

A Prospective Randomized Double-Blind Study Comparing the Efficacy of Intrathecal Dexmedetomidine and Intrathecal Fentanyl as Adjuvants to Hyperbaric Bupivacaine in Lower Limb Orthopedic Surgeries

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ABSTRACT

Background: Spinal anaesthesia is commonly used for lower limb orthopaedic surgeries; however, limited duration of postoperative analgesia remains a challenge. Intrathecal adjuvants such as fentanyl and dexmedetomidine enhance the quality and duration of spinal block. This study compared the efficacy and safety of intrathecal dexmedetomidine and fentanyl added to hyperbaric bupivacaine. **Methods:** This prospective, randomised, double-blind comparative study was conducted in the Department of Anaesthesiology, CSI Redfern Mission Hospital, Hassan, over a period of 6 months. A total of 75 patients undergoing elective lower limb orthopaedic surgeries under spinal anaesthesia were randomised into two groups. Group D (n=38) received intrathecal dexmedetomidine with hyperbaric bupivacaine, while Group F (n=37) received intrathecal fentanyl with hyperbaric bupivacaine. Onset and duration of sensory and motor block, duration of postoperative analgesia, rescue analgesic requirement, haemodynamic changes, and adverse effects were assessed. **Results:** Demographic characteristics were comparable between the two groups. The onset of sensory and motor blockade showed no significant difference. Duration of sensory block was significantly longer in the dexmedetomidine group compared with fentanyl (286.4 ± 32.5 vs 221.6 ± 28.9 min; $p < 0.001$). Motor block duration was also prolonged with dexmedetomidine (258.3 ± 30.6 vs 198.7 ± 26.4 min; $p < 0.001$). Postoperative analgesia duration was significantly higher in Group D (8.6 ± 1.2 vs 5.4 ± 1.0 hours; $p < 0.001$), with reduced rescue analgesic requirement (23.7% vs 64.9% ; $p < 0.001$). Haemodynamic parameters were comparable between groups. Pruritus was significantly more frequent in the fentanyl group. **Conclusion:** Intrathecal dexmedetomidine provides superior prolongation of sensory and motor blockade with extended postoperative analgesia and reduced rescue analgesic requirement compared with fentanyl when used as an adjuvant to hyperbaric bupivacaine. It is an effective and safe alternative for spinal anaesthesia in lower limb orthopaedic surgeries.

Keywords: *Dexmedetomidine, Fentanyl, Intrathecal adjuvant, Spinal anaesthesia, Hyperbaric bupivacaine, Orthopaedic surgery.*

INTRODUCTION

Spinal anaesthesia is one of the most commonly used regional anaesthetic techniques for lower limb orthopaedic surgeries due to its rapid onset, reliable surgical anaesthesia, excellent muscle relaxation, and favourable safety profile. Hyperbaric bupivacaine remains the most frequently used local anaesthetic agent for spinal anaesthesia; however, its duration of action is often limited, resulting in inadequate postoperative analgesia after regression of the spinal block. To overcome this limitation, various intrathecal

adjuvants have been investigated to enhance the quality and duration of spinal anaesthesia while reducing the requirement of systemic analgesics (1). Opioids such as fentanyl are commonly used as intrathecal adjuvants because of their synergistic analgesic effect with local anaesthetics. Intrathecal fentanyl improves the quality of intraoperative analgesia, accelerates the onset of sensory block, and provides better postoperative pain relief. However, its use is associated with adverse effects including pruritus, nausea, vomiting, urinary retention, sedation, and respiratory depression, which may limit its clinical

utility (2).Dexmedetomidine, a highly selective α_2 -adrenergic receptor agonist, has gained increasing attention as an intrathecal adjuvant due to its potent analgesic and sympatholytic properties. It produces analgesia by inhibiting the release of nociceptive neurotransmitters and enhancing endogenous pain-modulating pathways in the spinal cord. Studies have demonstrated that intrathecal dexmedetomidine can prolong sensory and motor blockade duration without causing significant respiratory depression (3).The addition of dexmedetomidine to hyperbaric bupivacaine may provide prolonged postoperative analgesia, reduce rescue analgesic requirements, and improve patient satisfaction. Previous clinical studies have shown variable results regarding the comparative efficacy and safety of intrathecal dexmedetomidine and fentanyl, necessitating further evaluation in different surgical populations (4).Lower limb orthopaedic procedures often involve significant postoperative pain, requiring effective and prolonged analgesic strategies. An ideal intrathecal adjuvant should enhance the duration of spinal anaesthesia while maintaining haemodynamic stability and minimizing adverse effects. Therefore, this prospective randomised double-blind study was undertaken to compare the efficacy of intrathecal dexmedetomidine and intrathecal fentanyl as adjuvants to hyperbaric bupivacaine in patients undergoing lower limb orthopaedic surgeries.

Although both intrathecal dexmedetomidine and fentanyl have been widely investigated as adjuvants to hyperbaric bupivacaine, available studies have reported inconsistent findings regarding block characteristics, duration of postoperative analgesia, haemodynamic effects, and adverse events. Furthermore, comparative evidence in patients undergoing lower limb orthopaedic surgeries remains limited. Therefore, further prospective randomized double-blind studies are required to determine the optimal intrathecal adjuvant.

Aim and Objectives

Aim:

To compare the efficacy of intrathecal dexmedetomidine and intrathecal fentanyl as adjuvants to hyperbaric bupivacaine during spinal anaesthesia for lower limb orthopaedic surgeries.

Objectives:

1. To compare the onset and duration of sensory and motor blockade between the two groups.
2. To evaluate the duration of postoperative analgesia.
3. To compare rescue analgesic requirements.
4. To assess haemodynamic changes and adverse effects associated with both adjuvants.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomised, double-blind comparative clinical study was conducted in the Department of Anaesthesiology, CSI Redfern Mission Hospital, Hassan. The study was carried out over a period of 6 months (second half of the study year) following approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrollment.

Study Population

A total of 75 patients scheduled for elective lower limb orthopaedic surgeries under spinal anaesthesia were included in the study. Patients were randomly allocated into two groups to receive either intrathecal dexmedetomidine or intrathecal fentanyl as an adjuvant to hyperbaric bupivacaine.

The sample size was calculated based on the primary outcome of postoperative analgesia duration using data from previous studies, assuming a power of 80% and a significance level of 5%. A minimum of 36 patients per group was required. To compensate for possible dropouts, 75 patients were enrolled.

Inclusion Criteria

Patients fulfilling the following criteria were included:

- Age group: 18–65 years
- American Society of Anesthesiologists (ASA) physical status I and II
- Patients undergoing elective lower limb orthopaedic procedures
- Patients willing to participate and provide informed consent
- Surgery expected to be completed under spinal anaesthesia

Exclusion Criteria

Patients with any of the following were excluded:

- Patient refusal
- ASA physical status III or above
- Known allergy or contraindication to study drugs
- Coagulopathy or bleeding disorders
- Infection at the site of spinal injection
- Significant cardiovascular, renal, hepatic, or neurological disease
- Pregnant patients
- Patients requiring conversion to general anesthesia

Preoperative Assessment

All patients underwent detailed preoperative evaluation including history, physical examination, airway assessment, and routine investigations. Baseline investigations included complete blood count, blood glucose estimation, renal function tests, liver function tests, serum electrolytes, coagulation profile

when indicated, electrocardiogram, and chest radiography whenever clinically required. Baseline vital parameters including heart rate, non-invasive blood pressure, respiratory rate, and oxygen saturation (SpO₂) were recorded. Patients were kept fasting according to standard preoperative fasting guidelines.

Randomization and Blinding

Patients were randomly assigned into two groups using a computer-generated randomization sequence.

- **Group D (Dexmedetomidine group, n = 38):** Received intrathecal hyperbaric bupivacaine with dexmedetomidine as an adjuvant.
- **Group F (Fentanyl group, n = 37):** Received intrathecal hyperbaric bupivacaine with fentanyl as an adjuvant.

The study drugs were prepared by an anaesthesiologist not involved in patient assessment. Patients and the investigator assessing outcomes were blinded to the group allocation.

Anaesthetic Technique

On arrival in the operating room, standard monitoring including electrocardiography, non-invasive blood pressure monitoring, and pulse oximetry was initiated. An intravenous line was secured, and patients received appropriate preloading with intravenous crystalloid solution.

Under strict aseptic precautions, spinal anesthesia was performed at the appropriate lumbar interspace using a suitable spinal needle. Patients received the assigned intrathecal drug combination containing hyperbaric bupivacaine with either dexmedetomidine or fentanyl according to group allocation.

The onset and progression of sensory and motor block were assessed intraoperatively. Supplemental oxygen was administered whenever required.

Intraoperative Monitoring

Heart rate, systolic and diastolic blood pressure, mean arterial pressure, and oxygen saturation were recorded at baseline and at regular intervals throughout the surgery.

Patients were monitored for intraoperative complications including hypotension, bradycardia, nausea, vomiting, respiratory depression, and allergic reactions. Hypotension and bradycardia were managed according to standard institutional protocols.

Study Parameters

The following parameters were evaluated:

Primary Outcome Measures:

- Duration of sensory block
- Duration of motor block
- Duration of postoperative analgesia

Secondary Outcome Measures:

- Onset time of sensory block
- Onset time of motor block
- Maximum sensory level achieved
- Time to two-segment regression of sensory block
- Time to complete motor recovery
- Hemodynamic changes (heart rate and blood pressure)
- Requirement of rescue analgesia
- Incidence of adverse effects

Postoperative Assessment

Postoperative pain was assessed using the Visual Analogue Scale (VAS). Patients were monitored for the duration of analgesia and requirement of rescue analgesics. Any adverse effects such as nausea, vomiting, sedation, pruritus, urinary retention, or respiratory depression were recorded.

Statistical Analysis

Data collected were entered into Microsoft Excel and analyzed using appropriate statistical software. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Comparison between groups was performed using Student's t-test, Chi-square test, or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

Table 1: Demographic Characteristics of Study Participants

Parameter	Group D (Dexmedetomidine) (n=38)	Group F (Fentanyl) (n=37)	p-value
Age (years)	42.6 $\pm$ 12.4	43.1 $\pm$ 11.8	0.86
Male/Female ratio	25/13	24/13	0.95
Weight (kg)	63.8 $\pm$ 8.7	64.5 $\pm$ 9.1	0.73
ASA I/II	21/17	20/17	0.98

Observation: Both groups were comparable regarding demographic characteristics, with no statistically significant difference.

Table 2: Distribution of Orthopaedic Procedures

Type of Surgery	Group D (n=38)	Group F (n=37)
Femur fracture fixation	12	11
Tibia fracture fixation	10	9
Ankle surgeries	8	9
Foot surgeries	5	5
Other lower limb procedures	3	3

Observation: The distribution of surgical procedures was similar between both groups.

Table 3: Comparison of Onset of Sensory Block

Parameter	Group D	Group F	p-value
Time to sensory block onset (min)	5.8 ± 1.2	6.1 ± 1.4	0.32

Observation: Sensory block onset was slightly faster in the dexmedetomidine group but the difference was not statistically significant.

Table 4: Comparison of Onset of Motor Block

Parameter	Group D	Group F	p-value
Time to motor block onset (min)	8.2 ± 1.6	8.5 ± 1.7	0.44

Observation: No significant difference was observed in the onset of motor blockade between groups.

Table 5: Comparison of Duration of Sensory Block

Parameter	Group D	Group F	p-value
Duration of sensory block (min)	286.4 ± 32.5	221.6 ± 28.9	<0.001

Observation: Duration of sensory blockade was significantly prolonged in the dexmedetomidine group compared with fentanyl.

Table 6: Comparison of Duration of Motor Block

Parameter	Group D	Group F	p-value
Duration of motor block (min)	258.3 ± 30.6	198.7 ± 26.4	<0.001

Observation: Patients receiving dexmedetomidine showed significantly longer motor block duration.

Table 7: Duration of Postoperative Analgesia

Parameter	Group D	Group F	p-value
Duration of analgesia (hours)	8.6 ± 1.2	5.4 ± 1.0	<0.001

Observation: Dexmedetomidine significantly prolonged postoperative analgesia compared with fentanyl.

Table 8: Requirement of Rescue Analgesia

Rescue Analgesia Requirement	Group D (n=38)	Group F (n=37)	p-value
Required	9 (23.7%)	24 (64.9%)	<0.001
Not required	29 (76.3%)	13 (35.1%)	

Observation: Rescue analgesic requirement was significantly lower in the dexmedetomidine group.

Table 9: Hemodynamic Changes During Surgery

Parameter	Group D	Group F	p-value
Mean HR (beats/min)	72.4 ± 8.6	75.1 ± 9.2	0.19
Mean MAP (mmHg)	82.6 ± 7.8	84.1 ± 8.1	0.42
Episodes of bradycardia	3 (7.9%)	2 (5.4%)	0.65
Episodes of hypotension	5 (13.2%)	4 (10.8%)	0.75

Observation: Hemodynamic parameters remained comparable between both groups.

Table 10: Incidence of Adverse Effects

Adverse Effect	Group D (n=38)	Group F (n=37)	p-value
Nausea/Vomiting	4 (10.5%)	6 (16.2%)	0.47
Pruritus	1 (2.6%)	8 (21.6%)	0.014
Sedation	5 (13.2%)	2 (5.4%)	0.23
Respiratory depression	0	1 (2.7%)	0.31

Observation: Pruritus was significantly higher in the fentanyl group, while other adverse effects were comparable.

DISCUSSION

The present prospective randomized double-blind study compared the effects of intrathecal dexmedetomidine and intrathecal fentanyl as adjuvants to hyperbaric bupivacaine in patients undergoing lower limb orthopaedic surgeries. The major findings of the study demonstrated that dexmedetomidine significantly prolonged sensory block duration, motor block duration, and postoperative analgesia compared with fentanyl, with reduced requirement of rescue analgesics.

In the present study, demographic characteristics including age, sex distribution, body weight, and ASA physical status were comparable between both groups, indicating adequate randomization and homogeneity of study participants. Similar baseline characteristics have been reported in previous comparative studies evaluating intrathecal α_2 agonists and opioids (5).

The onset of sensory and motor blockade was comparable between dexmedetomidine and fentanyl groups. Although dexmedetomidine showed a slightly faster onset of sensory block, the difference was not statistically significant. Similar findings were reported by Al-Mustafa et al., who observed that dexmedetomidine enhanced block characteristics without significantly affecting the onset time when added to bupivacaine (6).

A significant prolongation of sensory blockade was observed in the dexmedetomidine group compared with fentanyl in the present study. Dexmedetomidine acts through spinal α_2 receptors, causing hyperpolarization of interneurons and suppression of nociceptive transmission, thereby prolonging the duration of spinal anaesthesia (7). Previous studies have also demonstrated prolonged sensory and motor block duration with intrathecal dexmedetomidine compared with fentanyl.

The duration of motor blockade was significantly longer in patients receiving dexmedetomidine. Similar results were observed by Gupta et al., who reported that intrathecal dexmedetomidine significantly prolonged motor recovery time compared with fentanyl when used with hyperbaric bupivacaine (8). Although prolonged motor block may delay early mobilization, it can be beneficial in painful orthopaedic procedures requiring extended anaesthetic effect.

Postoperative analgesia duration was significantly longer in the dexmedetomidine group (8.6 ± 1.2 hours) compared with the fentanyl group (5.4 ± 1.0 hours). The prolonged analgesic effect of dexmedetomidine may be attributed to its direct spinal analgesic action and modulation of inflammatory pain pathways. Similar findings have been reported in previous randomized trials demonstrating superior postoperative analgesic duration with intrathecal dexmedetomidine (9).

The requirement for rescue analgesics was significantly lower in the dexmedetomidine group. This indicates better postoperative pain control and improved quality of analgesia. Reduction in opioid consumption is an important advantage, particularly in orthopaedic patients where effective pain control facilitates early rehabilitation.

Haemodynamic parameters including heart rate, mean arterial pressure, and incidence of hypotension and bradycardia were comparable between both groups. Although dexmedetomidine has sympatholytic effects, clinically significant haemodynamic instability was not observed in the present study. Similar safety profiles have been reported in previous studies evaluating intrathecal dexmedetomidine (10).

Regarding adverse effects, fentanyl was associated with a significantly higher incidence of pruritus compared with dexmedetomidine. Opioid-induced pruritus is a well-recognised adverse effect of neuraxial opioids. Other adverse events, including nausea, vomiting, sedation, and respiratory depression, showed no significant difference between groups. These findings support the favourable safety profile of dexmedetomidine as an intrathecal adjuvant.

Overall, the findings of the present study suggest that intrathecal dexmedetomidine provides superior prolongation of spinal anaesthesia and postoperative analgesia compared with fentanyl when added to hyperbaric bupivacaine in lower limb orthopaedic surgeries. It reduces rescue analgesic requirements without producing significant haemodynamic instability or major adverse effects.

Strengths of the Study

The strengths of the present study include its prospective randomized double-blind design, standardized spinal anaesthesia protocol, objective assessment of sensory and motor blockade, and comprehensive evaluation of postoperative analgesic efficacy and safety.

Limitations of the Study

The present study was conducted at a single centre with a relatively small sample size. Long-term postoperative outcomes, patient-reported quality of recovery, functional rehabilitation, and chronic pain development were not evaluated.

Future Recommendations

Future multicentre randomized controlled trials with larger sample sizes are recommended to evaluate long-term postoperative outcomes, quality of recovery, functional rehabilitation, chronic postoperative pain, patient satisfaction, and cost-effectiveness of intrathecal dexmedetomidine compared with other intrathecal adjuvants.

CONCLUSION

Intrathecal dexmedetomidine as an adjuvant to hyperbaric bupivacaine provides prolonged sensory and motor blockade with significantly longer postoperative analgesia compared with intrathecal fentanyl in lower limb orthopaedic surgeries. It reduces rescue analgesic requirements without causing significant haemodynamic instability. Dexmedetomidine may therefore be considered a superior and effective alternative to fentanyl for enhancing the quality and duration of spinal anaesthesia.

Ethical Approval

Ethical approval was obtained from the Institutional Ethics Committee, and written informed consent was obtained from all participants.

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Conflict of Interest

The authors declare no conflict of interest.

Author Contributions

Dr. Divyashri C.N.: Conceptualization, study design, patient recruitment, supervision, manuscript drafting.

Dr. Bharath M.S.: Data collection, perioperative patient management, data interpretation, critical revision of the manuscript.

Dr. Shruthi Jayaram: Statistical analysis, literature review, manuscript preparation, and critical revision of the manuscript.

All authors read and approved the final manuscript.

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Data Availability Statement

The datasets generated and analysed during the current study are available from the corresponding author upon reasonable request.

Abbreviations

ASA – American Society of Anesthesiologists

HR – Heart Rate

MAP – Mean Arterial Pressure

VAS – Visual Analogue Scale

IEC – Institutional Ethics Committee

CTRI – Clinical Trials Registry India

ECG – Electrocardiogram

SpO₂ – Peripheral Oxygen Saturation

SAP – Systolic Arterial Pressure

DAP – Diastolic Arterial Pressure

SD – Standard Deviation

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