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Comparative Study of Effect of Low Dose Intrathecal Bupivacaine with Fentanyl for Caesarean Delivery

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Abstract: *Many drug combinations have been used to improve the quality of subarachnoid block during caesarean section. The synergistic effect of combining local anaesthetic with opioid intrathecally has numerous advantages. Amongst the opioids, Fentanyl addition has been suggested to have various benefits and this has proved in various studies. Hence, this prospective and randomized double blind study was undertaken to compare the efficacy and safety of two different intrathecal fentanyl doses with hyperbaric bupivacaine in terms of the quality and intensity of subarachnoid block in patients undergoing elective caesarean sections.*

METHODS - 100 healthy parturients, scheduled for elective caesarean section with singleton pregnancy were allocated randomly into two groups, 50 in each group. Group I received intrathecal 0.5% Bupivacaine Heavy 1.8 ml with Fentanyl 10ug (0.2 ml) with 0.2 ml saline. Group II was given Intrathecal 0.5% Bupivacaine Heavy 1.8 ml with Fentanyl 20 ug (0.4ml). Total volume of both solutions was 2.2 ml. During the study, cardiorespiratory parameters, time required to achieve highest sensory block to T4-T6 level, duration of anaesthesia, onset and total duration of motor blockade, intraoperative analgesic supplementation, postoperative pain relief, vasopressor requirement, duration of effective analgesia, maternal and neonatal side effects were monitored.

RESULTS - The duration of anaesthesia and effective analgesia was significantly prolonged in Group II as compared to group I. Onset and duration of complete motor blockade in both groups were similar. Subjective pain score was lowest in Group II than Group I. The duration of analgesia assessed by visual analogue scale was significantly more in Group II with a mean effective analgesia time of 289.60±11.75 minutes than Group I of 146.06±8.75 minutes. The incidence of maternal side effects and neonatal outcome were comparable in both groups.

CONCLUSION - Addition of fentanyl 20ug as compared to 10 ug to intrathecal hyperbaric bupivacaine in caesarean section markedly enhances quality of surgical anaesthesia, prolonged duration of sensory block and effective analgesia, without affecting maternal and fetal well-being.

Keywords*– intrathecal Fentanyl, Caesarean Delivery, Hyperbaric Bupivacaine, Subarachnoid Block*

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I. Background

One of the primary aim of anaesthesia is to render adequate pain relief, thereby permitting the performance of surgical procedures without stress and discomfort to patients and allowing fast recovery postoperatively. Recently, there is an increased popularity of regional anaesthesia amongst obstetric anaesthetists. However, it is not without risk.

Morbidity and mortality in regional anaesthesia are primarily related to excessive high regional blocks and toxicity of local anaesthetics. Drug doses reduction and improved technique to avoid higher block levels and heightened awareness of local anaesthetics toxicity have led to the reduction of complications related with regional anaesthesia. The neuroaxial blocks in obstetric patients require precise dose estimation as the drugs are directly injected in intrathecal space. With minimum dose changes, the chances of complication and side effects are enhanced. All these key factors made an enormous contribution to carry out this study. Various adjuvants are added to local anaesthetics to avoid systemic toxicities. It has proved in various studies about advantages of using intrathecal Fentanyl with bupivacaine in caesarean section. This study monitored the effect of intrathecal Fentanyl with low dose bupivacaine on reduction of higher block incidence and avoiding the complications of higher doses of local anaesthetics used in spinal anaesthesia in caesarean section. This study could be implicated to select the best possible doses of opioids with local anaesthetics used in spinal anaesthesia in caesarean section.

In our prospective and randomized double blind study, we evaluated surgical anaesthesia, haemodynamic stability, and perioperative analgesia, maternal and neonatal outcome following intrathecal hyperbaric bupivacaine with two different doses of intrathecal Fentanyl.

II. Materials and Methods

The present study was carried out in the Department of Anaesthesiology, JNMC and Acharya Vinobha Bhave Rural Hospital Sawangi during the period of NOVEMBER 2008 to SEPTEMBER 2010 after approval from the Institutional Ethical Committee. This study was a randomized and prospective double blind study in which, 100 parturients posted for elective caesarean section under spinal anaesthesia were studied, and compared Intrathecal bupivacaine with two varying doses of Fentanyl in elective caesarean section cases.

100 women of ASA class I and II posted for elective caesarean section at term with singleton pregnancy, aged 20-30 years with Mallampati class I were allocated randomly into two groups of 50 patients each. Patients with history of pre–eclampsia, multiple pregnancies, weight > 90kg, height < 150 cm or >175cm, major systemic illness, acute foetal distress or any contraindication to regional anaesthesia were excluded from the study. Parturients were explained about the technique of anaesthesia, surgery and were familiarized with intraoperative and postoperative questionnaires. Also, informed written valid consent were taken from all participants. All patients were given Inj. Ranitidine (50 mg) and Inj. Metoclopramide (10 mg) intravenously before shifting to operating room. No parenteral opioids or benzodiazepines were administered.

Study was conducted in a randomized, double blind manner in the operating theatre. All patients were infused with 1000cc of Ringer's lactate solution through 18G intravenous cannula. Group I (n = 50) received Intrathecal Bupivacaine Heavy 1.8 ml (0.5%) with fentanyl (10 ug) 0.2 ml with 0.2 ml saline to make total volume - 2.2 ml. Group II (n = 50) received Intrathecal Bupivacaine Heavy 1.8 ml (0.5%) with fentanyl (20 ug) 0.4 ml. Total volume given was 2.2 ml. Subarachnoid block was instituted with a 25 G spinal needle in left lateral position at L3 - L4 space. After this, patients were immediately placed in supine position with 20° left lateral tilt. They all received oxygen by nasal cannula at 41/min. Time of induction of anaesthesia was noted.

The following parameters were monitored - Pulse, Systolic and Diastolic BP, Respiratory rate and Oxygen Saturation were noted every 2 minutes until T4 dermatomal level was reached, then every 5 minutes for the initial 30 minutes, followed by every 15 minutes till 2 hours and then every 30 minutes till block receded to T12 level, then every 40 minutes till patient demand analgesia and then monitoring was continued every 60 minutes till 7th postoperative hours. If systolic blood pressure fell below by 30% of preoperative base line values, Inj. Ephedrine was given intravenously in 3 mg increments. Dermatomal sensory blockade to pinprick was assessed every 2 minutes till T 4 – T6 dermatomal level was reached then every 15 minutes till regression to T12 level. Degree of motor block was assessed using Bromage Scale.

Subjective Pain Rating Score was used for intraoperative Analgesic supplementation. Patients with Grade 3 pain score was given Inj Fentanyl 0.5 – 1 ug/kg IV. Visual analogue scale (VAS) was used for postoperative pain relief assessment. Patient were asked 60-minute post operatively to rate pain on 100 mm VAS. Intraoperative comfort score was used to assess patients comfort level during surgery. Incidence of nausea, vomiting, pruritus, high level of blocks were recorded. Neonatal outcome was assessed by Apgar score at 1 min and 5 min after delivery. For rescue analgesia, patients were administered intramuscular Inj. Diclofenac 75 mg.

Statistical analysis: In this study, for each parameter of both the groups, mean and standard deviations were calculated by using statistical computer software package SPSS and graph pad. To find out the significant difference between the groups for quantitative data Z test was used and paired "t" test to see the change within a group. Z test was used to find out statistical difference in comfort and Pain Scores. Incidence of the side effects was compared by Chi square test. A P–value of <0.05 was taken as statistically significant.

III. Results

A total of 100 patients participated in the study and were randomised into two groups, group I(n=50) and group II(n=50). The results obtained from the demographic data show that both groups were comparable in terms of age, weight, height and parity distribution (Figure 1). Duration of surgery in both groups showed no statistical difference (Figure 1). The highest median peak sensory level achieved in both the groups was T6. The time required for highest sensory level in both groups was comparable. The time to T12 and time of effective analgesia was significantly higher in group II as compared to group I.

The basal mean systolic blood pressure (Figure 4) in Group I was 119.84 ± 6.28 mm Hg and in Group II was 117.40 ± 6.78 mm Hg which was comparable and difference was not statistically significant (p>0.05). At 2 minutes, significant fall in blood pressure was observed in both the group. From 20 minutes, the mean systolic pressure gradually increased. From 90 to 420 minutes interval, the systolic blood pressure in Group I and II was stable and showed no statistical difference (p-value>0.05). The comparison of respiratory rate and oxygen saturation in both groups showed no statistical difference. Nausea was noted in 6% of patients in group I , and

10% in group II .1 patient had vomitting in group I and 2 patients in group II. The incidence of pruritus was observed more in group II (18%) as compared to 4% in group I. However, the Apgar score at 1 minute and 5 minutes in both groups were comparable.

Figure1: Demographicdataanddurationofsurgeryinbothgroups

	Group1(n=50)	Group2(n=50)	P-Value
1.Age(years)			
20-25	31	35	
26-30	19	15	0.39
2.Weight(Kg)			
50-60	34	33	
61-70	15	17	0.56
71-80	1	0	
3.Height(cm)			
150-160	37	42	
161-170	11	8	0.07
171-180	4	0	
4.Parity			
Primigravida	32	28	
Multigravida	18	22	0.41
5.DurationofSurgery(min)			
40-50	11	10	
51-60	23	29	
61-70	14	10	0.62
71-80	2	1	

Figure2: Comparisonofcharacteristicsofsensoryblockinboththegroups

Characteristics	GroupI	GroupII	z-value	p-value
Timerequiredforhighestsensorylevel(min)	8.92±0.94	9.20±0.59	1.80	0.07
TimetoT12regression(min)	160.32±8.02	183.38±8.73	13.75	0.000
Timeforrescueanalgesia (effectiveanalgesia) (min)	146.06±8.75	289.60±11.75	69.23	0.000

Figure3: ComparisonofVisualAnalogueScaleinboththegroupsatpostoperativeperiod

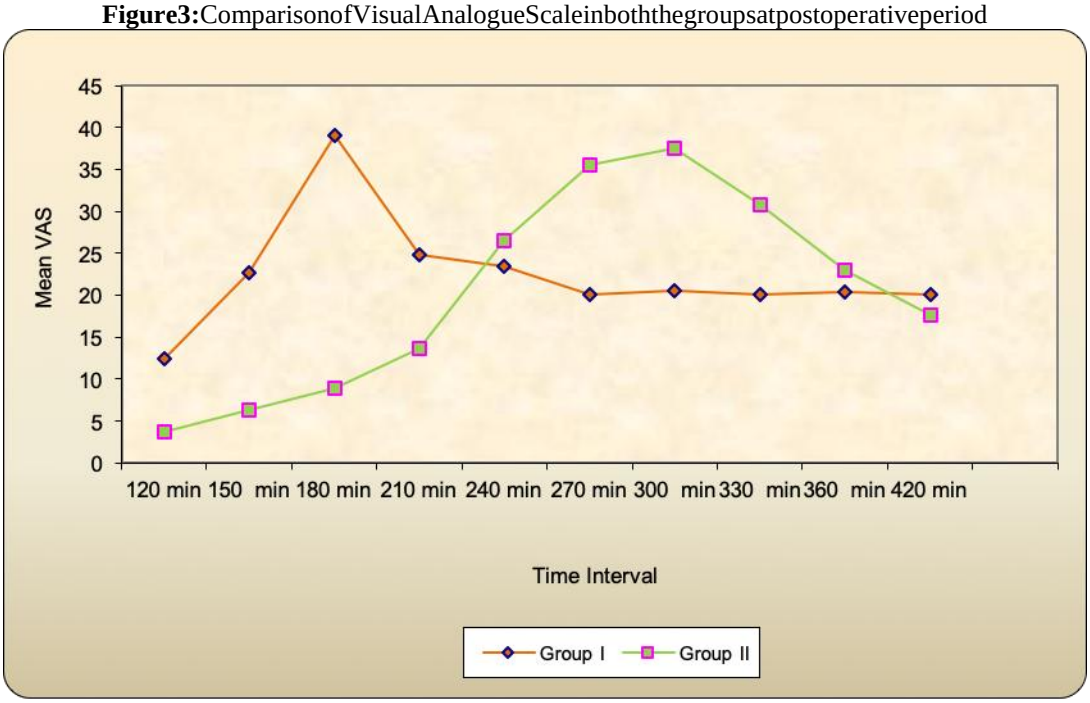


Figure 4: Comparison of systolic blood pressuer in both groups

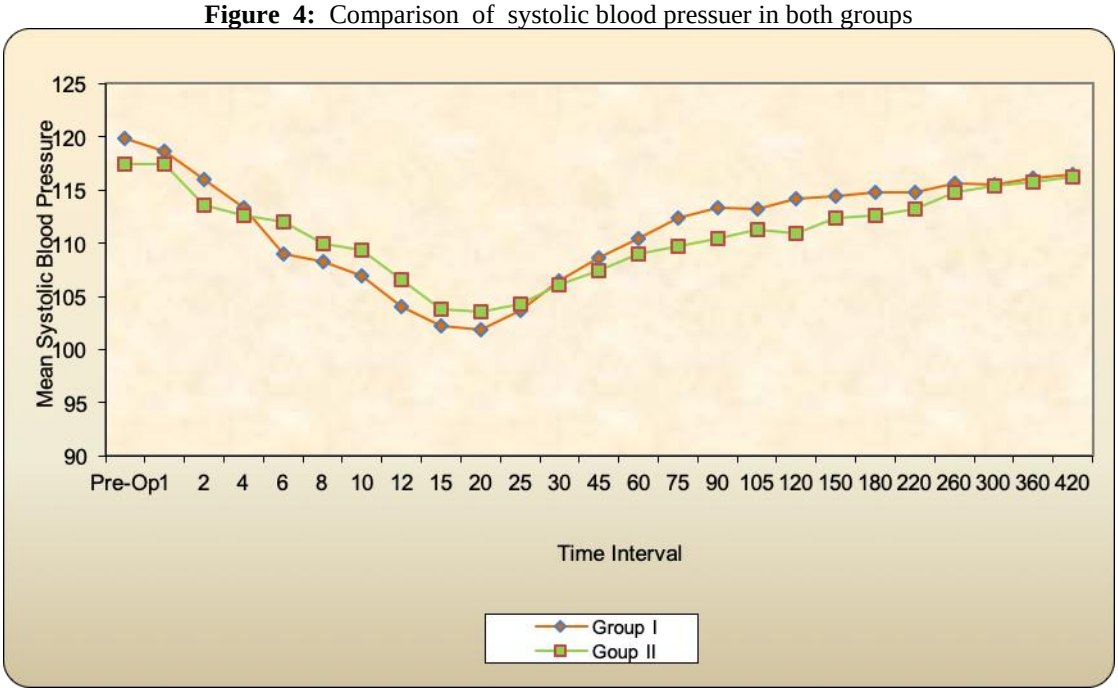
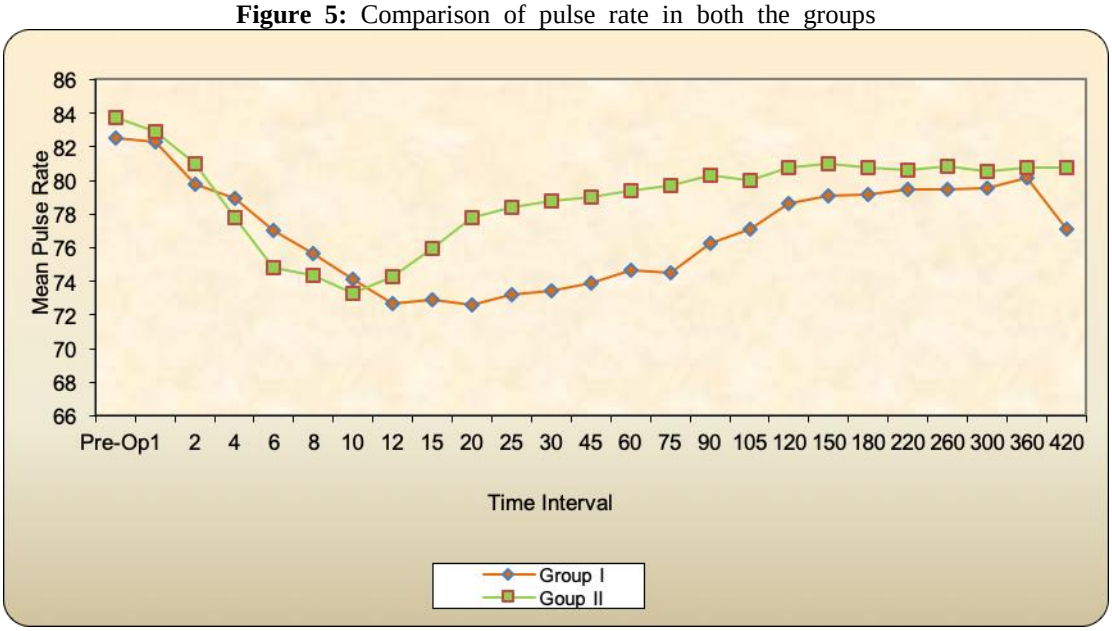


Figure 5: Comparison of pulse rate in both the groups



IV. Discussion

Spinal anaesthesia has attained a widespread popularity for elective caesarean section due to advantage of awake patient, feasibility, minimal drug and equipment cost. 0.5% bupivacaine hyperbaric is now the most commonly used agent for spinal anaesthesia. However, the disadvantage of using bupivacaine alone intrathecally for caesarean section is a high incidence of intraoperative nausea during manipulation of uterus and at the time of peritoneal closure and a relatively short duration of action, thereby resulting in the need for additional analgesic supplement intraoperatively. This greatly adds to maternal discomfort during surgery.

Dose of Bupivacaine and Fentanyl

In our study Group I received 9 mg of 0.5 % bupivacaine with 10 ug Fentanyl and Group II received 9 mg of 0.5 % Bupivacaine with 0.4 ml 20 ug Fentanyl. Although hemodynamic stability was found in both groups, the quality of intraoperative analgesia was better in Group II. In numerous studies varying doses of fentanyl were combined with with low dose bupivacaine suggesting better surgical and postoperative analgesia, less hemodynamic upsets, less vasopressors requirement, less nausea and shivering compared to usual doses used which was similar to our result.

Hence, we chose the dose of hyperbaric bupivacaine 9 mg with two doses of 10 and 20ug of Fentanyl to determine whether single dose of subarachnoid Fentanyl provide analgesia of good quality and long duration in a dose dependent manner in caesarean section patients.

a) Comparison of mean time to achieve sensory block to T 4 level (Figure 2)
The mean time (minutes) to achieve the highest sensory block in Group I was 8.92±0.94 minutes and in Group II was 9.20±0.59 min. This difference was statistically not significant (p >0.05). The findings of present study are in accordance with those of Catherine OH, et al 4 (1989), Randalls B, et al 11 (1991), all of whom reported that Fentanyl provided good surgical analgesia without affecting onset of sensory block.

b) Comparison of Regression Time to T 12 level (Figure 2) The mean regression time T12 by pinprick technique in minutes was 160.32 ± 8.02 in Group I and 183.38 ± 8.73 in Group II. The difference between two were statistically comparable. The duration of subarachnoid sensory block was significantly prolonged in higher dose group II, similar to observation by was Shende D 12 (1998). The increased duration of sensory block in our study from approximate 2.6 hours in Group I to 4 hours Group II is in line with earlier studies[13, 14]. However, this result was not correlated to the findings of Catherine O Hunt et al (1989) 4.

c) Comparison of characteristics of Motor Block Mean Bromage score in Group I and Group II at 2 minutes after administration of subarachnoid block was 1.12 ± 0.32 and 1.1± 0.30 respectively. The difference between the above values was comparable. Bromage scale score of '3' was achieved at 12 min in group I and group II which was comparable. The mean time duration of motor blockade (Bromage scale '0') in Group I was 131.06 ± 8.75 and 128.36 ± 5.70 minutes in Group II, which was not statistically significant. This result is similar with the study result of Choi et al 3 (2000) where they found that motor recovery time did not change with additional dose of Fentanyl.

Comparison of Quality of Intraoperative spinal Anaesthesia

a) Subjective pain rating score was used to quantify the pain, if any, experienced by the patients and the need for supplementary analgesia intraoperatively. The mean subjective pain rating score of patients in group I and II were comparable and statistically not significant. None of the patients in both groups required supplemental analgesia intraoperatively.

b) Visual Analogue Comfort Score [15] - The pain intensity was assessed by Visual analogue score (VAS). In our study, patient comfort during surgery was assessed on a 10 cm visual linear analogue scale (0 = Totally uncomfortable and 10 cm = totally comfortable) 30 minutes after surgery. Mean visual analogue score of group I was 8.22 ± 0.84 and that of group II was 8.68 ± 0.78. The average comfort score of group II during surgery was higher and statistically significant.

In the initial postoperative period (2 to 4 hours) VAS was much less in Group II (8.90 ± 1.09) than Group I (39.04 ± 4.70) at 3rd hour, which was significant. After 3 hours, Group I received rescue analgesia and VAS score remained around 20.06 ± 0.86 at 7th hour. The VAS score in Group II was only 26.50 ± 5.08 after 4 hours, thus showing that patients in Group II were more comfortable and had mild to no pain during immediate postoperative period. They did not require rescue analgesics in this period extending for 289.60 ± 11.75 minutes for Group II as compared to Group I which received rescue analgesics at 146.06 ± 8.75 minutes. Shende, Cooper, et al [15] had observed that combination of bupivacaine with Fentanyl significantly improved comfort scores to 8.2 ± 2.5 in Fentanyl group from 6.8±2.8 in saline group.

Thus, the addition of Fentanyl to bupivacaine intrathecally significantly improved the quality of surgical anaesthesia as substantiated in our study by superior comfort assessed by visual analogue scores in Fentanyl group (20ug) than group I (10ug) and no patient required analgesia supplementation intraoperatively.

Trend Of Changes in Systolic Blood Pressure (Figure 3)
The systolic blood pressure values decreased from 0 to 20 minutes to 101.86 ± 4.06 in Group I. From 20 minutes, the mean systolic pressure gradually increased from 101.86 ± 4.4.06 to 110.40±3.02 at 60 minutes. From 90 to 420 minutes interval, the systolic blood pressure in Group I was stable between 113.28 ± 2.51 to 116.44 ± 3.45. In group II, there was fall of systolic blood pressure from 2 minutes (113.56 ± 6.05) to 20 minutes (103.60 ± 4.91)mm Hg. The mean systolic blood pressure gradually increased to 110.40 ± 3.56 mm Hg

at 90 minutes. Further from 90 minutes to 420 minutes, the systolic blood pressure in Group II was between 110.40 ± 3.56 to 116.28 ± 2.96 mm Hg. Between two Groups, the systolic blood pressure was comparable.

In 1992, Belzarena SD[14] studied the clinical effects of Intrathecal Fentanyl in caesarean section and found systolic blood pressure was not influenced significantly by Fentanyl.

Trend of Changes in Diastolic Blood Pressure (Figure 4)

The mean diastolic blood pressure in both groups preoperatively, were comparable. After administering subarachnoid block in Group I, there was a fall in mean diastolic pressure from 70.84± 5.45 mmHg to 67.60 ± 4.74 mmHg in 6 to 15 minutes interval, which was not significant. From 15 minutes interval, mean diastolic blood pressure gradually increased from 67.60± 4.74 mm Hg to 72.80 ± 3.70 mmHg at 105 minutes which was comparable to preoperatively value, after 105 min interval onwards, the diastolic pressure was stable throughout post operative period.

In group II, there was a gradual fall in mean diastolic blood pressure from 6 to 20 minutes from 71.76 ± 4.99 mmHg to 68.52 ± 4.38 mmHg and was not significant statistically. Beyond 20 minutes, the mean diastolic blood pressure gradually increased to 71.888 ± 8.67 at 120 minutes comparable to preoperative values, then afterward it remained stable throughout postoperative period. Our findings was in accordance with the findings of Belzarena SD[14]

Comparison of Need for Ephedrine

The total dose of Ephedrine required in Group I was 6.75 ± 1.35 mg and 5.66 ± 1 mg in group II.

Trend of Changes in Pulse Rate (Figure 5)

The mean pulse rate in preoperative period was 82.50 ± 6.58/min and 83.72 ± 6.40/min respectively in Group I and Group II. After administration of subarachnoid block, the pulse rate falls to 78.92 ± 5.72/min and 77.82 ±5.30 / minutes in Group I and Group II at 4 min, which was as compared to preoperative level, statistically not significant. This drop continued till 20 min in Group I and group II which was 72.62 ± 4.71 and 77.82 ±3.52, the drop in pulse rate. From 30 minutes onwards, the mean pulse rate remained stable throughout the course of anaesthesia and post-operative period.

The low pulse rate exhibited by most patients during spinal anaesthesia is explained by predominance of Bainbridge reflex[16]. Similar fall in pulse rate were noted in previous studies [17, 18].

Throughout the course of spinal anaesthesia, the respiratory rate and SPO2 remained stable in both the groups. The Apgar score at 1 minute was 9.3 ± 0.47 and 9.20 ± 0.67 in Group I and II respectively, while at 5 minutes in Group I was 9.64 ± 0.48 and Group II, 9.48 ± 0.50 were unaffected.

V. Conclusion

Intrathecal 20ug Fentanyl as compared to fentanyl 10ug added to hyperbaric bupivacaine provides better quality of surgical anaesthesia and prolongs the duration of sensory analgesia. Addition of fentanyl can reduce the intrathecal hyperbaric bupivacaine dose thereby rendering stable haemodynamic without affecting maternal and neonatal outcome.

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