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A Cross Sectional Study to Compare Dexmedetomidine and Fentanyl as An Adjuvants to Intrathecal Bupivacaine in Orthopaedic Procedure in Lower Limbs

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KEYWORDS

Dexmedetomidine, Fentanyl, Intrathecal Bupivacaine, Lower limb, Orthopaedic procedure, Spinal anaesthesia, Sensory Motor block, Analgesia, Bromage.

ABSTRACT:

BACKGROUND

Orthopaedic procedures involving the lower limb requires effective pain management. One commonly used technique is the administration of Intrathecal Bupivacaine, a local anaesthetic, to provide spinal anaesthesia. To enhance the analgesic effect of intrathecal Bupivacaine, adjuvant such as Dexmedetomidine and Fentanyl have been investigated. Dexmedetomidine is a selective A2- adrenergic against with sedative analgesia and sympatholytic properties. It has been shown to prolong the duration of analgesia when added to local anaesthetics in various regional anaesthesia techniques. Fentanyl, a potent opioid analgesic, is commonly used as an adjunct to spinal anaesthesia to improve postoperative pain control.

The purpose of the study is to compare the efficacy of Dexmedetomidine and Fentanyl added to intrathecal Bupivacaine in Orthopaedic procedures in lower limbs.

The aim of the study is to compare the efficacy of Dexmedetomidine and Fentanyl as an adjuvant to intrathecal Bupivacaine in orthopaedic procedures in lower limbs.

METHODS

The study was conducted in 40 patients belonging to either gender who scheduled for lower limb orthopaedic surgeries under Spinal Anesthesia. After obtaining informed consent from each patient, the patients were selected and divided into two, group BD and group BF, each group containing 20 patients.

Group BD was given 2.8ml of Bupivacaine + 5mcg of Dexmedetomidine)0.05ml +0.15ml of Normal saline). Group BF was given 2.8ml of Bupivacaine + 0.2ml of Fentanyl.

RESULTS

The duration of sensory block lasted significantly longer in Group BD (251 ± 14.79) compared to Group BF (216 ± 11.94) showing p value <0.0001 significant. Similarly, duration of analgesia was also found to be longer in Group BD (288 ± 13.26) compared to Group BF (242 ± 18.8) showing p value <0.0001 significant.

CONCLUSION

On the basis of our observational study, conclusions were drawn that using Dexmedetomidine as an adjuvant to Bupivacaine for intrathecal analgesia in lower limb surgeries has longer duration of sensory and motor block, longer postoperative analgesia with low side effects.

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INTRODUCTION

Lower limb surgeries could be performed under local, neuraxial and general anaesthesia, but neuraxial block is the preferred method.

Under proper aseptic conditions, spinal anaesthesia was given at the level of L4-L5 interspace in sitting position by a Quincke spinal needle. The anaesthetic medication is injected at a rate of approximately 2 ml/sec; and then all patients were made supine. Spinal block has rapid onset, deep block, lower risk of infection and is cost effective.

Bupivacaine is a potent local anaesthetic with unique characteristics from the amide group of local anaesthetics. Local anaesthetics generally block the generation of an action potential in nerve cells by increasing the threshold for electrical excitation. The progression of anaesthesia is dependent on factors such as the diameter, degree of myelination, and conduction velocity of nerve fibers.

Administrating the combinations of other classes of analgesics with local anaesthetics has used to increase the duration and reduce side effects of analgesia. Some drugs have been used as adjuvants in spinal anaesthesia to prolong intraoperative and postoperative analgesia including opioids, α2 agonists, neostigmine, vasoconstrictors, etc. Clonidine and dexmedetomidine are two α2 agonists affecting via pre- and post-synaptic α2 receptors.

Dexmedetomidine has been widely used for anaesthesia and analgesic purposes. It is a new generation highly selective α2-adrenergic receptor (α2-AR) agonist that is associated with sedative and analgesic sparing effects, reduced delirium and agitation, perioperative sympatholytic, cardiovascular stabilizing effects, and preservation of respiratory function. The mechanism of action is unique and differs from those of currently used sedative agents, including clonidine. Activation of the receptors in the brain and spinal cord inhibits neuronal firing, causing hypotension, bradycardia, sedation, and analgesia. The responses to activation of the receptors in other areas include decreased salivation, decreased secretion, and decreased bowel motility in the gastrointestinal tract; contraction of vascular and other smooth muscle; inhibition of renin release, increased glomerular filtration, and increased secretion of sodium and water in the kidney; decreased intraocular pressure; and decreased insulin release from the pancreas

Fentanyl is a potent synthetic opioid, which, similar to morphine, produces analgesia but to a greater extent. Fentanyl molecules target a subclass of opioid receptor systems in the body, many of which are localized in the brain within specialized neuroanatomical structures, particularly involving the control of emotions, pain, and speaking to the point of its infamous addictive properties, reward. When used as a sedative, it is most commonly administered as a drip. As pre-medication for procedures, namely those anticipated to cause discomfort, fentanyl is also an option perioperatively.

Dexmedetomidine and fentanyl have been used as adjuvant to local anaesthetics in different surgeries to provide superior analgesia and to improve the duration of the block. In this study, we aim to compare the efficacy of dexmedetomidine and fentanyl added to intrathecal bupivacaine in orthopedic procedures in lower limbs in terms of block strength and time [1].

The aim of the study is to compare the efficacy of Dexmedetomidine and Fentanyl as an adjuvant to intrathecal Bupivacaine in orthopedic procedures in lower limbs. We also evaluated the duration and level of sensory motor block achieved with addition of Dexmedetomidine and fentanyl to intrathecal Bupivacaine. To assess the quality of analgesia provided by Dexmedetomidine and Fentanyl in addition to intrathecal Bupivacaine.

MATERIALS AND METHODS

This Cross sectional Observational study was done in Sree Balaji Medical College and hospital during the year 2023. The study was conducted on 40 ASA patients of both genders and age group between 20 - 45 years old who were scheduled for orthopedic procedures in lower limbs under spinal anesthesia. Ethical clearance was taken from Ethical and Research Committee of Sree Balaji Medical College and Hospital and Written Consent was taken from all patients.

40 patients undergoing orthopedic procedures in lower limb under spinal anesthesia at Sree Balaji Medical College and Hospital. The patients were selected and divided into two groups. Group BD and Group BF with 20 patients each. The 6 months of study period.

Group BD received 2.8ml of Bupivacaine + 5mcg of Dexmedetomidine)0.05ml +0.15ml of Normal saline).

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Group BF received 2.8ml of Bupivacaine + 0.2ml of Fentanyl.

Inclusion criteria where : Adult patients of age 20 – 45 years old, Both male and female, Patients schedules to undergo lower limb orthopaedic procedures, ASA physical status I and II, Patients with mild comorbidities like asthma, diabetes mellitus, hypertension, thyroid, Patient planned for spinal anesthesia using intrathecal bupivacaine as the primary anesthetic agent, No history of allergy or any sensitivity to any local anesthetic solutions.

Exclusion criteria where : Patients < 20 years of age and > 45 years of age, Pregnant or breastfeeding women, Patients with contraindication to any drug, Patients with the history of allergy to Dexmedetomidine, Fentanyl, Bupivacaine, Patients with significant coagulation disorder, ASA III and above patients, Patients with severe cardiovascular disease, respiratory disease, hepatic and renal dysfunction, Infection at the local site, Patients who have difficulty in positioning, Patient's refusal.

METHODOLOGY

1. After obtaining Approval from Ethical Committee and written informed consent, ASA grade I and II patients of either gender aged 20 – 45 years old was scheduled for lower limb orthopaedic procedures under spinal anesthesia.

2. The patient was randomly divided into two equal groups, Group BD and Group BF. GROUP BD - 2.8ml of Bupivacaine + 5mcg of Dexmedetomidine (0.05ml + 0.15ml of Normal saline).

GROUP BF - 2.8ml of Bupivacaine + 0.2ml of Fentanyl.

3. Selected patients were advised to be on NPO for 8 hours. Procedure details was explained to patients in their mother tongue and consents were taken.

4. Pre- operative evaluation for both groups included a detailed investigations like history of illness, history of allergic to any drugs, history of previous surgery, height, weight, body mass index, blood group, hemoglobin level, random blood sugar level, bleeding clot clotting time, serology test, PT-INR.

5. After examining the patient pre operatively, patients were taken into the operation theatre. IV access was secured and monitoring devices was properly connected to patient. After painting and draping of lumbar region, initiation of Spinal anesthesia was administered.

6. Monitoring parameters such as heart rate, oxygen saturation, and blood pressure were recorded for every 30 minutes. They were also recorded before and after giving drug for any variations. ECG was monitored throughout for the change of any rate of rhythm.

7. Sensory and motor block and pain score were also recorded before and after the procedure.

8. Under strict aseptic condition, patient's skin was anesthetized and were administered the test dose of 2ml of 2% lignocaine. After confirming the free flow of CSF, study drug-local anesthetic as spinal block was administered via 25G spinal needle in the sitting position at L3-L4 intervertebral space.

9. The patients were then positioned for surgery after ensuring effective sensory and motor block.

10. The following variables was observed and recorded:

- Baseline of sensory block was observed right after positioning the patient using Pin Prick Method/light touch.
- Baseline of motor block was also observed using Bromage Scale.
- Time taken for onset, peak and duration of motor and sensory block was observed at regular intervals.
- Regression of motor block and time for first rescue analgesia was also recorded in the post-operative period.

RESULTS :

<u>Demographic Characteristics:</u>

There were no significant differences in baseline demographics between the two groups.

Age Distribution: In Group BD, 35% were aged 20–35 years and 65% were 36–45 years. In Group BF, 25% were 20–35 years and 75% were 36–45 years. The difference was statistically non-significant ($p = 0.822$).

Gender Distribution: Group BD included 70% males and 30% females, whereas Group BF had 65% males and 35% females ($p = 0.733$), indicating no significant difference.

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Hemodynamic Parameters

Across all time intervals, there were no statistically significant differences in mean heart rate or blood pressure between the groups.

Heart Rate: At baseline, the mean heart rate was 80.3 ± 6.87 bpm in Group BD and 82.1 ± 7.11 bpm in Group BF ($p = 0.4206$). Subsequent measurements at post-block, 5 min, and 30 min also showed non-significant differences.

Systolic Blood Pressure: Baseline SBP was 123.5 ± 12.25 mmHg in Group BD vs 126.5 ± 11.94 mmHg in Group BF ($p = 0.4377$). Measurements post-block and at 5 and 30 minutes remained statistically non-significant.

Diastolic Blood Pressure: A significant difference was observed at 5 minutes post-block, with Group BD at 78.45 ± 5.89 mmHg and Group BF at 73.05 ± 10.46 mmHg ($p = 0.0514$). All other time points were non-significant.

Block Characteristics (Table 1)

Onset of Sensory Block: Group BD achieved sensory block faster (3.35 ± 0.47 min) than Group BF (5.55 ± 0.49 min), with a highly significant p-value (<0.0001).

Onset of Motor Block: Motor block onset was also significantly faster in Group BD (5.6 ± 0.48 min) compared to Group BF (7.65 ± 0.47 min) ($p < 0.0001$).

Time to Sensory Level T10: Group BD reached T10 in 4.65 ± 0.47 min vs 6.65 ± 0.47 min in Group BF ($p < 0.0001$).

Time to Motor Block Level 3 (Modified Bromage Scale): Time was significantly shorter in Group BD (7.6 ± 0.58 min) vs Group BF (9.4 ± 0.8 min) ($p < 0.0001$).

Duration of Anesthesia and Analgesia

Duration of Sensory Block: Significantly longer in Group BD (251 ± 14.79 min) compared to Group BF (216.5 ± 11.94 min) ($p < 0.0001$).

Duration of Motor Block: Group BD showed a significantly prolonged motor block (223.5 ± 14.92 min) compared to Group BF (185 ± 8.06 min) ($p < 0.0001$).

Time to First Rescue Analgesia: Group BD had a prolonged analgesia duration (288 ± 13.26 min) versus Group BF (242 ± 18.8 min) ($p < 0.0001$).

Complications (Table 2)

Complications were minimal and statistically non-significant. In Group BD, 10% experienced hypotension and 5% had bradycardia, whereas in Group BF, hypotension occurred in 4% and bradycardia in 13%. Most patients in both groups had no complications (85% in BD, 83% in BF).

TABLE 1 : Block characteristics

Parameter	**Group BD (Mean ± SD)**	**Group BF (Mean ± SD)**	**p-value**	**Significance**
Onset of Sensory Block (min)	3.35 ± 0.47	5.55 ± 0.49	<0.0001	Significant
Onset of Motor Block (min)	5.6 ± 0.48	7.65 ± 0.47	<0.0001	Significant
Time to Sensory Level T10 (min)	4.65 ± 0.47	6.65 ± 0.47	<0.0001	Significant
Duration of Sensory Block (min)	251 ± 14.79	216.5 ± 11.94	<0.0001	Significant
Duration of Motor Block (min)	223.5 ± 14.92	185 ± 8.06	<0.0001	Significant
Time to Rescue Analgesia (min)	288 ± 13.26	242 ± 18.8	<0.0001	Significant

TABLE 2 : Complications

Complication	Group BD (n=20)	Group BF (n=20)
Hypotension	2 (10%)	1 (4%)
Bradycardia	1 (5%)	3 (13%)
Without Complications	17 (85%)	16 (83%)

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DISCUSSIONS

Lower limb surgeries could be performed under local, neuroaxial and general anesthesia, but neuroaxial block is the preferred method. Spinal block has rapid onset, deep block, lower risk of infection and is cost effective. However, post-operative pain is an important problem as the used drugs have limited duration of effect; so, the post-operative analgesic administration is necessary.

Administrating the combinations of other classes of analgesics with local anesthetics has used to increase the duration and reduce side effects of analgesia. Clonidine and dexmedetomidine are two α2 agonists affecting via pre- and post-synaptic α2 receptors.

Dexmedetomidine has been widely used for anesthesia and analgesic purposes. This drug has sedative, anti-anxiety, analgesic, neuroprotective, and anesthetic-sparing effects. Dexmedetomidine along with other drugs have been used to increase the duration of analgesia in subarachnoid, epidural and caudal blocks [1].

Rahimzadeh et al., evaluated the efficacy of three spinal anesthesia methods, bupivacaine alone or with dexmedetomidine or fentanyl in lower limb orthopedic surgeries. Although there was no significant difference between groups in time to onset of Bromage 3 and complete motor block, BD group had lower time to reach the highest sensory level than BF group, with no difference with BN group but it was not statistically significant. (P-value = 0.08).

In our study, time taken for mean onset of sensory block was earlier in group BD (3.35 ± 0.47) compared to group BF (5.55 ± 0.49). The difference between both the group were significant (p value <0.0001) and correlates with the study group.

Regarding the time taken for mean onset of motor block by Mahendru et al. [2] found no significant difference in onset of motor block between dexmedetomidine and fentanyl groups. While Yektas et al., [3] and Ravipati [4] reported faster onset of motor block for dexmedetomidine compared to fentanyl.

In our study, the mean onset of motor block was earlier in group BD (5.6 ± 0.48) compared to group BF (7.65 ± 0.47). The difference between both the group were statistically significant (p value <0.0001) and correlates with our study.

The mechanism of how dexmedetomidine prolongs sensory and motor blockade is not known. Dexmedetomidine is a highly-selective α2-adrenergic receptor agonist that causes analgesia by suppression the release of C fiber transmitters and hyperpolarization of post-synaptic neurons. Regarding the time taken to highest sensory level T10 by Rahimzadeh et al., states that the highest sensory level in BD and BF group were T6 and T5 while in BN group was T6 and T7. dermatomes. One study reported the highest sensory level at T5 dermatome [3] and Mahendru [2] reported in T6 dermatome. Other study reported the highest sensory level at T5 dermatome in dexmedetomidine and T6 in fentanyl group [5].

In our study, the meantime taken to reach sensory level T10 was shorter in group BD (4.65 ± 0.47) compared to group BF (6.65 ± 0.47). The difference between both the groups were significant statistically (p value <0.0001) and thus correlates with our study.

In our study, the meantime taken to reach maximum motor that is bromage 3 was earlier in group B D (7.6 ± 0.58) compared to group BF (9.4 ± 0.8). The difference between both the groups were significant (p value <0.0001).

Regarding the duration of sensory and the duration of analgesia by Rahimzadeh et al., states that None of the patients requested analgesic during the surgery. Bromage 3 occurred in all patients before operation. Complete regression of motor block (Bromage 0) was reached in all patients and with the highest duration in BD group. Moreover, time to regression to S1 sensory level and regression of two sensory levels in BD group was significantly longer than the other groups. These patients also experienced lower pain intensity six hours after surgery indicative of the highest postoperative analgesia duration in BD group.

In our study, the meantime taken for duration of sensory block was longer in group BD (251 ± 14.79) compared to group BF (216.5 ± 11.94). The findings were statistically significant (p value <0.0001) and correlates with the study.

Similarly, the meantime taken for duration of motor block was also longer in group BD (223.5 ± 14.92)

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compared to group BF (185 ± 8.06). The findings were also significant (p value <0.0001) and correlates with the study group.

The mean time taken for first rescue analgesia was significantly longer in group BD (288 ± 13.26) compared to group BF (242 ± 18.8). The difference between both the group were also statistically significant (p value <0.0001). Thus, correlates with the study group.

Reduced need for analgesics in the post-operation period, more stable hemodynamics, longer duration of sensory and motor block for dexmedetomidine have been reported in previous studies comparing this drug with other drugs such as clonidine, fentanyl and sufentanil. In orthopedic surgeries of lower limb, better results have also been reported for dexmedetomidine compared to fentanyl. [4,5]

Regarding the hemodynamic effects by Rahimzadeh et al., observed that changes in SBP, DBP and HR in BF was higher than BD and BN groups, with no difference between BD and BN patients. The highest decline occurred 5 min after spinal injection and was rather stable afterwards. Unlike our findings, other studies did not report any significant difference between fentanyl and dexmedetomidine regarding hemodynamic status. Decline in HR and blood pressure are common effects of opioids. The difference in hemodynamic findings could be due to the response of each individual to the drug, demographic profile, volume of IT injectate and volume of diluent used [2,6].

In our study, the difference between both the group in hemodynamic was not found to be statistically significant at any time interval except at 5 mins interval in Diastolic Blood Pressure (p value = 0.051).

Rahimzadeh et al., observed that Side effects may occur by using any anesthesia medications. The best medication is the one with the highest efficacy and lowest side effects. We observed no significant difference in the rate of hypotension, bradycardia, nausea and vomiting and chilling between groups. Previous studies have reported different rate of side effects. Similar to our findings, Ravipati [7] observed pruritus only in fentanyl group while nausea and vomiting was more common in dexmedetomidine, with no significant difference between groups. There is also only one study reporting increase in hemodynamic side effects, bradycardia and hypotension, in dexmedetomidine [8]. Another important side effect of anesthesia medications is respiratory system suppression. However, we observed no respiratory suppression. First, fentanyl compared to other opioids is less likely to cause respiratory suppression. Second, this complication is not common in dexmedetomidine.

In order to reach better efficacy, we can increase the dose of the used dexmedetomidine. Gupta [5] reported that increasing the dose of dexmedetomidine from 2.5 µg to 10 µg would show better and longer sensory and motor block, with longer duration of anesthesia and comparable hemodynamic and side effects profile.

CONCLUSION

On the basis of our observational study, conclusions were drawn that using dexmedetomidine as an adjuvant to bupivacaine for intrathecal analgesia in lower limb surgeries has longer duration of sensory and motor block, longer postoperative analgesia with low side effects

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