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Original research article

Study to access the effect of intrathecal Ropivacaine–fentanyl versus intrathecal Bupivacaine-fentanyl for lower limb orthopaedic surgeries in a tertiary care hospital

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Abstract

Introduction: Administration of lignocaine intrathecal is a traditional practice however discontinued due to its shorter duration of action and complications like cauda equina syndrome. Use of intrathecal adjuvants extends the period of block, leads to a better success rate, patient satisfaction and provides adequate pain management. Intrathecal bupivacaine is widely used in spinal anesthesia over a long period of time.A newer drug by name Ropivacaine has evolved, which is being widely used for epidural blocks and nerve plexus blocks. Ropivacaine has an improved safety profile over bupivacaine with respect to central nervous system and cardio toxic potential. Though ropivacaine is being used significantly in epidural and nerve blocks, the research on the effectiveness regarding its use in intrathecal route is very limited.

Material and Methodology: Study was conducted in the Department of anesthesia, NRI Medical College and Hospital. Patients of both gender with physical status ASA 1 and ASA2 of age between 18 to 60 years undergoing different lower limb orthopedic surgeries under spinal anesthesia were included in the study. This is a prospective randomized parallel group, double blinded study. This study was conducted during the period of 1st January 2022 to 31st December 2022.The data is entered into MS excel spread sheet. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was represented using bar diagram, pie diagram and box plots.Pearsons'correlation and Annova was used for correlating the variables. Statistical analysis was made with IBM SPSS 20.0 software and P value of <0.05 was considered significant.

Results: In the present study, subjects in group RF took an average of 8.47 min to reach their peak motor function, whereas subjects in group BF took an average of 8.93 min to reach their peak motor function. Subjects in group RF took statistically significantly less time (P = 0.045) than those in group BF to reach peak motor. The mean duration of analgesia in patients of group RF was 241.47 ± 13.1min whereas the mean duration of analgesia in patients of group BF was 288.87 ± 16.51min. When compared to patients in group RF, there was a statistically significant lengthening of analgesia (P = 0.00010) in the group BF.

Keywords: Intrathecal analgesia, ropivacaine, fentanyl, bupivacaine

Introduction

Regional anesthesia comprises spinal, epidural and various peripheral nerve blocks. It is the most common practice for lower limb and abdominal surgeries. Airway manipulation is avoided and it provides good analgesia [1, 2] .Spinal anesthesia is deliberated higher to general anesthesia, as it reduces the problem related with general anesthesia like airway inhibits the stress hormone release, decreases intraoperative blood loss, delivers post-operative analgesia, and drops the incidence of thromboembolic complications [3]. Administration of lignocaine intrathecal route is a traditional practice however discontinued due its shorter duration of action and complications like cauda equine syndrome [5, 6]. Use of intrathecal adjuvants extends the period of block, leads to a better success rate and patient satisfaction, and provides adequate pain management [2]. Various adjuvants have been studied to prolong the effect of spinal anesthesia such as opioids, sodium bicarbonate, vasoconstrictors (epinephrine), N-methyl -d-aspartate antagonists, centrally acting α-2 adrenoceptor agonists and γ-aminobutyric acid receptor agonists [7]. Thus, intrathecal additive is a reliable method to prolong the duration of spinal anesthesia

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and prolong postoperative analgesia [8, 9]. Intrathecal bupivacaine is widely used in spinal anesthesia over a long period of time. In this setting, a newer drug Ropivacaine has emerged, which is being widely used for epidural blocks and nerve plexus blocks. Ropivacaine has an improved safety profile over bupivacaine with respect to central nervous system and cardio toxic potential. Though ropivacaine is being used frequently, in epidural and nerve blocks, the literature regarding its use in intrathecal route is very limited [10]. So the present study was conducted to compare the efficacy of intra-thecal Ropivacaine + fentanyl and Bupivacaine + fentanyl among patients undergoing orthopaedic operations in lower limb. The aim of this present study is to compare the efficacy and safety of intra thecal Ropivacaine - Fentanyl and Bupivacaine-Fentanyl for lower limb orthopaedic surgeries, with respect to spinal block characteristics along with hemodynamic effects and side effects.

Materials and Methods

This is a Hospital based study conducted in the Department of anesthesia, NRI Medical College and Hospital. Patients of both gender with physical status ASA 1 and ASA 2 of age between 18 to 60 years undergoing different lower limb orthopedic surgeries under spinal anesthesia were included as study participants. This is a prospective randomized parallel group, double blinded study with convenience sampling method. The study sample is 60(Patients). The study participants are divided into two groups. Group A receiving Ropivacaine plus Fentanyl and group B receiving bupivacaine plus fentanyl. The present study was conducted for a period of one year from 1st January 2022 to 31st December 2022.

Inclusion criteria: ASA grade I & II, Age between 18 to 60 years, both genders, cases for lower limb Orthopaedics surgery.

Exclusion criteria

Unwilling patients, Known hypersensitivity to any of the products used in the study, any contra-indications to spinal anesthesia, Cardiac arrhythmias, pregnant women. Institutional human ethics committee prior approval was taken to conduct this study. Informed written consent was obtained from all the study participants and only those participants willing to sign the informed consent were included in the study. Confidentiality of the study participants was maintained.

A pre-anaesthetic evaluation was done by taking history and by clinical examination. Patients pulse rate, blood pressure, respiratory rate, relevant clinical signs and symptoms were noted. Routine investigations like complete blood picture, blood grouping and typing, blood urea, serum creatinine. All the data collected was spread into MS excel office. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram and Line Charts.Pearsons‘ correlation and Annova was used for correlating the variables.Statistical analysis is done by using SPSS 20.0 software and P value of <0.05 was considered significant.

Results

All patients were randomly allocated into following groups. Group RF - 30 patients received 15mg of 0.5% ropivacaine (hyperbaric) 3.0ml + 25mcg fentanyl 0.5ml and Group BF - comprising 30 patients received 15mg of 0.5% bupivacaine (heavy) 3.0ml + 25mcg fentanyl 0.5ml.

In the present study, majority of patients (36.7%) belong to age group of 51 to 60 years followed by 26.7% of patients belong to age group of 21 to 30years, 20% of patients belong to age group of 41 to 50years and 16.7% of patients belong to age group of 31 to 40 years with mean age of 42.63 ± 13.04years and minimum age of 21years & maximum age of 60years in group RF.

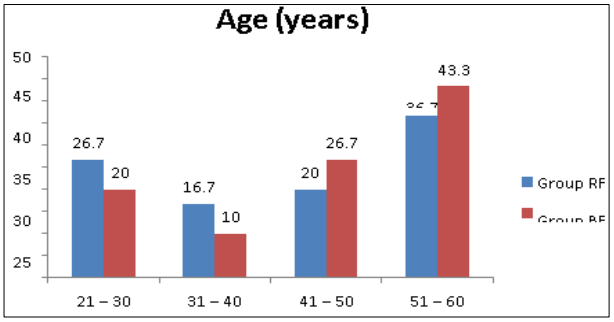

Fig 1: Bar diagram showing comparison of age among the patients in the study groups

Majority of patients (43.3%) belong to age group of 51 to 60years followed by 26.7% of patients belong to age group of 41 to 50years, 20% of patients belong to age group of 21 to 30years and 10% of patients belong to age group of 31 to 40years with mean age of 44.93 ± 11.54years and minimum age 22years & maximum age 58years in group BF. There is no statistical significance (P value 0.472).

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Table 1: Gender wise patients distribution among the study groups (n=60)

Gender	Group RF		Group BF	
	N	%	N	%
Male	24	80.0	26	86.7
Female	6	20.0	4	13.3
Total	30	100.0	30	100.0
Chi square	0.48			
P value	0.488			

80% of patients were males and 20% of patients were females in group RF. whereas 86.7% of patients were males and 13.3% of patients were females in group BF. There was no statistical significance (P value 0.488).

Table 2: Comparison of mean body mass index in patients among the study groups (n=60)

Parameter	Group RF		Group BF	
	Mean	SD	Mean	SD
BMI (kg/m^2)	24.63	1.67	24.68	1.82
P value	0.911			

The mean BMI of the patients in group RF was 24.63 ± 1.67kg/m^2. Whereas the mean BMI of the patients in group BF was 24.68 ± 1.82kg/m^2. There was no statistical significance (P value 0.911).

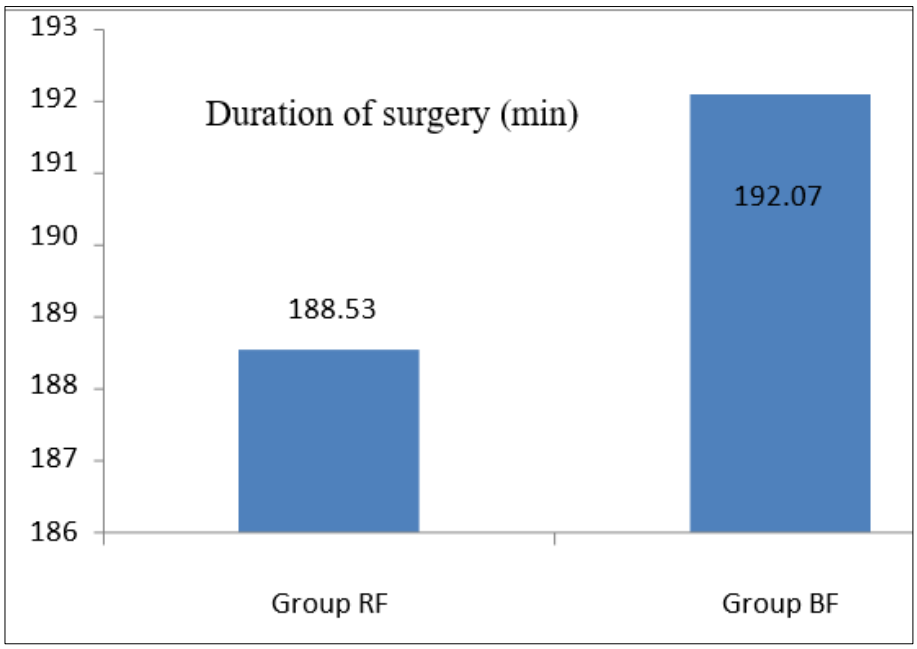

Fig 2: Comparison of mean duration of surgery in patients among the study groups

The mean duration of surgery in patients of group RF was 188.53 ± 19.9mins.whereas the mean duration of surgery in patients of group BF was 192.07 ± 22.43mins. There was no statistical significance (P value 0.521).

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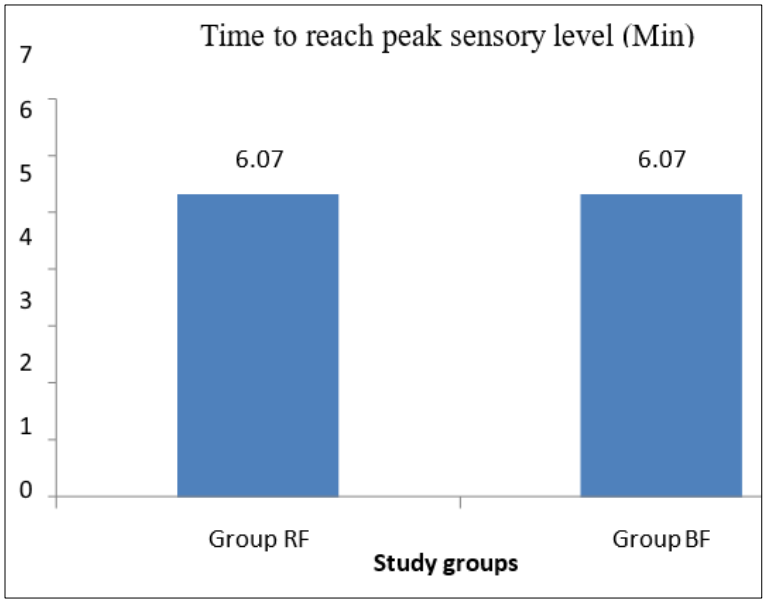

Fig 3: Bar chart showing comparison of mean time to reach peak sensory level in patients among the study groups

The mean time to reach peak sensory level in patients of group RF was 6.07 ± 0.87mins. Whereas the mean time to reach peak sensory level in patients of group BF was 6.07 ± 0.78mins. There was no statistical significance (1.000).

Table 3: Comparison of mean time to reach peak motor level in patients among the study groups (n=60)

Parameter	Group RF		Group BF	
	Mean	SD	Mean	SD
Time to reach peak motor level (min)	8.47	0.97	8.93	0.78
P value	0.045			

The mean time to reach peak motor level in patients of group RF was 8.47 ± 0.97min whereas the mean time to reach peak motor level in patients of group BF was 8.93 ± 0.78min. There is statistically significant shorter time to reach peak motor block in patients of group RF when compared with patients of group BF (P value 0.045).

Table 4: Comparison of mean duration of analgesia in patients among the study groups (n=60)

Parameter	Group RF		Group BF	
	Mean	SD	Mean	SD
Duration of analgesia (min)	241.47	13.1	288.87	16.51
P value	<0.0001			

The mean duration of analgesia in patients of group RF was 241.47 ± 13.1mins. Whereas the mean duration of analgesia in patients of group BF was 288.87 ± 16.51min. There was statistically significant increase in duration of analgesia in patients of group BF when compared with patients of group RF (P value (<0.00010).

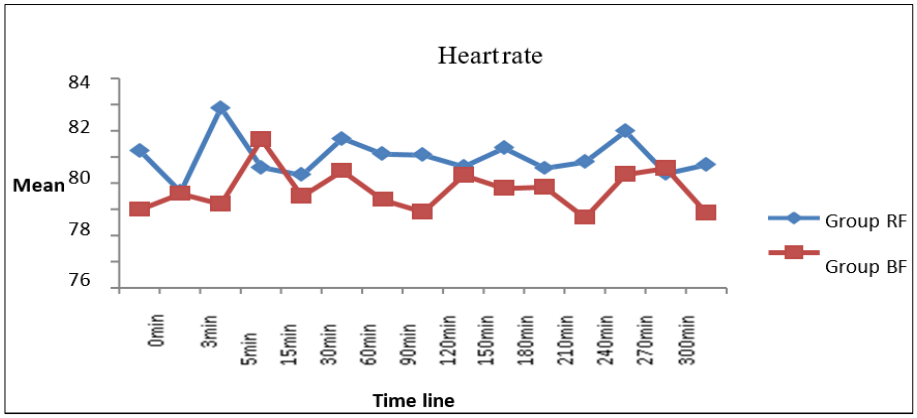

Fig 4: Line chart showing comparison of mean heart rate in patients among study groups

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There was significance difference in heart rate among the study groups during 5min (P value 0.007) whereas the mean heart rate was comparable among the study groups during baseline, 3min, 15min, 30min, 60min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value >0.05).

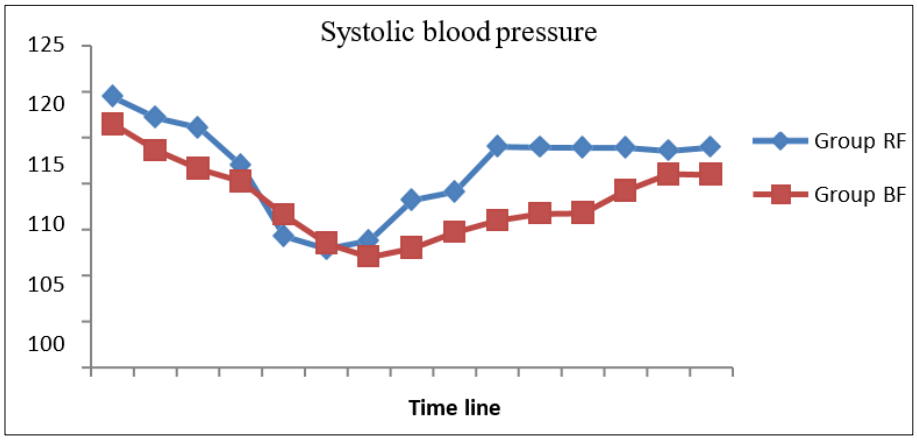

Fig 5: Comparison of mean systolic blood pressure in patients among the study groups

There was significant reduction in SBP in patients of group BF when compared with patients of group RF during baseline, 3min, 5min, 15min, 30min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value <0.05).

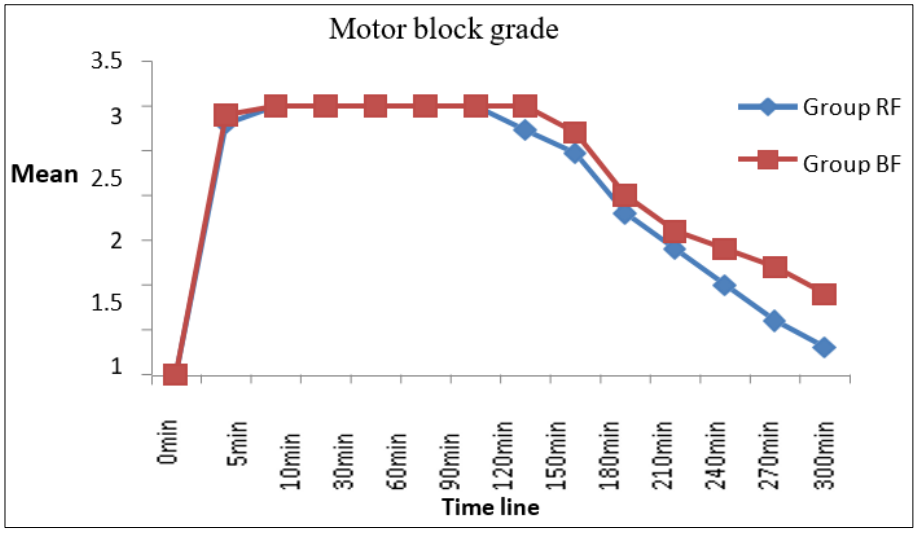

Fig 6: Comparison of mean motor block grade in patients among the study participants

There was no statistically significant difference in motor block grading in patients among the study groups during 5min, 15min, 30min, 60min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value >0.05). There was significantly early motor block recovery among patients of group RF when compared with patients of group BF (P value <0.05). Majority of cases had motor recovery completely within 300mins and there was longer duration of motor block in patients of group RF.

Table 5: Comparison of complications in patients among the study groups (n=60)

Complications	Group RF		Group BF	
	N	%	N	%
Nausea/vomiting	1	3.3	2	6.7
Hypotension	2	6.7	9	30.0
Bradycardia	0	0.0	1	3.3
Shivering	2	6.7	1	3.3
P value	0.362			

3.3% of patients in group RF and 6.7% of patients in group BF had nausea or vomiting. 6.7% of patients in group RF and 30% of patients in group BF had hypotension. 3.3% of patients in group BF had

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bradycardia. 6.7% of patients in group RF and 3.3% of patients in group BF had shivering. There was no statistical significance (P value >0.05).

Discussion

In this study, majority of patients (36.7%) belong to age group of 51 to 60 years followed by 26.7% of patients belong to age group of 21 to 30years, 20% of patients belong to age group of 41 to 50years and 16.7% of patients belong to age group of 31 to 40years with mean age of 42.63 ± 13.04years and minimum age of 21years & maximum age of 60years in group RF. Majority of patients (43.3%) belong to age group of 51 to 60years followed by 26.7% of patients belong to age group of 41 to 50years, 20% of patients belong to age group of 21 to 30years and 10% of patients belong to age group of 31 to 40years with mean age of 44.93 ± 11.54years and minimum age 22years & maximum age 58years in group BF. There was no statistical significance (P value 0.472) and when compared with similar studies conducted by Koltka K *et al*, [11] showed that the mean age of the patients in group B was 44 ± 16years whereas the mean age of the patients in group R was 41 ± 15years.Study conducted by Jagtap S *et al*, [12] showed that the mean age of the patients in group RF was 41.54 ± 15.58years whereas the mean age of the patients in group BF was 39.63 ± 15.19years.Study conducted by Swarup PV *et al*, [13] showed that the mean age of the patients in group R was 40.8 ± 11.7years whereas the mean age of the patients in group B was 39.79 ± 10.98years where there was significance (P value 0.85).In a study done by Kuber K *et al*[14] showed that the mean age of the patients in group R was 37.5years whereas the mean age of the patients in group B was 42.33years where there was significance (P value 0.109).In current study, 80% of patients were males and 20% of patients were females in group RF whereas 86.7% of patients were males and 13.3% of patients were females in group BF. There was no statistical significance (P value 0.488).In a study done by Jagtap S *et al*, [12] showed that 66.7% of patients were males and 33.3% of patients were females in group RF whereas 63.3% of patients were males and 36.7% of patients were females in group BF. In current study, 46.7% of patients belong to ASA grade I and 53.3% of patients belong to ASA grade II in group RF whereas 43.3% of patients belong to ASA grade I and 56.7% of patients belong to ASA grade II in group BF. There was no statistical significance (P value 0.795).In a study done by Koltka K *et al*, [11] showed that 32% of patients belong to ASA grade I and 68% of patients belong to ASA grade II in group B whereas 40% of patients belong to ASA grade I and 60% of patients belong to ASA grade II in group R.In a study done by Swarup PV *et al*, [13] showed that 76.7% of patients belong to ASA grade I and 23.3% of patients belong to ASA grade II in group R whereas 86.7% of patients belong to ASA grade I and 13.3% of patients belong to ASA grade II in group BF. There was no statistical significance (P value 0.15). In current study, the mean BMI of the patients in group RF was 24.63 ± 1.67kg/m^2 whereas the mean BMI of the patients in group BF was 24.68 ± 1.82kg/m^2. There was no statistical significance (P value 0.911).In a study done by Swarup PV *et al*, [13] showed that the mean BMI of the patients in group R was 23.3 ± 1.23kg/m^2 whereas the mean BMI of the patients in group B was 22.9 ± 1.34kg/m^2. There was no statistical significance (P value 0.07). In current study, the mean duration of surgery in patients of group RF was188.53 ± 19.9min whereas the mean duration of surgery in patients of group BF was 192.07 ± 22.43min. There was no statistical significance (P value 0.521).In a study done by Koltka K *et al*, [11] showed that the mean duration of surgery in patients of group B was 91 ± 25min whereas the mean duration of surgery in patients of group R was 90 ± 30min in patients of group R.

In this study, majority of patients (46.7%) had highest level of T4 followed by 30% achieved T5 level, 13.3% of patients achieved T3 level and 10% of patients achieved T6 level in group RF whereas majority of patients (46.7%) followed by 36.7% of patients achieved T5 level, 13.3% of patients achieved T6 level and 3.3% of patients achieved T3 level. There was no statistical significance (P value 0.543).In a study done by Jagtap S *et al*, [12] showed that majority of patients in group RF and group BF achieved T6 highest sensory level.In a study done by Kuber K *et al*, [14] showed that median level of sensory block in patients of group B was T5 and the median level of sensory block in patients of group R was T6.

In current study, the mean time to reach peak sensory level in patients of group RF was 6.07 ± 0.87min whereas the mean time to reach peak sensory level in patients of group BF was 6.07 ± 0.78min. There was no statistical significance (1.000).In a study done by Koltka K *et al*, [11] showed that the mean time onset of sensory block was 10 ± 4.5min in patients of group B whereas the mean time of onset of sensory block was 9 ± 4min in patients of group R which was not statistically significant. In a study done by Jagtap S *et al*, [12] showed that the mean time to reach peak sensory level in patients of group RF was 6.86 ± 3.73min whereas the mean time to reach peak sensory level in patients of group BF was 7.07 ± 2.99min. There was no statistical significance (P value 0.34).

In current study, the mean time to reach peak motor level in patients of group RF was 8.47 ± 0.97min whereas the mean time to reach peak motor level in patients of group BF was 8.93 ± 0.78min. There was statistically significant shorter time to reach peak motor block in patients of group RF when compared with patients of group BF (P value 0.045).In a study done by Jagtap S *et al*, [12] showed that the mean time to reach peak motor level in patients of group RF was 6.02 ± 2.1min whereas the mean time to reach peak motor level in patients of group BF was 6 ± 3.6min where there was no significance (P value 0.31).

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In this study, the mean duration of analgesia in patients of group RF was 241.47 ± 13.1 mins. Whereas the mean duration of analgesia in patients of group BF was 288.87 ± 16.51min. There was statistically significant increase in duration of analgesia in patients of group BF when compared with patients of group RF (P value<0.00010).In a study done by Koltka K *et al*, [11] showed that the mean duration of analgesia in patients of group B was 182 ± 46min whereas the mean duration of analgesia in patients of group R was 139 ± 39min where there was statistical significance (P value <0.05).

In this study there is significance difference in heart rate among the study groups during 5min (P value 0.007) whereas the mean heart rate was comparable among the study groups during baseline, 3min, 15min, 30min, 60min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value >0.05).In a study done by Koltka K *et al*[11] showed that the mean heart rate during pre-operative period was 81 ± 10per min in patients of group B whereas the mean heart rate during pre-operative period was 76 ± 13per min in patients of group R. There was no statistical significance.

In this study, systolic blood pressure was recorded during baseline, 3min, 5min, 15min, 30min, 60min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min.There was significant reduction in SBP in patients of group BF when compared with patients of group RF during baseline, 3min, 5min, 15min, 30min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value <0.05).In a study done by Swarup PV *et al*[13] showed that in the study groups fall in SBP was documented after giving spinal anesthesia. Maximum decrease in systolic BP among both the study groups was observed during 10min and 25min. The extent of reduction in systolic BP was comparable among the study groups where there was no statistically significance. In this study, motor block grade was recorded during baseline, 5min, 15min, 30min, 60min, 90min, 120min, 180min, 210min, 240min and 270min.There was no statistically significant difference in motor block grading in patients among the study groups during 5min, 15min, 30min, 60min, 90min, 120min, 150min, 180min, 210min, 240min, 270min, 300min and 330min (P value >0.05). There was significantly early motor block recovery among patients of group RF when compared with patients of group BF (P value <0.05). Majority of cases had motor recovery completely within 300mins and there was longer duration of motor block in patients of group RF.In an investigation done by Jagtap S *et al*, [12] showed that 70% of convalescents in group RF and 40% of patients in group BF recovered with bromage grade 1 during 240min.In a survey by Kuber K *et al*, [14] showed that there was relatively early motor block recovery in patients of group R when compared with patients of group B (P value 0.000) at 5min whereas it was comparable among the study groups at 0min, 10min and 15min. 3.3% of participants in the Ropivacaine-Fentanyl group and 6.7% of participants in the Bupivacaine-Fentanyl group experienced nausea or vomiting in the current study. The prevalence of hypotension was 6.7% in the RF patient group and 30% in the BF patient group. Bradycardia was present in 3.3% of those in group BF. Shivering was present in 6.7% of participants in the RF group and 3.3% of participants in the BF group. (P value > 0.05) The results were not statistically significant.In a research by Koltka K *et al*, [11] showed that 8% of patients in group B and 12% of patients in group R had bradycardia. 32% of patients in group B and 20% of patients in group R had hypotension. In an investigation, Jagtap S. *et al*, [12] found that 10% of Bupivacaine-Fentanyl group and 3.3% of RF group convalescents, respectively, had hypotension. Bradycardia was present in 3.3% of both group RF and group BF convalescents. Both group RF and group BF's convalescents (10%) had pruritis. Vomiting and/or nausea occurred in 3.3% of patients in the Ropivacaine-Fentanyl group. Shivering was experienced by 3.3% of patients in group R.

Conclusion

In this study it was concluded that intrathecal ropivacaine + fentanyl offers an acceptable anesthesia and has an improved hemodynamic constancy for lower limb orthopedic surgeries. The shorter duration of motor block when equated to intrathecal Bupivacaine + Fentanyl was obliging in relationships with prompt ambulation, voiding and for preliminary physiotherapy previously. Additional studies with more sample sizes are desirable to give a conclusive result on the efficacy and effectiveness of intrathecal Ropivacaine in lower limb and other major operative procedures.

Conflict of Interest: None Declared

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