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Original Research Article

Assessment and Comparison of Effect of Combination of (1%) Chloroprocaine and (0.5%) Hyperbaric Bupivacaine with Fentanyl and (1%) Chloroprocaine and (0.5%) Isobaric Ropivacaine with Fentanyl in LSCS.

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Abstract

Introduction: Sub arachnoid block (SAB) provides a rapid and reliable anaesthetic technique for caesarean section. The principal side effects of SAB are a reduction in maternal blood pressure and hence uteroplacental blood flow; inadequate effect leading to maternal pain and conversion to general anaesthesia. Decreasing dose of intrathecal local anaesthetic (LA) improves cardiovascular stability. Addition of opioid allows safe reduction of LA dose with equal success and less severe side effects.[1] The present study was done to evaluate combination of (1%) Chloroprocaine and (0.5%) Bupivacaine with Fentanyl and (1%) Chloroprocaine and (0.5%) Ropivacaine with Fentanyl in LSCS along with assessment of intra-operative hemodynamics, onset and duration of blockade, Apgar score of newborn, and various adverse effects.

Materials and Methods: This randomized controlled trial study was carried out in the Department of Anaesthesia, Sri Aurobindo Medical College and PG Institute, Indore, among 100 consented patients allocated into 2 groups of 50 each: Group CB [Chloroprocaine (1%) 1 ml+Hyperbaric Bupivacaine (0.5%) 1.5ml+20 mcg Fentanyl] and Group CR [Chloroprocaine (1%) 1 ml+Isobaric Ropivacaine (0.5%) 1.5ml+20 mcg Fentanyl] posted for LSCS using a proforma, pre-anaesthetic evaluation, investigations followed by induction of anaesthesia and administration of test drug. Data was collected, compiled and analysed using R Studio (Open source analytical tool).

Result: Mean age, weight and height of the study participants in Group CR and CB was 30.68±3.717 years, 59.18±6.249 kg, 159.32±5.219 cm and 31.08±3.741 years, 58.98±5.334 kg and 158.98±5.752 cm respectively. In terms of onset of sensory block, achievement of peak sensory level, onset of motor block and achievement of max motor blockade, the duration in CR was significantly shorter compared to CB (p-value<0.05). Similarly, duration of motor and sensory block was also less in CR and was statistically significant (p-value<0.05). At all the time intervals, the difference between the mean HR, RR, MAP and VAS of the two groups was found to be statistically non-significant (P>0.05) i.e. these parameters did not vary with the groups they belonged to. Majority patients in both the groups (CR=54%; CB=70%) did not require a dose of analgesia (p-value>0.05). Apgar score of the newborn did not vary according to the group and the association was found insginficant (p-value=>0.05). However, association

of the groups with maximum level of sensory analgesia was highly significant (p-value=0.000).More patients (32%) in group CB had side effects such as bradycardia, hypotension, nausea & vomiting, shivering etc. as compared to group CR (18%).

Conclusion: Intrathecal combination of (1%) Chloroprocaine and isobaric Ropivacaine (0.5%) with fentanyl provides clinically effective anaesthesia in LSCS with adequate sensory and post operative analgesia. It causes shorter duration of motor analgesia without causing change in hemodynamic parameters which helps in early ambulation and improved patient satisfaction, addition of chloroprocaine causes faster onset, reduce dosage and better hemodynamic stability with no adverse effects.

Keywords: Chlorprocaine, Bupivacaine, Ropivacaine, Fentanyl, Apgar, LSCS.

Introduction

Anaesthetic technique must produce enough surgical anaesthesia of adequate duration and minimal maternal and neonatal side effects during caesarean delivery. Sub arachnoid block (SAB) provides a rapid and reliable anaesthetic technique for caesarean section that may provide greater safety than general anaesthesia. The principal side effects of SAB for caesarean section are a reduction in maternal blood pressure and hence uteroplacental blood flow, inadequate effect leading to maternal pain and conversion to general anaesthesia. Decreasing the dose of intrathecal local anaesthetic (LA) will improve cardiovascular stability, but may not provide adequate surgical anaesthesia. The addition of an opioid will allow the safe reduction of the LA dose with equal success and less severe side effects. [1] Bupivacaine is the most widely used anaesthetic agent in SAB. The onset of action of bupivacaine is 5-8 minutes but major limitation of bupivacaine is that it has an increased cardiotoxic potential. Ropivacaine is a pure enantiomer which is used in spinal anaesthesia and is less cardiotoxic than bupivacaine but major limitation of its use is that it has a more sensory effect than motor effect. Chloroprocaine has a fast onset of action with major limitation of its use that it cannot be used in prolonged surgery. Therefore various adjuvants have been tried such as opioids to counter side effects of local anaesthetic but they have their own disadvantages as they cause maternal and neonatal respiratory depression. The present study was carried out to evaluate the combination of (1%) Chloroprocaine and (0.5%) Bupivacaine (H) with Fentanyl and (1%) Chloroprocaine and (0.5%) isobaric Ropivacaine with Fentanyl in LSCS along with assessment of intra-operative hemodynamics, onset and duration of sensory and motor blockade, evaluation of APGAR score of newborn, and detection of adverse effects.

Materials and Methods: This prospective randomized controlled trial study was carried out in the Department of Anaesthesiology and Critical Care, Sri Aurobindo Medical College and Post Graduate Institute, Indore, Madhya Pradesh after approval by the Institutional Ethics Committee over a period of one year.

Inclusion Criteria:

- Age 20 to 35 years.
- ASA Grade 1& 2 Patients.
- Patients undergoing elective and emergency LSCS.
- Patients with normal coagulation profile.
- Patients free from cardio-respiratory and autonomic dysfunction.
- This sample size was 100 consented patients calculated based on average number of cases i.e. 10-15 cases per

month posted for LSCS in the hospital and who fulfilled the inclusion criteria. The patients were randomly allocated into 2 groups of 50 each and were named as Group CB [Chloroprocaine (1%) 1 ml + Hyperbaric Bupivacaine (0.5%) 1.5 ml with 20 mcg Fentanyl] and Group CR [Chloroprocaine (1%) 1 ml + Isobaric Ropivacaine (0.5%) 1.5 ml with 20 mcg Fentanyl].

Pre-anaesthetic evaluation was done one day before the surgery, recording a detailed history and performing a complete physical examination. Basic routine investigations were carried out. Prior to surgery i.e. night before the operation, patients were instructed to fast for 6–8 hours. On the day of surgery patients were shifted to operating room, were connected to Multichannel monitor (Philips intelliviue Mp20) and baseline heart rate, non-invasive blood pressure (systolic & diastolic) was recorded. After insertion of 18G IV cannula, patients were co-loaded with ringer lactate (RL) at 15ml/kg over 30 minutes. The anaesthesia machine, emergency resuscitation trolley, circuits and airway equipment were kept ready. Patients were put in left lateral position/sitting position, L3-L4 interspace identified. Under all strict aseptic precautions, after local anaesthetic infiltration, 25G Quincke spinal needle introduced into L3- L4 space, after confirming clear flow of CSF and negative aspiration for blood, 2.5 ml drug as per the group was injected intrathecally and continuous monitoring will be done. After adequate blockade patient was repositioned based on the surgical requirements.

Assessment of Sensory Blockade – Was tested by Pin Prick Test using hypodermic needle and the time of onset, highest level of sensory blockade, time for 2 segment regression of sensory level, duration of sensory block was noted.

Assessment of Motor Blockade – Was done by Modified Bromage Scale. The scale is as follows:

0 = able to perform a full straight leg raise over the bed for 5 seconds.

1 = unable to perform a leg raise but can flex the leg on knee articulation.

2 = unable to flex knee but can flex ankle.

3 = unable to flex ankle but can move the toes.

4 = unable to move toes (total paraluysis).

Assessment of health of newborn child – Was done by Apgar score recorded at 1 min and 5 minutes.

0-3 = low

4-6 = moderately abnormal

7-10 = reassuring

Intraoperatively, vital parameters like Heart Rate, Non-Invasive Blood Pressure, and SpO2 were recorded every minute for the first 5 minutes, thereafter every 5 minutes till 1 hour of surgery and then every 15 minutes till the end of surgery; postoperatively, every 30 minutes till the patient started complaining of pain.

All the patients were given Oxygen @ 6L/min through face mask. No IV analgesics or opioids were administered during the surgery. Patients with inadequate spinal block, if any, or who required supplementation during surgery were excluded from study. All the data was recorded in a pre-structured proforma specifically designed for the study.

Statistical Analysis: The descriptive statistics was performed by using the proportional or frequency distribution of the parameters. Student t test for two sample means was applied to calculate the significant difference the mean values of different numeric parameters of two groups. Paired t-test is applied to compare the changes in the pre and post values at different time intervals of numeric parameter within group. Chi Square Test

was applied to determine association between two variables. The different parameter distribution was associated with different morbidities by using the Chi square test. The p-value < 0.05 was considered as level of significance. Microsoft Excel and R Studio (Open source analytical tool) was used to perform the basic calculation, presentation and statistical analysis of data.

Result:

Table 1: Comparison of mean values of different variables between two groups

Parameters	Groups	Mean±SD	p-values
Socio demographic variables			
Age (in years)	CR	30.68±3.717	*0.593*
	CB	31.08±3.741	
Weight (in kg)	CR	59.18±6.249	*0.864*
	CB	58.98±5.334	
Height (in cm)	CR	159.32±5.219	*0.758*
	CB	158.98±5.752	
Time taken and duration of various blockades			
Onset of sensory block (min)	CR	9.160±1.543	*0.000**
	CB	10.700±1.555	
Achievement of peak sensory level (min)	CR	14.760±1.673	*0.000**
	CB	16.560±1.606	
Onset of motor block (min)	CR	12.180±1.574	*0.708*
	CB	12.080±1.029	
Achievement of max motor blockade (min)	CR	19.600±1.772	*0.062*
	CB	18.96±1.615	
Two segment sensory regression (min)	CR	105.5±12.586	*0.012**
	CB	113.4±17.969	
Duration of motor block (min)	CR	125.20±13.626	*0.000**
	CB	142.80±10.359	
Duration of sensory block (min)	CR	162.6000±7.84024	*0.121*
	CB	165.2000±8.74584	

**p-value significant. Unpaired t-test applied*

Table 2: Comparison of vitals and VAS score at different time intervals between the two groups

Vitals	Group CR			p-value (within group) between pre-op value and at different time intervals)	Group CB		p-value (within group) between pre-op value and at different time intervals)	p-value (between groups)
	N	Mean	SD		Mean	SD		
Pre-op HR	50	89.22	8.615	-	90.14	5.973	-	*0.536*
HR-2 min	50	85.26	7.261	*0.010**	83.04	8.164	*0.000**	*0.154*
HR-3 min	50	83.70	7.265	*0.000**	81.04	8.164	*0.000**	*0.088*
HR-5 min	50	80.92	7.298	*0.000**	78.54	7.492	*0.000**	*0.111*

HR-10 min	50	78.66	7.104	*0.000**	77.36	7.992	*0.000**	*0.392*
HR-15 min	50	77.46	7.686	*0.000**	76.78	7.665	*0.000**	*0.659*
HR-20 min	50	77.00	8.497	*0.000**	76.36	7.782	*0.000**	*0.695*
HR-25 min	50	77.00	7.602	*0.000**	76.94	7.950	*0.000**	*0.969*
HR-30 min	50	77.62	8.271	*0.000**	76.94	8.110	*0.000**	*0.679*
HR-35 min	50	77.72	8.132	*0.000**	76.06	7.744	*0.000**	*0.298*
HR-45 min	50	78.56	8.706	*0.000**	76.76	5.161	*0.000**	*0.212*
HR-60 min	50	79.16	8.723	*0.000**	78.56	5.470	*0.000**	*0.681*
Pre-op RR	50	14.54	0.952	-	14.24	0.938	-	*0.116*
RR-2 min	50	13.50	1.717	*0.000**	13.26	1.771	*0.000**	*0.493*
RR-3 min	50	12.34	1.136	*0.000**	12.60	1.245	*0.000**	*0.278*
RR-5 min	50	12.14	1.125	*0.000**	12.46	1.232	*0.000**	*0.178*
RR-10 min	50	12.16	1.113	*0.000**	12.22	1.166	*0.000**	*0.793*
RR-15 min	50	12.10	1.111	*0.000**	12.22	1.166	*0.000**	*0.599*
RR-20 min	50	12.08	1.085	*0.000**	12.22	1.148	*0.000**	*0.532*
RR-25 min	50	12.06	1.038	*0.000**	12.14	1.088	*0.000**	*0.708*
RR-30 min	50	11.96	1.009	*0.000**	11.94	1.058	*0.000**	*0.923*
RR-35 min	50	12.18	1.004	*0.000**	11.92	1.066	*0.000**	*0.212*
RR-45 min	50	12.06	1.132	*0.000**	12.22	1.183	*0.000**	*0.491*
RR-60 min	50	12.00	1.107	*0.000**	12.10	1.035	*0.000**	*0.642*
Pre-op MAP	50	109.26	8.649	-	110.28	5.869	-	*0.492*
MAP-2 min	50	108.46	9.265	0.579	103.18	8.048	*0.000**	*0.003**
MAP-3 min	50	106.28	9.293	0.042*	100.80	8.028	*0.000**	*0.002**

MAP-5 min	50	102.64	9.367	0.000*	97.60	8.164	*0.000**	*0.005**
MAP-10 min	50	100.40	7.980	0.000*	96.70	8.335	*0.000**	*0.026**
MAP-15 min	50	101.50	7.815	0.000*	96.48	7.587	*0.000**	*0.002**
MAP-20 min	50	99.62	8.664	0.000*	97.24	7.615	*0.000**	*0.148*
MAP-25 min	50	100.34	9.458	0.000*	97.56	7.600	*0.000**	*0.108*
MAP-30 min	50	107.66	7.509	0.000*	96.96	8.134	*0.000**	*0.000**
MAP-35 min	50	107.88	8.116	0.213	97.68	8.195	*0.000**	*0.000**
MAP-45 min	50	108.68	7.662	0.352	102.28	7.307	*0.000**	*0.000**
MAP-60 min	50	110.32	6.956	0.613	103.88	7.891	*0.000**	*0.000**
VAS-2 hour	50	1.66	0.798	-	1.74	0.565	-	*0.564*
VAS-4 hour	50	2.22	0.679	-	2.46	0.762	-	*0.099*
VAS-6 hour	50	2.96	0.903	-	3.12	0.940	-	*0.387*
VAS-8 hour	50	2.48	0.646	-	2.66	0.593	-	*0.150*

**p-value significant. T-test applied.*

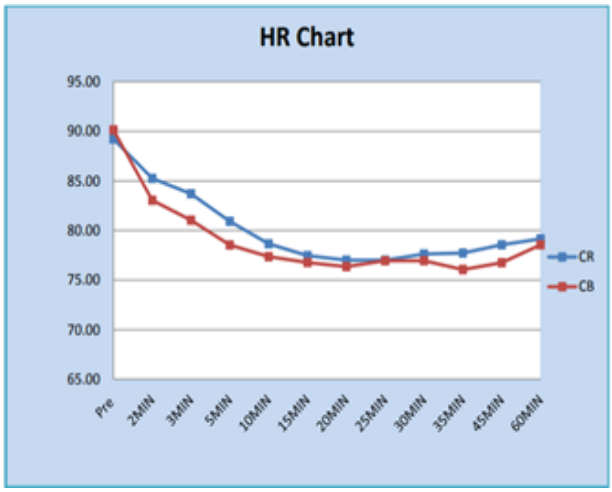

Figure 1: Comparison of HR at different time intervals in both groups

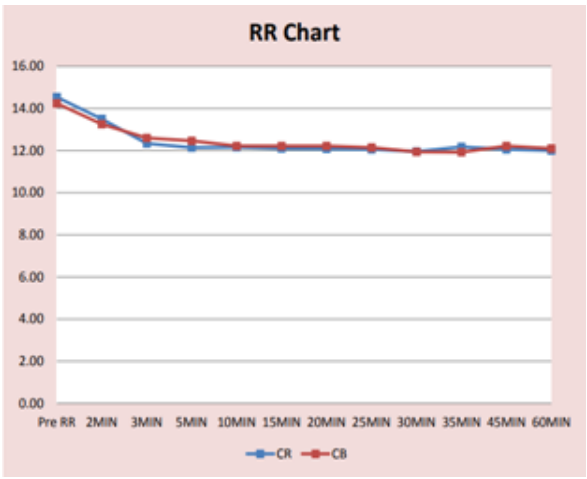

Figure 2: Comparison of RR at different time intervals in both groups

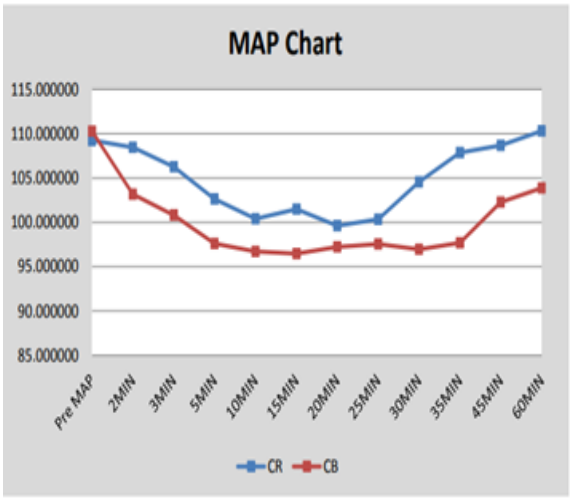

Fig 3: Comparison of MAP at different time intervals in both groups

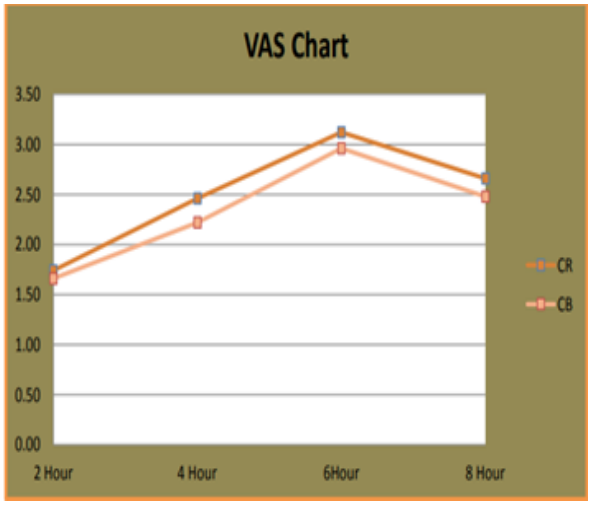

Fig 4: Comparison of VAS at different time intervals in both groups

Table 3: Distribution of study participants on the basis of various parameters in both groups

Parameters	Group CR		Group CB		Total		P-value
Analgesia given	**N**	**%**	**N**	**%**	**N**	**%**	
No	27	54.00%	35	70.00%	62	62%	0.099
Yes	23	46.00%	15	30.00%	38	38%	
APGAR at 1 minute							
8.00	39	78.00%	35	70.00%	74	74%	0.362
9.00	11	22.00%	15	30.00%	26	26%	
APGAR at 5 minutes							
8.00	23	46.00%	17	34.00%	40	40%	0.221
9.00	27	54.00%	33	66.00%	60	60%	
Maximum level of sensory analgesia							
T4	0	0.00%	26	52.00%	26	26%	0.000*
T5	17	34.00%	16	32.00%	33	33%	
T6	33	66.00%	8	16.00%	41	41%	
Total	***50***	***100%***	***50***	***100%***	***100***	***100%***	

**p-value significant. Chi-square test applied.*

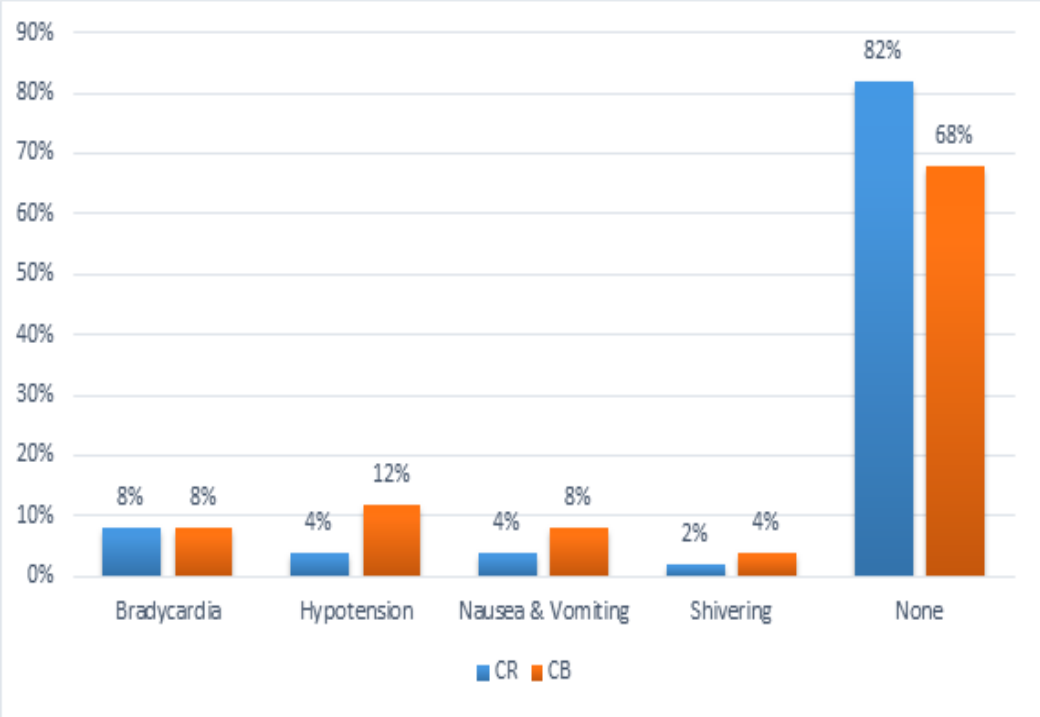

Figure 5: Distribution of study participants on the basis of complications in both groups

Discussion

All patients posted for LSCS in both the groups were comparable in terms of demographic values. Age ranged between 22 to 35 years. Mean age, weight and height in Group CR was 30.68+ 3.717 years, 59.18±6.249 kg and 159.32±5.219 cm respectively; while in Group CB was 31.08±3.741 years, 58.98±5.334 kg and 158.98±5.752 cm respectively. Association of these parameters with the groups was insignificant (p-value<0.05). The mean heart rate in CR and CB was 79.36±7.86 and 77.80±7.42 beats/ min respectively; and at all time intervals, the difference between mean HR of both groups was statistically non-significant (p-value>0.05). Bradycardia, in the present study, was observed in 8% patients in group CR and CB each; and these patients responded to 0.6 mg atropine. The mean RR in CB was 12.3±1.19 and in CR was 12.23±1.14 per min. The difference between mean RR of both groups was statistically non-significant (p-value>0.05). The mean MAP in CR was 104.88±8.37mmhg and in CB was 99.12±7.90mmhg. The mean difference in the blood pressure in both the groups was statistically significant (p-value<0.05) at all time intervals except pre-operatively and at 20 and 25 minutes intra-operatively (p-value>0.05). 4% patients in Group CR and 12% patients in Group CB developed hypotension; and responded to I.V. bolus dose of 6 mg ephedrine. Our results were consistent with studies done by Gunaydin B et al [2] where they compared intrathecal hyperbaric bupivacaine and isobaric ropivacaine with fentanyl. They used ephedrine in both groups and it was more significant in bupivacaine group. Our results are in contrast to the study done by Koltka K et al [3] in which they compared isobaric ropivacaine and bupivacaine with fentanyl and there were no statistically significant changes in HR and MAP. Similarly, Konda RR et al [4] and Gadre AK et al [5] compared hyperbaric bupivacaine and isobaric ropivacaine and no statistical difference in SBP, DBP, RR and SpO_2 was observed. In the present study, mean time taken for onset of sensory block at T10 in CB was 10.700±1.555 min and in CR was 9.160±1.543 min i.e. it was faster in CR; and this difference was statistically significant (p-value=0.000).

Similarly Koltka K et al [3] observed that the onset of sensory analgesia in ropivacaine-fentanyl was 9 min and in bupivacaine fentanyl was 10 min, though results were statistically insignificant. The results of our study are in contrast to Konda RR et al [4], where onset was faster with bupivicaine (2.38±0.36 min) compared to ropivacaine (4.45±0.03 min). In the present study, mean time to achieve maximum sensory block was faster in CR (14.760±1.673 min) compared to CB (16.560±1.606 min) with a statistically significant difference (p-value=0.000). In group CB the maximum dermatome level to reach was T4 in 26 patients (52%) and in group CB was T6 in 33 patients (66%) with the difference being statistically significant (p-value<0.05). Jagtap S et al [6] compared ropivacaine+fentanyl (RF) and bupivacaine+fentanyl (BF) and the highest level to reach in both groups was T6; time taken to achieve maximum sensory block in RF was 6.02±2.1min and in BF was 6±3.6min (p>0.05; insignificant). Un Canan et al [1] compared hyperbaric ropivacaine and bupivacaine with fentanyl in which time to reach T4 dermatome with RF was 4.8±1.1 and with BF group was 5.00±1.0min (p>0.05; insignificant). Koltka K et al [3] found maximum level of the sensory analgesia with ropivacaine was T7 and with bupivacaine was T4 with statistically significant results (p<0.05). Konda RR et al [4] observed time of onset of sensory block in bupivacaine group 2.38±0.36min and in ropivacaine group 4.45±0.03min (statistically significant; p-value<0.05). In the present study, mean duration of sensory block in group CB and CR was 165.200±8.74 and 162.600±7.84min respectively (statistically insignificant; p=0.121). Our study was similar to Konda RR et al [4], Un Canan et al [1] and Gadre AK et al [5] in which duration of sensory block was statistically non-significant (p>0.05) between the groups. The result of our study was in contrast to Jagtap S et al 6 in which duration of sensory block in group RF was 234.44±58.76 and group BF was 263.33±63 min which was statistically insignificant (p<0.05). In the present study, mean time of onset of motor block in CR and CB was 12.180±1.57 and 12.080±1.029 min respectively, the difference being statistically insignificant (p=0.708). Our findings were similar to Lee YY et al [7] who compared ropivacaine and bupivacaine with fentanyl and the onset time for motor block in both the groups was statistically non-significant. In contrast to our study, Konda RR et al [4] observed the time of onset for motor block in bupivacaine group 3.06±0.9 min and ropivacaine group 6.42±2.48min (statistically significant; p-value<0.05). Mean time of maximum motor block, in the present study, was 18.96±1.61 and 19.60±1.77 min in Group CB and CR respectively with statistically insignificant difference (p-value=0.062). The results of our study were similar to Un Canan et al [1] in which the degree of motor block was statistically insignificant (p-value>0.05). Similarly, Jagtap S et al [6] reported time to reach maximum motor blockade grade 3 in RF was 6.02±2.1min and group BF was 6±3.6min which was statistically insignificant (p>0.05). The study done by Konda RR et al [4] and Vaishali R et al [8] was in contrast to our study where time for maximum motor block grade 3 was faster with bupivacaine than ropivacaine. Mean duration of motor block in CB and CR was 142.800±10.35 and 125.200±13.62 min respectively, in the present study, with statistically significant difference (p=0.000). The result of our study was similar to Koltka K et al [3], Gunaydin B et al [2] and Lee YY et al [7] in which duration of motor block was longer in bupivacaine-fentanyl group compared to ropivacaine-fentanyl group. In the present study none of the babies had any complications. APGAR in both groups was >7 at both the intervals; statistically insignificant. There was no statistical difference between Apgar score in both the groups taken in 1min and 5min which was consistent with the studies done

by Gadre AK et al [5], Un Canan et al [1], Konda RR et al [4] and Gunaydin B et al [2]. The mean time for regression in group CB and CR was 113.44±17.96 and 105.500±12.58 min respectively which was statistically significant ($p<0.05$). The result was similar to Shahid N et al [9] who observed that two segment regression with bupivacaine was 146.41±12.81min and ropivacaine was 130.34±15.26 min (statistically significant; $p=0.005$). Bhasakara B et al [10] observed the time for two segment regression to L1 with Chlorprocaine+fentanyl was 76.87±12. 47min and with Ropivacaine+fentanyl was 135.24±18.54min (statistically significant; $p<0.005$) similar to our study. Our study was in contrast to studies done by Konda RR et al [4] in which time for the two segment regression in bupivacaine group was 92.40±20.7min and in ropivacaine group was 90.6±20.7min (statistically insignificant; $p>0.05$). Jagtap S et al [6] found two segment regression with ropivacaine+fentanyl was 226±46.90min and bupivacaine+fentanyl group was 229±50.51min (statistically insignificant; $p>0.005$). In our study the interval taken for assessment of VAS was 2, 4, 6 and 8 hours. The mean VAS at all intervals was statistically insignificant.

Conclusion

Intrathecal combination of (1%) Chloroprocaine and isobaric Ropivacaine (0.5%) with fentanyl provides clinically effective anaesthesia in LSCS with adequate sensory and post operative analgesia. It causes shorter duration of motor analgesia without causing change in hemodynamic parameters which helps in early ambulation and improved patient satisfaction, addition of chloroprocaine causes faster onset, reduce dosage and better hemodynamic stability with no adverse effects.

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