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Comparative study of intrathecal ropivacaine-fentanyl and bupivacaine-fentanyl for lower limb orthopaedic surgeries

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Abstract: Intrathecal bupivacaine results in a longer duration of complete anaesthetic block than ropivacaine. Fentanyl used as an adjuvant may improve the quality of spinal block of ropivacaine, while maintaining its advantage of early motor recovery. The aim of the study was to compare the efficacy and safety of intrathecal ropivacaine-fentanyl (RF) with bupivacaine-fentanyl (BF) for lower limb orthopaedic surgeries. In this Single Centered, Prospective, Randomized, Parallel group, Double-Blind study, sixty patients were randomly allocated to receive either intrathecal 15 mg of 0.5% ropivacaine with 25 mcg fentanyl (Group RF) or 15 mg of 0.5% bupivacaine with 25 mcg fentanyl (Group BF). The onset, duration, spread of sensory and motor block, hemodynamic parameters, and side effects were recorded. Data analysis was done using SPSS software and Sigma Stat 3.5 version (2012). The time to reach the highest sensory level, complete motor block, and two-segment sensory regression time were comparable between the two groups. The motor recovery to Bromage scale 1 was faster in Group RF. The hemodynamic stability was better in Group RF. However, the time duration of analgesia was prolonged in Group BF. Intrathecal RF provided satisfactory anesthesia with hemodynamic stability for lower limb orthopaedic surgeries. It provided a similar sensory but a shorter duration of motor block compared to BF, which is a desirable feature for early ambulation, voiding, and physiotherapy.

Keywords: Ropivacaine; Bupivacaine; Fentanyl; Intrathecal; Orthopaedic surgery.

1. Introduction

Spinal Anaesthesia is the widely used method for lower limb orthopaedic surgeries, providing a faster onset and effective motor and sensory blockade. It is simple, easy to perform and has got a definite endpoint. Intrathecal bupivacaine is widely used in spinal anaesthesia 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 sparse.

The aim of study is to compare the efficacy and safety of intra thecal Ropivacaine- Fentanyl and Bupivacaine-Fentanyl for lower limb Orthopaedic surgeries, with respect to 1. Primary outcome- spinal block characteristics 2. Secondary outcome- haemodynamic effects and side effects

2. Material and Methods

Study setting and design It is a single centre, prospective, randomized, parallel group, double – blind study. This study was done in Tirunelveli medical college hospital at department of Anaesthesiology and critical care. After obtaining institutional ethical committee approval, 60 patients between the age group of 18-60 were posted for elective lower limb orthopaedic surgeries were recruited for the study. These 60 patients were randomized using a computer generated table, into two groups of 30 patients each as followsGroup RF - 15 mg of 0.5% Ropivacaine (3.0 ml) + 25 mcg Fentanyl (0.5 ml) Group BF - 15 mg of 0.5% Bupivacaine (3.0 ml) + 25 mcg Fentanyl (0.5 ml).

2.1. Inclusion criteria

- ASA physical status 1 & 2
- Age 18 – 60 years
- Both gender
- Lower limb orthopaedic surgery

2.2. Exclusion criteria

- Known hypersensitivity to any of the test drugs
- Any contra – indication to spinal anaesthesia
- Cardiac arrhythmias

3. Procedure

Masking Pre-filled labelled syringes loaded with the drugs were prepared by an anaesthesiologist not participating in the study. The anaesthesiologist who did the intervention and observation was unaware of the contents of the syringes and the group allocation. When the patient arrived the operation room, IV access was established, and 500 ml of RL was started. Multipara monitor attached, and baseline parameters - EGG, NIBP, SPO2, respiratory rate were recorded. After skin infiltration with 2% lidocaine, 25GQuincke's needle was inserted through L3-4 interspace in the midline, with the patient in sitting position. Correct placement of the needle was identified by free flow of cerebrospinal fluid and 3.5 ml of the study drug was injected over 10 seconds, and the patient was then placed supine. Standard monitoring was used throughout the surgical procedure. ECG and pulse– oximetry were continuously monitored, while NIBP was measured at 5-min intervals. Heart rate and NIBP were recorded before intrathecal injection, 3, 5, 15, 30 minutes after the intrathecal drug administration, and thereafter every 30 minutes till the end of the surgery and one hour after the end of the surgery, at the ward. Any hypotension (systolic blood pressure lower than 20% from the baseline) was treated with i.v ephedrine 6 mg and bradycardia (heart rate < 50/min) incidents was treated i.v atropine 0.6 mg increments.

3.1. Parameter Observed (Primary)

Spinal block characteristics – Time to reach peak sensory level - Pinprick test Time to reach peak motor block - Bromage scale grade 3 Two segment sensory regression time Time to motor regression to Bromage scale grade 1 Duration of analgesia Post –operative period - Time to first analgesic demand (VAS > 4)

3.2. Parameter Observer (Secondary)

Heart rate (< 50 /min - bradycardia) Blood pressure (> 20% fall from baseline SBP - hypotension) Oxygen saturation Pruritus Nausea Vomiting Shivering.

3.3. Time of Onset of Secondary Block

The time interval between end of anesthetic injection and appearance of cutaneous analgesia in the dermatomes assessed by the pin prick test using 20 G hypodermic needle in T-12, T-10, T-8, T-6 or higher levels (T-4).

3.4. Motor Block Duration

It is the time taken between administration of anesthetic and the attainment of grade 0 in Bromage motor scale.

3.5. Two Section Sensory Regression Time

The time taken for the sensory block to regress to two segment down from the maximum level of blockade is defined as the two segment regression time.

3.6. Analgesia

It is the time of administration of anesthetic and the disappearance of cutaneous level of sensation, at each dermatomal level.

3.7. Post OP Analgesia Duration

The time between the administration of anesthetic and time of analgesic requirement (visual analog scale > 4) in PACU.

4. Results

The information which was collected regarding all the selected cases, were recorded in a master chart. Data analysis was done with the help of computer by using SPSS software and Sigma Stat 3.5 version (2012). Using this software, percentage, mean, standard deviation and 'p' value were calculated through one way ANOVA, and Chi square test and a P value of < 0.05 was taken as significant.

Table 1. Age Distribution

Age in years	Group RF	Group BF
21-30	9	5
31-40	4	4
41-50	4	9
51-60	13	12
Total	30	30
Mean	42.97	44.93
SD	13.91	10.83
P value	0.544 Not significant	

The age distribution between two groups were comparable.

Table 2. Gender Distribution

Gender	Group RF	Group BF
Male	25	25
Female	5	5
Total	30	30
P value	0.848 Not significant	

The distribution of gender between the two groups was comparable.ie statistically not significant.

Table 3. Comparison of Weight

Weight	Group RF	Group BF
Mean	69.5	68.37
SD	7.22	5.01
P value	0.482 Not significant	

The mean weight distribution between two groups were comparable. i.e statistically not significant.

Table 4. Comparison of Height

Height	Group RF	Group BF
Mean	167.83	166.7
SD	8.11	5
P value	0.482 Not significant	

The mean distribution of height between two groups were comparable. i.e statistically not significant.

Table 5. Peak Sensory Level (Thoracic)

Peak sensory level (thoracic)	Group RF	Group BF
Mean	4.37	4.6
SD	0.85	0.77
P value	0.270 Not significant	

The peak sensory levels attained between the two groups were comparable. They are statistically not significant

Table 6. Time to Reach Peal Sensory Level

Time to reach peak sensory level in min	Group RF	Group BF
Mean	6.17	6.17
SD	0.91	0.79
P value	1.0 Not significant	

The time to reach peak sensory level between the two groups is statistically not significant.

Table 7. Two Segment Sensory Regression Time

Two segment sensory Regression time	Group RF	Group BF
Mean	65.43	67.03
SD	3.12	3.71
P value	0.076 Not significant	

The two segment sensory regression time between the two groups were comparable. i.e statistically not significant.

4.1. Comparison of Systolic BP

After an initial moderate fall produced by the sympathetic blockade in both groups, the systolic BP got stabilized after 90 min in RF group, indicated by the recovery of BP to a higher level comparing to BF group , This reflects the better haemodynamic stability in RF group. There is a statistical significant difference among the two groups with respect to systolic blood pressure. This also coincides with the early recovery of motor power in RF group, when compared to the BF group.

Table 8. Systolic Blood Pressure

Systolic BP	Group RF	Group BF	Group RF -SD	Group BF-SD	p value
Min 0	124.6	121.5	3.73	2.45	<0.001
3	122.4	118.5	4.79	4.52	0.002
5	12.2	116.5	3.52	4.31	<0.001
15	116.9	115.3	2.55	1.91	0.006
30	109.3	111.8	2.02	2.76	<0.001
60	107.6	108.5	2.88	3.98	0.333
90	108.0	106.7	2.70	3.15	0.021
1220	113.2	107.8	2.24	1.06	<0.001
150	114.2	109.9	2.49	0.96	<0.001
180	118.7	111.0	1.51	1.47	<0.001
210	119.1	111.8	1.76	1.16	<0.001
240	118.8	111.9	3.24	1.88	<0.001
270	119.0	114.3	2.44	2.20	<0.001
300	118.5	116.0	2.79	1.88	<0.001
Min 330	119.1	116.0	0.83	1.68	<0.001

There was statistically significant difference in the systolic blood pressure between the two groups from 120 to 240 minutes. i.e $p < 0.05$. ie. There is early stabilization of systolic BP in group RF.

Table 9. Duration of Analgesia

Duration of Analgesia (min)	Group RF	Group BF
Mean	242.27	289.2
SD	12.81	16.38
P value	< 0.001 Not significant	

There is a statistical significance in the difference between the two groups RF and BF. p value < 0.001 .ie, The duration of analgesia is more in BF group .

Table 10. Side Effects

PARAMETER	Group RF	Group BF
Hypotension	3	8
Bradycardia	1	1
Nausea- vomiting	1	2
Shivering	1	1
Pruritus	-	-

5. Discussion

The present study has demonstrated that using either ropivacaine or bupivacaine intrathecally, with fentanyl as an adjuvant has provided satisfactory anesthetic conditions for lower limb ortho surgeries. Most of the sub arachnoid block characteristics were similar. There was a significant early motor recovery in RFgroup with haemodynamic stability, but BF provided a prolonged duration of post operative analgesia. Koltka et al. [1] compared doses of equal potency of the isobaric bupivacaine- 13 mg and ropivacaine-19.5 mg and, both with fentanyl- 20 mcg for the sub-arachnoid block in lower abdominal surgery. They found that the RF had a lower level of sensory block with a shorter duration of motor block, when compared to BFI proposed to study the efficacy of ropivacaine for major orthopaedic surgeries as an alternative to bupivacaine, using equimilligram dose (15 mg) as used by Luck et al. [2]. While maintaining the advantage of low dose local anaesthetic intrathecally, the use of analgesic adjuvants can improve the quality of intra operative anaesthesia. Sangeeta Varun et al. [3], hypothesized that intrathecal use of ropivacaine, provides a similar anaesthesia with lesser duration of motor blockade when compared to bupivacaine. In their study, they concluded that the intrathecal use of ropivacaine- fentanyl, has a faster onset, and a faster sensory regression, delayed onset, but a comparable motor block regression, and shorter duration of analgesia when compared to intrathecal bupivacaine-fentanyl. They also concluded that ropivacaine-fentanyl when administered intrathecally, is associated with decreased episodes of hypotension, when compared to bupivacaine-fentanyl group combination Both intrathecal RF and BF produced an initial moderate fall in blood pressure in keeping with the expected sympathetic blockade produced by the spinal anaesthesia. Although the Systolic BP stabilized after 30 min, there was a statistically significant difference among the two groups from 120 to 240 minutes, where the systolic BP comes near the baseline values in RF group. This recovery profile of systolic blood pressure in the ropivacaine-fentanyl group more or less coincides with the recovery of motor block. My results are consistent with Lee et al. [4]. Sheetal Jagtap et all5 did a Comparison of intrathecal ropivacaine fentanyl and bupivacaine fentanyl for major lower limb orthopaedic surgery: A randomised double blind study concluded the haemodynamic stability was better in Group RF than Group BF.

As I observed comparable levels of highest dermatome blocked, the time taken to reach the peak sensory and motor level and the two segment sensory regression time. The motor block was significantly shorter with Group RF, although it outlasted the duration of surgery. This feature is desirable as it encourages early ambulation, voiding and physiotherapy. Neurological side effects, if any, can also be detected early. The mean time duration of analgesia is significantly prolonged in Group BF when compared to Group RF. No patient in either group required intra-operative analgesia, since the duration of surgery is within the duration of sensory block in both groups. Intra operative hypotension requiring treatment with ephedrine occurred in 3 patients

in Group RF as compared to 8 patients in Group BF. One patient in each group was also treated with 0.6 mg i.v atropine for bradycardia. The most common adverse effect noted was nausea and vomiting, experienced in both the groups. Shivering also occurred in both the groups.

6. Conclusion

Intrathecal ropivacaine-fentanyl provides a satisfactory anesthesia and has a better hemodynamic stability for lower limb orthopaedic surgeries. The shorter duration of motor block compared to intrathecal Bupivacaine – Fentanyl is helpful in terms of early ambulation, voiding and for starting physiotherapy earlier. Although certain trends could be established in this study with encouraging results, further studies with larger sample sizes are needed to form a definitive opinion regarding the application of intrathecal Ropivacaine

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