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To Compare Quality, Duration and Recovery Profile Of Combined Spinal Epidural Technique and Epidural Technique with Ropivacaine and Fentanyl for Labor Analgesia

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ABSTRACT
BACKGROUND: The present study compares the efficacy of epidural versus combined spinal-epidural technique with ropivacaine and fentanyl and the goal here is to provide painless labor with minimal or no side-effects.
METHODS : This is a prospective,randomized, double-blind study. sixty,consenting laboring parturient of ASA I/II in active labor were randomized to receive either Epidural(E) or Combined-Spinal Epidural(CSE) technique for labor analgesia. Group E received 0.125% ropivacaine with 2microgram/cc fentanyl epidurally and group CSE received 20 microgram fentanyl intrathecally and 0.125% ropivacaine with 2microgram/cc fentanyl epidurally. Onset of analgesia, duration of labor, maternal haemodynamic, Visual Analog Scale (VAS), Foetal Heart Sounds (FHS), mode of delivery, motor blockade, total top-ups, side-effects, and neonatal outcomes were observed.
RESULTS : Onset of analgesia was significantly earlier in the CSE group (3.01±0.90mins) then E group (13.15±3.01min). Duration of the first stage of labor was significantly shorter (P<0.05) in the CSE group (199.27±35.51mins) then in E group (252.97±68.33mins). Maternal Haemodynamic were maintained throughout the study. VAS was significantly lower in the CSE group as compared to the E group. Fewer Top-ups were needed in the CSE group. Common side effects were pruritis and nausea in the CSE group. Neonatal outcomes were comparable in both of these group.
CONCLUSION : CSE provides earlier onset of analgesia with shorter duration of first stage of labor with fewer top-ups, good foetal outcome, and good maternal satisfaction.
KEYWORDS:*Epidural, combined spinal-epidural, ropivacaine, fentanyl.*

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I. Introduction

Childbirth may be the most beautiful and rewarding journey a woman in labor has ever known, but it is also a very painful process. Women have experienced this pain early on with little or no access to a remedy for the pain and some even with little or no support.

With the introduction of ether as a pain-relieving agent for labor by Dr Crawford Long in 1845, who first administered inhalational ether to his own wife for childbirth[1] and in 1853, John Snow gave Queen Victoria chloroform for the birth of prince Leopold and princess Beatrice which put a major impact on women and revolutionised the concept of painless labour.[2]

By 1949 the concept of continuous lumbar epidural block for labor analgesia was described by Cleland[3] and by 1990s use of low-concentration bupivacaine with fentanyl mixtures, patient-controlled epidural, and combined spinal–epidural analgesia became popular.**[3]**

There are various techniques of labor analgesia, but Neuraxial techniques are accepted as the gold standard for intrapartum labor analgesia. [4][5] Epidural analgesia satisfies the basic requirements of labor analgesia by fulfilling the objective of decreasing the pains of labor without affecting other sensations such as a

desire to push and to allow normal walking while preserving the tone of pelvic floor muscles as well as retaining the sensation of the baby's head in the vagina; thus, allowing labor to proceed unhindered.[6]

In addition to their analgesic benefits, the physiological benefits of neuraxial analgesia for the mother and fetus are well-documented. Neuraxial analgesia has been shown to improve maternal cardiovascular and pulmonary physiology, and the acid–base status of the fetus.

Epidural analgesiaallows for continuous pain relief throughout labour with 'top-up' boluses of local anaesthetics. It has no impact on the risk of caesarean section or long-term backache and did not appear to have an immediate effect on neonatal status as determined by Apgar scores or in admissions to neonatal intensive care. [7]

The Combined Spinal Epidural (CSE) technique has gained increasing popularity in recent years. Here, a lipid soluble opioid is injected in the spinal space with added advantage of epidural via boluses and top-ups doses of local anaesthetics injected into the epidural space. It provides rapid onset of analgesia with minimal local anaesthetic doses. [8]

Various anaesthetic agents have been used in the past but, Ropivacaine is becoming the safer alternative to be used in these techniques. It is a new long-acting amide local anaesthetic agent; a pure S-enantiomer, with a high pKa and relatively low-lipid solubility. Ropivacaine being cardio stable and with less side effect is preferred over bupivacaine . It also causes less motor blockade and hereby promoting the concept of "Walking Epidural".[9]

Fentanyl as an adjunct cause reduction in the amount of ropivacaine required. There is a synergistic action of fentanyl and ropivacaine at the dorsal horn of the spinal cord and combinations of opioid and local anaesthetic produce effective labour analgesia.[10][11][12]

Intrathecal administration of fentanyl in the combined spinal-epidural technique produces rapid and effective labour pain relief with less incidence of motor block but also has side-effects like pruritis, nausea, vomiting, maternal urinary retention. [13]

II. Material And Method

This is a hospital based, Prospective, randomized control, double blind Comparative study. After getting approval from the institutional ethical committee and the scientific committee. We included 60 laboring parturient admitted in the labor room of the Mahatma Gandhi Medical College , Jaipur. The patients were counselled about the procedure. After getting detailed informed written consent, detailed history of the patients was taken, and routine investigations were sent as per the hospital protocol. Patients giving consent, fulfilling the inclusion criteria were randomly allocated to either epidural group or the combined spinal epidural group on the basis of chit and box method.

We included consenting pregnant females of ASA grade I / II , with cervical dilatation of 3cm or morewithreassuring Foetal heart sound.

After doing the Pre-Anaesthetic Checkups and obtaining written informed consent, Patients of each group, were taken into the operating room with Monitoring of Blood Pressure, Pulse, Spo2, 5 leads E.C.G. and securing an Intra-Venous line, 500ml of Ringer Lactate was infused before the procedure. Patients were then placed in either the left lateral or sitting position. Taking all the aseptic precautions a 18G tuohy"s needle was inserted at intervertebral space of L2-L3 or L3-L4 and epidural space was recognised with the loss of resistance technique andcatheter was then inserted into the epidural space.

Patients were then equally divided into epidural and combined spinal epidural group of 30 each.

Group EPIDURAL (E) received 10ml of 0.125% Ropivacaine with fentanyl 2 microgram/ml as loading dose and after which intermittent boluses were given on demand.

Group COMBINED SPINAL-EPIDURAL (CSE) : Here 20 micrograms of fentanyl were given intrathecally via 25G Quinke's spinal needle in the L3-L4 level. Then 10ml of 0.125% Ropivacaine with fentanyl 2 microgram/ml was given epidurally and intermittent boluses were given on demand.

Catheter site was then cleaned with chlorhexidine solution and Catheter was then secured by the tape. After the procedure, patients were placed supine with wedge under the hip with head end elevated by 30^0 . After the procedure all the patients were monitored for onset of analgesia, pulse, blood pressure, foetal heart rate, visual analog scale(VAS), motor blockade with modified bromage criteria every 5min for first 30min then on hourly basis. In case of maternal complain of pain with VAS>= 4, 6 ml 0.125% ropivacaine with 2microgram/ml fentanyl was administered on request. After the delivery, baby was handed over to the paediatrician and its APGAR was assessed. Patients were then asked about their experience and the success of the procedure and their willingness of for labor epidural in subsequent deliveries.

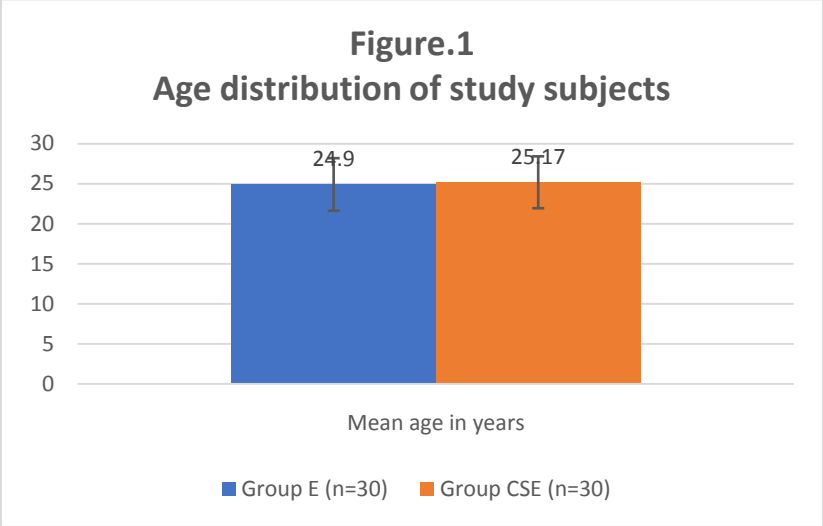
STATISTICAL ANALYSIS

The statistical analysis was performed with the SPSS, version 20 for windows statistical software package (SPSS inc., Chicago, il, USA). The data were presented as numbers (percent) and were compared

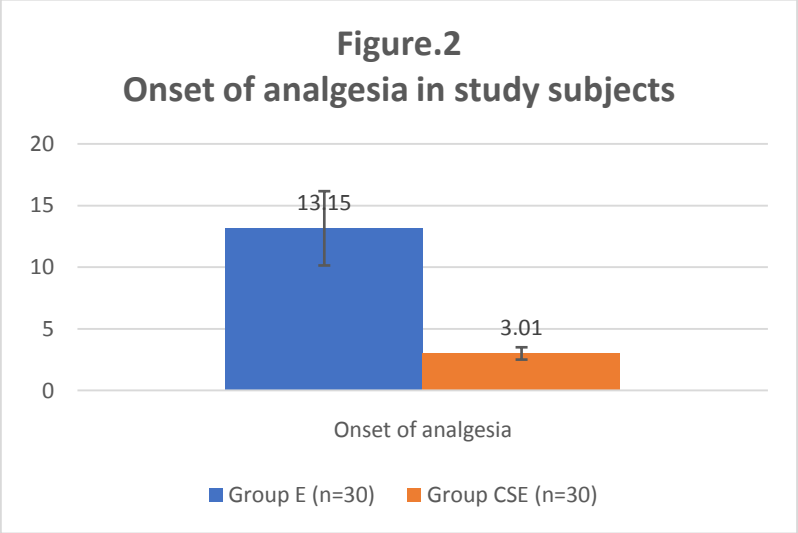
among the groups using chi square test. Data was recorded in terms of mean and standard deviation and analysis done using student t-test. Probability P value<0.05 was considered statistically significant.

III. Result

The participants in our study ranged between 19 years to 32 years and the mean age of the parturient in E group was 24.90±3.28 years and in the CSE group it was 25.17±3.24 years.(Figure.1)



Onset of analgesia was earlier in the CSE group as compared to the E group and the results were statistically significant (p = <0.001).(Figure.2)

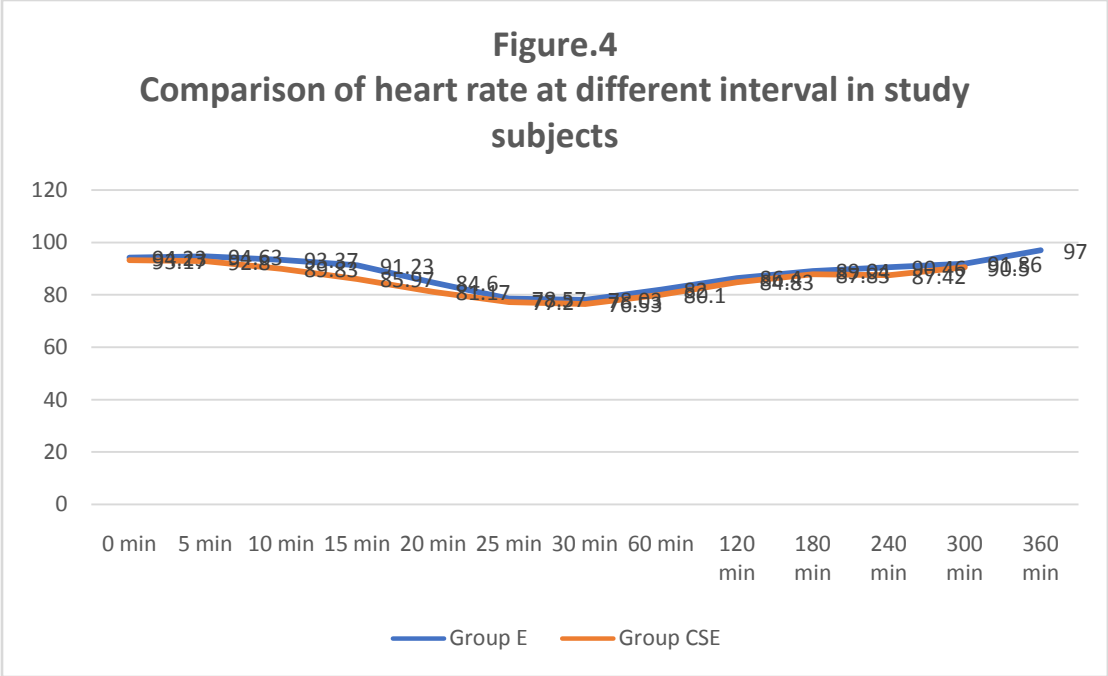


CSE group had significant shorter duration of first stage of labor than the E group. The mean duration of second and third stage of labor were comparable and statistically non-significant.(Figure.3)

Figure.3

Duration of Labor (min)	**Group E (n=30)**		**Group CSE (n=30)**		**Total (n=60)**		**p-value**
	Mean	SD	Mean	SD	Mean	SD	
Stage 1	252.97	68.33	199.27	35.51	226.12	60.39	<0.001
Stage 2	18.10	2.58	16.67	3.10	17.38	2.91	0.05
Stage 3	7.00	2.18	6.97	2.09	6.98	2.12	0.95

The CSE group had significantly decreased heart rate as compared to the E group at 10 min to 20 mins owning to the effect of fentanyl and additive effect of ropivacaine. Though there was decrease in the heart rate, but none of the parturient required any intervention.(Figure.4)



Serial systolic blood pressure monitoring was done throughout the study. The parturient in the CSE group had statistically significant decrease in systolic blood pressure at 10 mins to 30 mins as compared to the E group. This fall in BP was within normal range and no medical intervention was done. The results of the diastolic blood pressure of the parturient in our study were comparable and statistically non-significant**.**(Figure.5 and 6)

Figure.5
Comparison of systolic BP (mm Hg) at different interval in study subjects

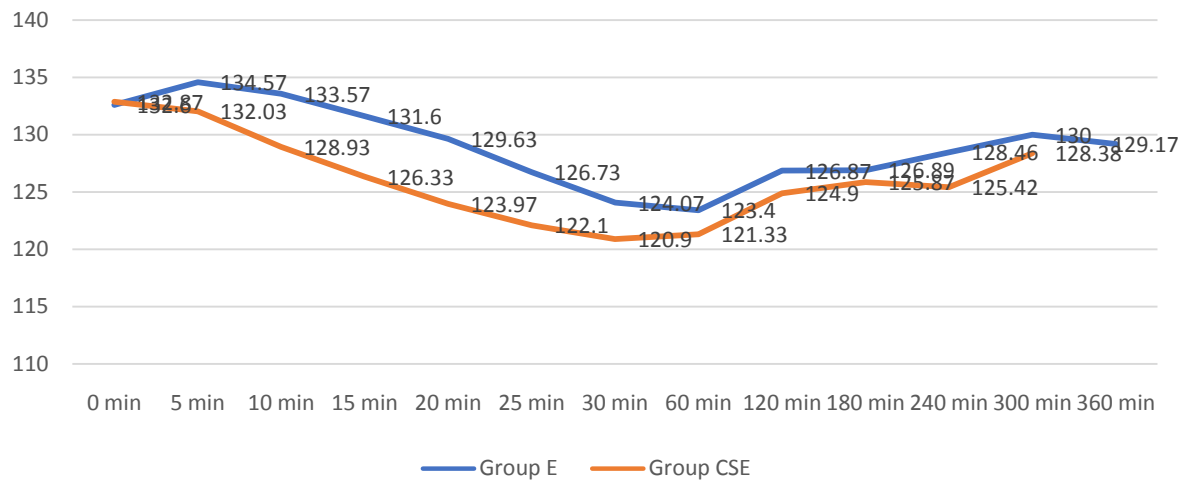
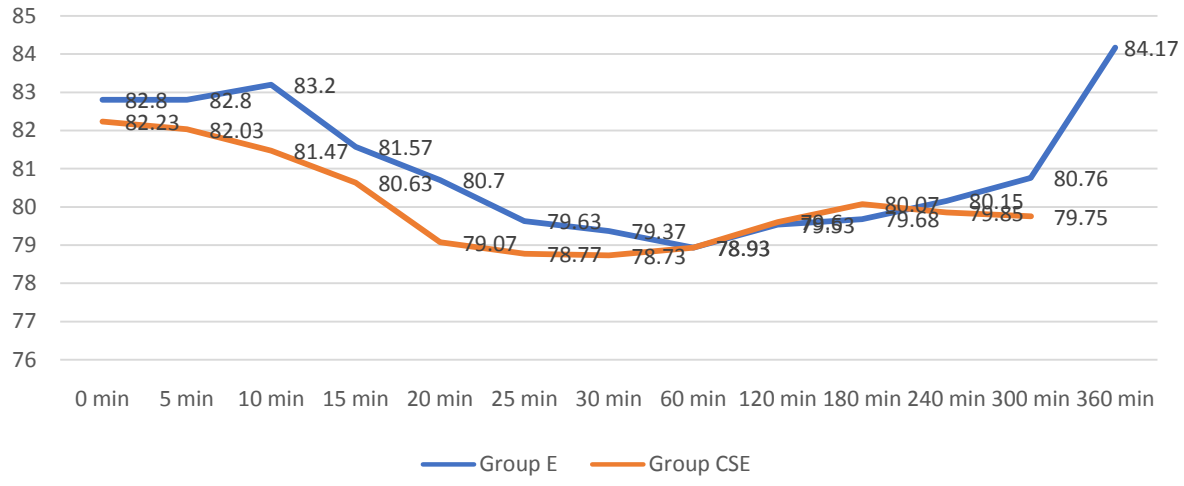
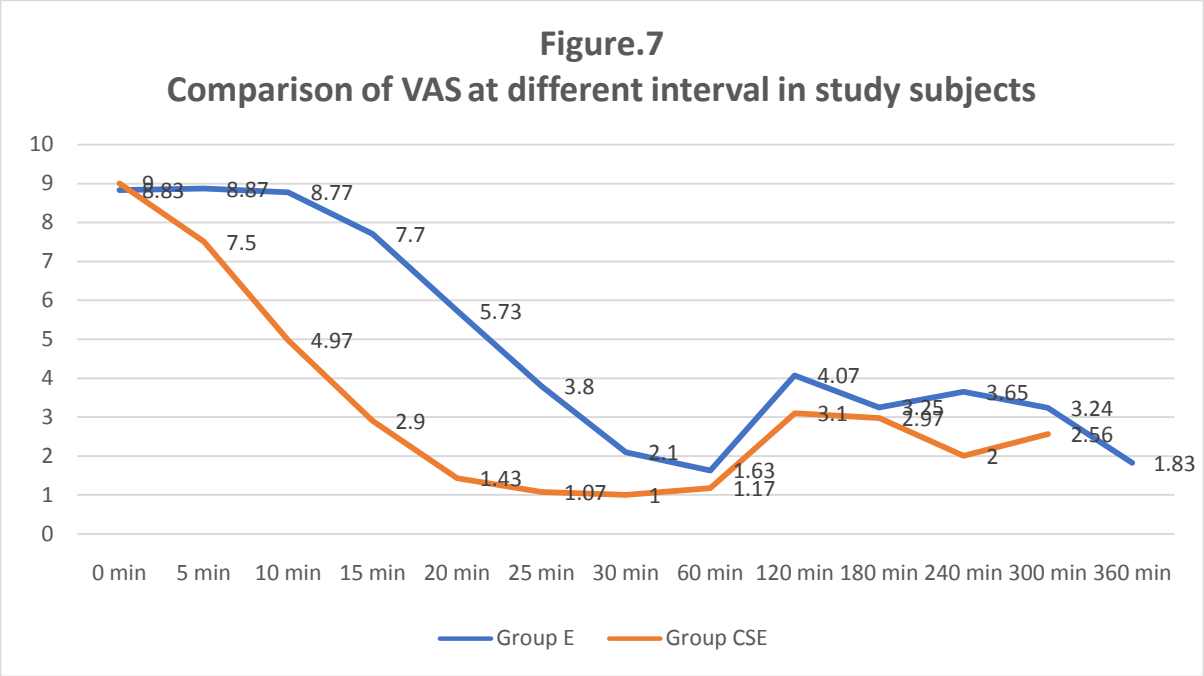


Figure.6
Comparison of Diastolic BP (mm Hg) at different interval in study subjects

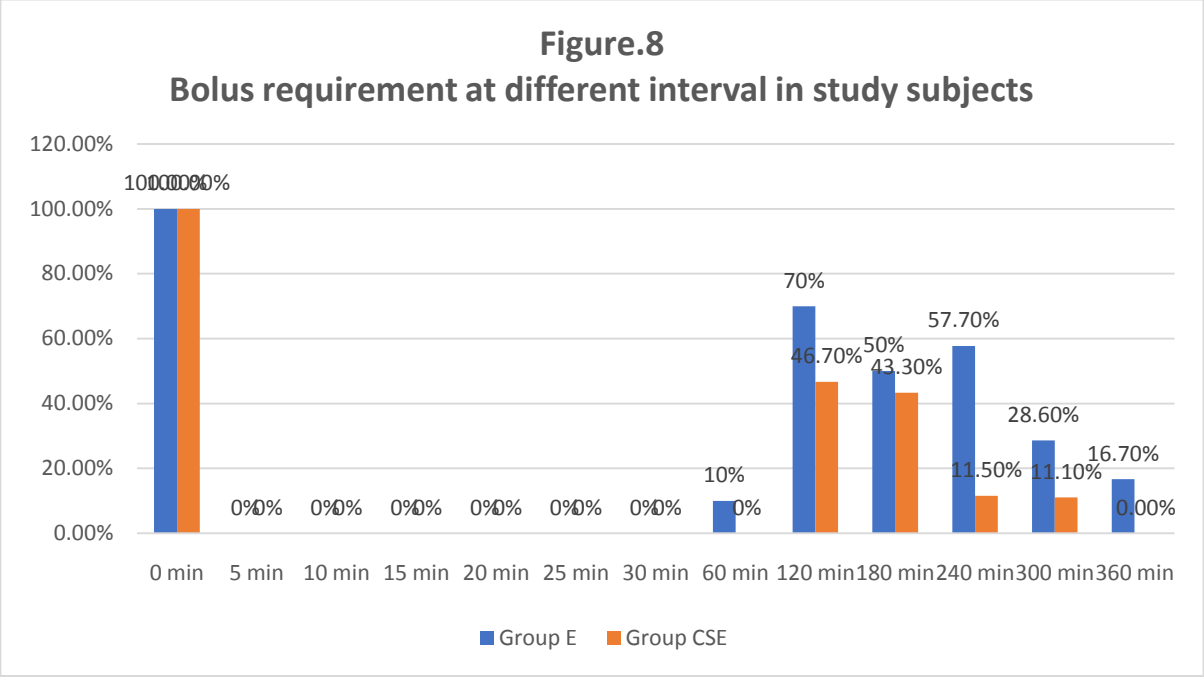


Throughout our study all the parturient had constant CTG monitoring for the Foetal heart rate monitoring. None of the foetus had any non-reassuring heart rate with no significant acceleration or deacceleration.

All the parturient in our study were evaluated for the pain scale or the VAS scale. There was significant less VAS scoring in the CSE group as compared to the E group, especially from 5min to 30 mins.(Figure.7)



We in our study found that the parturient in the CSE group needed less rescue analgesia or the top-ups as compared to the E group. (Figure.8)



There were significant complain of pruritis in the CSE group with significant incidence of nausea in the CSE group as compared to E group,but none complained of vomiting.There was no other side effect like maternal sedation, respiratory distress, or urinary retention in both of these groups.

In our study there was only one parturient in the E group who had motor blockade of grade 4 of modified bromage scale at 20 mins after the administration of the bolus dose. This blockade was resolved at 32

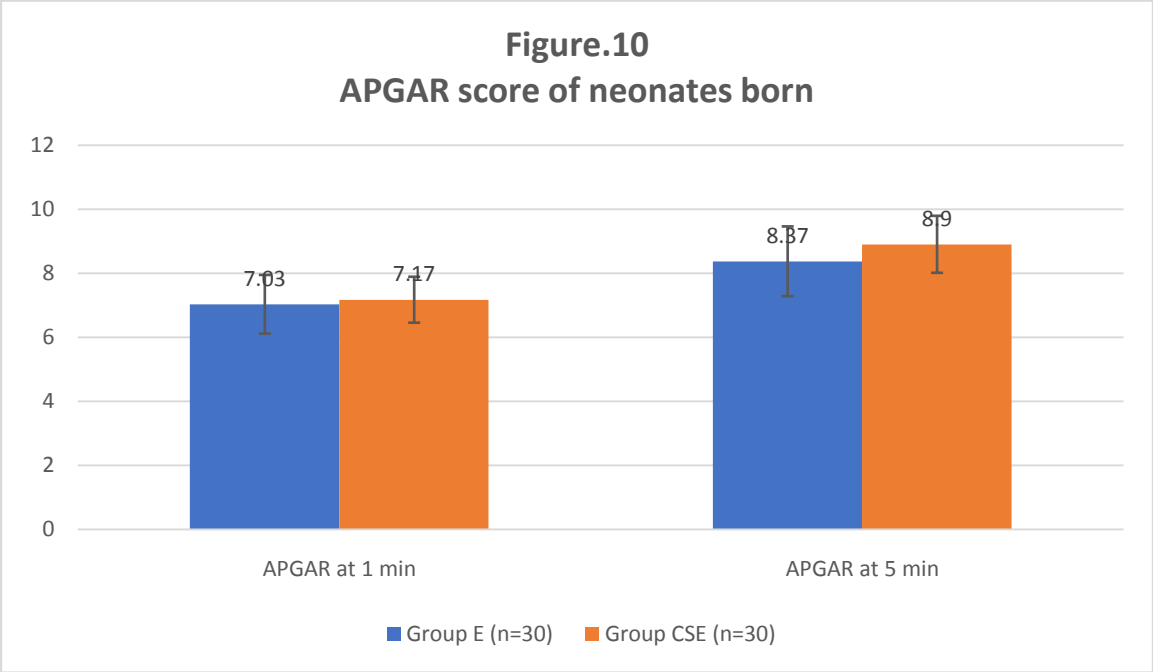
mins and patient was able to ambulate with an assistant after that. There was no complain of motor blockade in the CSE group.

Out of 30 parturient in the E group, 90% delivered vaginally (NVD) and 10% delivered via forceps(FD). Out of 30 parturient in the CSE group, 90% delivered vaginally and 6.7% delivered via forceps while 3.3% landed into caesarean (LSCS). The results were statistically not significant (p = 0.54).(Figure.9)

Figure.9

Mode of delivery	Group E (n=30)		Group CSE (n=30)		Total
	No.	%	No.	%	
NVD	27	90.0	27	90.0	54
LSCS	0	0.0	1	3.3	1
FD	3	10.0	2	6.7	5

The neonatal outcomes were assessed by APGAR score at the 1 min and 5 min interval after the delivery of the neonate.The results were statistically not significant with mean APGAR of 7.10 ± 0.83 at 1 min (p=0.54) and 8.63 ± 1.23 at 5 min (p=0.09).(Figure.10)



IV. Discussion

Childbirth is a very painful process which a parturient endures. It takes a toll on both mother and foetus and can be the worst pain a women can experience in her lifetime thus, making the process of childbirth a bitter experience which can have a negative impact on a mother's psychology. Neuraxial technique for labor analgesia is the most versatile and the gold standard technique for pain control in obstetrics that is currently available. As supported by *Mędrzycka-Dabrowska W et.al* [5]and *Mousa WF et.al* [15]

As per the American College of Obstetricians and Gynaecologists (ACOG),It can be used in any woman wanting the epidural if not contraindicated, a parturient should receive labour analgesia and under no circumstances labour pain should be untreated[14].

ONSET OF ANALGESIA

It is the point of injection to the starting of the pain relief. In our study, the onset of analgesia is faster in the cse group as compared to the epidural group. The results were clinically very significant making the CSE technique, the better intervention for the labor analgesia. This difference is due to the addition of intrathecal fentanyl injection in the CSE group making the pain relief. This is also supported by the COMET trial [16] and Rajappa GC et.al [17].

DURATION OF LABOR

The mean duration of active part of first stage of labour was found to be significantly shorter in the CSE group as compared to the Epidural group. Preservation of motor power of pelvic floor muscle could be the one of the reasons for above explanation. The duration of second stage and the third stage of labour was similar and comparable in both of these groups and this was also supported by study done by*Joel JJ et. al* [18],*Tsen LC et.al* [19] and *Rajappa GC et.*al [17].

MATERNAL HEART RATE

In our study the heart rate was decreased more significantly in the cse group as compared to to the E group. Severe maternal bradycardia is a rare condition with the combined spinal epidural in labouring parturient but, can happen after intrathecal injection of fentanyl which causes sympathetic blockade leading to the decrease in the heart rate. Adding to it the analgesic effect of the local anaesthetic with the addition of opioid in the epidural space leads to further decrease in the heart rate from the rate prior to experiencing the pain as observed by *Joel JJ et. al* [18].

MATERNAL BLOOD PRESSURE

Neuraxial anaesthesia or analgesia usually causes hypotension because of vasodilatation. Intrathecally administered opioids act on preganglionic sympathetic nerve fibres thereby, exerting weak local anaesthetic effect leading to decrease in blood pressure. Fall in systolic blood pressure was more significant in the CSE group with significance showing in 10 mins after the intrathecal fentanyl injection and remained low till 30 mins after the epidural injection, more significantly in the CSE group. The diastolic blood pressure remained comparable in both the group. There was fall in mean arterial blood pressure in both the groups but significantly in the CSE group. In our study though, there was fall in the systolic and the mean blood pressure, but it was within the normal limit and did not require any sort of intervention. This may be due to the adequate preloading with the 500ml of Ringer lactate before the initiation of the procedure, which may have counteracted the life threatening or deleterious fall in the maternal blood pressure as supported by *Hofmeyr G. et.al*.[20], *Collins KM, Bevan DR, Beard RW* [21] and Kinsella SM et. al. [22].

VISUAL ANALOG SCALE

We in our study observed the significant lower VAS scoring in the CSE group as compared to the Epidural group which may be attributed to the intrathecal injection of Fentanyl. This is due to intrathecal administration of fentanyl. The fact supported by *Ngamprasertwong P et.al* [23],*Joel JJ et. al* [18] and the COMET trial [16].

FOETAL HEART SOUND

We in our study observed that there were not any significant changes in the FHS with the CSE technique as compared to the epidural technique.

Top-Up,s or RESCUE ANALGESIA

We in our study found that the amount of the rescue analgesia or the top-ups were lower in the CSE group as compared to the epidural group with lower number of parturient having VAS>4 thus requiring less top-up˝s.the same was also observed by *Joel JJ et. al* [18] and *Simmons SW et.al from Cochrane Pregnancy and Childbirth Group's Trials Register* [24].

MODE OF DELIVERY ANDDELIVERY OUTCOME

27 parturient gave birth with normal vaginal delivery and 3 delivered via forceps due to non-progress of labour in the epidural group while 27 parturient in the combined spinal epidural group delivered via normal vaginal route and 1 was delivered via LSCS due to the failure to progress of labour and 2 of the parturient in the CSE group had forceps delivery due to non-progress of labour. one neonate delivered in the epidural group was admitted to the NICU and put on BIPAP for 1.5 day, rest all babies were fine and were handed to their mother for the feeding after the thorough check-up of the neonate by the paediatrician.

FOETAL OUTCOME

Both Epidural and CSE group had comparable results in our study.

SIDE EFFECTS

There was significant incidence of pruritis in the CSE group. Out of 30, 19 parturient complained of pruritis. The incidence occurred at 2-3 min and subsided at 20-25 mins after the administration of the fentanyl in the intrathecal space.Several parturient also complained about nausea in the CSE group and none of them had vomiting No intervention was required and these subsided subsequently.

At end of the study all the parturient were handed over the questionnaire about their overall experience about the procedure and were asked to fill up the form. All the participants were satisfied with the experience and were willing to undergo the same procedure in their next pregnancy.

V. Conclusion

CSE technique has few advantages like faster onset of analgesia which was beneficial in patients with advanced labor, also it decreased the duration of first stage of labor and there was also rapid cervical dilatation. We concluded that both CSE and Epidural methods of painless delivery provided satisfactory labor analgesia and both were very safe as far as maternal and foetal wellbeing is concerned. Both this technique also allows parturient to ambulate during her labor making it more pleasurable for the laboring women. Further large trials may be required to support the above findings.

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