	100.0
Mean ± SD	23.4	3±2.87	22.6	3±2.94

Samples are age matched with P=0.291 Both the groups, L (Levobupivacaine) and B (Bupivacaine) were similar with respect to age of the parturients. Mean age in group L was 23.43 and SD of 2.87. In group B mean age was 22.63 with SD of 2.94. P-value was 0.291 and statistically insignificant.

Table 2: Height (cm) distribution in two groups of patients studied

Height (cm)	Group L		Gro	oup B
	No	%	No	%
141-150	6	20.0	4	13.3
151-160	23	76.7	23	76.7
161-170	1	3.3	3	10.0
Total	30	100.0	30	100.0
Mean ± SD	154.:	154.17±4.12		90±4.37

Samples are height matched with P=0.506

Height of parturient studied ranged from 145 cm to 165 cm. Shortest height was 147cm and tallest being 163cm in group L . Shortest height 146 cm and tallest being 162 cm in group B. The mean height and standard deviation were 154.17 cm and 4.12 in group L and 154.9 cm and 4.37 in group B respectively. The P-value of 0.506 was statistically not significant.

Table 3: Weight (kg) distribution in two groups of patients studied

Weight (kg)	Group L		Gr	oup B
	No	%	No	%
<50	2	6.7	1	3.3
50-60	16	53.3	21	70.0
61-70	10	33.3	7	23.3
71-80	2	6.7	1	3.3
Total	30	100.0	30	100.0
Mean ± SD	59.8	0±6.55	58.7	0±6.16

Samples are weight matched with P=0.505Most of the parturients weighed between 50-60 kgs in both the groups. In group L the mean weight was 59.8 kg and SD 6.55. In group B the mean weight was 58.7 kg and SD 6.16. Table 4: Parity distribution in two groups of patients studied

Parity	Group L		Gr	oup B
	No	%	No	%
Gravida	15	50.0	15	50.0
Para	15	50.0	15	50.0
Total	30	100.0	30	100.0
P=1.000, Not significant, Chi-Square test				

There was 15 parturients who were primigravida in each group and 15 members who were multigravida, Both were equally divided in each group .P value was 1 hence not significant.

Table 5: Cervical dilatation distribution in two groups of patients

studied					
Cervical	Group L		Gro	oup B	
dilatation	No	%	No	%	
3	12	40.0	14	46.7	
4	18	60.0	16	53.3	
Total	30	100.0	30	100.0	

50% of patient in group L and 43% of patient in group B had cervical dilatation of 5 cm 33% of patient in group L and 43% of patient in group B had cervical dilatation of 6 cm.

Table 6: Motor Blo	ckade Grade	e distribution i	n two	groups	of
	nationte	ctudiad			

	putients studied					
Мо	Motor Blockade		Group L		Group B	
	Grade	-	No	%	No	%
	0		26	86.7	19	63.3
	1		4	13.3	9	30.0
1	2		0	0.0	2	6.7
1	Total	0	30	100.0	30	100.0
0	X2 = 6.3 P=0.04 S					

Table 6 shows grade of motor blockade by Bromage scale. 86.7% parturients in the levobupivacaine group compared to 63.3% parturients in bupivacaine group had grade 0 motor blockade while grade 1 motor blockade was observed in 13.3% parturients of levobupivacaine group and 30% parturients of bupivacaine group. Grade II motor blockade was not present in levobupivacaine group but was present in 6.7% parturients of bupivacaine group. P value of 0.04 was statistically significant hence signifies more motor blockade in the bupivacaine group than in the levobupivacaine group.

 Table 7: Comparison of Heart Rate (min) in two groups of patients

 studied

	studied		
Heart Rate (min)	Group L	Group B	P value
Before Spinal	96.63±10.99	94.67±7.75	0.426
epidural			
On epidural 0 min	88.77±7.76	87.90±7.55	0.663
5 min	86.13±7.66	112.63±14.70	0.334
10 min	80.43±8.19	83.90±6.78	0.079
15 min	79.77±9.18	81.93±6.19	0.288
20 min	79.47±6.22	79.73±6.63	0.873
25 min	79.30±7.08	79.73±8.05	0.825
30 min	79.27±7.22	77.43±8.33	0.366

60 min	77.73±6.71	75.40±8.87	0.255		
90 min	81.53±5.33	74.97±6.90	<0.001**		
120 min	81.07±5.23	76.20±6.00	0.001**		
150 min	81.20±6.46	75.83±6.36	0.002**		
180 min	85.00±9.86	90.14±14.39	0.192		
210 min	91.90±13.24	101.50±19.09	0.395		
** Strongly significant (P value : $P \le 0.01$)					

Table 7 shows mean pulse rate \pm SD per min. It was statistically significant at end of 90 min with mean difference being 6.9 and p of <0.001 which was significant.

At 120 min with mean difference of 6 and p 0.001 which was statistically significant and 150 min with mean difference of 6.36 and p 0.002 which was statistically significant.

Heart rate was significantly decreased in the bupivacaine group at 90, 120 and 150 min i.e in the later stages of labour.

Table 8: Comparison of SBP (mm Hg) in two groups of pati	ents
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	studied		0.00
SBP (mm Hg)	Group L	Group B	P value
Before Spinal	120.13±6.62	120.50±7.61	0.843
epidural			
On epidural 0 min	118.60±6.50	119.80±7.01	0.495
5 min	117.47±6.12	118.20±6.35	0.651
10 min	116.93±8.17	114.87±6.62	0.286
15 min	118.67±5.34	111.40±11.73	0.003**
20 min	117.33±6.29	112.93±5.25	0.005**
25 min	106.60±20.75	111.77±10.25	0.226
30 min	99.97±32.05	106.13±13.29	0.334
60 min	106.33±25.75	106.00±13.35	0.950
90 min	113.4 <mark>0±</mark> 23.48	110.40±13.22	0.544
120 min	111.93±21.08	114.87±8.48	0.482
150 min	110.13±9.60	112.07±8.56	0.414
180 min	118.00±6.63	116.09±7.3 <mark>9</mark>	0.393
210 min	119.67±5.90	121.00±12.73	0.800

** Strongly significant (P value : $P \le 0.01$)

Table – 8 shows the mean systolic pressure changes. Systolic pressure showed a decline to 111.40±11.73 mm of Hg in bupivacaine group at 15 min and 112.93 ± 5.25 at 20 min which was statistically significant.

This indicates that there was more fall of systolic pressure initially after the first bolus of epidural injection. The difference was not significant after the initial fall of systolic pressures.

Table 9: Comparison of DBP (mm Hg) in two groups of patients studied

DBP (mm Hg)	Group L	Group B	P value
Before Spinal	80.80±5.14	78.20±6.79	0.100
epidural			
On epidural 0 min	78.00±14.98	78.80±4.51	0.780
5 min	79.73±2.86	78.13±3.71	0.067+
10 min	78.27±8.01	75.33±9.77	0.209
15 min	80.47±2.39	76.93±4.83	0.001**
20 min	79.60±5.72	74.00±10.18	0.011*

25 min	72.20±11.10	74.77±10.66	0.365
30 min	73.90±10.95	76.93±9.38	0.254
60 min	75.47±9.70	74.87±9.58	0.810
90 min	76.63±8.22	78.00±9.60	0.556
120 min	74.33±9.10	74.27±10.38	0.979
150 min	76.47±8.45	75.73±9.27	0.750
180 min	82.64±4.42	77.26±7.58	0.008**
210 min	86.00±2.83	78.00±7.29	0.162
** Strongly si	ignificant (P value	$\cdot P < 0.01$	

Strongly significant (P value : $P \le 0.01$)

Table - 9 shows the mean diastolic pressure changes. Diastolic pressure showed a decline in the bupivacaine group at 15 min, 20 min and 180 min which was statistically significant. This indicates that there was more fall of diastolic pressure initially after the first bolus of epidural injection. The difference was not significant after the initial fall of diastolic pressures except at 180 min.

Table 10: Comparison of Visual Analogue Scale (pain score) in two groups of patients studied

_	0 1			
	Visual analogue scale	Group L	Group B	P value
	Pain			
	Before Spinal Epidural	8.33±0.61	8.43±0.57	0.513
	On epidural 0 min	2.40±0.62	2.40±0.67	1.000
	5 min	2.37±0.49	2.40±0.50	0.795
	10 min	2.40±0.62	2.33±0.66	0.689
	15 min	1.77±0.50	1.40±0.56	0.010**
	20 min	1.33±0.48	1.30±0.47	0.786
	25 min	1.40±0.62	1.10±0.31	0.021*
	30 min	1.40±0.50	1.30±0.47	0.425
	60 min	2.17±1.15	1.83±0.59	0.163
	90 min	2.07±1.23	2.47±1.36	0.414
	120 min	1.83±2.09	1.70±1.21	0.763
	150 min	1.47±0.57	1.47±0.51	1.000
	180 min	1.83±0.79	2.55±0.74	0.005**
	210 min	2.40±1.26	4.00±1.41	0.138

** Strongly significant (P value : $P \le 0.01$)

Table 10 shows pain relief during labour by patient feed back method using visual analogue scale.

VAS scores were less and statistically significant in Group B at 15, 25 and 180 min.

Table 11: Mode of deliver	y of foetus in t	the two groups o	of patients
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studied							
Outcome	Gr	oup L	Gr	oup B			
	No	%	No	%			
Normal	22	73.3	19	63.3			
Forceps	4	13.3	6	20.0			
Caesarean	4	13.3	5	16.7			
Total	30	100.0	30	100.0			

P=0.735, Not significant, Chi-Square test

Table-11 shows mode of delivery in which 73.3% of parturients in levobupivacaine group went for normal delivery, 13.3% for forceps and 13.3% for caesarean section while in the bupivacaine group 63.3% went for normal delivery, 20% for forceps and 16.7% for caesarean section

Table 12: Foetal Bradycardia in two groups of patients studied

Foetal Bradycardia	Group L		Group B		
	No	%	No	%	
No	26	86.7	24	80.0	
yes	4	13.3	6	20.0	
Total	30	100.0	30	100.0	
P=0.488, Not significant, Chi-Square test					

Table 12 shows the occurrence of Foetal bradycardia which was 13.3 % in levobupivacaine group and 20 % in bupivacaine group with p value of 0.488 which was not statistically significant

Table 13: APGAF	score in two	groups of	patients studied
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-							
Apgar	Gro	oup L		Group B		Р	
score	(n:	=30)	Mean	(n:	=30)	value	Mean
	No	%	Score	No	%	-	Score
1 min							
≤7	8	26.7		5	16.7	0.347	7.83±0.38
>7	22	73.3	7.80±0.55	25	83.3		
5 min							
≤7	2	6.7		1	3.3	1.000	8.90±0.40
>7	28	93.3	8.53±0.63	29	96.7		

Chi-Square test/ fisher Exact test

Table-13 shows the APGAR Score of the newborn at 1 and 5 min. Mean score was 7.80±0.55 for group L and 7.83±0.38 for group B. 26.7% of cases in group L and 16.7 % in group B had a score of \leq 7 while 73.3% of group L and 83.3% of group B had a score of >7 at 1 min resulting in a P value of 0.347 which was not significant. Mean score was 8.53±0.63 for group L and 8.90±0.40 for group B. 6.7 % of cases in group L and 3.3% in group B had a score of ≤ 7 while 93.3% of group L and 96.7 % of group B had a score of >7 at 5 min resulting in a P value of 1 which was not significant.

Table 14: Comparison of Analgesia duration / Duration of labour

Variables	Group L	Group B	P value
Analgesia	104.33±19.38	82.67±16.17	<0.001**
duration			
Duration of	194.13±24.70	185.97±15.00	0.127
labour			

** Strongly significant (P value : $P \le 0.01$) Table 14 shows the analgesia duration was 104.33±19.38 in group L and 82.67±16.17 in group B with a P value of <0.001 which was highly significant. Duration of labour was 194.13±24.70 in group L and 185.97±15.00 in group B with a P value of 0.127 which was not significant.

Table 15: Comparison of total Dose of drug used and no of top ups givon

	given		
Variables	Group L	Group B	P value
Total Dose of drug used	33.18±5.25	31.80±1.31	0.167
No of top ups given	3.63±1.63	3.13±0.87	0.0038**
** Strongly sig	gnificant (P val	ue: P < 0.01)	

Strongly significant (P value : U.UI)

Table 16 shows the total dose of drug used which was 33.18±5.25 mg in group L and 31.80±1.31 mg in group B with a P value of 0.167 which was not significant. The total no of top ups showed a significant difference with the bupivacaine group requiring less no of top ups than the levobupivacaine group. Mean number of top ups in group L is 3.63 ± 1.63 and 3.13 ± 0.87 in group B with a P value of 0.0038 which was significant.

Table 16: Comparison of the side effects in two groups studied							
Side effects	Group L		Group B		P value		
	(n	i=30)	(n=30)		=30) (n=30)		_
	No	%	No	%	-		
Sedation	10	33.3	11	36.7	0.787		
Nausea	8	26.7	8	26.7	1.000		
Vomiting	5	16.7	5	16.7	1.000		
Pruritis	30	100.0	30	100.0	1.000		
Hypotension	3	10.0	13	43.3	0.004**		

Table 16 shows the side effects in the parturients among the two group sedation was present in 33% of parturients in levobupivacaine group compared to 37% in bupivacaine group which was statistically not significant. Nausea (26.7% of parturients) and vomiting (16.7% of parturients) was equal in both the groups while pruritis was present in all parturients. Hypotension was present in 10% of parturients in levobupivacaine group compared to 43% in bupivacaine group which was statistically significant.

DISCUSSION

Labour is a painful process and pain increases the maternal stress, fatigue, oxygen demand, increased catecholamine release during the labour leads to uterine vasoconstriction, increased uterine contractility, hypoperfusion of fetoplacental unit, fetal hypoxia, fetal acidosis; these responses can easily be obtunded by providing analgesia during the labour. Development in drugs, needle designs, catheter technology have contributed to the development of combined spinal epidural anaesthesia technique which aims at improving the quality, efficacy and safety of neurological blockade. Palma C M et al.⁹ compared the dose response relation of intrathecal fentanyl for labour analgesia and concluded that it produces rapid, profound labour analgesia with minimal side effects; In our study, combined spinal epidural analgesia is used. Intrathecal fentanyl has increased maternal satisfaction by decreasing the pain and also placement of epidural catheter was easier as patient was comfortable and cooperative. The mean duration of action of intrathecal fentanyl alone was found to be 62.5 minutes by Buvanendran Asok Kumar et al.¹⁰ Clinical studies have found epidural levobupivacaine and bupivacaine to be similar when they are compared at equal concentrates for epidural anaesthesia^{11,12} and for maintenance of labour analgesia¹³,¹⁴ The total number of top ups showed a significant difference with bupivacaine group receiving less number of top ups than levobupivacaine group; Mean number of top ups was 3.13 ± 0.87 in Group B and 3.63 ± 1.63 in Group L with p value of 0.0038 which was significant; Inspite of longer duration of action in levobupivacaine group, higher number of subsequent top ups were required; this was also observed by Lee H L *et al.*¹⁵ when comparing Levobupivacaine with Ropivacaine;

Effect on duration of labour

There is no much difference in duration of labour between two groups as observed by R G Minty *et al.*¹⁶

Haemodynamic variables: Systolic pressure was lower and statistically significant at 15 minutes and 20 minutes in bupivacaine group; after 1st bolus; later it was not found; Similarly diastolic BP also showed a decline in bupivacaine group at 15 minutes, 20 minutes and 180 minutes which was statistically significant. Difference in mean pulse rate was statistically significant and less in bupivacaine group at the end of 90 minutes. VAS score were similar between two groups. Total dose of drug used showed no significant difference. There was no significant difference in duration of labour, neonatal outcome and APGAR scores of newborn and mode of delivery. Adverse effects: In our study we did not encounter any inadvertent complications except in both groups one parturient had post dural puncture headache which was managed conservatively. Pruritis was noted after intrathecal fentanyl which subsided gradually without any intervention. Nausea and vomiting was equal in both groups. On conclusion we found that levobupivacaine 0.125% was as effective as bupivacaine 0.125 % for combined spinal epidural analgesia of labour with longer initial duration of analgesia, less motor block and hypotension, similar amount of drug usage, similar patient satisfaction and neonatal outcome.

RECOMMENDATIONS

A national level media coverage, wider publicity and information to the general public regarding the options available for labour analgesia. Availability of safe labour analgesia be provided to a larger population of parturients. Anaesthesiologists to be trained and deputed to rural areas for providing safe labour analgesia services. Manufacturers to be encouraged to reduce the cost of epidural sets.

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