www.jmscr.igmpublication.org
Impact Factor 5.84
Index Copernicus Value: 83.27
ISSN (e)-2347-176x ISSN (p) 2455-0450
crossref DOI: https://dx.doi.org/10.18535/jmscr/v5i5.219

IGM Publication
Journal Of Medical Science And Clinical Research
An Official Publication Of IGM Publication

Clinical Investigation

Lower Dose of Hyperbaric Bupivacaine with Dexmeditomedine and Conventional Dose of Hyperbaric Bupivacaine for Subarachnoid Block in Lower Limb Surgeries (Orthopaedic Cases) - A Comparative Study

Authors
Dr Ajith Kumar G, Dr Geethakumari. P, Dr R.S. Usha Devi
Dept of Anesthesiology, Medical College, Trivandrum, Kerala, India
Corresponding Author
Dr Ajith Kumar G
Dept of Anesthesiology, Govt. Medical College, Trivandrum, Kerala- 695011 India
Email: *drajithkumarg@gmail.com*

ABSTRACT

Background and Aims: *It is universally agreed that the anaesthesia of choice for lower limb surgeries is a subarachnoid block and a sensory level of T – 10 is recommended to provide excellent anaesthesia for the patient. It is well established that opioids has got a prominent analgesic action at the spinal cord level and it can be used safely for subarachnoid block. If you can add a α-2 adrenoreceptor agonist like Dexmeditomedine to hyperbaric bupivacaine (the standard drug used for sub arachnoid block) and thus reduce the dose of bupivacaine used, without compromising on the analgesic effect.*

Aim of the study: Primary aim: *To measure analgesic efficacy in terms of duration of analgesia by adding dexmeditomedine to lower dose Hyperbaric bupivacaine.*

Secondary aim: *To compare side effects such as nausea, vomiting, bradycardia, hypotension, sedation, shivering and pruritis.*

Methods: *This study was prospective, randomized, comparative study double blind in nature and conducted after obtaining institutional Ethics Committee approval and written informed consent. The person giving the drug and the monitoring personnel were blinded 60 adult patients of ASA grade I and II aged between 20 – 50 year. Undergoing various elective lower limb (Orthopaedics) surgeries.*

Results: *Dexmeditomedine in a dose of 5µg was used for supplementation spinal Bupivacaine, showed the duration of sensory block in study group (Dexmeditomedine) is 295+40 min and control group bupavacaine 219±15 (P< 0.001) and it is highly significant.*

Conclusion: *5 µg Dexmeditomedine to 2cc of hyperbaric Bupivacaine 0.5% is associated with lessor incidence of Hypotension and lessor degree of motor blockade but with prolonged sensory block.*

Keywords: *Dexmeditomedine, Hyperbaric Bupivacaine, Spinal anaesthesia.*

INTRODUCTION

Dexmeditomedine is an α-2 adreno receptor agonist, which is approved as an intravenous sedative and analgesic drug. It is useful adjuv ant in regional anesthesia. Kanazi et al, found that 5µg clonidine are equipotent intrathecally when added to Bupivacaine in patients undergoing major surgeries in the abdomen and lower extremeties. Dexmeditomedine given intrathecally along with Bupivacaine produce significantly

longer duration of sensory and motor block than Bupivacaine alone without serious side effects. It maintains patient arousability and respiratory function. Dexmeditomedine has a role in the field of critical care and it also facilitates easy weaning from mechanical ventilation.

MATERIALS AND METHODS

This prospective comparative study was conducted after obtaining institutional Ethics Committee approval and written informed consent. The person giving the drug and the monitoring personnel were blinded 60 adult patients of ASA grade I and II aged between 20 – 50 year. Undergoing various elective lower limb (Orthopaedics) surgeries. Patient were randomly allocated to one of the two group of 30 each according to completed generated randomized table satisfying inclusion and exclusion criteria's.

Inclusion criteria

- ASA-I/II
- Age group between 20 - 50
- Height- 155-175 cm

Exclusion criteria

- History of allergy to local anaesthetics.
- Patients with spinal deformities, peripheral neuropathy, bleeding disorders or anticoagulation therapy.
- Patients with serious systemic illness, psychiatric illness, mental retardation. Patients with Diabetes mellitus ,systemic Hypertension and Ischaemic heart disease,

Patients satisfying the selection criteria were randomly divided into two groups of 30 each as per the random number chart. Both the patient and the principal investigator were blinded for the drug, which was being administered during the period of observation and the drug being prepared by a qualified assistant.

Monitors

- Non-invasive Blood pressure monitoring
- Pulse oximeter
- ECG
- Visual assessment of respiration

Interventions

Preparation: All the patients were selected after pre-op evaluation and written informed consent from all the patients. Psychological preparation was done and the procedure explained to all the patients in advance.

On the table: An IV access was secured using an 18G cannula under local anesthesia in the left forearm vein and an isotonic saline drip was started at a rate of 8ml/kg/hr. Monitors including a pulse oximeter, B.P apparatus & an ECG monitor were routinely used. Midazolam was titrated with increments of 0.25 mg each and used up to a maximum dose of 0.025mg/kg to have sufficient anxiolysis without producing too much sedation. The patient was kept left lateral and positioned for a subarachnoid block. Under strict aseptic precautions after giving local anaesthesia with a 26 G needle, lumbar puncture was done with a Quinke needle of 23 G size using either the midline or paramedian approach in the L 3/4 or L 2/3 space. After clear CSF was flowing freely, (the study group received 5µg (0.5) cc of Dexmeditomedine with 0.5% 2 cc (10 mg) hyperbaric bupivacaine and the Bupavacaine group (control group) who received of 0.5% 2.5cc of hyperbaric bupivacaine) was injected into the subarachnoid space. The table was kept horizontal throughout. The patient was turned supine immediately. Throughout the procedure patient received an oxygen supplementation of 4L/minute via a simple oxygen mask.

Main outcome and measurements

- The following parameters were assessed and compared.
- Time for onset of adequate level of analgesia- level (T10, assessed with pinprick).
- Peak sensory level reached during the procedure (assessed with pinprick).
- Time for motor block to recede to L3/4 level, (Grade 1 Bromage motor scale).
- Duration of analgesia in terms of time for onset of mild pain postoperatively as reported by the patient.

- Incidence of complications including- respiratory depression, hypotension brady-cardia, nausea and vomiting, pruritus, sedation and shivering.

Data Collection: The principal investigator himself collected the data. Pulse rate and blood pressure were checked every minute for the first 20 minutes and every two-minute for the next 20 minutes and every five minutes till the end of surgery and then every 10-15 minutes for three hours post operatively. They were followed up for 24 hours thereafter with routine post-op care hi the post-surgical wards.

Complications during surgery were treated as follows: Hypotension (defined as a systolic blood pressure of < 100 mm Hg or fall of 30% or more of initial reading, whichever was higher) was treated with 6mg increments of iv ephedrine and 200 ml normal saline. Bradycardia (defined as a heart rate < 50bpm) was treated with iv atropine 0.3-0.5 mg, if it was associated with hypotension.

The motor block was assessed using a modified Bromage motor scale.

- 0 – No - full movement of lower limb
- 1 – Partial paresis-ability to flex knee, ankle
- 2– Partial paresis-ability to flex foot only
- 3 – Partial paresis -ability to flex toes only
- 4 – Full paresis -no movement

Sedation status were assessed as

- 1 = Awake and alert – None
- 2 = Respond's to voices – Mild
- 3 = Response to touch – Moderate
- 4 = Response to pain – Severe
- 5 = No response – Sleeping

Analgesia

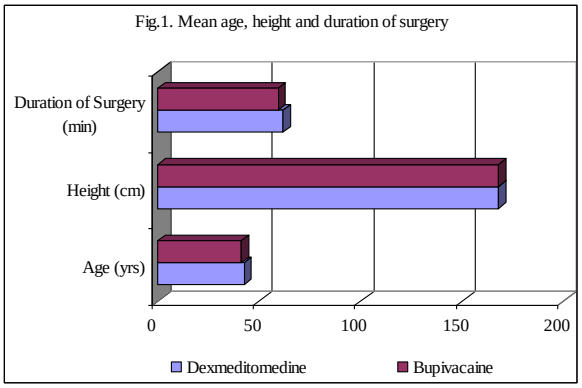
If patient complain of pain, Rescue Analgesia given by using I/V Diclofinac Infusion (75 mg).

OBSERVATIONS AND RESULTS

The observations made were tabulated and analysed using appropriate statistical tools. The patients in both Dexmeditomedine (test) group & the Bupivacaine (Control) group were comparable with respect to their ages, height and duration of surgery (unpaired T test).

Parameter	Group	Mean	± SD	t value	P value	Comments
Age (yrs)	Dexmeditomedine	42.53	5.64	0.959	> 0.05	Not significant
	Bupivacaine	41.17	5.40			
Height (cm)	Dexmeditomedine	168.07	4.21	-0.059	> 0.05	Not significant
	Bupivacaine	168.13	4.49			
Duration of Surgery (min)	Dexmeditomedine	61.73	10.88	0.835	> 0.05	Not significant
	Bupivacaine	59.37	11.08			

Fig.1. Mean age, height and duration of surgery

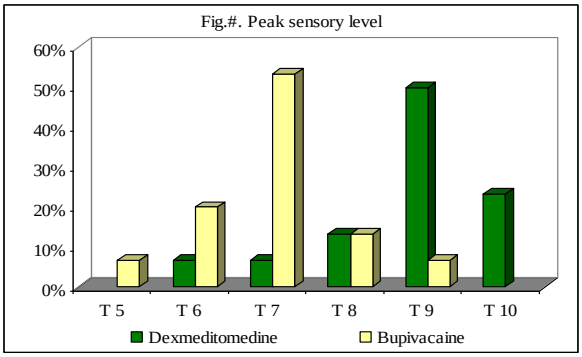


PEAK SENSORY LEVEL OF BLOCK

The peak sensory level attained was notably lower in the case of Dexmeditomedine group 23 among 30 persons studied has a peak sensory level at or below T-9, 28 subjects out of total of 30 had a peak sensory level above T-9.

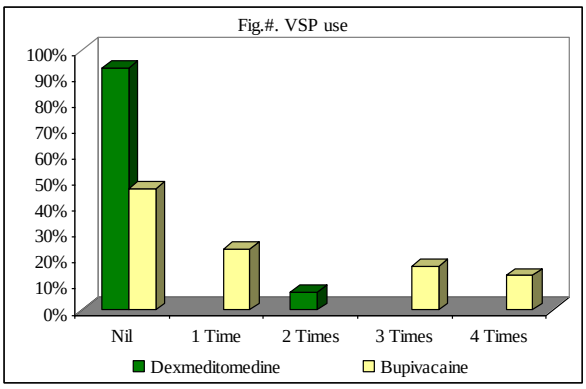
Peak Sensory Level	Group		Total
	Group I (Dexmeditomedine)	Group II (Bupivacaine)	
T 5		2	2
		6.70%	3.30%
T 6	2	6	8
	6.70%	20.00%	13.30%
T 7	2	16	18
	6.70%	53.30%	30.00%
T 8	4	4	8
	13.30%	13.30%	13.30%
T 9	15	2	17
	50.00%	6.70%	28.30%
T 10	7		7
	23.30%		11.70%
Total	30	30	60
Chi Square: 31.831; P < 0.001			

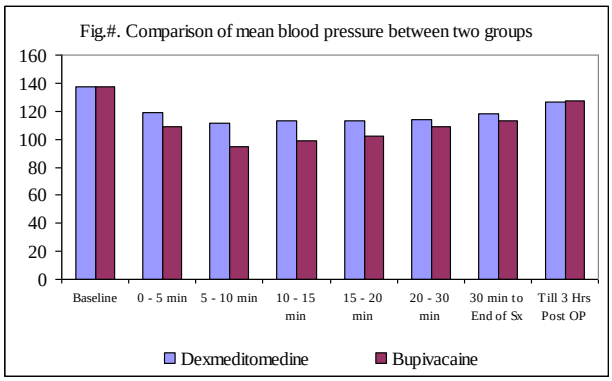
Fig.#. Peak sensory level



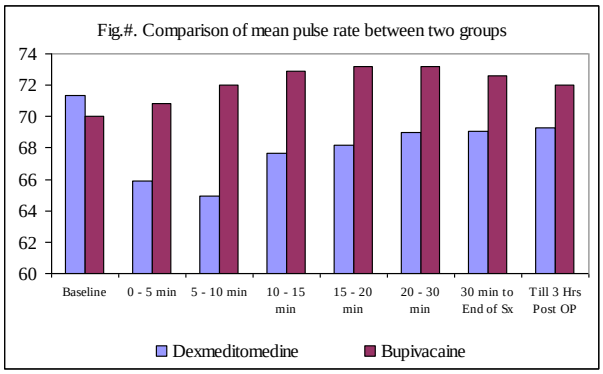
Cardiovascular side effects: Pulse rate & blood pressure were checked every minute for the first 20 minutes and every two - minute for the next 10 minute for the next 10 minutes and every five minutes till the end of surgery and then every 10-15 minutes for three hours post operatively. They were followed up to 24 hours thereafter with routine post-op care in the post-surgical wards.

Hypotension: While analyzing the two parameters - pulse rate & blood pressure, we included the data of only the first 30 minutes of these variables for out statistical analysis because it is the period during which the intrathecal drug usually gets fixed and exerts its significant sympatholytic effect. Only two subjects among the Dexmeditomedine (test) group had episodes of hypotension that required vasopressors, whereas 16 among the Bupivacaine (control) group had incidence of hypotension in the first 30 minutes after administering the subarachnoid block. Moreover 9 among these 16 subjects, among Bupivacaine (control) group, had persistence of hypotension that required more than two boluses of the vasopressor, while none among the Dexmeditomedine (test) group required that.





The most significant side effects reported about the use of intrathecal α2 - adrenoreceptor agonists are bradycardia and Hypotension, In present study, these side effects were not significant probably because we used small dose of intrathecal Dexmeditomedine which was confirmed by findings. In present study hypotension was more in the Bupivacane group than in the Dexmeditomedine group.

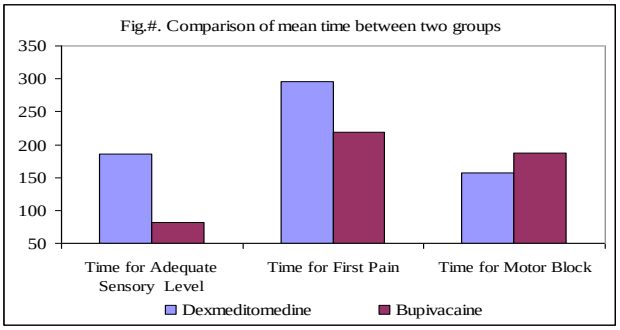


Time Parameters

The time of onset of adequate level of sensory block was longer among the Dexmeditomedine (test) group while they had a lower peak sensory level of block. Dexmeditomedine (test) group had their motor block returned back to normal considerably earlier than those among the Bupivacaine (control) group, while both groups demonstrated comparable degree of post op analgesia in terms of the time of onset of the experience that "it pains". Study group using Dexmetditomedine, showed significant improve-ment in the analgesic part.

Comparison of time measurements

Parameter	Group	Mean	± SD	t value	P value	Comments
Vasopressor use	Dexmeditomedine	0.13	0.51	-3.851	< 0.001	Clinically Significant
	Bupivacaine	1.27	1.53			
Time for onset of Adequate block (T10) (seconds)	Dexmeditomedine	185.00	34.72	14.039	< 0.001	Clinically Significant
	Bupivacaine	82.00	20.24			
Time for onset of pain(First)(minutes)	Dexmeditomedine	295.20	40.40	9.611	< 0.001	
	Bupivacaine	219.00	15.94			Clinically Significant
Time for recession of motor block(minutes)	Dexmeditomedine	157.67	9.58	-8.027	< 0.001	Clinically Significant
	Bupivacaine	186.83	17.44			



Other Side Effects

No subjects among either group had any incidence of sedation or respiratory depression or pruritis. 2 subjects from Bupivacaine (control) group had intra operative nausea and vomiting, while only one subject among the Dexmeditomedine group had it. The incidence of shivering was higher among the Bupivacaine (control) group with 9 subjects experienced shivering, while none had in Dexmeditomedine (test) group.

Symptoms	Group		Total	Chi Square	P value
	Group I (Dexme ditomedine)	Group II (Bupi vacaine)			
Pruritis	0	0	0	0.000	> 0.05
	0.00%	0.00%	0.00%		
Shivering	1	9	10	7.661	< 0.001
	3.30%	30.00%	16.70%		
Nausea & Vomiting	1	2	3	0.351	> 0.05
	3.30%	6.70%	5.00%		
Sedation	0	0	0	0.000	> 0.05
	0.00%	0.00%	0.00%		
Respiratory Depression	0	0	0	0.000	> 0.05
	0.00%	0.00%	0.00%		

DISCUSSION

The result of the study shows that the supplementation of lower dose of Bupivacaine with 5 µg Dexmeditomedine significantly[1-5] prolonged sensory block compared with intrathecal Bupivacaine alone. Dexmeditomedine improved the quality of intraoperative analgesia and diminished the risk of supplementation of general anesthesia. Intrathecal Dexmeditomedine when added to spinal local anesthetics significantly reduces visceral and somatic pain and this analgesic effect has been proved by many studies.

The American Journal of applied sciences, Publication effect of adding Dexmedetomedine versus Fentanyl to Intrathecal Bupavacine on spinal block in Gynaecological procedures, the purpose of this study was evaluated the onset and duration of sensory and block as well as operative analgesia and adverse effects of Dexmedito-medine or fentanyl given intrathecally with plain 0.5% Bupivacaine for spinal anaesthesia. Patient were randomly allocated toe receive either 10 mg isobasic bupivacaine plus 5 µg dexmedetomedine (group D n=38) or 10 mg isobaric bupicaine plus 25 mg fentanyl (group Fn = 38), results patients in group D had significant longer sensory and motor block than patients in group F. The mean time sensory regression to S1 was 274 $\pm$ 73 min in group D and 179$\pm$ 47 min in group F (P<0.001).

In the present study and based on the above study's findings Dexmeditomedine in a dose of 5µg was used for supplementation spinal Bupivacaine, showed the duration of sensory block in study group (Dexmeditomedine) is 295+40 min and control group bupavacaine 219±15 (P< 0.001) and it is highly significant. Dexmeditomedine is a highly selective α2 adrenoreceptor agonist approved as intravenous sedative and adjuvant to anesthesia. Dexmeditomedine when used intravenously during anesthesia reduces opioid and Inhalatonal anesthetics requirements. Compared with clonidine a α2 adrenoreceptor agonist, the affinity of Dexmeditomedine to α2 receptors has been reported to be 10 times more than clonidine. Moreover, Kalso et al. and post et al. reported a 1:10 dose ratio between intrathecal Dexmedito-medine and clonidine in animals. Clinical studies in surgical patients showed that intrathecal clonidine increases the duration of sensory block when added to spinal local anesthetics and this effect of clonidine in dose dependent. From Kanazi study and animal studies, we assumed that 3 - 5 µg Dexmeditomedine would be equipotent to 30 - 45 µg clonidine when used for supplementation of spinal Bupivacaine.

Intrathecal Dexmeditomedine when combined with spinal bupivacaine prolongs the sensory block by depressing the release of C-fibers transmitters and by hyperpolarization of post-synaptic dorsal horn neurons. Motor block prolongation by α2 adrenoreceptor agonist may result from binding these agonist to motor neurons in the dorsal horn of the spinal cord Intrathecal α2 receptor agonist have been found to have antinociceptive action for both somatic and visceral pain. In this study intrathecal Dexmeditomedine and Bupivacaine block has resulted in significantly less side effects that intrathecal Bupivacaine alone. The most significant side effects reported about the use of intrathecal α2 adrenoreceptor agonist are bradycardia and hypotension, in present study these side effects were not significant probably because we used small dose of intrathecal Dexmeditomedine, which was confirmed by the findings of Kanazi report. In present study hypotension was more in the Bupivacaine group than in the Dexmeditomedine group.

CONCLUSION

After analyzing the results our study, we find that addition of 5 µg Dexmeditomedine to 2cc of hyperbaric Bupivacaine 0.5% is associated with lessor incidence of Hypotension and lessor degree of motor blockade but with improved analgesic efficacy. Intrathecal Dexmeditomedine supplem-entation of spinal block seems to be a good alternative to intrathecal fentanyl since it produces prolonged sensory block, and it is evident that this type of block may be more suitable for major surgeries on the abdomen and lower extremities. The dose of Dexmeditomedine (5µg) used in present study was suitable and comparable to clonidine 45 µg as suggested by De kock et al. However, Intrathecal dose of Dexmeditomedine use in present study needs further clinical studies to prove its efficacy and safety and to be considered the suitable dose of Dexmeditomedine for supplementation of spinal local anesthetics.

In conclusion, 5 µg Dexmeditomedine seems to be an attractive alternative as adjuvant to spinal bupivacaine in surgical procedures especially in those that need quite long time with minimal side effects and excellent quality of spinal analgesia.

Financial support and sponsorship: Nil
Conflicts of Interest: There are no conflicts of Interest

REFERENCES

1. Addition of Clonidine and Dexmedito-medine to Bupivacaine prolongs caudal analgesia in children – Department of Anesthesiology; faculty of Medicine, Ain-Shama University Cairo, Egypt, Accepted May 6, 2009.
2. Schnaider TB, Viera AM, Brandao ACA, Lobo MVT; Intraoperative analagesic effect of Epidural Dexmeditomedine, Clonidine and Ketamine for upper abdominal Surgery – Rev Bras Anestesiol 2005; 55:525-31.
3. Viera AM, Schnider TB, Brandao ACA, Pereira PA, Costa ED, Fonseca CEPT – Epidural Clonidine and Dexmeditomedine for post – cholecystectomy analgesia and sedation. Rev- Bras Anestescol 2004; 54:473-8.
4. The effect of intrathecal Dexmeditomedine in spinal anaesthesia using low dose hyperbaric Bupivacaine for TURP in elderly.
5. Efficacy of intrathecally administered Dexmeditomedine versus with fentanyl in patient undergoing Major abdominal cancer surgery – from : South Egypt Cancer Institute, Anaesthesia Intensive Care and Pain Management Department, Assiut Egypt.
6. A comparative study of Intrathecal Dexmeditomedine and fentanyl as adjuvant to Bupivacaine – Journal of Anaesthesiology clinical Pharmacology :2011 July –Sept 27; 339-343.

7. Effect of low dose of Dexmeditomedine and clonidine on the characteristics of Bupivacaine (Acta Anaesthesiology Scand 2006).
8. Intrathecal fentanyl prologs Sonsory Bupavacaine spinal block – Cand J. Anesthesia – 1995.
9. Fukushima K, Nishimi Y, Mori K, Takeda J, - Effect of epidurally administered Dexmeditomedine on sympathetic activity and post operative pain management – Anesthesia: Analog 1996; 82-S 121.
10. Gupta R, Verma R, Bogra J, Kohili M, Rama R, Khushwaha JK, - A comparative study of Intrathecal dexmeditomedine and fentanyl as adjuvant to Bupivacaine. Journal Anaesthsiology and Clinical Pharmacology 2011; 27: 339-343.
11. G.E.Kanazi, M.T.Aouad, S.I.Jabbour – Khoury, M.D.AI Jazzer, M.M. Alameddine, R. A1-Yaman, M. Bulbul and A.S.Baraka. Effect of low-dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block. Acia Anesthesiol Scnad 2006; 50: 227 – 117. DOI 10.1111/j.1399-6576-2006.00919.x