



COMPARISONS OF EFFECTS OF DIFFERENT DOSES OF DEXMEDETOMIDINE AS ADDITIVE IN INTRATHECAL BLOCKADE WITH 0.5% HYPERBARIC BUPIVACAINE IN LOWER LIMB ORTHOPEDIC SURGERIES

Anaesthesiology

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ABSTRACT

INTRODUCTION

Lower limb surgeries may be performed under local, regional (spinal or epidural) or general anaesthesia, but neuraxial blockade is the preferred mode of anaesthesia. Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection as from catheter in situ, less failure rates and cost-effectiveness. ¹ Intrathecal local anaesthesia alone is associated with relatively short duration of action and thus early analgesic intervention is needed in post-operative period.

AIMS AND OBJECTIVES

With use of dexmedetomidine in 3 different graded doses with hyperbaric bupivacaine intrathecally as regional anaesthesia for lower limb surgeries.

MATERIALS AND METHODOLOGY

This Prospective double blinded randomized controlled study. The study will be conducted in adult patients aged between 18-50 years undergoing lower limb surgeries under spinal anaesthesia in orthopedic OT, dept. of Anaesthesiology, Medical college & hospital, Kolkata. Duration of the study One year (9 months for data collection & 3 months for data analysis, review & report writing). Total 63 patients in our study.

RESULTS

We found the mean of two segment regression time from highest sensory level in Group B was 130.56min; in group C was 171.34min; in group D was 217.85min. So, block regression was significantly slower with the addition of intrathecal dexmedetomidine (Group D) as compared to group C & B ($P < 0.0001$). The mean regression time to S1 from highest sensory level for Group B was 289.43 min (SD- 12.43). For Group C, the mean regression time to S1 from highest sensory level was 402.71 min (SD- 28.60). For Group D, the mean regression time to S1 from highest sensory level was 584.43min (SD- 38.92). Overall the mean regression time to S1 from highest sensory level was 425.52 min (SD- 125.71). The sensory regression time to S1 from highest sensory level was significantly higher with increasing dose of dexmedetomidine i.e. $D > C > B$. ($P < 0.0001$).

CONCLUSION

We recommend the use of 10mcg of intrathecal dexmedetomidine as an adjuvant to bupivacaine as it seems to be a good alternative to other additives for long duration surgical procedures due to its profound intrathecal anesthetic and analgesic properties. It provides good quality of intraoperative analgesia, thermodynamically stable conditions, minimal side effects, and excellent quality of postoperative analgesia.

KEYWORDS

Dexmedetomidine, Intrathecal Blockade, Hyperbaric Bupivacaine and Lower Limb Orthopedic Surgeries

INTRODUCTION

Lower limb surgeries may be performed under local, regional (spinal or epidural) or general anaesthesia, but neuraxial blockade is the preferred mode of anaesthesia. Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection as from catheter in situ, less failure rates and cost-effectiveness. ¹

Intrathecal local anaesthesia alone is associated with relatively short duration of action and thus early analgesic intervention is needed in post-operative period. Various drugs are used along with local anaesthetics to facilitate the prolongation of duration of spinal block both for long procedures and for postoperative pain relief. ²

These spinal adjuncts are used to prolong analgesia. Intrathecally fentanyl exerts its effects by combining with opioid receptors in the dorsal horn of spinal cord and may have a supraspinal spread and action. Intrathecal α_2 receptor agonists have antinociceptive action for both somatic and visceral pain. Dexmedetomidine shows more specificity towards α_2 receptor (α_2/α_1 1600:1) compared with clonidine (α_2/α_1 200:1). Several studies have shown that α_2 receptor agonists when administered intrathecally will enhance the analgesia provided by subtherapeutic doses of local anaesthetics like bupivacaine due to synergistic effects & also minimal haemodynamic alteration. Most of the clinical studies about the intrathecal α_2 adrenergic agonist are related to clonidine. Dexmedetomidine, a highly selective α_2 adrenergic agonist has evolved as a panacea for various applications and procedures in the perioperative and critical care settings. It is also emerging as a valuable adjunct to regional anaesthesia and analgesia, where gradually evolving studies can build the evidence for its safe use in central neuraxial blocks. Based on earlier

human studies, it is hypothesized that intrathecal 5 μ g dexmedetomidine would produce more postoperative analgesic effect with hyperbaric bupivacaine in spinal anaesthesia with minimal side effects ³. In our study we will compare effects after giving 3 different doses 5microgr, 10 microgr, & 15microgr with intrathecal hyperbaric bupivacaine in 3 different group of patients scheduled for lower limb orthopaedic surgery. ⁴

AIMS AND OBJECTIVES

With use of dexmedetomidine in 3 different graded doses with hyperbaric bupivacaine intrathecally as regional anaesthesia for lower limb surgeries.

MATERIALS AND METHODOLOGY

Study design:

Prospective double blinded randomized controlled study.

Study area:

The study will be conducted in adult patients aged between 18-50 years undergoing lower limb surgeries under spinal anaesthesia in orthopedic OT, dept. of Anaesthesiology, Medical college & hospital, Kolkata.

Study period:

One year (9 months for data collection & 3 months for data analysis, review & report writing).

Sample size:

Sample size calculation revealed that 21 patients per group is required for the study.

Total study population = 3N = 63

Selection of study population:

After institutional ethical committee approval, 63 adult patients aged between 18-50 years undergoing elective lower limb surgery under spinal anaesthesia were selected. A detailed history, complete physical examination and investigations were done for all patients. Informed written consents were taken.

The study population was randomly divided into 3 groups with 21 patients in each group-

• INCLUSION CRITERIA-

- Adult patients aged between 18-60 years of both sex.
- Patients belonging to ASA physical status Grade I and II.

• EXCLUSION CRITERIA-

- Patient refusal for spinal anaesthesia,
- Local infection at the site of proposed puncture for spinal anaesthesia,
- Known hypersensitivity to local anaesthetics, opioids or dexmedetomidine,
- Patients with coagulation disorders or on anticoagulant therapy,
- Emergency surgeries,
- Patients with medical conditions like anaemia, heart disease, severe hypovolemia, septicaemia, hypertension;
- Patients with history of spine surgery,
- Patients having impaired renal functions or severe liver diseases,
- Pregnant patients, chronic alcoholics and malnourished patients.

Table no. Distribution of patients according to the surgery performed in each group.

Type of surgery	Group B		Group C		Group D		Total	
	No.	%	No.	%	No.	%	No.	%
DHS	6	28.57	5	23.80	7	33.33	18	28.57
Shaft of femur ORIF	5	23.80	7	33.33	6	28.57	18	28.57
Tibia ORIF	5	23.80	4	19.04	4	19.04	13	20.63
ACL reconstruction	4	19.04	5	23.80	3	14.28	12	19.04
Malleolar Fracture ORIF	1	4.76	0	0	1	4.76	2	3.17

Table no. Distribution of patients by sedation score (Ramsay Hunt scale) at 1 hour after giving spinal anaesthesia in both groups.

Ramsay Hunt scale	Group B (n=21)		Group C (n=21)		Group D (n=21)	
	No.	%	No.	%	No.	%
Score 1	3	14.28	4	19.04	5	23.89
Score 2	12	57.14	11	52.38	14	66.66
Score 3	4	19.04	6	28.57	6	28.57
Score 4	0	-			0	-
Score 5	0	-			0	-
Score 6	0	-			0	-

(P > 0.05)

Table no. Distribution of patients according to the incidence of side effects perioperatively in 3 groups.

Side effects	Group B (n=21)		Group C (n=21)		Group D (n=21)		Total (n=63)		P value
	No.	%	No.	%	No.	%	No.	%	
Nausea	2	9.52	1	4.76	2	9.52	5	7.9	> 0.05
Vomiting	1	4.76	1	4.76	1	4.76	3	4.76	> 0.05
Pruritus	0	-	0	-	0	-	0	-	> 0.05
Respiratory depression	0	-	0	-	0	-	0	-	-
Hypotension	2	9.52	3	14.28	6	28.57	11	17.46	> 0.05
Bradycardia	2	9.52	3	14.28	7	33.33	12	19.04	> 0.05
Urinary retention	0	-	0	-	0	-	0	-	> 0.05
Shivering	1	4.76	2	9.52	1	4.76	4	6.35	> 0.05

RESULTS

Our study shows among total 63 patients: 21 patients were allotted in 'Group B' i.e. bupivacaine + dexmedetomidine 5microgm; 21 patients were allotted in 'Group C' i.e. bupivacaine + dexmedetomidine 10microgm; 21 patients were allotted in 'Group D' i.e. bupivacaine + dexmedetomidine 15microgm. It was observed that majority of

patients i.e. 12 numbers in Group B were male and rest. 9 numbers were female. In Group C majority of patients were female i.e. 11 numbers and rest were male 10. In Group D majority of patients were male i.e. 11 numbers and rest were female i.e. 10. Over all 33 patients were male and rest 30 were female.

We found the mean age in Group B was 45.62 years (SD-13.73), where the mean age in Group C was 44.86 years (SD-12.96), mean age in Group D was 38.67 (SD-9.57) Overall the mean age was 43.05 (SD-12.30). The mean body weight of patients was 59.24kg (SD-11.42) for Group B, where the mean body weight for Group C was 60.43kg (SD-8.78), mean body wt for Group D was 60.29 (SD-10.51) Overall the mean body weight was 65.27Kg (SD-7.32). It was observed that mean BMI in Group B was 25.94 kg/mt2 (SD-2.45), where the mean BMI in Group C was 25.27 kg/mt2 (SD-2.37), mean BMI in Group D was 26.98kg/ mt2 (SD-3.84). Overall the mean BMI was 26.13kg/mt2 (SD-2.98) in 3 groups.

We showed that the majority of the patients in Group B was in ASA grade I 15, the rest were in ASA grade II i.e. 6 In Group C of patients were in ASA grade I 14, where patients were in ASA grade II 7. In Group D of patients were in ASA grade I no.14, where patients were in ASA grade II no. 7. Overall 43 patients were in ASA grade I, and 20 patients were in Grade II. The mean onset time for sensory block to T10 level in Group B was 5.41 min (SD-0.912). The mean onset time for sensory block in Group C 4.76min (SD-0.831). The mean onset time for sensory block in Group D was 4.24 min (SD-0.625). In majority of cases highest level of sensory block was T5. In Group D it was 66.66%, where in 'Group- C was 66.66% ; in Group B was 61.90% 2 patients (i.e. 9.52%) of Group D and 1 patient (i.e. 4.76%) patients of Group C & B had highest level of sensory block of T4. Overall 65.07 % patients had highest sensory level of T5 and in 22.22% patient the highest sensory level was T6.

We found the mean of two segment regression time from highest sensory level in Group B was 130.56min; in group C was 171.34min; in group D was 217.85min So, block regression was significantly slower with the addition of intrathecal dexmedetomidine (Group D) as compared to group C & B (P < 0.0001) The mean regression time to S1 from highest sensory level for Group B was 289.43 min (SD- 12.43) For Group C, the mean regression time to S1 from highest sensory level was 402.71 min (SD- 28.60) For Group D, the mean regression time to S1 from highest sensory level was 584.43min (SD- 38.92) Overall the mean regression time to S1 from highest sensory level was 425.52 min (SD- 125.71) The sensory regression time to S1 from highest sensory level was significantly higher with increasing dose of dexmedetomidine i.e. D > C > B. (P < 0.0001). The mean motor onset time to Bromage 2 in Group B was 5.10 min (SD-0.70) In Group C, the mean motor onset time was 4.67 min (SD-0.85). In Group D, the mean motor onset time was 4.05 min (SD-0.66). Overall the mean motor onset time for both groups was 4.60min (SD-0.85). P value < 0.0001. time B > C > D

DISCUSSION

Our study was conducted to compare the effects of different doses of dexmedetomidine as adjuvant to 0.5% hyperbaric bupivacaine for orthopaedic lower limb surgery.

For this comparative dose dependent study a total of 63 patients undergoing orthopaedic lower limb surgery under spinal anaesthesia using hyperbaric bupivacaine were enrolled. Of these 63 patients, 1/3 each were randomly allocated to 3 study groups: - Group B- patients received 5microgm; Group C- patients received 10 microgm; Group D- patients received 15microgm along with 0.5% hyperbaric bupivacaine. The 3 groups were comparable demographically including age, sex, weight, BMI, ASA grade and type of surgery to rule out any confounding effect.

In our study, mean time to onset of sensory block to T10: Group B- 5.41m; Group C- 4.76m; Group D- 4.24m. Sensory onset time is statistically significantly faster in Group D compared to Group C & compared to Group B. Al-Mustafa et al. ⁵ found that the mean time of sensory block to reach T10 was 4.7 ± 2 min in D10 group (10 µg dexmedetomidine), 6.3 ± 2.7 min in D5 (5 µg dexmedetomidine), and 9.5 ± 3 min in Group N (control). Kim et al. ⁹ observed that the patients in dexmedetomidine demonstrated a shorter time to reach the peak sympathetic and sensory block level compared to the patients in control.

In present study, the mean time for 2 segment regression was 130.56min in group B; 171.34min in group C; 217.85min in group D. Time is significantly prolonged in group D compared to group C, compared to group B. In our study there is significant difference among the groups in the term of the time to sensory regression to S1, group D (584.43min) > group C (402.71min) > group B (289.43min). Mustafa et al.⁵ found that the regression time to S1 dermatome was 338.9 ± 44.8 min in group D10, 277.1 ± 23.2 min in D5, and 165.5 ± 32.9 min in Group N (control) ($P < 0.001$)

There was an insignificant difference among the groups in maximum level of sensory block. The median of the maximum sensory level reached in 3 groups was T4. Hala et al found different sensory level in 3 groups. Gupta et al found no difference between 2 groups in the highest level of block (T5 and T6, respectively) when dexmedetomidine was added to ropivacaine as intrathecal adjuvant (D) versus control (R).⁶

The mean time to onset of Bromage 2 motor block was 5.10min in gr B; 4.67min in gr C; 4.05min in gr D. There was a significant difference among the groups ($P < 0.0001$). It correlates with the study by Al-Mustafa et al.⁵ who found that the mean time to reach Bromage 3 scale was 10.4 ± 3.4 min with $10 \mu\text{g}$ dexmedetomidine, 13 ± 3.4 min with $5 \mu\text{g}$ dexmedetomidine, and 18 ± 3.3 min in control group.

The mean duration of motor block in Gr B, C, D were 286.85min, 391.23min, 470.95min respectively ($P < 0.0001$). There is significant prolongation of duration of motor block by dexmedetomidine by increasing dose. Mustafa et al found similar results.⁵

There is significant difference between groups in total duration of analgesia. Group D (526.81min) having much longer duration compared to Group C (455.86min); Group C has much longer duration compared to Group B (310.86min). So, the analgesic requirement in first 24hr was significantly lesser in Group D than Gr. C; & group C than group B. Similarly, significantly improved analgesic efficacy was seen by Gupta et al.,⁶ Al Mustafa et al.,⁵ and Sunil BV et al.⁷

The mean value of Mean arterial pressure (MAP) & Heart rate (HR) were comparable among the groups throughout the duration of study.

Bradycardia occurred in 10% cases in gr B; 14% in gr C; 29% in gr D. Hypotension occurred in 10% cases in gr B; 14% cases in gr C; 33% in gr D. Incidence of bradycardia & hypotension is high in gr D. Patients required supplementation of inj mephenteramine to counteract hypotension. The incidence of bradycardia & use of atropine was significantly high in gr D.

All the patients had peripheral O₂ saturation >95% at all times. No patient had a respiratory rate below 10/min. Shivering cases were minimal, were managed by inj tramadol 25mg. The median Ramsay sedation score in all groups in 2. Al-Mustafa et al, RSS 2 in their study. Complete recovery of sensory & motor function was observed in all studied patients at the post operative follow up visit, patients did not show any neurological deficit.⁵

In our study there were significant increase in the duration of sensory and motor block of spinal anaesthesia and prolonged postoperative analgesia. The effect was more as the dose increased. This effect can be utilized in patients undergoing prolonged surgery and it can be a good alternative to epidural anaesthesia which requires a much higher dose of drug and to general anaesthesia. But one has to be vigilant because a good number of patients had a fall in heart rate and BP when 15 mcg dose of dexmedetomidine was used intrathecally.

CONCLUSION

Dexmedetomidine significantly enhances the onset of sensory and motor block in a dose dependent manner and so is the duration of blocks and the analgesia provided. Hence it can be exploited in long duration surgery. But higher doses like 15mcg cause higher incidence of hypotension and bradycardia. Significant prolongation of analgesia and significantly less side effects leads us to conclude that 10 mcg of dexmedetomidine is the optimum dose. We recommend the use of 10mcg of intrathecal dexmedetomidine as an adjuvant to bupivacaine as it seems to be a good alternative to other additives for long duration surgical procedures due to its profound intrathecal anesthetic and analgesic properties. It provides good quality of intraoperative analgesia, thermodynamically stable conditions, minimal side effects, and excellent quality of postoperative analgesia.

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