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Original Research Article

A prospective randomized study comparing the efficacy of intrathecal clonidine versus dexmedetomidine as adjuvants to hyperbaric bupivacaine in patients undergoing spinal anesthesia for pelvic and lower limb orthopedic surgeries

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ABSTRACT

Background: Low-dose bupivacaine used in spinal anaesthesia results in speedy recovery. Adjuvants could be added to provide sufficient anaesthesia for surgery. Dexmedetomidine and clonidine are selective α-2 adrenoceptor agonists and are used as adjuvants in different doses to prolong the duration.

Aim & Objective: Aim is to determine time of onset of motor and sensory block, time to achieve highest level in sensory block, duration of motor block and sensory block and need for first rescue analgesia and any side effects.

Materials and Methods: Fifty patients scheduled for lower limb and pelvic orthopedic surgeries under spinal anesthesia were divided into two groups. The dexmedetomidine group (D10, n=25) received 3.4 ml of 0.5% heavy bupivacaine combined with 10 μg of dexmedetomidine, totaling 3.5 ml. The clonidine group (C15, n=25) received 3.4 ml of 0.5% heavy bupivacaine with 15 μg of clonidine, also totaling 3.5 ml, administered intrathecally.

Result: The onset of sensory and motor block was significantly earlier, and the duration of both motor and sensory block was longer in the dexmedetomidine group compared to the clonidine group (p-value < 0.05). Additionally, the time to first rescue analgesia was significantly extended in the dexmedetomidine group, which also reported better quality of postoperative analgesia compared to the clonidine group.

Conclusion: Intrathecal administration of bupivacaine with 10 μg of dexmedetomidine results in an earlier onset and longer duration of both sensory and motor block compared to 15 μg of clonidine. This combination also provides increased analgesia time and delays the need for the first rescue analgesia. Dexmedetomidine proves to be a superior adjuvant to clonidine, enhancing patient satisfaction and offering better quality of analgesia.

1. Introduction

The most often used block for pelvic and lower limb orthopaedic surgeries is spinal anaesthesia.[1] Numerous adjuvants have been tested to prolong the duration of the analgesic effect of local anaesthetics along with the duration of sensory and motor blockage, including fentanyl, midazolam, tramadol, nalbuphine, magnesium sulphate, etc. Although low-dose bupivacaine can quickly promote recovery and reduce the spinal block level with little hemodynamic consequences, it occasionally might not provide sufficient anaesthesia for surgery.[1]

Although effective, neuraxial opioids have a number of unfavourable side effects that limit their usage, for example

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delayed respiratory depression seen with morphine use and nausea, vomiting and itching seen with use of fentanyl.[2] Non-opioid spinal receptors that prevent the transmission of pain signals have been the subject of current study.[3] When α-2 adrenergic agonist medications are injected concurrently, regional vasoconstriction occurs and C fibres blockade is facilitated or spinal action is brought on by the retrograde transport through the axon combined with just simple diffusion alongside the nerve to improve the ability of local anaesthetic to inhibit nerves.[2] With an excellent safety profile, clonidine and dexmedetomidine has been demonstrated to greatly extend the duration of anaesthesia generated by hyperbaric or isobaric bupivacaine.[2–4] Hence, we chose to evaluate and compare α-2 agonists as adjuvants.

Lower limb and pelvic orthopedic surgeries need adequate motor and sensory blockage for effective surgery and also need adequate postoperative analgesia for patient comfort. Effective postoperative analgesia is crucial for enhancing patient recovery and satisfaction, yet traditional methods like epidural anesthesia can be cumbersome and costly. This study investigated the use of potent adjuvants, specifically α-2 adrenergic receptor agonists, administered intrathecally in safe and effective doses, as a viable alternative. The primary objective was to evaluate the onset and duration of sensory and motor block, as well as the duration of postoperative analgesia. Additionally, the study assessed hemodynamic parameters, levels of sedation, quality of analgesia, patient satisfaction, and any potential complications or side effects. The findings aim to identify the more effective medication among the studied options, contributing to improved pain management strategies in postoperative care.

2. Materials and Methods

This randomized controlled trial was approved by the institutional ethical committee (reference number SVIEC/MEDI/SRP/JUNE/23/79). The study involved patients of both genders, aged 18 to 65 years, who were scheduled for lower limb and pelvic orthopaedic surgeries requiring spinal anesthesia. Eligible patients were identified and informed consent was obtained prior to enrolment. Participants were randomly assigned into two equal groups using a computer-generated randomization chart.

2.1. Interventions

1. Group D (Dexmedetomidine): Patients received 3.4 ml of 0.5% heavy bupivacaine combined with 10 μg of dexmedetomidine (total 3.5 ml) administered intrathecally.
2. Group C (Clonidine): Patients received 3.4 ml of 0.5% heavy bupivacaine combined with 15 μg of clonidine (total 3.5 ml) administered intrathecally.

The sample size was determined based on the mean duration of motor blockade reported in previous studies by Singh R et al.[5] A target sample size of 22 patients per group was calculated using a 95% confidence interval and 80% power, with a 10% adjustment for non-response. To adequately assess other study variables, the final sample size was increased to 25 patients in each group.

In this single-blind, interventional study, each patient received a comprehensive explanation of the study's nature and objectives in a language they could understand. The study duration was 12 months. Patients were kept unaware of the specific medication used as a supplement to hyperbaric bupivacaine during spinal anesthesia.

Eligible participants included males and females aged 18 to 65 years who provided written, informed consent for elective pelvic and lower limb orthopedic surgeries and were classified as ASA Grade I or II. Exclusion criteria encompassed patients under 152 cm in height, those with systemic illnesses, shock, septicemia, anemia, uncontrolled hypertension, anticoagulant therapy, coagulation disorders, local infections at the puncture site, spinal deformities, modifications to the anesthetic plan during the procedure, or known drug allergies.(Diagram 1)

All patients underwent a thorough preoperative evaluation, including assessments of weight, heart rate, respiratory rate, blood pressure, and a systemic examination. Necessary preoperative investigations were conducted, and additional tests were ordered if required. Patients were instructed to maintain nil per oral status for 6 hours prior to surgery.

An 18 G green intravenous (IV) catheter was inserted, and Ringer's lactate IV fluid was initiated upon the patient's arrival in the operating room. Each subject was connected to a multichannel monitor for continuous vital sign assessment. As premedication, all patients received 0.2 mg of glycopyrrolate and 4 mg of ondansetron intravenously.

With the patient in a sitting position, the back was prepared using painting and draping techniques. The Tuffier's line, which passes across the L4 and L5 intervertebral spaces, was utilized to identify the appropriate puncture level. A 23 G spinal needle was inserted at the L3-L4 interspace, and the drug was administered at a rate of 0.2 ml per second following the confirmation of free-flowing clear cerebrospinal fluid (CSF). After drug administration, the patient was repositioned to supine.

Intraoperative monitoring included vital signs such as pulse rate, blood pressure (systolic, diastolic, and mean arterial pressure), respiratory rate, and arterial oxygen saturation (SpO2). Sensory blockade was assessed using the pinprick test, with key outcomes measured including the onset of sensory block (time from intrathecal injection to loss of pinprick sensation at the L1 level), duration of sensory block, the time to reach the T10 level, and the time to attain the highest sensory level.

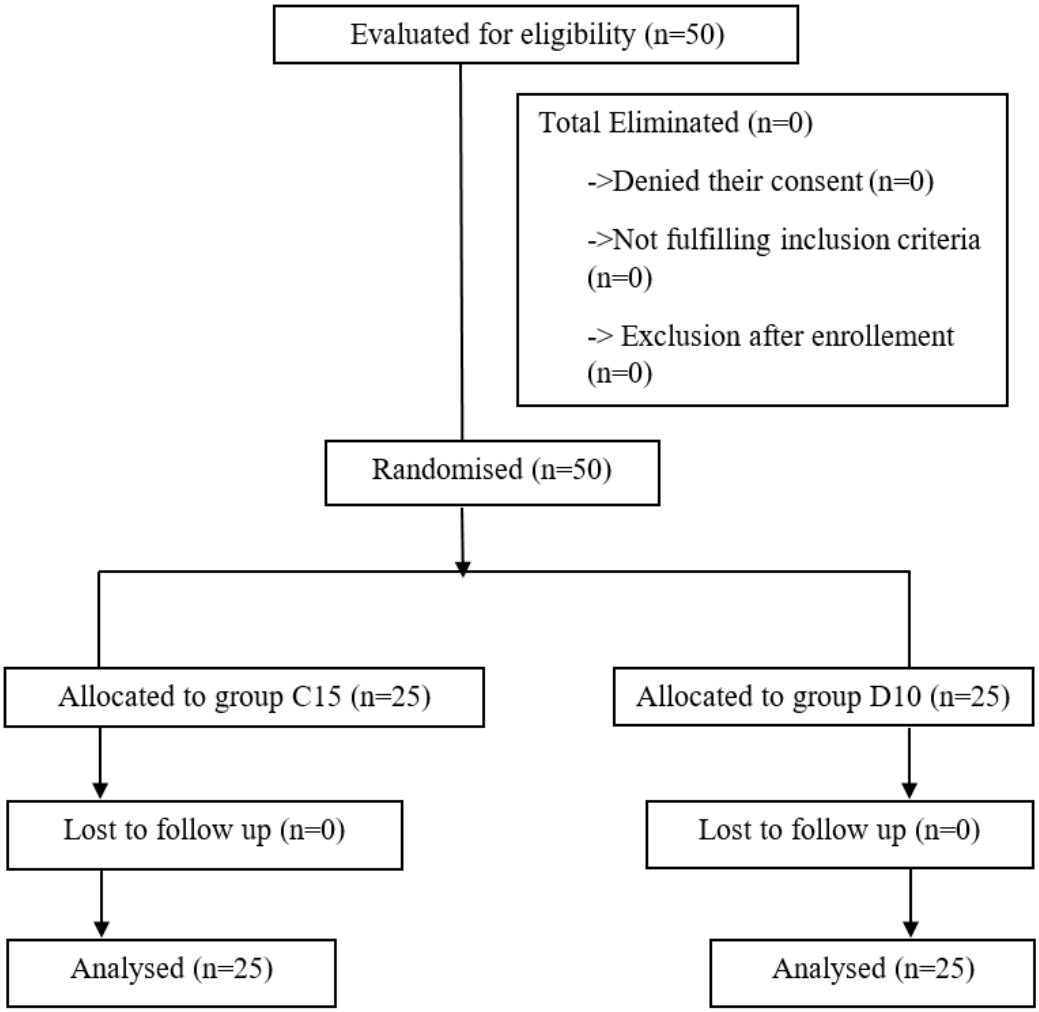


Diagram 1: Consort flow diagram

The criteria chosen for the 3-point pinprick scale was: Score 0 indicated appreciation of sharp pain; Score 1 indicated only touch sensation was appreciated; and Score 2 indicated that the patient could not appreciate even touch sensation.[6]

Motor blockade was assessed using the Modified Bromage scale, which measured the onset of motor block (time taken from intrathecal injection to achieve grade-3 motor block) and the duration of the motor block.[7] The Modified Bromage scale consisted of the following scores: Score 0 for mobile hip, knee, and ankle; Score 1 for an immobile hip with unaffected knee and ankle movement; Score 2 for an immobile hip and knee with affected ankle movement; and Score 3 for immobile hip, knee, and ankle.

Sedation levels were evaluated using the Ramsay sedation score, assessed every 10 minutes throughout the surgical procedure.[8]

Postoperatively, patients were monitored for vital signs at regular intervals for up to 12 hours. The time for rescue analgesia was determined when the Visual Analogue Scale (VAS) score reached 4 (where 0 indicates no pain and 10 indicates the worst pain imaginable).[9] Recovery from both sensory and motor blockade was also documented. The rescue analgesia used was intravenous diclofenac 75 mg.

Patient satisfaction regarding analgesia was measured using a five-point Likert scale, where 1 represented very dissatisfied, 2 indicated dissatisfied, 3 was neutral, 4 was satisfied, and 5 indicated very satisfied.[10] A checklist was also utilized to capture additional feedback.

2.2. *Statistical analysis*

The differences between the groups in demographic data, observed outcomes, and baseline values were analyzed using various statistical tests, including the unpaired t-test, Mann-Whitney U test, and chi-square test. Numerical data were presented as mean ± standard deviation, while categorical data were reported as percentages and

frequencies. A p-value of less than 0.05 was considered statistically significant, indicating meaningful differences between the groups.(Diagram 1)

3. Results

The demographic data for both groups (C15 and D10) were comparable, as shown in Table 1. The mean age was 37.2 years (±7.33) for group C15 and 35.48 years (±7.28) for group D10, with a p-value of 0.1132 indicating no significant difference. The average weight was also similar, with group C15 at 58.2 kg (±6.90) and group D10 at 56.8 kg (±6.43) (p = 0.4743). Gender distribution revealed 80% males in group C15 and 64% in group D10, with a non-significant p-value of 0.2123. The ASA classifications were comparable, confirming the homogeneity of the sample (p = 0.7795).

Table 1: Demographic parameters

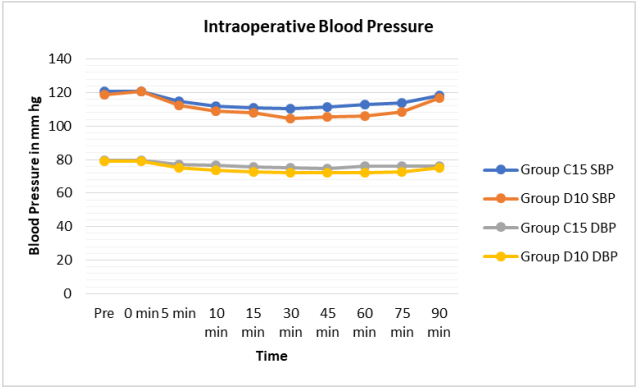
Parameter	Group C15 Mean ± SD	Group D10 Mean ± SD	P value
Age (in years)	37.2 ± 7.33	35.48 ± 7.28	0.1132(NS)
Weight (KG)	58.2 ± 6.90	56.8 ± 6.43	0.4743(NS)
Gender	N%	N%	
Male	20 (80%)	16 (64%)	0.2123(NS)
Female	5 (20%)	9 (36%)	
ASA			
I	13(52%)	12(48%)	0.7795(NS)
II	12(48%)	13(52%)	

(NS – Non-Significant, S – Significant)

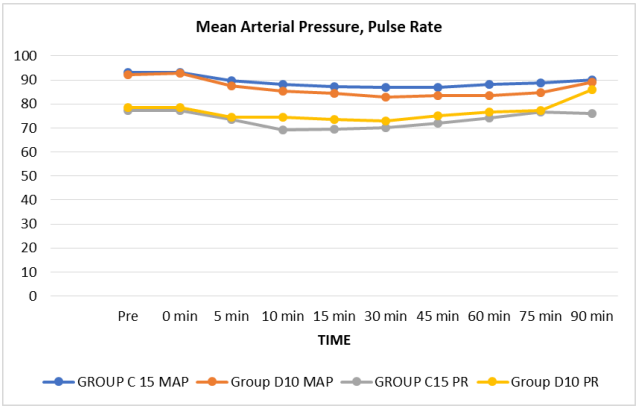
In terms of hemodynamic parameters, a trend of decreased systolic and diastolic blood pressure was observed in both groups, but these changes were not statistically significant (p > 0.05). This is illustrated in Graph 1, which depicts the blood pressure values over time, indicating stable hemodynamic conditions throughout the procedure. Graph 2 further supports this observation, showing that mean arterial pressure and pulse rate remained comparable between the groups, with no significant differences noted in bradycardia or hypotension. Side effects were minimal, as detailed in Table 2, where it can be seen that bradycardia occurred in only a few patients in both groups, and there were no instances of hypotension. Intraoperative SpO_2 and respiratory rate were stable and comparable in both the groups (p >0.05).

Table 2: Comparision of side effects

Side effects		Group C15	Group D10
Bradycardia	Yes	1(4%)	2(8%)
	No	24(96%)	23(92%)
Hypotension	Yes	0(0%)	0(0%)
	No	25(100%)	25(100%)



Graph 1: Comparision of systolic (SBP) and diastolic (DBP) blood pressures at different time intervals

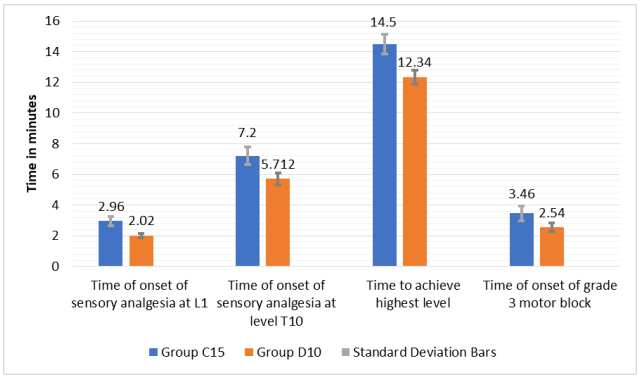


Graph 2: Mean arterial pressure and pulse rate comparison

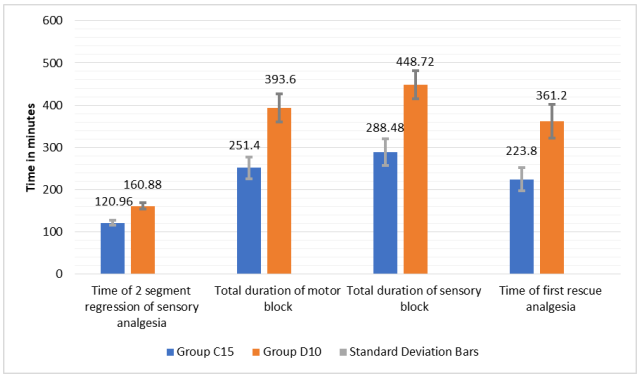
The onset and duration of both sensory and motor block were significantly better in group D10, as indicated in Graph 3. The time of onset for sensory analgesia at L1 and the onset of grade 3 motor block were significantly faster in group D10 than in group C15 (p < 0.0001). Additionally, the time to achieve sensory analgesia at T10 and the highest sensory level was also significantly shorter in group D10. In terms of duration, Graph 4 shows that the total duration of motor block, two-segment regression time, and total duration of sensory block were all significantly longer in group D10 (p < 0.0001). The need for first rescue analgesia was notably earlier in group C15, further highlighting the extended analgesic effect in group D10.

Postoperative pain levels, assessed via VAS scores, demonstrated significant differences between the groups. As shown in Table 3, group D10 reported significantly lower VAS scores at 1, 2, 3, and 4 hours postoperatively compared to group C15, indicating better pain control (p < 0.00001). The results confirm that patients in group D10 experienced delayed increases in pain levels.

Finally, patient satisfaction scores revealed that group D10 had a higher median satisfaction score of 4 (IQR



Graph 3: Onset and duration of sensory and motor blocks



Graph 4: Duration of motor block, two-segment regression time, and total duration of sensory block

Table 3: Quality of VAS score

Post-operative Time	Group C15 Median (Q1 - Q3)	Group D10 Median (Q1 - Q3)	p value
1 HR	2(1-2)	1(1-1)	<0.00001
2 HR	4(2-4)	1(1-1)	<0.00001
3 HR	4(4-4)	1(1-2)	<0.00001
4 HR	4(4-4)	2(1-4)	<0.00001
5 HR	-	4(2.75-4)	-
6 HR	-	4(4-4)	-

3-4) compared to group C15, which had a median score of 3 (IQR 2-3), as detailed in Table 4. The difference was statistically significant ($p < 0.05$), suggesting that dexmedetomidine not only improved analgesia but also enhanced overall patient satisfaction with the pain management strategy.

Table 4: Patient satisfaction score (1-5)

Score	Group C15	Group D10	p-value
Median (IQR)	3(2-3)	4(3-4)	<0.05

4. Discussion

Currently widely used and favoured anaesthetic technique is spinal anaesthesia. One of its advantages is that a small quantity of local anaesthetic can be injected quite simply, producing deep nerve block all over a vast portion of the body.[11]

In this study, we utilized 15 μg of clonidine as an adjuvant based on findings by Anil Thakur et al., who compared 15 μg and 30 μg of clonidine added to heavy bupivacaine.[12] Their results indicated that the 15 μg group experienced fewer hypotensive episodes while achieving superior sensory and motor block compared to the 30 μg group. This evidence supports the safety and efficacy of using a lower dose of clonidine in enhancing the anesthetic effects without significantly increasing the risk of hypotension. In our study, the demographic parameters in both allocated groups were not statistically significant. ($p>0.05$).

Similarly, the decision to use 10 μg of dexmedetomidine was informed by a study conducted by Shagufta et al., which compared intrathecal doses of dexmedetomidine at 10 μg and 15 μg for lower abdominal surgeries.[13] Their results showed that the 15 μg group experienced notable hypotension, leading us to select the 10 μg dose to minimize potential adverse effects while still maximizing analgesic efficacy.

In our study, we monitored key physiological parameters including blood pressure, oxygen saturation, heart rate, and respiratory rate. We observed no statistically significant differences between group C15 (clonidine) and group D10 (dexmedetomidine). This aligns with findings from Mahendru V et al., who reported no significant drop in blood pressure during surgeries when either dexmedetomidine or clonidine was administered alongside bupivacaine.[14]

Shah S et al. demonstrated that dexmedetomidine significantly enhances the duration of both sensory and motor blockade, reduces postoperative analgesic requirements, and improves patient satisfaction scores compared to clonidine, all without a notable increase in adverse effects such as hypotension or bradycardia.[15] Our findings corroborate these results, as we also noted an increase in patient satisfaction in the dexmedetomidine group, alongside a better quality of postoperative analgesia.

Research by Sarkar C et al. indicated that using low doses of intrathecal α-2 adrenergic agonists with bupivacaine resulted in a quicker onset of motor block and significantly prolonged sensory and motor block durations.[16] Our study similarly found that administering 10 μg of dexmedetomidine led to a quicker onset of both sensory and motor blocks, and a longer duration of analgesia compared to 15 μg of clonidine.

Mahendru V et al. also found that using 5 μg of dexmedetomidine significantly delayed the need for rescue analgesics compared to 30 μg of clonidine and 25 μg

of fentanyl.[14] In our research, we observed that the time to first rescue analgesia was significantly longer in group D10 (361.2 ± 40.13 min) compared to group C15 (223.8 ± 27.28 min). These results align with findings by S. L. Solanki et al., who noted that the need for rescue analgesia postoperatively was significantly less in both the clonidine and dexmedetomidine groups compared to plain bupivacaine, highlighting the efficacy of these adjuvants.[17]

Ganesh M et al. found significant differences in the duration of sensory onset and motor blockade across three groups, with dexmedetomidine demonstrating the quickest sensory onset and the longest motor blockade.[18] Our findings were in consistence with these conclusions, reinforcing the advantages of dexmedetomidine in enhancing anesthesia.

Additionally, Jahnabee Sarma et al. compared plain bupivacaine with clonidine and dexmedetomidine and found that both adjuvants led to quicker onset and longer duration of motor and sensory blocks, with dexmedetomidine providing the longest effects.[19] This supports our observations of dexmedetomidine's superior efficacy.

Throughout our study, no deep sedation was noted in either group, allowing us to consider supplementation with intravenous ketamine when necessary. This aligns with observations from Singh R et al. and Eid HE et al., reinforcing the safety and effectiveness of our anesthesia protocols.[5,20]

Previous research, including studies by Dwivedi G et al., Choudhary DR et al., and Priyadharshini PL et al., has similarly compared various doses of dexmedetomidine and clonidine, yielding results consistent with our findings.[21–23]

A meta-analysis by Changsheng Zhang MD et al. comparing dexmedetomidine and clonidine as adjuvants to local anesthetics for intrathecal anesthesia concluded that dexmedetomidine is associated with earlier and prolonged sensory block characteristics and a delayed need for analgesics compared to clonidine.[24] These results mirror our findings and highlight the potential advantages of dexmedetomidine in clinical practice.

Our study has several limitations. It was conducted at a single center with a homogenous ethnic group, which may limit the generalizability of our findings. A larger sample size would have enhanced statistical power, and multicentric studies would provide broader applicability.

Additionally, we lacked a placebo group for comparison, limiting our ability to attribute outcomes directly to the interventions. All participants were ASA grade I and II, so the safety and efficacy of the drugs in ASA grade III patients, those with cardiovascular comorbidities, and individuals over 60 years old were not evaluated.

Lastly, we did not explore varying doses of dexmedetomidine and clonidine, which could impact safety and efficacy. These limitations indicate the need for further research to confirm our findings in a more diverse patient population.

5. Conclusion

Intrathecal dexmedetomidine (10 μg) significantly improves the onset and duration of sensory and motor blockade, as well as delaying the need for rescue analgesia compared to intrathecal clonidine (15 μg) when used with bupivacaine 0.5% heavy (3 ml) in pelvic and lower limb orthopedic surgeries. This study highlights dexmedetomidine as a superior adjuvant to clonidine, enhancing patient satisfaction and quality of analgesia while reaffirming its benfits in improving postoperative outcomes.

6. Source of Funding

Nil.

7. Conflict of Interest

There were none.

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