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ORIGINAL RESEARCH

Effect of combined spinal- epidural analgesia using ropivacaine and fentanyl during labour on fetomaternal outcome

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ABSTRACT

Aim : The purpose of the study was to observe maternal outcome in terms of duration of labourand mode of delivery and neonatal outcome considering Apgar score with the combined spinal-epidural(CSE) analgesia using ropivacaine and fentanyl during labour. **Materials & Methods**: In this study,60 nullipara patients with singleton pregnancy, term gestation, cephalic presentation, scheduled for normal vaginal delivery were randomly selected. After informed consent, they received combined spinal-epidural analgesia at 3-5cm cervical dilatation with 0.2% Ropivacaine 4mg and Fentanyl 25µg. Duration of first stage, second stage and total duration of labour were noted. Mode of delivery was also recorded. Mean visual analogue score before and after CSE block was noted. Apgar score of the baby at 1 ,5 and 10 min. was recorded. Patient satisfaction was assessed. **Results**: In our study, duration of first stage of labour was 587.44±87.040 minutes. Second stage of labour was 108.67±12.412 minutes .Total duration of labour was 701.33±91.149 minutes . Rates of normal vaginal deliveries were 83.3% (50/60) , instrumental deliveries were 3.3% (2/60) while 13.3% (8/60) patients underwent caesarean .Mean VAS score before and after CSE analgesia was 9.2 and 0. None of the babies in our study had Apgar score<7.Patient satisfaction was excellen.t in 96.67% parturients **Conclusion**: CSE analgesia using ropivacaine and fentanyl is an effective method of labour analgesia with no harmful effects on mother and fetus.

Keywords: Combined spinal epidural (CSE) analgesia, Apgar score, Visual analogue scale (VAS)

INTRODUCTION

Childbirth a natural phenomenon, is a major life event. Agony and stress that a woman suffers is beyond description. If pain is not adequately controlled, it can lead to maternal and foetal adverse outcomes because of maternal sympathetic activation which in turn predisposes to dysfunctional labour and compromises foetal oxygenation[1]. Visceral distension originating from rhythmic uterine contractions and progressive cervical dilatation causes much of the pain experienced during the first stage of labour. Afferent impulses from the cervix and uterus are transmitted to the spinal cord via segments T10-L1[2]. Later in labour, perineal stretching transmits painful stimuli through the pudendal nerve and sacral nerves S2-S4. Studies in healthy pregnant females showed that psychological stress or pain increased maternal plasma levels of epinephrine by 25% and decreased uterine blood flow by 50%[3]. So. Normal labour and birth, although viewed as a normal physiological process, can produce significant pain, requiring appropriate pain management. Several variables may help physicians predict which parturients are more likely to have severe pain during labour and delivery, allowing them to know which patients would potentially receive the greatest benefit from painless delivery. [4-6]Several non-pharmacological as well as pharmacological methods of relieving pain during labour have been advocated[7].Regional techniques provide excellent analgesia with minimal depressant effect on mother and fetus. Most commonly used regional techniques are spinal, epidural or combined spinal-epidural analgesia.

Combined spinal-epidural analgesia is a technique that provides rapid onset profound epidural analgesia for labouring parturients at almost any stage of labour. It involves an initial intrathecal injection of opioid followed by epidural dose of any local anaesthetic

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along with opioid to establish analgesia and subsequent epidural injections to restore and maintain analgesia. The doses of drugs involved are such that ambulation in labour is possible.[8] Characteristics of the ideal combined spinal-epidural analgesic for labour are high quality analgesia, maternal safety, neonatal safety, high degree of maternal satisfaction, no interference with the progress of labour, no motor block, no side effects and easy to use. The purpose of this studywas to determine the effects of combined spinal-epidural analgesia using ropivacaine and fentanyl with regard to mode of delivery, foetal outcome, and patient satisfaction.

MATERIAL AND METHOD

This was a prospective randomised observational study. After approval from the institutional ethics committee, 60 pregnant women in the age group of 18-35 years, admitted in Gynaecology and Obstetrics Department of Bebe Nanki Mother and Child Care Centre, Guru Nanak Dev Hospital, Government Medical College, Amritsar and scheduled for normal vaginal delivery were recruited. The study group included primigravidae with term gestation, cephalic presentation, in active first stage of labour with Cervical dilation >3 cm and <5 cm . Pregnant females with gestational age <35 wks, multiple gestation, non vertex presentation, estimated foetal weight <2500 gms and > 4500 gms, non reassuring NST, malpresentations, raised intracranial tension, deformity of spinal column e.g. Scoliosis and Kyphosis, any sign of infection at puncture site, pre-existing neurological deficits in the lower extremities, females on treatment with α-adrenergic antagonists, hypnotics, sedatives, diazepam, amphotericin B, calcium channel blockers and anticoagulants were not included. Patients with medical disorders e.g. Hypertension, Diabetes mellitus, cardiac diseases and bleeding diathesis, history of anaphylaxis to local anaesthetic and drugs to be used and of course patients who refused were also excluded from this study. Each participant in the study was informed about the aims and objectives of the study and was required to sign an informed consent prior to her inclusion. The study group received combined spinal-Epidural analgesia using ropivacaine and fentanyl as a method of pain relief in normal labour.

Method of collection of data

Detailed general physical and systemic examination of the cardiovascular, respiratory, abdominal and central nervous system was performed. A detailed obstetrical examination was performed to confirm period of gestation, presentation of the fetus ,the position, consistency, effacement and dilatation of the cervix and the station of the presenting part. Foetal heart rate and its regularity was noted. Necessary investigations and ultrasound records were carried out to confirm foetal maturity and foetal and maternal well being.

Study design

A thorough pre-anaesthetic check-up was conducted by the anaesthetist. Onset of regular uterine contractions was taken as the onset of labour and time was noted. Patients were kept under observation during latent phase of first stage of labour. Start of the study was marked with the onset of active phase of labour when the woman had regular uterine contractions leading to progressive effacement and dilatation of cervix with ≥3cm and <5cm of cervical dilatation. Combined spinal-epidural was given using single space technique in L_{2-3} or L_{3-4} intervertebral space. Drugs used were intrathecal 0.2%Ropivacaine 4 mg and Fentanyl 25 µg. Epidural catheter was secured and dressed. Pain with contractions was assessed by 10 cm visual analogue scale. Epidural bolus with the study drug was given when patient reported VAS > 3. Progress of labour was noted with a partograph in which status of membranes, colour of liquor, cervical dilatation, descent of foetal head were noted every time per vaginal examination was done. Continuous multiparameter monitoring of pulse rate, NIBP (both systolic and diastolic) and foetal heart rate were recorded every 2 minutes for first 10 minutes, every 5 min for next 20 min and then every 15 minutes till delivery. Foetal heart rate was monitored by a continuous cardiotocograph.

Duration of first stage, second stage, third stage and total duration of labour were noted.Mode of delivery whether normal vaginal delivery, instrumental delivery, and caesarean section was noted.APGAR scores of the neonate at 1, 5 and 10 min were noted. Patients received a follow up visit after 24 hours then a satisfaction score (verbal rating scale 1- 5) and complication if any were recorded. The data was systematically collected, compiled and analyzed with descriptive statistics using percentages, means and standard deviation. The results were then compared with the previous studies.

RESULTS

A total of 60 parturients all with cephalic presentation received combined spinal epidural analgesia with 0.2% Ropivacaine 4mg and Fentanyl 25microgm. 57(95%) were primigravida and 3(5%) had history of one abortion . Table 1 depicts that mean of age, weight, height and gestational age was 23.35+_2.30, 62.23+_6.39, 155.95+_3.95 and 38.80+_1.10 respectively thus fulfilling the inclusion criterias.

Table 1: Demographic Characteristics

Parameter	Mean	+_SD
Age (years)	23.35	2.30
Weight (kg)	62.23	6.39

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Height(cms)	155.93	3.95
Period of gestation(weeks)	**38.80**	**1.10**
Obstetric history	**First term pregnancy**	
Presentation	**Cephalic**	

All the selected parturients were administered CSE analgesia at cervical dilatation between 3cm to 5cm.as depicted in Table 2

Table – 2. Cervical Dilatation (Cm)

Cervical dilatation (cm)	No. of parturients	%age
3	1	1.7
4	40	66.7
5	19	31.7

As shown in (Table 3),the mean baseline systolic blood pressure was 119.25± 5.239, mean baseline diastolic blood pressure was 78 ± 4.495 ,mean baseline pulse rate was 92.3±5.881 and mean baseline foetal heart rate was 141.02 ± 4.796. All these were within normal range.

Table -3. Mean Baseline Parameters Of Selected Parturients (on admission)

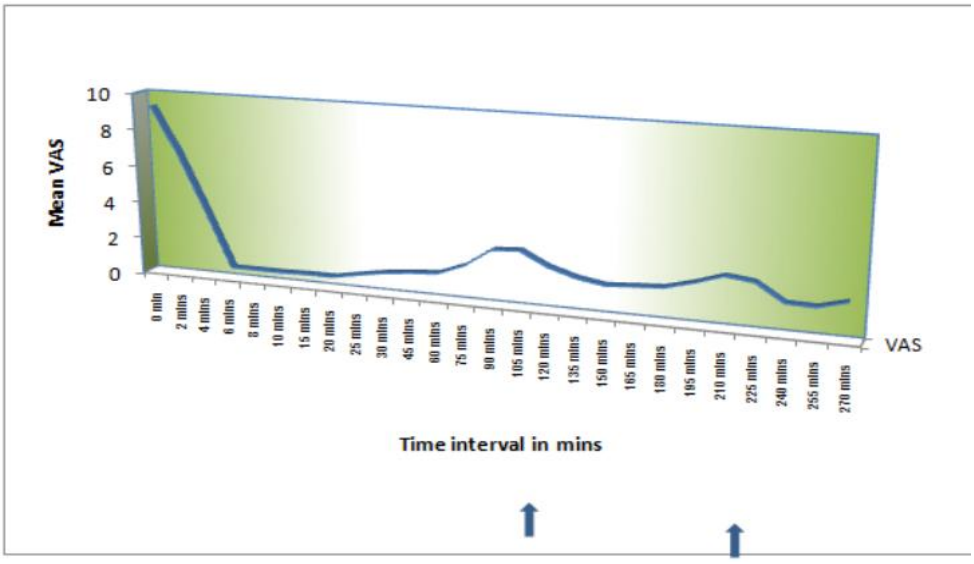
Vitals	Mean ± SD
Systolic blood pressure (mmHg)	119.25 ± 5.23
Diastolic blood pressure (mmHg)	78 ± 4.49
Pulse rate (beats/min)	92.3 ± 5.88
Foetal heart rate (min)	141.02 ± 4.79

Table 4: shows the mean time of onset of analgesia after spinal component of CSE analgesia was5.58±0.49 minutes. The mean time to reach the maximum sensory level of analgesia was 11.13±1.48 minutes. Spinal to delivery interval i.e the time between administration of intrathecal analgesia till the birth of foetus was 252.53±38.14 minutes.

Table – 4 Parameters Noted After Combined Spinal Epidural Analgesia

Parameter	Mean ± SD
Sensory onset of action (minutes)	5.58±0.49
Time for maximum sensory level (minutes)	11.13±1.48
Spinal to delivery interval (minutes)	252.53±38.14

Graph 1 shows that mean VAS reached to the level of 0.63 ± 0.76 (i.e. no pain) within 6 minutes. VAS again increased at 105 minutes and 210 minutes when patients perceived 2 contractions as painful and epidural top ups were given on request.



Graph :1 Visual Analogue Score (Vas) During Active Stage Of Labour (After Onset Of Cse Analgesia)

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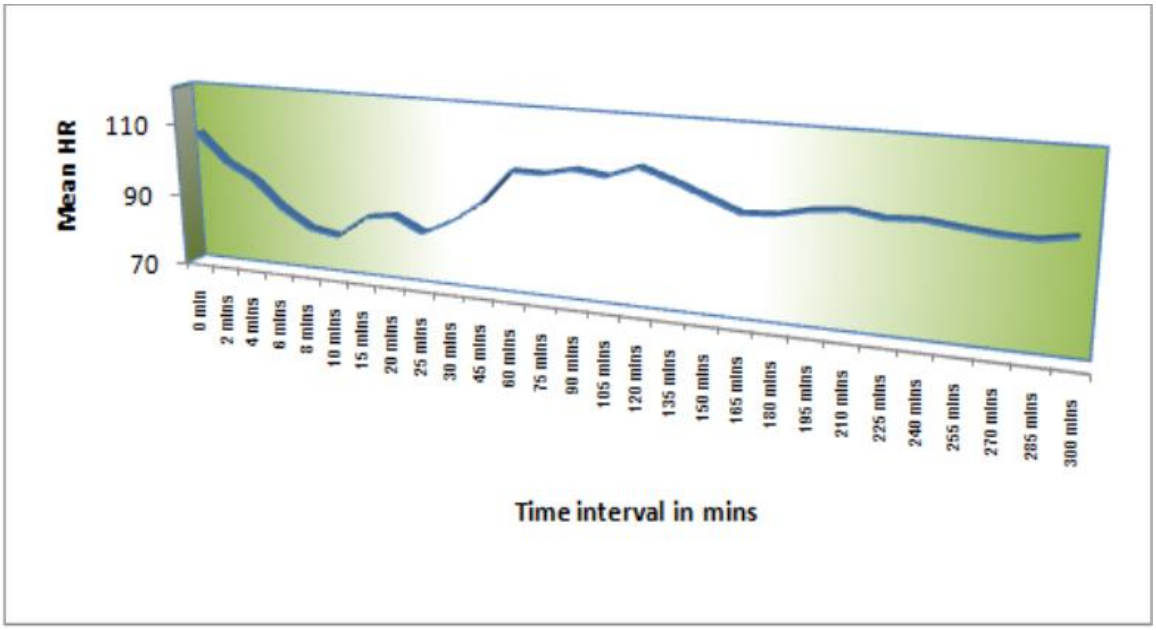
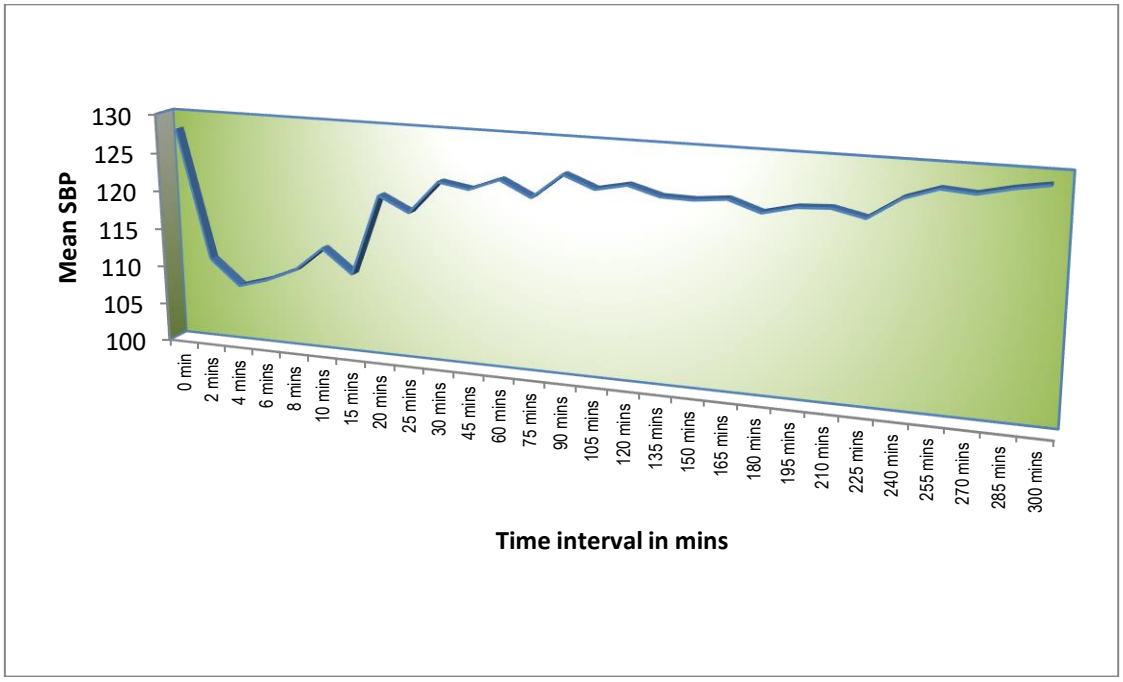
Graph 2, shows mean heart rate of parturients increases with increase in intensity of pain but is being normalised after CSE and after topups



Graph 2: Mean Heart Rate Per Minute

Graph 3 shows slight hypotension seen at the onset of CSE analgesia but SBP returned to the baseline within 20 minutes and remained near baseline thereafter till delivery.



Graph 3: Mean Systolic Blood Pressure (In Mmhg)

Graph 4 shows decrease in DBP at the onset of CSE analgesia which returned to baseline within 10 minutes and remained near baseline till delivery.

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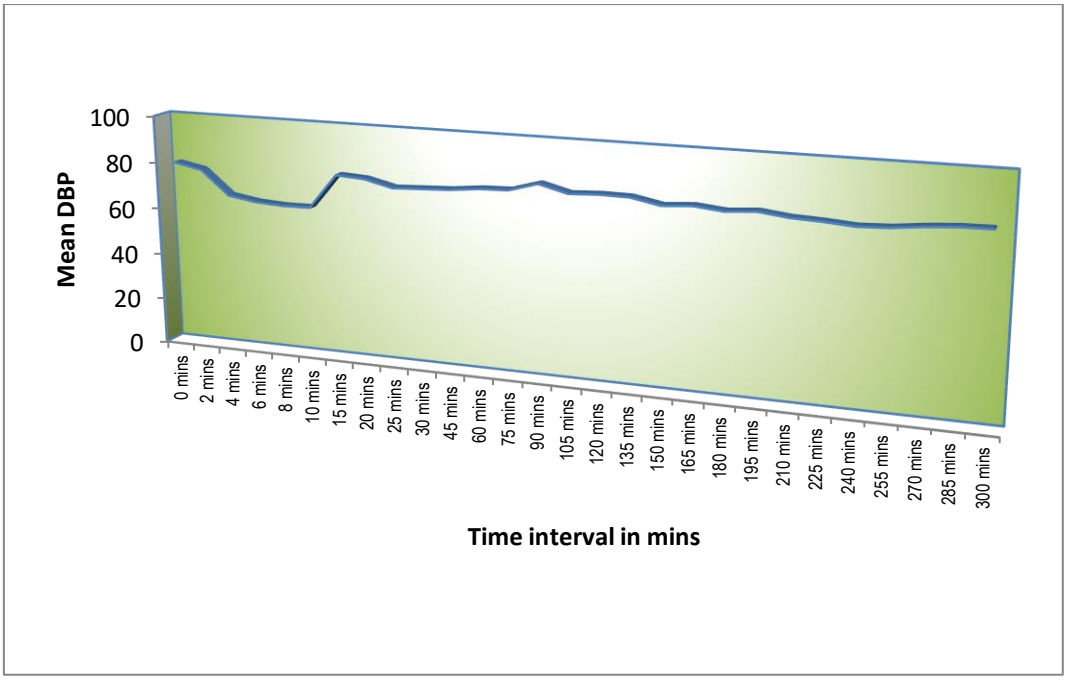
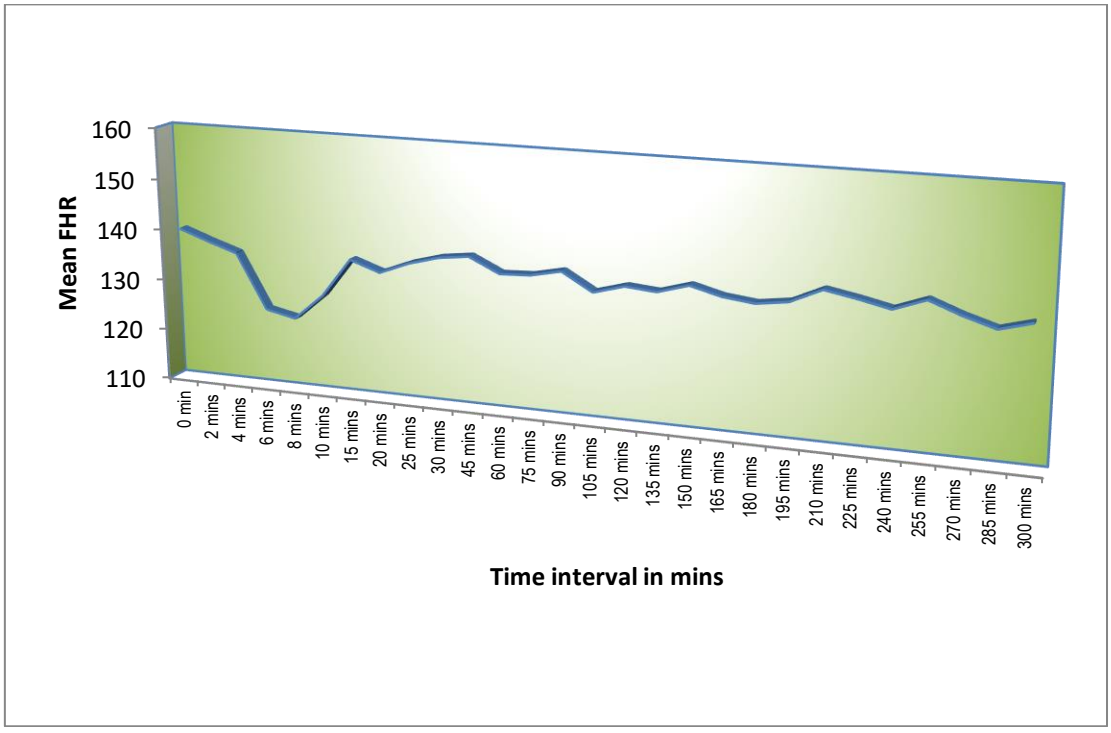


Graph 4: Mean Diastolic Blood Pressure (In Mmhg)

G raph 5 depicts that foetal heart rate dropped upto 110 per minute in selected parturients during first 10 minutes after CSE anaigesia. However, it was only transient which spontaneously recovered to normal with oxygen inhalation and with no adverse effects on foetus



Graph 5: Mean Foetal Heart Rate

Six out of 60 parturients underwent caesarean section due to foetal distress before full dilatation of the cervix so mean duration of first stage of labour was calculated among remaining 54 candidates.(Graph 6) shows the mean duration of first stage of labour was 587.44±87.040 min which is considered within normal range according to Friedman classification.

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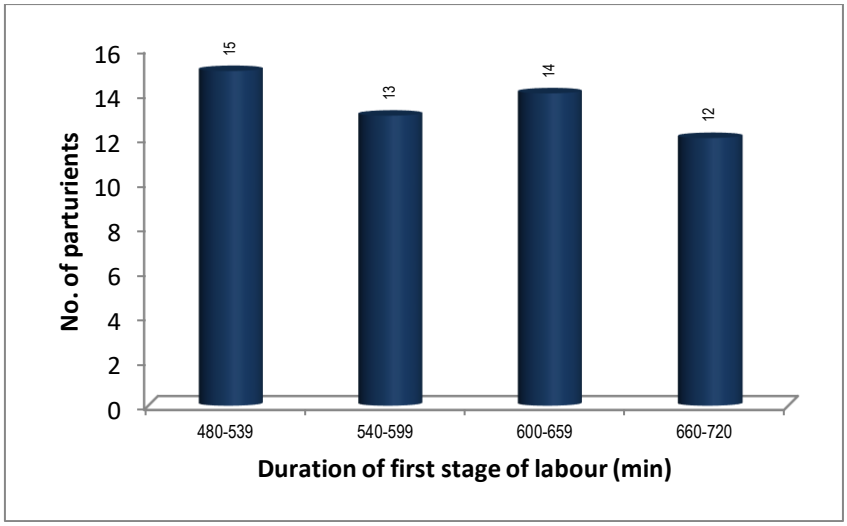
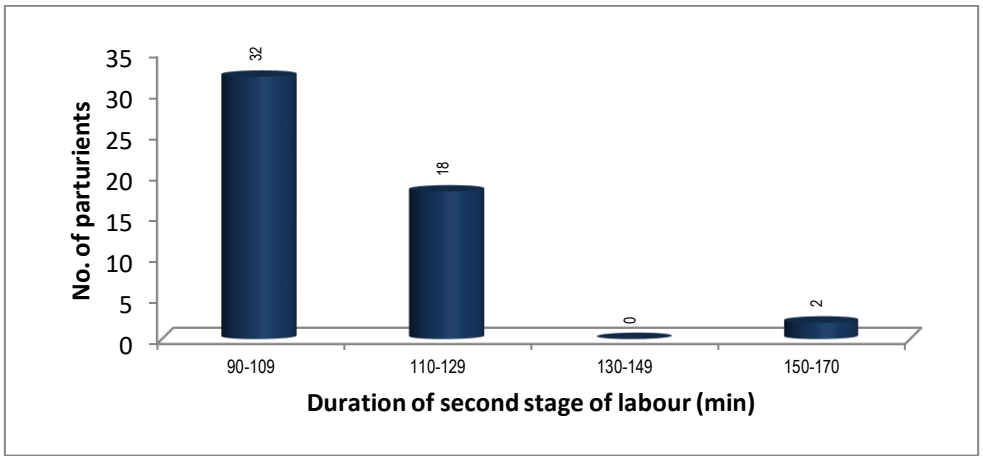


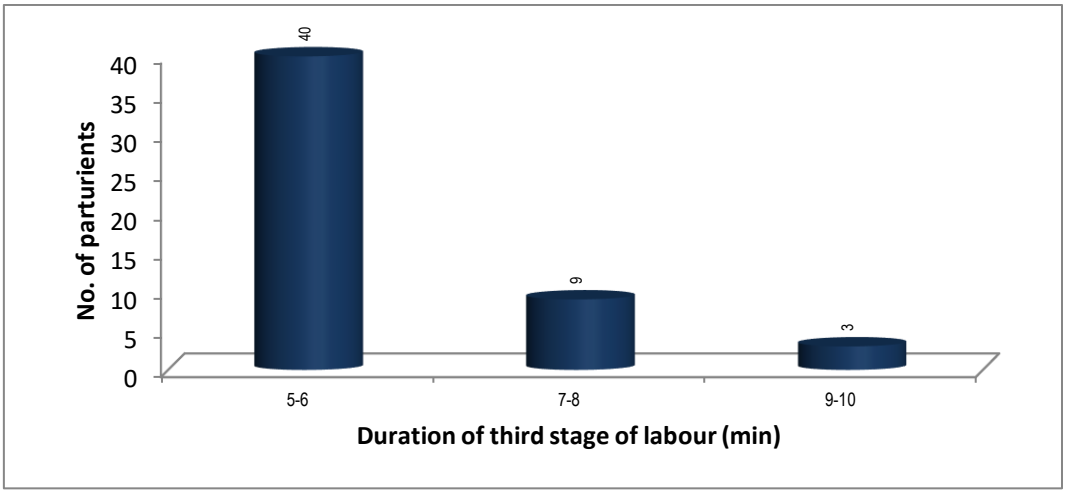
Graph –6: Mean Duration Of First Stage Of Labour

Two more patients underwent LSCS due to cervical dystocia and Deep Transverse Arrest. So, the mean duration of second stage of labour was calculated among remaining 52 parturients as shown in(graph 7) and it was calculated to be **108.67 ± 12.41** . Majority i.e 32(61.53%)delivered within 110min (1.8 hrs) and 18 (34.61%) within 130 min (2.15hrs). Only two candidates had second stage of more than 150 min (2.5 hrs) .



Graph – 7: Mean Duration Of Second Stage Of Labour

(Graph8) shows delivery of placenta was within 10 min among all the vaginally delivered cases .The mean duration of third stage of labour was6.12± 1. 36 (no effect with CSE analgesia)



Graph – 8: Mean Duration Of Third Stage Of Labour

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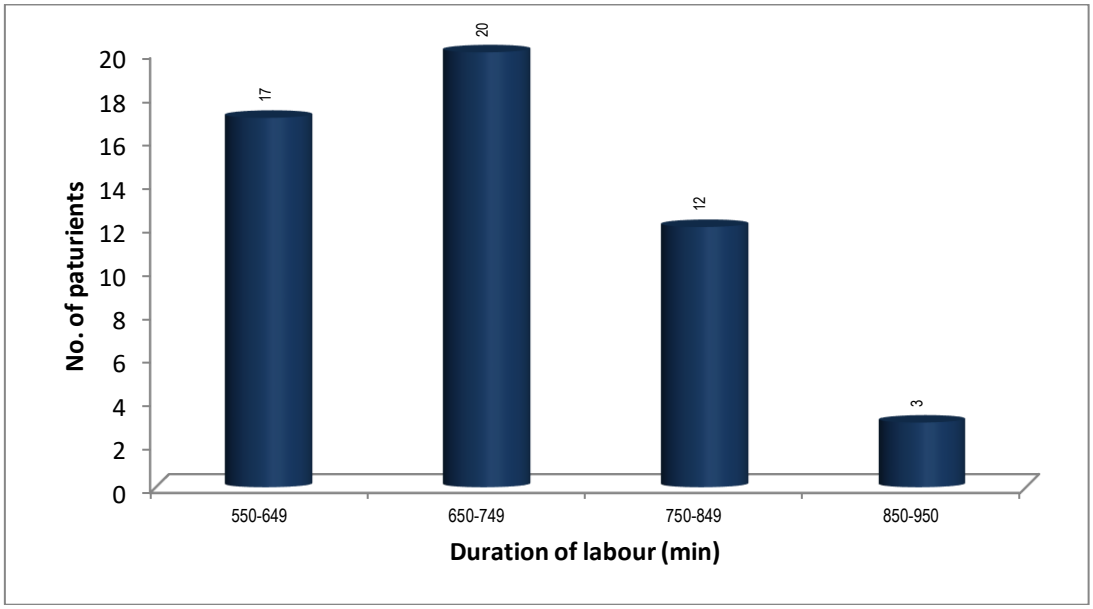
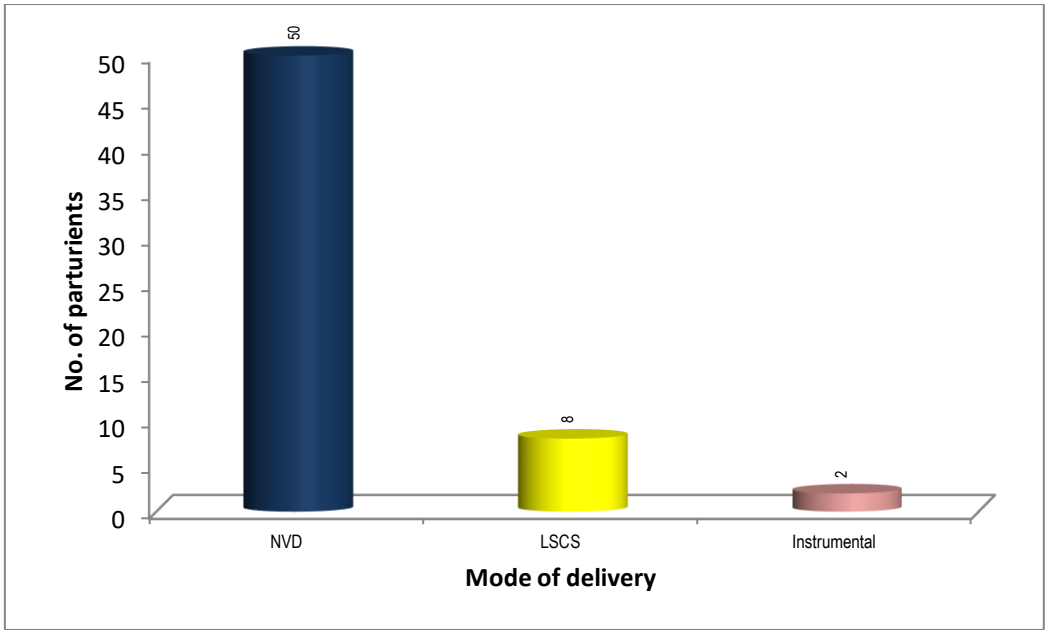
Graph 9 shows, total duration of labour was between 550-649 min (9.2 -10.8 hrs) in 17 (32.69%) of parturients who delivered vaginally and was 650-749 min (10.82-12.5 hrs) in 20 (38.46%) candidates, 750-849 min (12.5-14 hrs) in 12 (23.08%) and 850-950 min (14-58.8 hrs) in remaining 3 (5.77%) parturients. The mean duration of labour was701.33 ± 91.14 (11.68 hrs). (which is not prolonged)



Graph—9: Mean Duration Of Labour (In Minutes)

Graph 10 shows the maternal outcome , out of 60 parturients 50 (83.3%) delivered vaginally, eight (13.3%) underwent caesarean section and two (3.3%) had instrumental delivery.



GRAPH –10: NVD- Normal Vaginal Delivery, LSCS- Lower Segment Caesarean Section

Graph11 shows Six out of eight (75%) underwent LSCS due to foetal distress and one had deep transverse arrest and another one was operated upon due to cervical dystocia.

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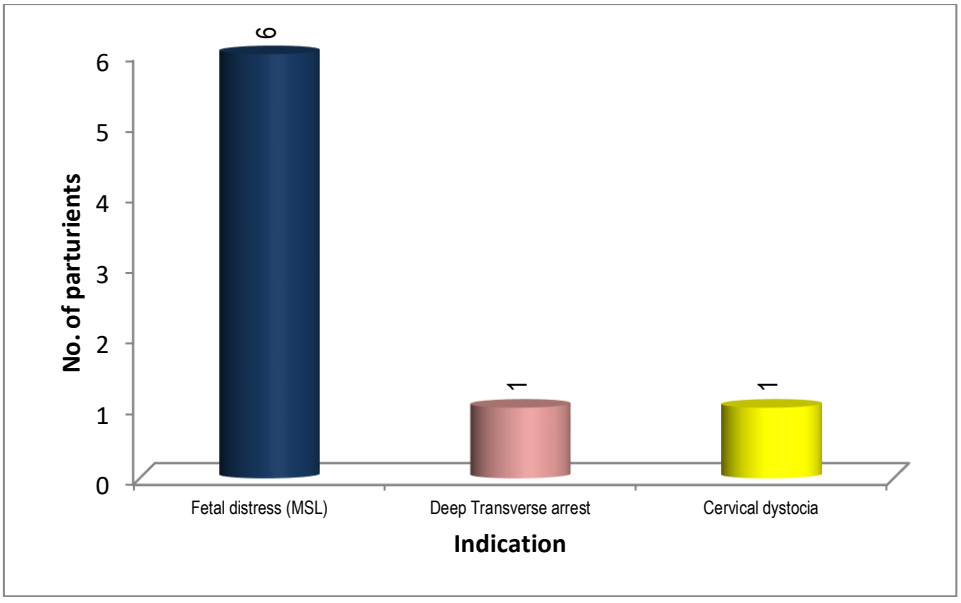

Graph 11: Indications of cesarean section

Table 5 shows APGAR score noted at 1 minute, 5 minutes and 10 minutes, all the newborn babies had APGAR score more than or equal to 7 at all the three intervals.

TABLE – 5: APGAR SCORE AT 1 , 5, 10 MINUTES

APGAR score	No. of Newborns At 1 minute	No. of Newborns At 5 minutes	No. of Newborns At 10 minutes
7	14 (23.33%)	6 (10.00%)	3 (5.00%)
8	27 (45.00%)	17 (28.33%)	9 (15.00%)
9	17 (28.33%)	31 (51.67%)	39 (65.00%)
10	2 (3.33%)	6 (10.00%)	9 (15.00%)
Total	60 (100%)	60 (100%)	60 (100%)

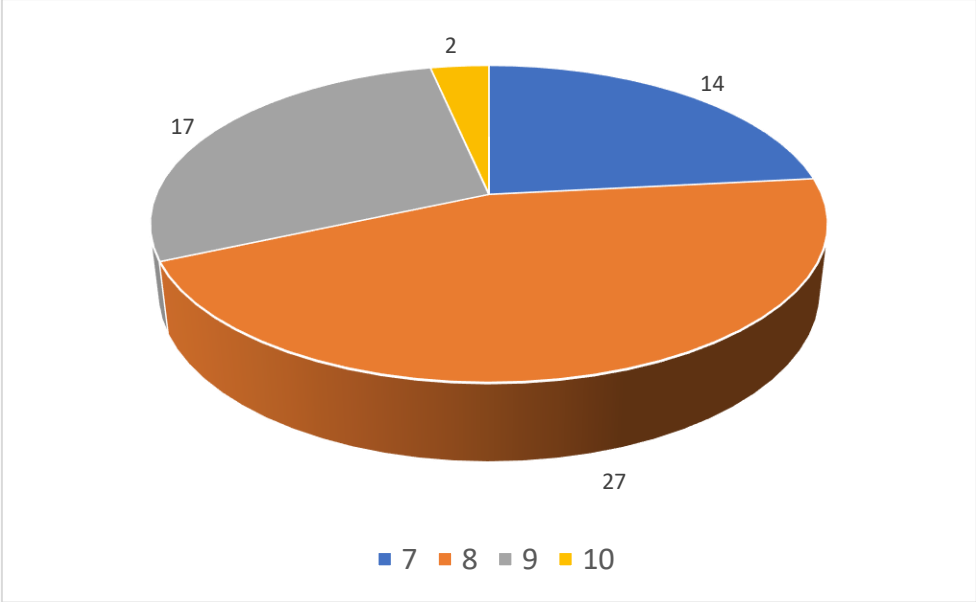

Figure 1: Apgar at 1 minute

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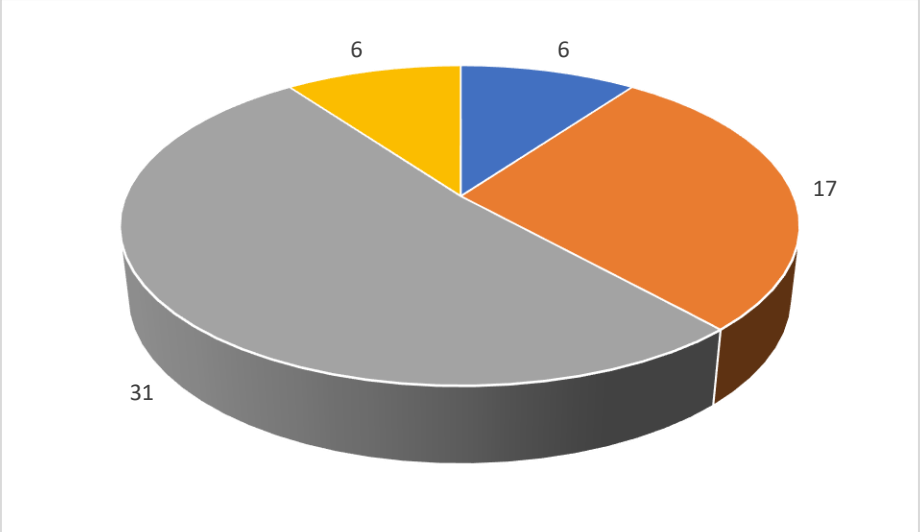

Figure 2 : Apgar at 5 minutes

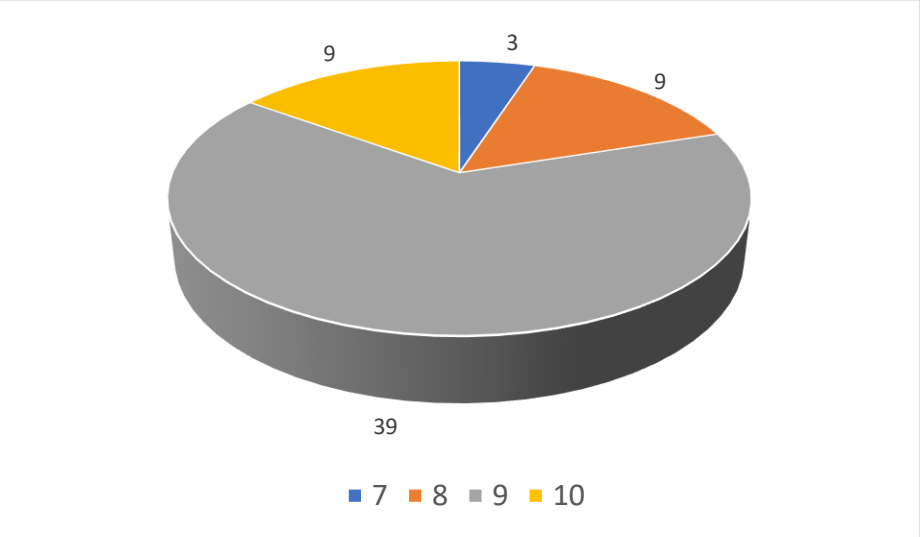

Figure 3: APGAR at 10 minutes

Table 6: in the present study, foetal bradycardia was present in five (8.33 %) patients . Backache and bowel dysfunction were not seen in any of the patient but bladder dysfunction was seen in two (3.33%) patients in whom combined spinal epidural analgesia was given.

Table 6: Incidence Of Side Effects And Complications

Complications	No. of parturients	%age
Foetal bradycardia	5	8.33%
Backache	0	0%
Bladder dysfunction	2	3.33%
Bowel dysfunction	0	0%

Table 7: patient satisfaction score was measured by scale in which 5 is given for excellent, 4 is very good, 3 is for good, 2 is for fair and 1 for poor. Majority of patients i.e. 96.67% had score of 5 and 3.33% had score of 4.

Table – 7: **Patient's Satisfaction Score**

Score	No. of parturients	%age
5	58	96.67
4	2	3.33
3	-	-
2	-	-
1	-	-

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DISCUSSION

The study was conducted at a tertiary care centre and all the pregnant females fulfilling the inclusion and exclusion criterias were given the choice to be a part of the study and the first 60 females who gave written consent for CSE analgesia were included in the study. All of them were with first term pregnancies with or without previous first trimester abortions with singleton pregnancy, longitudinal lie and cephalic presentation. They all had uncomplicated pregnancies with medical problems ruled out. Similar inclusion and exclusion criterias were taken in study done by Lyon[9] and another by Long[10]. In another study done at Spain, eligible individuals had to meet at least 2 out of 3 criteria (in addition to analgesia request): regular contractions every 2– 3 minutes, cervical effacement, and cervix dilation of at least 2 cm. The exclusion criteria were estimated foetal weight of less than 2500 g or more than 4500 g; gestational age of less than 35 weeks; nonsingleton; non-vertex presentation; ASA category3 mothers[11].The present study also had similar inclusion and exclusion criterias.

The mean baseline systolic blood pressure, diastolic blood pressure, pulse rate and fetal heart rate in CSE receiving parturients was 119.25±5.23 mmHg, 78±4.49mmHg 92.32±5.88 per minute and 141.02±4.79 per minutes respectively . Mean baseline parameters in our study were in concordance with the study done by Wang[12] where mean baseline systolic blood pressure was 124.6 mmHg, mean diastolic blood pressure was 76mm Hg and . The mean VAS reached to the level of 0.63 ± 0.76 (i.e. no pain) within 6 minutes just as in study done by Long [10]. It was observed that foetal heart rate dropped upto 110 per minute in selected parturients during first 10 minutes after CSE . However, it was only transient which spontaneously recovered to normal with oxygen inhalation and with no adverse effects on foetus. Similar results were observed in a study done at Belgium where foetal bradycardia within the first 10 min after the spinal injection was registered in six patients but none required emergency caesarean delivery. Instrumental delivery, caesarean delivery rate, neonatal birth weights, Apgar scores, and umbilical artery pH values were not affected.[13]

The mean duration of first stage, second stage ,third stage and total duration of labour in selected CSE receiving patients in our study was 587.44 min±87.04 (9.7hrs), 108.67±12.41 minutes (1.81hrs) ,6.12±1.36 minutes and 701.33±91.14 minutes (11.68 hrs) respectively. This was in concordance to the study done byDickinson [14] where there was no significant change in the duration of first stage of labour after giving CSE analgesia i.e it was 9.5hrs in that study ,second stage was slightly prolonged but within normal range according to Friedman classification.[8] Similar results were obtained by Lyon study[9] in which second stage was prolonged by only 10 minutes.In study done by Leiberman it was seen that second stage of labour was prolonged by 15.23 minutes in patients in whom CSE analgesia was given.[15] Dikinson et al observed no significant increase in duration of second stage of labour i.e 1.45 hrs.[14] Study by Lyon[9] and another by Leiberman[15] observed no difference in duration of third stage as well as total duration of labour with and without CSE analgesia. A comparative study by Mousa ,observed no statistical difference in the duration of the first and second stages of labour.[16]

The mode of delivery in parturients receiving CSE analgesia was not effected by CSE. 50 (83.3%) patients were delivered by normal vaginal delivery, eight (13.3%) underwent caesarean section and two (3.3%) had instrumental delivery. Yancey demonstrated no statistically significant differences in the rate of spontaneous vaginal delivery (69.5% vs 68.3%), the overall caesarean delivery rate (19.0% vs 19.4%), the primary caesarean delivery rate (13.2% vs 13.4%), or the operative vaginal delivery rate (11.1% vs 11.9%) between the periods when epidural analgesia was not being given to the period when labour analgesia was started with epidural analgesia.[17] The Cochrane database review also concluded that CSE analgesia did not increase the rate of caesarean section as compared to epidural analgesia.[18]

	Cesarean section rate	Instrumental delivery
Lyon	Not increased	-
Long	Decreased	-
Amini et al	Not increased	-
Aneiros	Not increased	Not increased
Yancey	Not increased	Not increased
Mousa	Not increased	Not increased
Cochrane review	Not increased	-

It was observed that six out of the eight patients underwent caesarean section due to foetal distress while one patient underwent caesarean section due to cervical dystocia and another one due to deep transverse arrest i.e ability of bearing down efforts is not effected much by CSE analgesia and doesnot increases the rate of LSCS. These were in concordance with the Leighton et al study in which indication of performing caesarean section was not effected whether CSE was given or not.[19] All the newborns in the study had APGAR score more than 7 at all the three intervals. Similar results were observed by Lyon[9] who found no statistical difference in Apgar score of newborn postnatal 1min and 5min.

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Study done at Istanbul ,Turkey also showed no effect of CSE analgesia on APGAR scores at 1 and 5 minutes.[20] A study done at Spain also observed that Apgar scores at 1 and 5 minutes in patients in whom CSE analgesia had been given were >9.[11] Mousa also concluded that there is no significant effect of epidural analgesia on neonatal Apgar scores at 1 and 5 minutes as compared to patients in whom no analgesia has been given.[16]

	Effect on APGAR Score
Lyon[9]	No effect
N Frikha et al	No effect
Ramirez JP et al	No effect
Mousa et al[16]	No effect
Lyon[9]	No effect
My study	No effect

In the present study, none of the patients had backache or bowel dysfunction and only two patients had retention of urine which was relieved within 24 hours. 96.67% of patients with CSE analgesia had an excellent experience with satisfaction score of 5 and 3.33% had score of 4 .On a 0-100 scale, study done at Tunisie observed mean patient satisfaction score of 95 with CSE analgesia[14] Similarly Dresner et al study reflected high mean patient satisfaction score with Ropivacaine and Fentanyl after CSE analgesia[21.] Complete satisfaction with CSE analgesia and mobility was reported 12-24 h post partum by 95% of mothers in a review by Collis et al[22].

LIMITATIONS

Ropivacaine is a newer local anaesthetic and there are only few studies supporting its use for obstetric analgesia, more studies are needed to establish the safety and efficacy of this drug in labour analgesia.

CONCLUSION

Intrathecalropivacaine and fentanyl provides effective analgesia enhancing the quality and duration of analgesia. Onset of analgesia is rapid with Ropivacaine 4 mg and Fentanyl 25 µg as in our study , the mean onset of analgesia was 5.58±0.49 minutes .CSE analgesia causes significant fall in VAS score which in our study reduced significantly from mean of 9.30±0.53 to 0.63±0.76 following CSA analgesia. Moreover there was no motor blockade allowing ambulation of the parturients. CSE analgesia does not effect the haemodynamics as well as duration of labour (701.33± 91.14 minutes (11.68 hrs) of the receipient mother. CSE analgesia doesnot effect the mode of delivery i.e it doesnot increase the rate of caesarean section or instrumental deliveries. CSE analgesia causes transient foetal bradycardia which spontaneously recover back to normal without any adverse effect on the foetus. Use of CSE analgesia during labour causes no adverse effect on the foetal outcome . Apgar scores of newborns at 1 minute, 5 minutes and 10 minutes were>7 i.e not effected adversally in the present study. There is no significant incidence of side effects like bowel or bladder dysfunction with CSE . The selected parturients had wonderful experience of their labour with excellent patient satisfaction scores of 5 in 96.67% and a score of 4 in remaining 3.33% cases.Thus, it is concluded that CSE analgesia using Ropivacaine 4 mg and Fentanyl 25 µg intrathecally is an effective and safe method of labour analgesia as all the parturients were haemodynamically stable and there was no adverse effect on maternal and foetal outcome.

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