IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Comparative Study of Effects of Intrathecal Dexmedetomidine versus Fentanyl as adjuvants to Hyperbaric 0.75% Ropivacaine in Patients Undergoing Infraumbilical Surgeries

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Abstract: Spinal anaesthesia is a neuraxial anaesthesia technique in which local anaesthetic is placed directly in the intrathecal space (subarachnoid space). It is the most widely used technique for infraumbilical surgeries providing a fast onset and effective sensory and motor blockade and prolonged postoperative analgesia. First spinal anaesthesia was given in 1898 in Germany by August Bier. Various local anaesthetic drugs are available for spinal anaesthesia namely Bupivacaine, Levobupivacaine, and Ropivacaine. Hyperbaric Ropivacaine hydrochloride (ROPIN Heavy 0.75%) is extensively used because of its longer duration of motor and sensory blockade.

Dexmedetomidine is a highly selective α_2-adrenergic receptor agonistic activity with a relatively high ratio of α_2/α_1 activity (1620:1) compared to clonidine (220:1). Dexmedetomidine can be used as an adjuvant to local anaesthetics, to prolong the duration of both motor and sensory blockade without much side effects. They are found to attenuate stress response to surgery and anaesthesia. Intrathecal fentanyl is a potent lipophilic synthetic opioid with a rapid onset and duration of action with lesser incidence of respiratory depression. Hence, the aim of this study is to evaluate the onset and duration of sensory and motor block , hemodynamic effects, postoperative analgesia and adverse effects of hyperbaric 0.75% Ropivacaine with or without additives such as fentanyl or dexmedetomidine on spinal anaesthesia for infraumbilical surgeries.

Materials and Methods : 90 patients of ASA PS Class I and II of aged 18-60 years of either sex were presented for infraumbilical surgeries including lower limb orthopaedic surgeries were studied. Patients were randomly allocated into 3 groups of 30 each. Group RD (n = 30) received 2.5 ml of 0.75% hyperbaric ropivacaine + 10 µg dexmedetomidine (0.1ml)+0.4 ml normal saline, Group (RF) (n = 30) received 2.5 ml of 0.75% hyperbaric ropivacaine + 25 µg fentanyl (0.5ml), and Group (RC) (n = 30) received 2.5ml of 0.75% hyperbaric ropivacaine + 0.5 ml normal saline.

Results: Total 90 patients were studied (30 in each group). All the patients passed smooth intra operative course without complications within a mean duration range 50-90 min with no significant difference between both the groups.

In our study there was no significant difference in incidence of bradycardia. In group RD 8 patients, in group RF 9 patients , and in group RC 6 patients developed bradycardia. All patients responded to Injection Atropine 0.6mg IV bolus.

Hypotension was recorded in 12 patients (40%) in group RD, 10 patients in group RF and 6 patients in group RC without significantly difference. Early hypotension was more in group RD as compared to group RF at 5 min which was statistically significant. However late hypotension was not significant in these groups. All patients responded to Injection Mephentermine 6mg iv bolus. In our study there was no significant difference between onset time of sensory block between group RD and group RF , but statistically significant difference between group RD and group RC & between group RF and group RC .There was no significant difference in the peak level of the sensory block to pin prick.

Time to reach the maximum sensory level was significantly lower in group RD and group RF as compared to group RC .This difference was statistically significant between group RD or group RF and group RC. Time for 2 segment regression from maximum sensory block was significantly higher in group RD(126.5±8.84 min) and in group RF(120.83±8.99 min),as compared to group RC(101.5±6.74 min) .This difference was statistically significant (p value < 0.001).
In our study there was no significant difference between onset time of Motor block in these groups.(Table 12 & Figure 12). Time to achieve complete motor block was earlier in group RD (5.633±1.11min), in group RF(5.7±1.22 min) as compared to group RC (7.1±1.28 min). This difference was statistically significant between group RD and group RC and between group RF and group RC (p value 0.0001) , but statistically insignificant between group RD and group RF (p value was 0.22).
Total duration of analgesia was higher in group RD (297.16±16.04 min) and group RF (261.16±18.42 min) as compared to group RC (229.16±15.69 min) .This difference was statistically significant.(P value < 0.001). 12 patients developed nausea/ vomiting, 4 in group RD , 3 in group RF and 5 in group RC ,without any statistically significant difference in them .and all patients responded to IV ondansetron. No respiratory depression or any other complications, other than mentioned above, were recorded in either of the groups.
Conclusions: Adding of Dexmedetomidine or fentanyl as an adjuvant to hyperbaric ropivacaine provide significant improvement in the quality of Sensory block and Motor block without incidence of hypotension and provide prolonged postoperative analgesia as compared to ropivacaine alone. Duration of analgesia in group RD (297.16±16.04 min) is greater than in group RF (261.16±18.42 min) and in group RC(229.16±15.69 min).

Key words **–** Ropivacaine , dexmedetomidine, fentanyl , spinal anaesthesia.

I . INTRODUCTION

Spinal anaesthesia is the most widely used technique for infraumbilical surgeries providing a fast onset and effective sensory and motor blockade and prolonged postoperative analgesia. A common problem during lower abdominal surgeries under spinal anaesthesia is visceral pain, nausea and vomiting[1]. The most important physical property affecting the level of analgesia after the intrathecal administration of local anaesthetic is its baricity.[2]
Ropivacaine structurally resembles the Bupivacaine with similar anaesthetic properties, It has reduced potential for cardiotoxicity and neurotoxicity with improved relative sensory and motor block profile.[3] It has low lipid solubility and blocks the nerve fibers which are involved in pain transmission to a greater degree than those involved in motor function, hence it has been used extensively to the local infiltration, epidural, and peripheral nerve block. Ropivacaine is well tolerated after intrathecal use and have a shorter duration of action than bupivacaine, making it a possible alternative to lignocaine for ambulatory surgery. Spinal hyperbaric ropivacaine may produce more predictable and reliable anaesthesia than plain Ropivacaine.[4]

To improve the block characteristics of intrathecal hyperbaric ropivacaine, adjuvants like dexmeditomedine ,fentanyl etc were added to hasten the onset and prolong the postoperative analgesia. Dexmedetomidine is a highly selective α_2-adrenergic receptor agonistic activity with a relatively high ratio of α_2/α_1 activity (1620:1) compared to clonidine (220:1).[5] Dexmedetomidine can be used as an adjuvant to local anaesthetics, to prolong the duration of both motor and sensory blockade without much side effects. They are found to attenuate stress response to surgery and anaesthesia.[6] Recent experimental studies indicated that dexmedetomidine produces a dose-dependent increase in the duration of the motor and sensory blocks induced by local anaesthetics regardless of the neuraxial route of administration (epidural, caudal, or spinal) without any evidence of neurotoxicity in human volunteers.[7] Fentanyl is a potent lipophilic synthetic opioid with a rapid onset and duration of action with lesser incidence of respiratory depression. It is a strong agonist at the μ opioid receptor. Intrathecal fentanyl selectively decreases nociceptive afferent input from Aδ and C fibers without affecting dorsal root axons or somatosensory evoked potentials.[8]

II . Materials and Methods :

The study was a prospective, hospital based, double blinded, randomized controlled, comparative study carried out in department of Anaesthesiology (Dr S. N. Medical Collage and associated groups of hospitals, Jodhpur, RAJ.) After approval of Institutional Ethical Committee (No .SNMC/IEC/2023/2134-2135 date17.04.2023 (Reference No. SNMC /2022 / Plan/708) and registration at Clinical Trial Registry of India (CTRI/2023/05/052458 date 10/05/2023), written informed consent was taken .The study was conducted from April 2023 to December 2023 .

Study Population :

90 Patients of age group 18-60 years of either sex were scheduled to undergoing infraumbilical surgeries including lower limb orthopedic surgeries under subarachnoid block . Patients in our study were randomly divided into 3 groups of 30 each by computer generated random number table and allocated into following 3 groups by sequentially numbered sealed opaque envelop method. Group RD (n=30) received 2.5ml of 0.75% hyperbaric ropivacaine + 10 µg dexmedetomidine (0.1ml)
+0.4 ml normal saline, Group (RF) (n=30) received 2.5ml of 0.75% hyperbaric ropivacaine + 25 µg fentanyl(0.5ml) ,Group (RC) (n=30) received 2.5ml of 0.75% hyperbaric ropivacaine + 0.5 ml normal saline.

Sample Size:

Sample size was calculated at alpha error 0.05 and study power 90% using the formula for hypothesis testing for two mean population : $n = \frac{2\times\left(Z_{1-\alpha/2}+Z_{1-\beta}\right)^2\times\sigma^2}{(\mu_1-\mu_2)^2}$

Where n = Sample size,$\left(Z_{1-\alpha/2}\right)$ = Standard normal deviate for alpha error (taken as 1.96 for alpha error 0.05), $(Z_{1-\beta})$ = Standard normal deviate for beta error (taken as 1.28 for 90% study power)

σ^2 = pooled variance of the two population. As it is not known, it is replaced by s_p^2- $s_p^2 = \frac{{s_1}^2+{s_2}^2}{2}$

Where, s_1^2 *and* s_2^2 are the variances of the two samples. $\mu_1-\mu_2$= The difference in mean duration of analgesia between the two population (as it is not known, it is replaced by the difference in sample means $(\ddot{x}_1-\ddot{x}_2)$.

Inclusion criteria:

1. Adult patients of either sex, aged between 18 and 60 years who will be undergoing for infraumbilical surgeries.
2. Patients belonging to ASA physical status Class I and Class II

Exclusion criteria:

1 Patients having any absolute contraindications for spinal anaesthesia such as patient not willing, raised intracranial pressure, severe hypovolemia, bleeding diathesis, local infection and severe cardiac, respiratory, and CNS diseases are excluded from the study

2 Pregnant females, uncontrolled diabetes and hypertension

3 Patients with body mass index >30 kg/m2

4 Patients shorter than 150 cm.

Pre Anaesthetic Evaluation:

During preoperative visit, each patient's detailed history, general physical examination and systemic examination was carried out. Basic demographic data e.g. age, sex, height, weight were recorded. Routine investigations e.g. Hemoglobin, Platelet count, Blood sugar, Renal function tests,Chest X-ray, ECG, Bleeding time, Clotting time, or any specific test were asked for, as per recent guidelines, for all patients. Patients were explained in detail about the anaesthesia procedure, drugs and linear Visual Analogue Score (VAS). Patients were kept nil per oral for solids 6 hours and clear fluids 2 hours before surgery.

On arriving inside operating room, all patients were monitored with ECG and peripheral O_2 saturation continuously and non-invasive arterial blood pressure was determined and recorded every 5 minutes during the intraoperative period in first half hour and after that at interval of every 15 minutes till the completion of surgery. An 18 gauge cannula was inserted in a peripheral vein and pre-hydration was started with a crystalloid solution with a dose of 10 mL/kg administered within 15 minutes. The spinal anaesthesia technique was similar in all patients as follows: The patient was put in the sitting position. After preparing the skin with betadine and then with the surgical spirit, a 25 G Quincke spinal needle was used to inject the drug to L3–L4 or L4–L5 interspace level at 0.2 $mL.s^{-1}$ speed. While injecting the drug, the bevel of the needle was pointed down. The Hyperbaric Ropivacaine 0.75% dosage was given with additive of 25 µg fentanyl in group RF, 10 µg dexmedetomidine with normal saline (volume 0.5ml) in group RD and 0.5 mL of normal saline was in group RC. After injecting the drug patients were made to lie supine immediately , and supplementary oxygen of 4 L was given through simple mask .

The following parameters were noted intraoperatively**.**

- Onset and duration of sensory blockade
- Maximum level of sensory blockade attained and the time taken for the same
- Time for two-segment sensory regression time
- Onset and duration motor blockade
- Total duration of analgesia
- Time of rescue analgesia.

Sensory blockade was tested using the pinprick method with 27G hypodermic needle at every 30s for first 2 min, and every 5 min for next 15 min and every 15 min till the end of surgery and thereafter every 30 min until sensory block is resolved.

Motor block:

Onset, quality, and duration of motor blockade was assessed by Modified Bromage Scale (0-3).

All patients was monitored during the surgery and perioperative period employing multiparameter monitor, which displays heart rate, systolic blood pressure (SBP), diastolic blood pressure, mean arterial pressure (MAP), ECG, and arterial oxygen saturation.

All Patients was monitored during the postoperative period for requirement of analgesia and side effects such as hypotension, bradycardia, shivering, pruritus, vomiting, urinary retention, and respiratory depression.

The intraoperative quality of surgical anaesthesia was estimated using **Ochsner Health System** which measures patient satisfaction in four grades:

Excellent- Patient felt comfortable during operation, no complaints;

Good- A little discomfort but no need for additive medication;

Fair – Discomfort, but controlled by fentanyl or tramadol and

Poor – Unable to be controlled even with additive medication and shifting to general anaesthesia was mandatory.

Sedation score was assessed with a four-point verbal rating scale (1 = no sedation, 2 = light sedation, 3 = somnolence, 4 = deep sedation). **Postoperative sedation was scored as per the modified Ramsay Sedation Scale:**

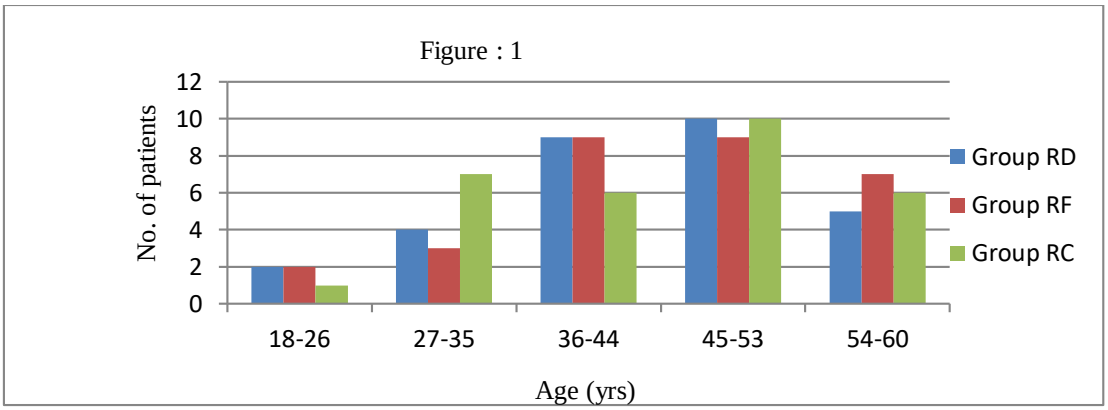
Score	Description	Response
1	Awake	Anxious or restless or both
2	Awake	Cooperative, oriented, and tranquil
3	Awake	Responding to commands
4	Asleep	Brisk response to stimulus
5	Asleep	Sluggish response to stimulus
6	Asleep	No response to stimulus

Pain scores: visual analog scale (VAS)was recorded intra- and post-operatively, between 0 and 10 (0 = no pain, 10 = the most severe pain), initially every 1 h for 2 h, then every 2 h for next 8 h and then after every 4 h till 24 h.

Injection fentanyl 0.5 µg/kg i.v. was given intraoperatively as rescue analgesia when VAS ≥2

All observations were recorded in the Study performa attached and analysed statistically (SPSS 15.0 Evaluation version).Data are expressed as either mean and standard deviation or numbers and percentages. Continuous covariates were compared using analysis of variance (ANOVA). The comparison was studied using the Chi-square test or Fisher's exact test as appropriate , with the P value reported at the 95% confidence interval . $P < 0.05$ was considered statistically significant.

Figure : 1



Above figure 1 shows age distribution among the three groups was apparently same. Statistically there was no significant difference in age as p value was 0.916

Table 2: ASA GRADING WISE DISTRIBUTION IN BOTH GROUPS

ASA grading	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
I	26	86.66	25	83.33	27	90
II	4	13.33	5	16.66	3	10
Total	30	100.00	30	100.00	30	100.00

p value 0.640 (Fisher exact test)

Figure: 2

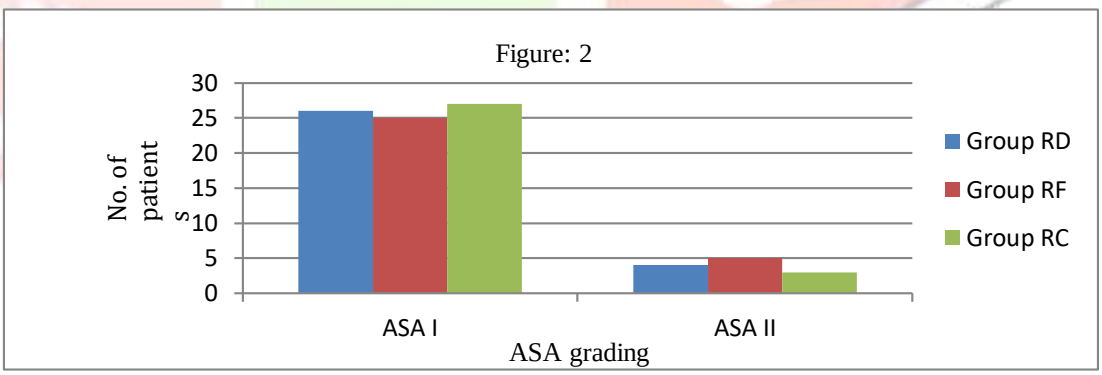


Table 3: WEIGHT AND HEIGHT DISTRIBUTION IN STUDY GROUPS

Parameters	Group RD	Group RF	Group RC	t value	P value
Weight (kg)	64.2±7.16	63±7.73	65.8±7.44	0.84	0.399
Height (cm)	163.06±6.49	161.03±5.65	164.4±7.16	1.29	0.20

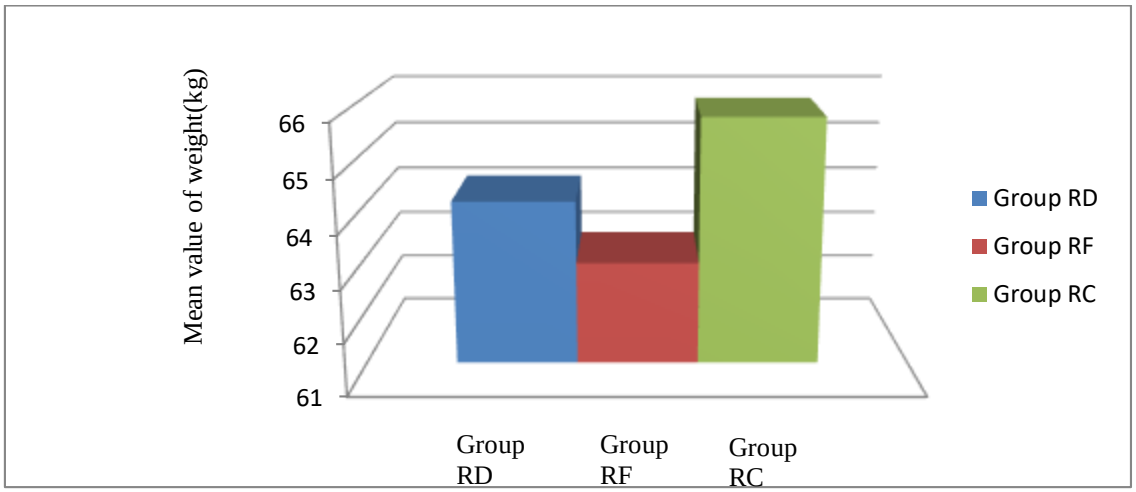


Figure 3(A) shows no statistically significant difference was found between these groups in mean weight (p=0.399).

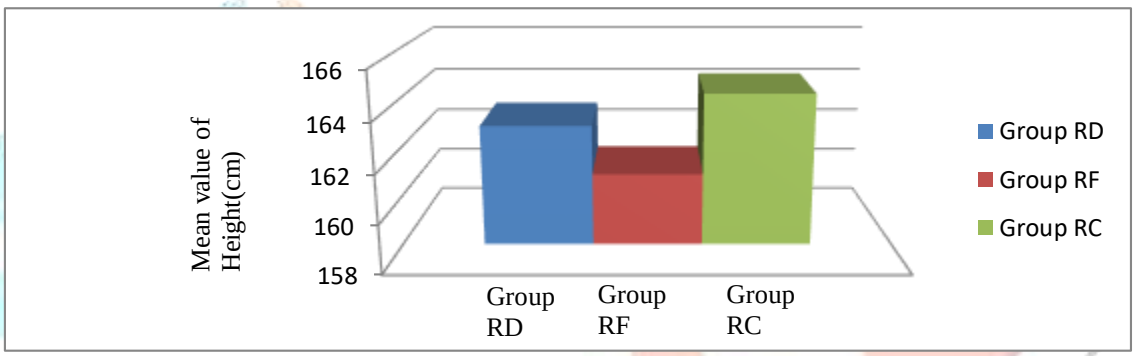


Figure 3(B) shows no statistically significant difference was found between these three groups in mean height (p=0.844).

Figure : 4

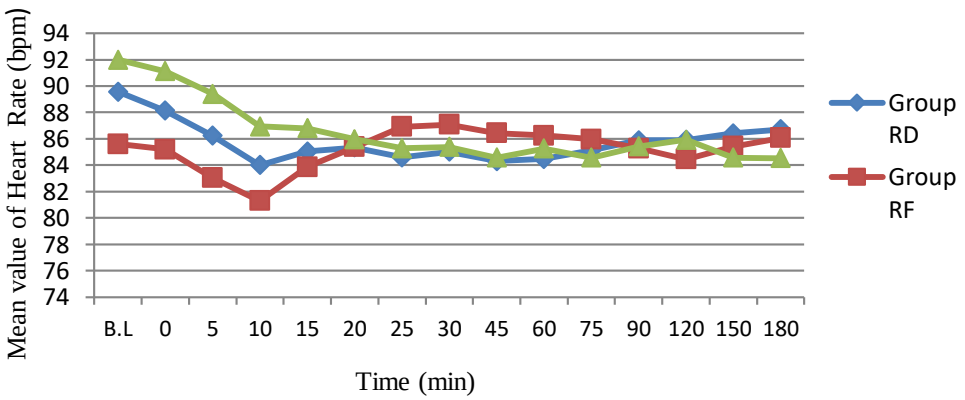


Figure 4 shows comparison of heart rate in these study groups. Student t-test was performed on the above and p value <0.05 was taken as statistically significant. The mean heart rate in group RD, group RF and group RC was similar and comparable at all the time of observation. The p value was >0.05(statistically insignificant).

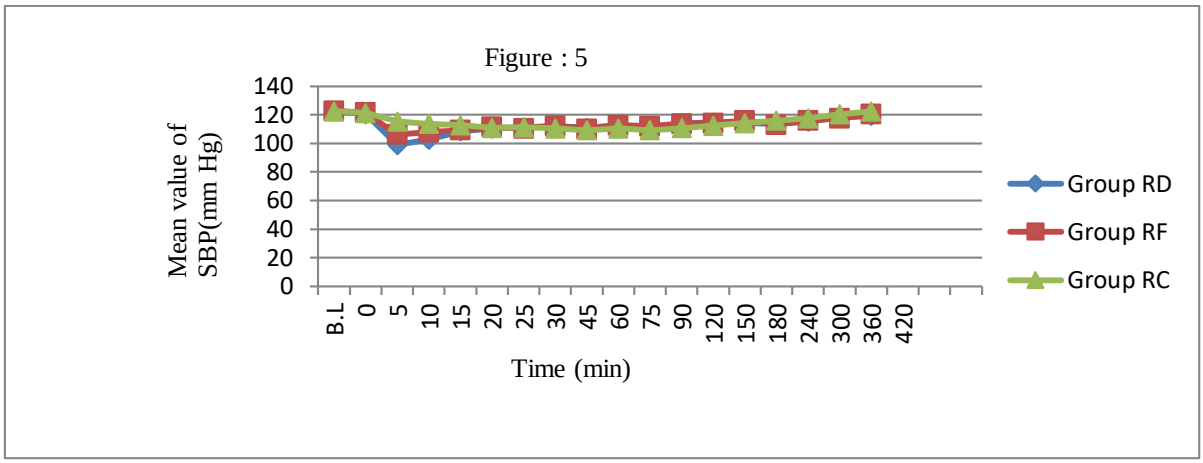


Figure 5 shows the comparison of systolic blood pressure (mean±SD) in these groups for 6 hours following surgery. The difference was found to be statistically significant in both groups at 5min from spinal anaesthesia. After SAB SBP fall in these groups but it was more in group RD as compare to group RF at 5min (p=0.0004).

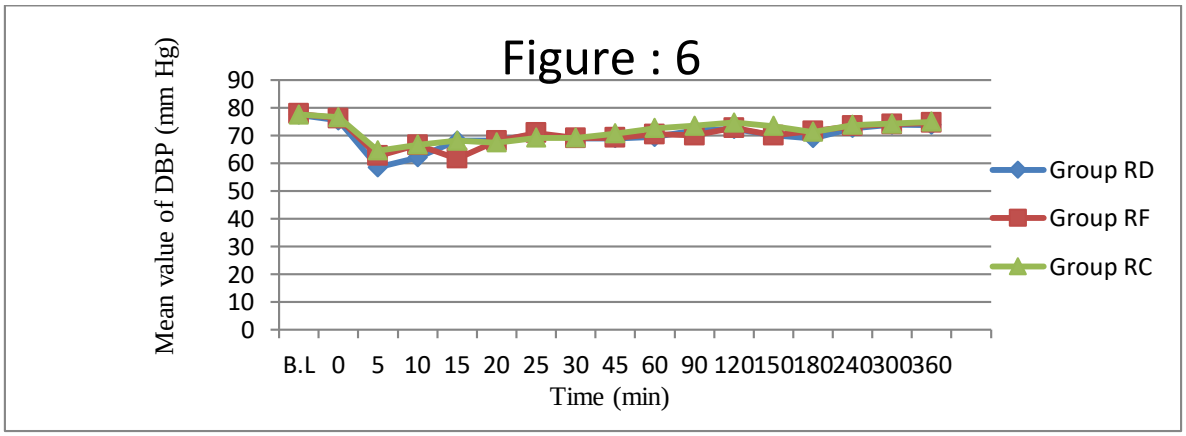


Figure 6 shows the comparison of Diastolic blood pressure (mean±SD) between these study groups for 6 hours following SAB. The difference was found to be statistically not significant.

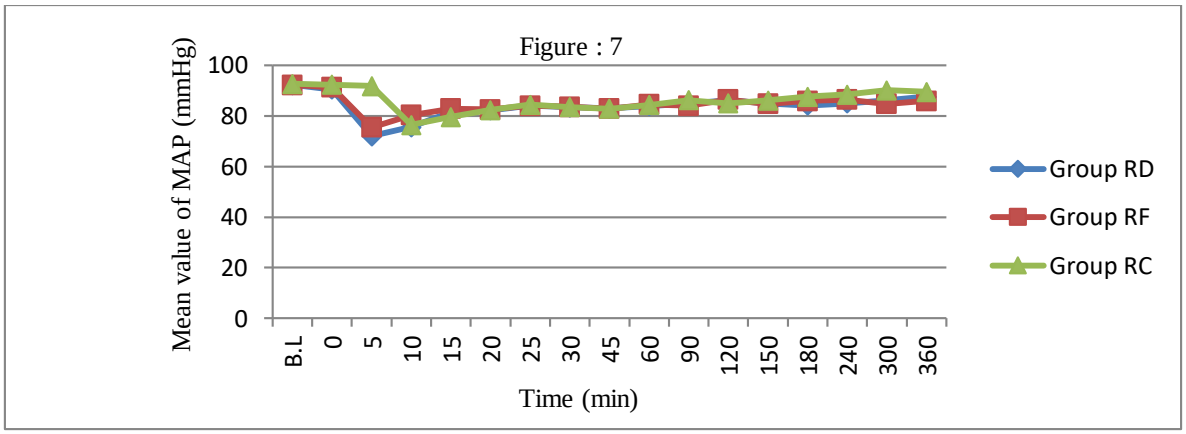


Figure 7 shows the comparison of mean blood pressure (mean±SD) between these groups for 6hours following SAB. The difference was found to be statistically insignificant in these groups before SAB and even after SAB. MAP remain around the base line for rest of the time after SAB

FIGURE: 8

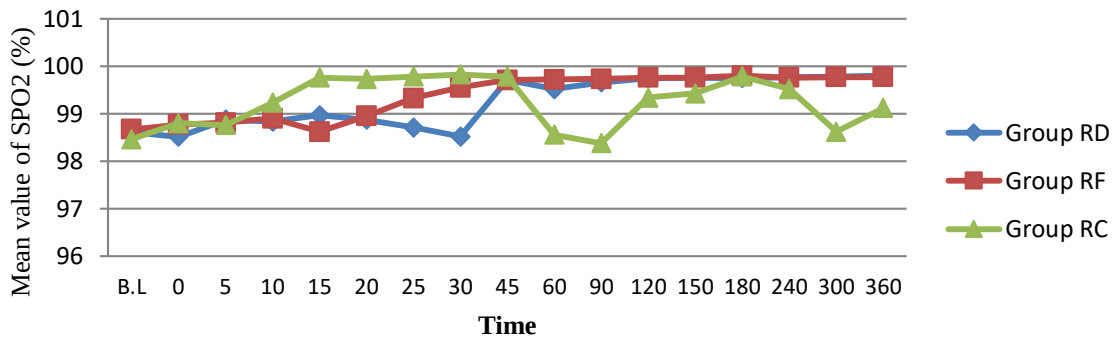


Figure 8 shows oxygen saturation (%) in these groups. Student t test was performed on the above and p value <0.05 was taken as statistically significant The mean saturation in these three groups was similar and comparable at all the time of observation. The p value was >0.05 (statistically insignificant).

Table 9:COMPARISON OF ONSET TIME TO REACH T10 LEVEL OF SENSORY BLOCK IN THESE GROUPS

Onset time of T10 level of sensory block(in sec)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
61-80	3	10	3	10	0	0
81-100	5	16.66	6	20	5	16.66
101-120	17	56.66	18	60	10	33.33
121-140	5	16.66	3	10	15	50
Median	108.73		107.16		120.5	
Range	61-140		61-140		81-140	
Mean±SD	106.5±16.65		104.5±15.62		117.16±14.90	
t & p value	2.613 ,0.0114		3.212,0.0022		0.479,0.0.6332	

Figure : 9

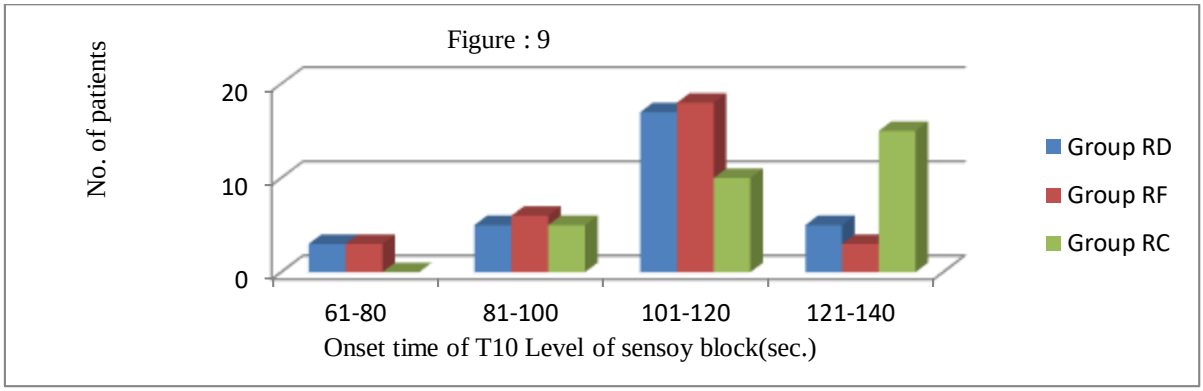


Table 10: COMPARISON OF MAXIMUM LEVEL OF SENSORY BLOCK ACHIEVED IN THESE STUDY GROUPS

Maximum cephaled spread (dermatome)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
T4	8	26.66	7	23.33	2	6.66
T7	22	73.33	23	76.66	12	40
T10	0	0	0	0	16	53.33
Total	30	100	30	100	30	100

Figure :10

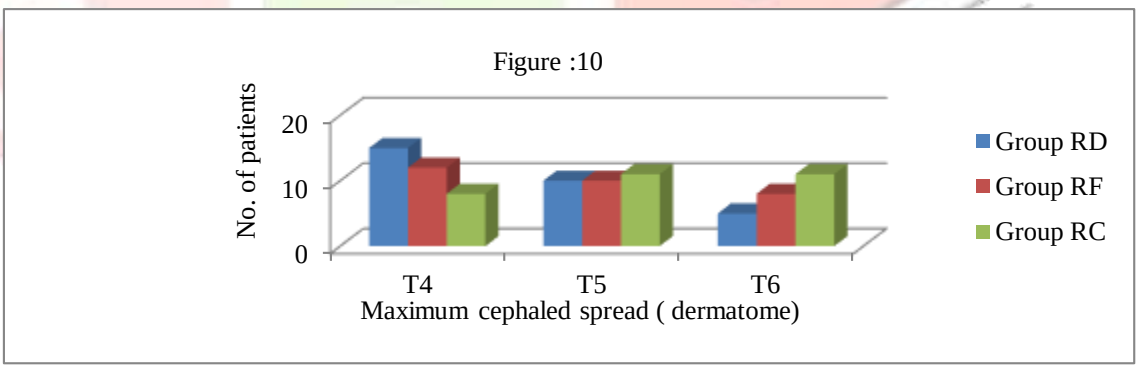


Table 11: COMPARISON OF TIME TAKEN TO REACH MAXIMUM SENSORY LEVEL IN THESE GROUPS

Time to maximum cephaled spread (min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
3-4	12	40	10	33.33	5	16.66
5-6	10	33.33	15	50	10	33.33
7-8	8	26.66	5	16.66	15	50
Median	5.1		5.08		6.5	
1Mean	5.233±1.61		5.129±1.44		6.166±1.49	
t & p value	2.32, 0.023		2.56, 0.034		3.64, 0.001	

Figure :11

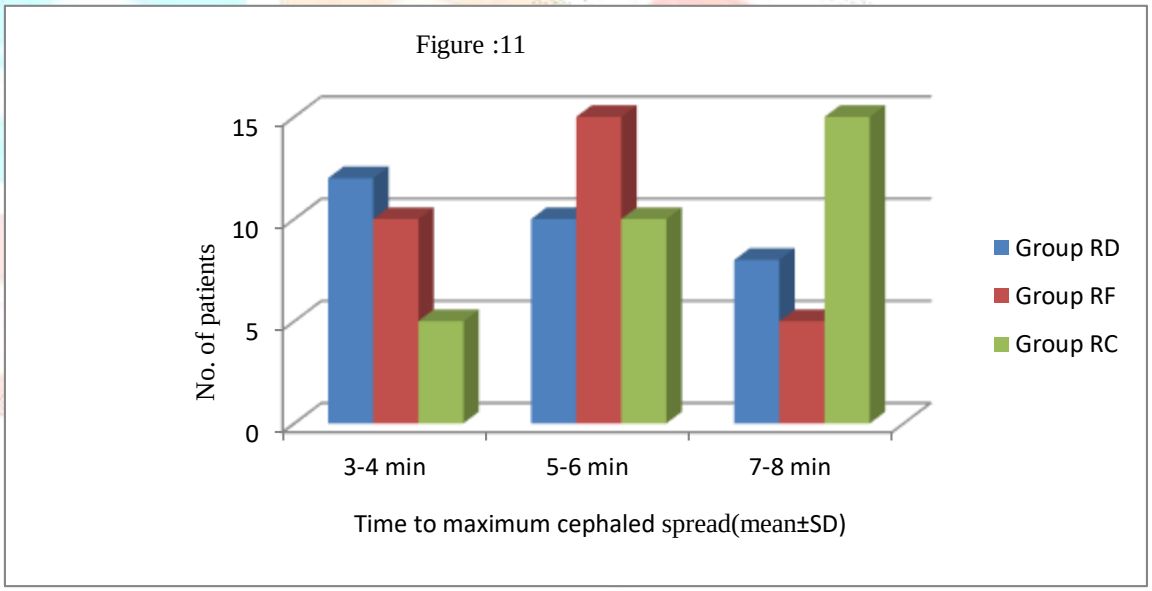


Table 12: COMPARISON OF 2 SEGMENT SENSORY REGRESSION FROM MAX SENSORY BLOCK IN THESE GROUPS

Time for 2 segment sensory regression from max sensory block(min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
91-100	0	0	0	0	15	50
101-110	1	3.33	4	13.33	12	40

111-120	7	23.33	10	33.33	3	10
121-130	10	33.33	12	40	0	0
131-140	12	40	4	13.33	0	0
Median	127		121		100	
Range	101-140		101-140		91-120	
Mean±SD	126.5±8.84		120.83±8.99		101.5±6.74	
t & p value	2.46 , 0.016		9.42, <0.0001		12.31, <0.001	

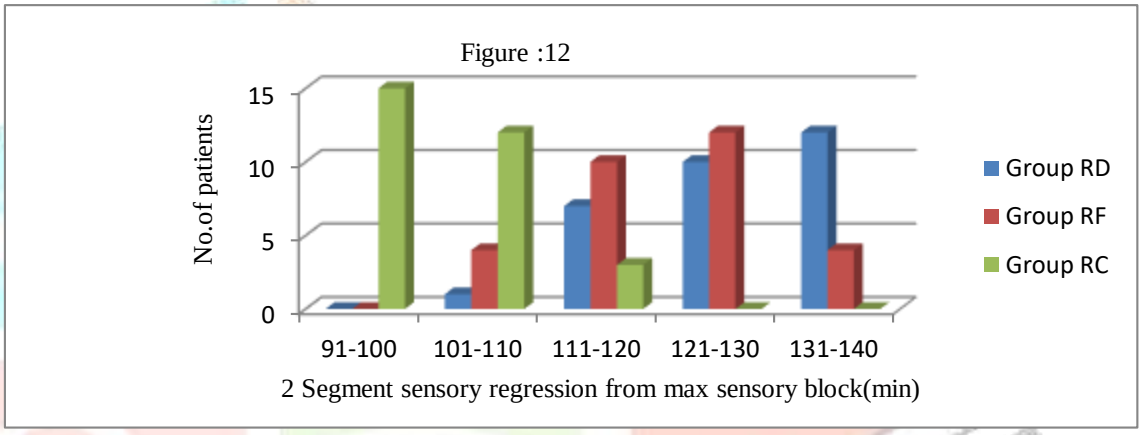


Table 13: COMPARISON OF TIME FOR ONSET OF MOTOR BLOCK UPTO GRADE III IN THE STUDY GROUPS

Time for onset of motor block upto grade III(min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
One	5	16.66	4	13.33	2	6.66
Two	15	50	18	60	12	40
Three	10	33.33	8	26.66	16	53.33
Median	2		2		2	
Mean±SD	1.59±1.50		1.62±0.56		2.07±1.89	
t & p value	0.369,0.711		1.211,0.196		1.450,0.094	

Figure :13

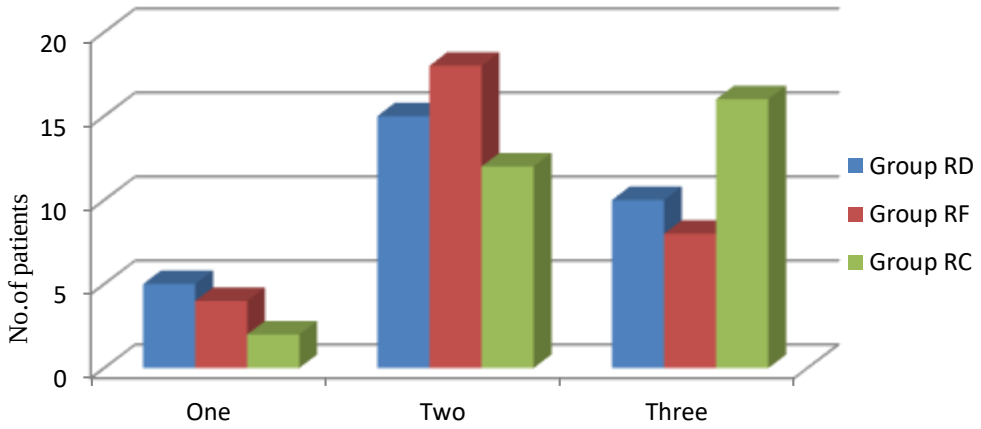


Table 14: COMPARISON OF TIME FOR COMPLETE MOTOR BLOCK IN THESE STUDY GROUPS

Time to maximum motor block (min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
4-5	14	46.66	14	46.66	3	10
6-7	15	50	14	46.66	15	50
8-9	1	3.33	2	6.66	12	40
Median	5.6		5.64		7.1	
Mean±SD	5.633±1.11		5.7±1.22		7.1±1.28	
t and p value	Pvalue 0.0001		P value <0.05		P value 0.0001	

Figure 14

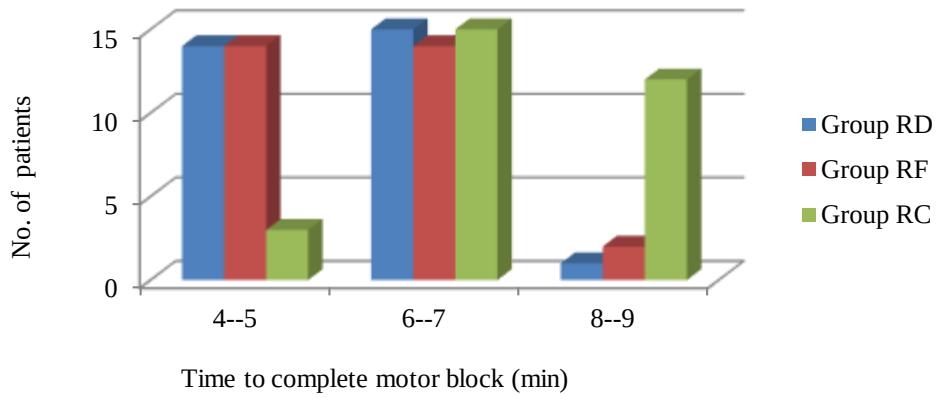


Table 15: COMPARISON OF DURATION OF MOTOR BLOCK IN THESE STUDY GROUPS

Duration of motor block(min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
141-160	0	0	0	0	2	6.66
161-180	0	0	0	0	6	20
181-200	6	20	12	40	12	40
201-220	6	20	10	33.33	8	26.66
221-240	10	33.33	8	26.66	2	6.66
241-260	8	26.66	0	0	0	0
Median	226		212		192	
Range	181-260		181-260		141-240	
Mean±SD	223.83±21.86		207.83±16.11		191.83±.19.95	
t & p value	4.130,0.0001		2.692,0.0092		3.227,0.002	

Figure :15

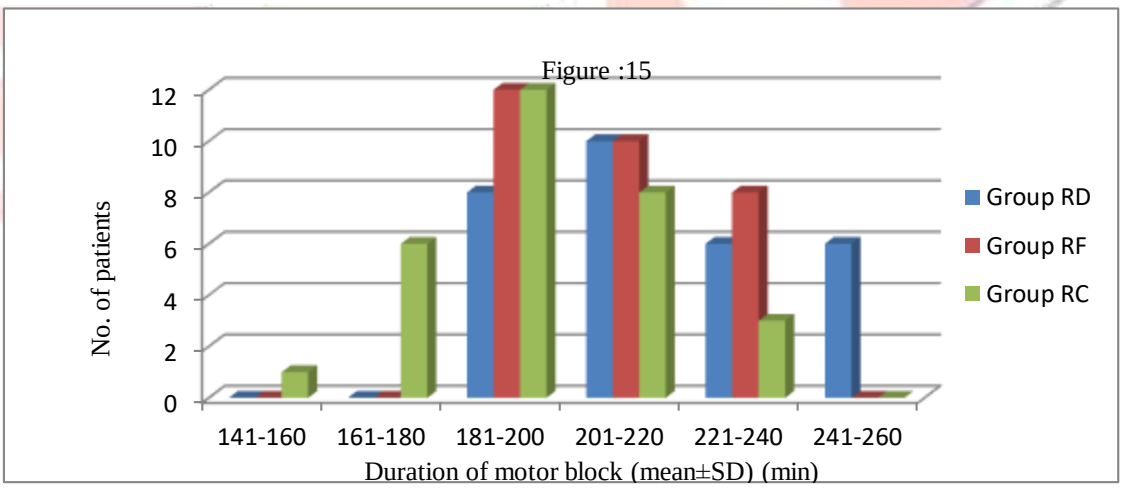


Table 16: COMPARISON OF DURATION OF SURGERY IN THESE STUDY GROUPS

Duration of surgery(min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
51-70	7	23.33	8	26.66	9	30
71-90	6	20	5	30	4	26.66
91-110	6	20	7	23.33	7	23.33
111-130	3	10	2	10	5	16.66
131-150	7	23.33	7	6.66	5	3.33
151-170	1	3.33	1	3.33	0	0
Median	97		66.05		65.5	
Mean±SD	100.5±31.94		99.16±32.34		95.83±29.56	
t & p value	0.097, 0.922		0.519, 0.60		0.58,0.559	

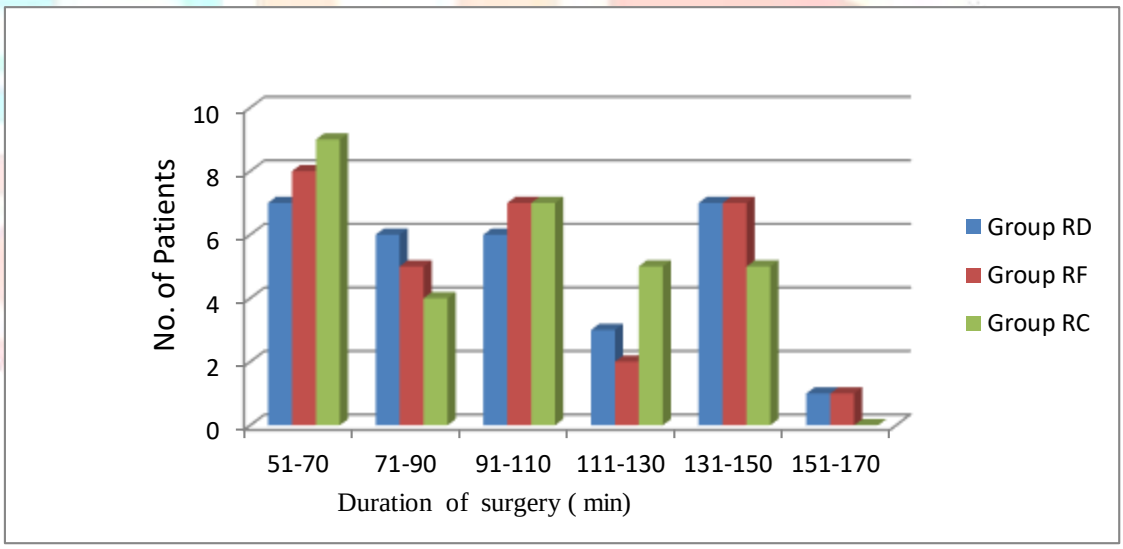


Table 17: COMPARISON OF TOTAL DURATION OF ANALGESIA IN THESE STUDY GROUPS

Total duration of analgesia (mean±SD) (min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
200-220	0	0	0	0	10	33.33
221-240	0	0	4	13.33	12	40
241-260	6	20	11	36.66	8	26.66
261-280	8	26.66	10	33.33	0	0
281-300	16	53.33	5	16.66	0	0
Median	301.75		283.5		233	
Mean±SD	297.16±16.04		261.16±18.42		229.16±15.69	
t & p value	9.03, 0.0001		7.29, 0.0001		5.28, 0.0001	

Figure : 17

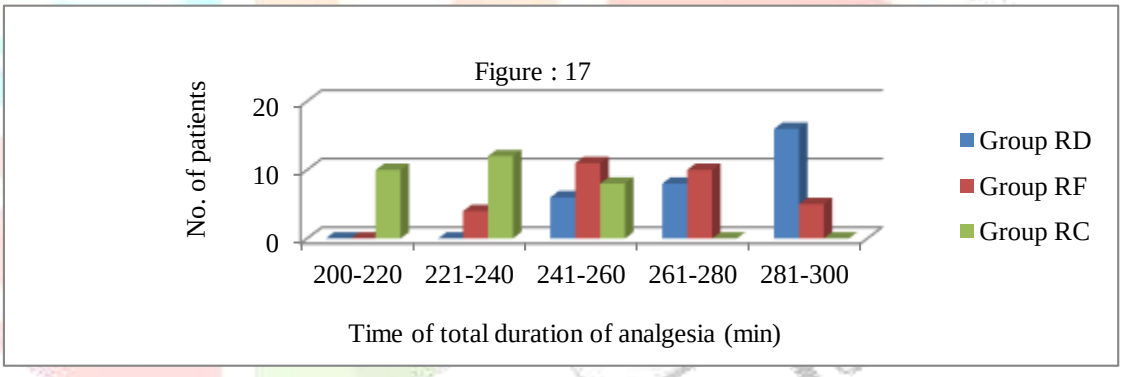


Table 18: COMPARISON OF TIME FOR FIRST ANALGESIC REQUIREMENT IN THESE STUDY GROUPS

Time of first analgesia requirement (min)	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
221-240	0	0	1	3.33	15	50
241-260	2	6.66	3	10	10	33.33
261-280	2	6.66	8	26.66	5	16.66
281-300	8	26.66	10	33.33	0	0
301-320	18	60	8	26.66	0	0
Median	303.83		280		240	

Range	261-340	221-340	221-280
Mean±SD	298.5±17.88	284.5±21.38	243.83±15.16
t & p value	8.864,<0.0001	6.78,<0.0001	2.75, <0.001

Figure 18

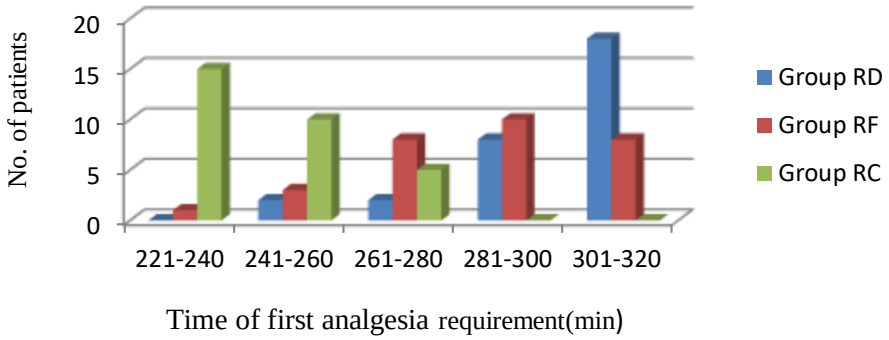


Table 19: COMPARISON OF SIDE EFFECTS IN THESE STUDY GROUPS

Complications	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
Hypotension	12	40	10	33.33	6	20
Bradycardia	8	26.66	9	30	6	20
Nausea/Vomiting	4	13.33	3	10	5	16.66
Sedation	5	16.66	4	13.33	0	0

Figure : 19

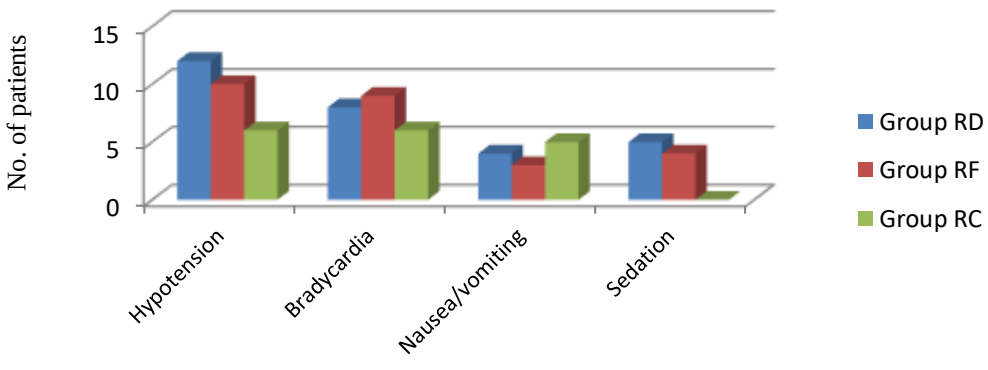
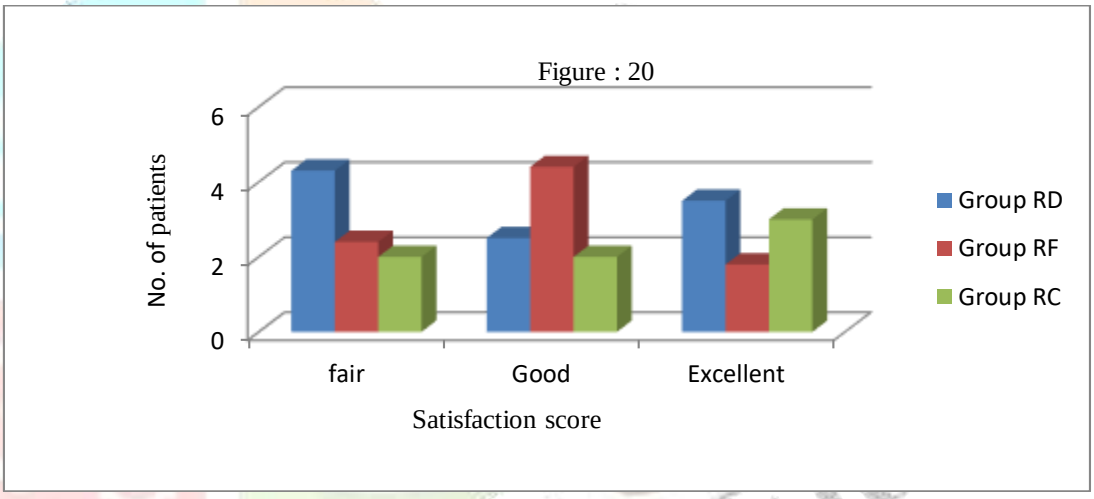


Table 20: COMPARISON OF PATIENT'S SATISFACTION SCORE

Satisfaction sore	Group RD		Group RF		Group RC	
	N	%	N	%	N	%
Poor	0	0	0	0	0	0
Fair	4	20	6	20	10	33.33
Good	12	40	12	40	12	40
Excellent	14	46.66	10	33.33	8	26.66
Total	30	100	30	100	30	100



III. RESULTS

Demographic parameters such as age, height, weight and American Society of Anaesthesiologists status were compared with each other between groups (Table 1,2,3, Figure 1,2,3a,3b).

All Patients passed smooth intra operative course without complications within a mean duration range 50-90 min with no significant difference between both the groups(Table 16 & Figure 16)

In our study there was no significant difference in incidence of bradycardia (table 4, Figure 4). In group RD 8 patients, in group RF 9 patients , and in group RC 6 patients developed bradycardia. All patients responded to Injection Atropine 0.6mg IV bolus.

Hypotension was recorded in 12 patients (40%) in group RD, 10 patients in group RF,and 6 patients in group RC without significantly difference. Early hypotension was more in group RD as compared to group RF at 5 min which was statistically significant. However late hypotension was not significant in these groups. All patients responded to Injection Mephentermine 6mg iv bolus (Table 5, 6,7& Figure 5,6,7)

In our study there was no significant difference between onset time of sensory block between group RD and group RF ,but statistically significant difference between group RD and group RC & between group RF and group RC (Table 9 & Figure 9) There was no significant difference in the peak level of the sensory block to pin prick (Table 10 & Figure 10).

Time to reach the maximum sensory level was significantly lower in group RD and group RF as compared to group RC .This difference was statistically significant between group RD or group RF and group RC .(Table 11, Figure 11)

Time for 2 segment regression from maximum sensory block was significantly higher in group RD(126.5±8.84 min) and in group RF(120.83±8.99 min),as compared to group RC(101.5±6.74 min) .This difference was statistically significant (p value < 0.001) (Table 12 & Figure 12).

In our Study there was no significant difference between onset time of Motor block in these groups.(Table 12 & Figure 12). Time to achieve complete motor block was earlier in group RD (5.633±1.11min), in group RF(5.7±1.22 min) as compared to group RC (7.1±1.28 min). This difference was statistically significant between group RD and group RC (p value 0.0001) , and between group RF and group RC (p value 0.0001) , but statistically insignificant between group RD and group RF (p value was 0.22) (Table 13 & Figure 13) .

Total duration of analgesia was higher in group RD (297.16±16.04 min) and group RF (261.16±18.42 min) as compared to group RC (229.16±15.69 min) .This difference was statistically significant. P value < 0.001.(Table 17 & Figure 17)

Incidence of Sedation was not statistically significant in group RD 5 patients and group RF 4 patients had mild sedation (asleepy arousable, responding to commands),not required any treatment.(Table 18 & Figure 18) .

12 patients developed nausea/ vomiting, 4 in group RD , 3 in group RF and 5 in group RC ,without any statistically significant difference in them .and all Patients responded to IV ondansetron. No respiratory depression or any other complications, other than mentioned above, were recorded in either of the groups.

In our study 46.66% patients in group RD labeled the effect as excellent and they prefer this technique, 33.33% patients in group RF labeled it as excellent, 26.66% in group RC labelled it as excellent. This difference was found to be statistically significant (p value < 0.05) (Table 19 & Figure 19).

IV. DISCUSSION

The study was carried out to find out hemodynamic effects and block characteristics of hyperbaric ropivacaine when added with dexmeditomidine or fentanyl as a adjuvants in patients undergoing infraumbilical surgeries in spinal anaesthesia. Results were compared with other studies under following headings.

1. Demographic parameters -

Age distribution - In our study , the mean age (in years) of patients in group RD, group RF and group RC were (43.43±9.786), (44.56±10.02) and (43.7±10.04) respectively, which was statistically insignificant (p= 0.410) (Table 1). Our results were similar to studies of Jagtap et al[11] , Pradipkumar et al[14], Prabhavathi et al[15], Shashikala T.K et al[20].

Weight wise distribution- In our study , the mean weight (in kg) of patients in group RD, group RF and group RC were (64.2±7.16),(63±7.73) and (65.8±7.44) respectively, which was statistically insignificant.(P= 0.399) (Table 3). Our results were similar to studies of Prabhavathi Ravipati et al[15], Makhni R et al[16] , Ashutosh Kumar et al[17] , Khare A et al[18], N. kumar et al[19] ,Shashikala T.K et al[20].

Height wise distribution- In our study , the mean Height (in cm) of patients in group RD ,group RF and group RC were (163.06±6.49), (161.03±5.65) and (164.4±7.16) respectively, which was not significant (p=0.20) (Table 3) . Our results were similar to the study of Prabhavathi Ravipati et al[15], Makhni R et al[16] , Ashutosh Kumar et al[17], Khare A et al[18], N. kumar et al[19] , Shashikala T.K et al[20].

ASA grading - In our study, Patients with ASA physical status I and II were taken and statistically insignificant difference were observed between these groups (p > 0.05) (Table 2) .Our results were in line with the Study of Jagtap et al[11] , Pradipkumar et al[14], Prabhavathi et al[15], Shashikala T.K et al[20].

2. Haemodynamic parameters -

In our Study there was significantly decrease in mean blood pressure in group RD, group RF, and group RC at 5 min, after administration of drug. This significant difference was also seen in DBP and SBP at 5 min (p <0.05). Overall incidence of hypotension was in 12 patients in group RD, 10 Patients in group RF and 6 Patient in group RC, which was statistically insignificant (p>0.05) .

Our results were in line with the Studies of Vidhi Mahendru et al[9], Rajni Gupta et al[10] , Jagtap et al[11] , Chatterjee et al[12], Pradipkumar et al[14], Prabhavathi et al[15], Shashikala T.K et al[20] .In Aamir laique khan et al[13] study Heart rate, SBP ,MAP,DBP at all the above intervals was lower in group D (dexmedetomidine) when compared to group F (fentanyl) . Difference of HR was statistically significant at all the above intervals except at before dural puncture, 35 min, 40 min, 120 min after dural puncture. Whereas difference of SBP was statistically significant at all the above intervals except at baseline, just after dural puncture and 5 min after

spinal and Mean DBP did not show a statistically significant difference at baseline, after spinal and 5 min after spinal and 55 min after spinal.

3. Block Characteristics -

1**. Onset of sensory and motor block**

In our study Mean time to onset of sensory and motor block was observed early in group RD (106.5±16.65 sec ; 1.59±1.50 min respectively) , group RF (104.5±15.64 sec ;1.62±0.56 min respectively) as compared to group RC (117.16±14.90 sec; 2.07±1.89 min respectively) and there was no statistically significant difference in onset time of sensory block between group RD and group RF, but statistically significant difference between group RD and group RC & between group RF and group RC (Table 9 & Figure 9). In our Study there was no significant difference between onset time of Motor block in these groups.(Table 13 & Figure 13). There was no significant difference in the peak level of the sensory block to pin prick (Table 10 & Figure 10) .Our results were consistent with that of Prabhavathi Ravipati et al[15] conducted a study on intrathecal dexmedetomidine and fentanyl as adjuvants to 0.75% isobaric ropivacaine for lower limb surgeries. Our result was also in line with that of Shashikala et al[20]

2. Time to reach the maximum sensory level

Time to reach the maximum sensory level was significantly lower in group RD (5.233±1.61 min) and group RF (5.129±1.44 min) as compared to group RC(6.166 ±1.49 min) . This difference was statistically significant between group RD and group RC (P=0.023) ,Statistically very significant between group RF and group RC (P=0.0081) , but statistically insignificant between group RD and group RF (Table 11, Figure 11) . Our result was similar to that of Shashikala et al[20] Study , time to reach maximum sensory level in group RD (5.94±1.88 min) , group RF (3.86± 1.22 min) and group RC(5.99±0.46 min) .Our study was comparable with Jagtap et al[11] study , time to reach the maximal sensory level in group RF was (6.86±3.73 min), in group BF (7.07±2.99 min) similar to our study.

3. Time of two segment sensory regression : Time for 2 segment regression from maximum sensory block was significantly higher in group RD (126.5±8.84 min) and in group RF (120.83±8.99 min),as compared to group RC (101.5±6.74 min) .This difference was statistically significant.(p value <0.001) (Table 13 & Figure 13). Our study result was similar to that of Shashikala et al[20] Study , time for 2 segment sensory regression in group RD (113.27±38.09 min) , in group RF (255.10±35.626 min) and in group RC (197.67± 37.605 min) .

4. Time to achieve complete motor block : Time to achieve complete motor block was earlier in group RD (5.633±1.11min), in group RF (5.7±1.22 min) a compared to group RC (7.1±1.28 min). This difference was statistically significant between group RD and group RC (p value 0.0001) and between group RF and group RC (p value 0.0001) , but statistically insignificant between group RD and group RF (p value was 0.22) (Table 14 & Figure 14) . Our results were consistent with that of Prabhavathi Ravipati et al[15]

5. Total duration of motor block : In our study total duration of motor block observed was maximum in group RD (223.83± 21.86 min), when compared to group RF (207.83± 16.11 min) and group RC(191.83±19.95 min) ,which was statistically highly significant (P<0.001 ; P<0.001). Our study was similar to Makhni et al[16] study in which , total duration of motor block in group D (dexmedetomidine group) was 224.2 ±39.2 min .Our study result was similar to that of Somjit Chatterjee et al[12] study , in their study , total duration of motor block in group RP (hyperbaric ropivacaine) was 112.70±9.96 min. In Shashikala et al[20] study found same result , where total duration of motor block in group RD 319.5 ±64.75 min , in group RF 236.83±33.797 min and group RC 183.93±35.252 min. Our study results were contrary to that of Vidhi Mahendru et al[9] study compared intrathecal dexmedetomidine , clonidine and fentanyl as adjuvants to hyperbaric bupivacaine for lower limb surgery and duration of motor block in group BF(Bupivacaine-fentanyl) 196.0±26.8 min , in group BD(Bupivacaine-dexmedetomidine) 273.3±24.6 min and group BS (Bupivacaine-saline) 161.5±19.8 min .In Jagtap et al[11] study compared intrathecal Ropivaine-fentanyl and Bupivacaine–fentanyl and found that totat duration of motor block in group RF (242.8 ±47.06 min) and in group BF (268 ±49.9 min) which were similar to our study results .Somjit Chatterjee et al[12] study showed similar result to our study , total duration of motor block in group RP(Hyperbaric Ropivacaine) 112.70±9.96 min and in group BP (Hyperbaric bupivacaine)129.2 ±9.333 min. Aamir Laique khan et al[13] study showed total duration of motor block in group D (dexmedetomidine) 377.25 ±11.32 min and group F(fentanyl)187.0 ±6.87 min. which were similar to our study. Pradip kumar et al[14] study compared ropivacaine group with bupivacaine group showed that total duration of motor block in group R 115.47 ±17.07 min and in group B 154.60±20.37 min (P < 0.001) which were similar to our study results.

6. Total duration of analgesia and Time to 1st rescue analgesia : Total duration of analgesia was higher in group RD (297.16±16.04 min) and group RF (261.16±18.42 min) as compared to group RC (229.16±15.69 min) . .So in our study there was statistically extremely significant difference between group RD and group

RC and between group RF and group RC. Also there is statistically significant difference between group RD and group RF. This difference was statistically significant. P value < 0.001. (Table 17 & Figure 17) Our results were similar to studies of Shashikala T.K et al[20] .in which total duration of analgesia in group RD (356.67±63.022 min) ,in group RF (255.10±35.626 min) and in group RC (197.67±37.605 min) .Time to 1st rescue analgesic requirement was higher in group RD (298.5 ± 17.88 min) , in group RF (284.5 ±21.38 min) and in group RC (243.83± 15.16 min) there was statistically extremely significant difference between group RD and group RC and between group RF and group RC. Also there is statistically significant difference between group RD and group RF. This difference was statistically significant. P value < 0.001 .Our results were similar to studies of Aamir Laique khan et al[13], time for 1st rescue analgesic requirement in group D (280 ±7.84 min) and in group F (173.88±8.12 min) .Our study was comparable with Shashikala et al[20] study in which time for rescue analgesia was maximum in group RD (390.63± 84.29 min), in group RF(255.10± 35.626 min) and group RC(243.77±41.007 min) , which was almost similar to our study.

7 . Adverse effects and complications:

In our Study the incidence of nausea/ vomiting, respiratory depression, bradycardia, were not statistically significant between the groups (p>0.05) . Our results were in line with the Study of Jagtap et al[11] , Chatterjee et al[12], Pradipkumar et al[14], Prabhavathi et al[15] , Shashikala T.K et al[20].

8. Duration of Surgery:

In our Study , the mean duration of Surgery (in min) in group RD was (72.56±5.57) , in group RF(67.68±56) and in group RC (56±57).The difference was statistically insignificant between groups (p>0.05). Our results were similar to Studies of Prabhavathi Ravipati et al[15], Makhni R et al[16] , Ashutosh Kumar et al[17] , Khare A et al[18], N. kumar et al[19] ,Shashikala T.K et al[20].

9. Patient satisfaction:

In our study , 55% Patient in group RD labelled the effect as excellent and they would prefer this technique in future whereas only 45% in group RF labelled it as excellent. The difference in both groups was found to be statistically significant (p < 0.001). Prabhavathi Ravipati et al[15], Makhni R et al[16] , Ashutosh Kumar et al[17] , Khare A et al[18], N. kumar et al[19] , Shashikala T.K et al[20].

Financial support and sponsorship:Multidisciplinary Research Unit (MRU), Dr S. N. Medical Collage Jodhpur.

Conflict of interest: There were no conflict of interest.

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