Original Research Article

Indian Journal of Emergency Medicine
Volume 4 Number 3, July - September 2018
DOI: http://dx.doi.org/10.21088/ijem.2395.311X.4318.13

A Prospective, Randomized Comparative Study of Addition of Dexmedetomidine to 0.75% Ropivacaine Versus 0.75% Ropivacaine Alone Intrathecally in Lower Limb Surgery

V.S.S.N. Murthy[1], S.V. Ravikanth[2], Anand Acharya[3]

Author's Affiliation:
[1,2]Associate Professor. Dept of Anaesthesia [3]Professor and Head, Dept of Pharmacology, Konaseema Institute of Medical Science, Amalapuram, Andhra Pradesh 533201, India.

Corresponding Author:
S.V. Ravikanth, Associate Professor Dept of Anaesthesia, Konaseema Institute of Medical Science, Amalapuram, Andhra Pradesh 533201, India.

E-mail: anand_kims@yahoo.co.in

Received on 22.05.2018,
Accepted on 09.06.2018

Abstract

Background: Dexmedetomidine, is a imidazole compound, is a pharmacological active of dextroisomer of medetomidine. It is selective and specific to α2A adrenoreceptor, which is responsible for its sedative and analgesic effect. This property has made it popular drug as adjuvant to local anaesthetic drug in regional anaesthesia. *Method:* The study was conducted on 60 patients undergoing lower limb orthopaedic surgeries under spinal anaesthesia patients were randomized and allocated into two groups using sealed envelope technique based on inclusion and exclusion criteria. All the patients enrolled for this study were examined preoperatively, and allocated into group I and group II. *Group I* – 3ml of 0.75% isobaric Ropivacaine. Plus 0.5ml of normal saline. *Group II* – 3ml of 0.75% isobaric ropivacaine plus 5ug of Dexmedetomidine in 0.5ml of Normal saline. *Result:* Time of onset of sensory block was 3.71+0.6min in group I in comparison to 4.94+1.12 min in group II with p value 0.01862. Maximum level of sensory level achieved in group I was T7 and in group II it was T6, with p value 0.0001. Time required to achieve maximum sensory level in group I was 12.6+1.96min, in group II it was 11.62+1.8min, with p value 0.204. Time for two segment regressions was 114.68+16.24min in group 1 but in group II it was 72.42+8.94min with P value 0.00001. Time to regression to S2 segment was 435.64+34.28min in group I and 259.46+26.45 in group II with p value 0.00001. *Discussion and conclusion:* Five micro gram of dexmedetomidine when added to ropivacaine is associated with faster onset and longer duration of sensory blocked, haemodynamic stability, absence of sedation and reduced need for analgesia in first 24 hour.

Keywords: Ropivacaine; Dexmedetomidine; Intrathecally; Lower Limb Surgery.

Introduction

Spinal anaesthesia is commonly used in lower limb surgery but the limitation with this is the local anaesthetic drugs are of shorter duration of action and having poor post-operative pain relief. So patient require early analgesic intervention in postoperative period [1].

A number of adjuvants are used for example opioids, α2- adrenoreceptor blockers, steroids and other drugs like ketamine, neostigmine, midazolam and magnesium sulphate [2]. Out of all these fentanyl is most commonly used but it is associated with prolongation of sensory block and also having more adverse effect like hypotension and pruritus [3].

Ropivacaine is a long acting amide anaesthesia agent causing differential motor and sensory block. It has a reduced risk of cardiotoxicity, neurotoxicity and has rapid recovery of motor function. It is used for epidural, spinal, caudal, peripheral nerve blocks and intrathecally [4,5].

Dexmedetomidine, is a imidazole compound, is a pharmacological active of dextroisomer of medetomidine. It is selective and specific to α2A adrenoreceptor, which is responsible for its sedative, and analgesic effect [6]. This property has made it popular drug as adjuvant to local anaesthetic drug in regional anaesthesia [7].

The present study has been conducted to evaluate the onset and duration of sensory block, haemodynamic changes, postoperative analgesic requirement and adverse drugs reaction, when dexmedetomidine added to intrathecal ropivacaine in lower limb surgeries.

Material and method

This is a prospective, randomised comparative study conducted in the dept. of anaesthesia Konaseema institute of medical science Amalapuram, Andrapradesh from Jan 2017 to May 2018.

Ethics: Before start of this study approval was taken from institutional ethics committee, all the patients enrolled for this study were informed about the procedure and drugs. A written informed consent was taken from each patient.

Study population: The study was conducted on 60 patients undergoing lower limb orthopaedic surgeries under spinal anaesthesia. Patients were randomized and allocated into two groups using sealed envelope technique based on inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Age between 18-60 yrs ASA I and II	Local infection, bleeding disorder, heart block, Hypertension, spinal deformity,

All the patients enrolled for this study were examined preoperatively, and allocated into group I and group II.

Group I – 3ml of 0.75% isobaric Ropivacaine. Plus 0.5ml of normal saline.

Group II – 3ml of 0.75% isobaric ropivacaine plus 5ug of Dexmedetomidine in 0.5ml of Normal saline.

In the operation theatre all the patients were preloaded with ringer lactate 15ml/ kg. No pre-anaesthetic medication was used in any group. Vitals like BP (blood pressure), HR (heart rate), RR(respiratory rate), and oxygen saturation were monitored. Patients were placed in sitting position. Under all aseptic precautions L3 L4 space was pierced with 25-Guage quincke needle by midline approach, and the study drug was deposited intrathecally. Immediately after performing the block all patients were placed in supine position. Blood pressure, Heart rate, respiratory rate, oxygen saturation (SpO_2) was monitored at 5min interval till the end of procedure, Hypotension was defined when SBP was below 90 mm of Hg. Bradycardia was defined when HR was below 50 and SpO_2 was detected below 90% then it was treated with oxygen supplementation, bradycardia was treated with atropine 0.6mg I.V (intra venous), hypotension was treated with ephedrine 6mg IV.

Following parameters were recorded, sensory block was assessed by loss of pin prick sensation to 23g hypodermic needle in the mid-axillary line, at every 2.min until T10 dermatomal level reached and then every 5min interval until no change level reached. Time to reach T10 level was taken as the time of onset of sensory block, duration of block was the time taken for the sensory regression of two segments from the highest level of sensory block, maximum level of sensory block achieved, duration of sensory block, was recorded.

Motor block was assessed every 5 min till completion of surgery by modified Bromage score, maximum motor block achieved, time required to reach maximum motor block and total. Duration of motor block that is recovery to Bromage was recorded [8].

0	No motor blockage
1	Unable to lift leg straight
2	Not able to flex knees
3	Not able to flex ankles

Sedation was assessed with four –point verbal rating scale, 1 = No sedation, 2= light sedation, 3 = somnolence, 4= Deep sedation.

Post-operative pain score was recorded by using visual Analogue, score (VAS) [9] between 0 and 10 (0=no pain, 10 the most severe pain) initially every 5 min for 15 min, till surgery over, post operatively, every half hourly for first 1 hr, then 1hourly for 12hr then 3hrly till 24hr. When VAS was >4 then 75mg i.m. inj. diclofenac was given repeated after 12hr if required. For breakthrough pain inj tramadol 100mg was given. Total consumption of diclofenac and tramadol in first 24hr was recorded in both groups.

Any side effect and complication like, hypotension, Bradycardia, headache,, nausea, and vomiting and back pain was recorded.

Statistical analysis: Data was analysed by using SPSS 16.0, the parametric data was by analysed by unpaired T-test and nonparametric data was analysed by chi square test. p value <0.05 was considered statistically significant.

Result and observation

As per Table 1 both the group were statistically comparable to each other with regard to

demographic profile, with p value more than 0.05. There was no statistical difference between two group regarding basal hemodynamic parameters also (Table 2).

Regarding sensory and motor block characteristics as per table 3, time of onset of sensory block was 3.71±0.6min in group I in comparison to 4.94±1.12 min in group II with P value 0.01862. Maximum level of sensory level achieved in group I was T7 and in group II it was T6, with p value 0.0001. Time required to achieve maximum sensory level in group I was 12.6±1.96 min , in group II it was 11.62±1.8min, with P value 0.204. Time for two segment regressions was 114.68±16.24min in group 1 but in group II it was 72.42±8.94min with P value 0.00001. Time to regression to S2 segment was 435.64±34.28min in group I and 259.46±26.45 in group II with p value 0.00001.

Time to complete motor block in group I was 26.82±6.25 Min in comparison to 25.34±2.8 in group II with p value 0.1436. The total duration of motor block in group I was 278.46±24.62 min in group II it was 210.46±42.68 min with P value 0.00001.

Time required of first dose of rescue analgesia was 462. 364±28.42 min in group I and 268.42±32.486 min in group II with P value 0.00001.

As per Table 4 all the patients in group I and group II required diclofenac supplementation but tramadol was required by 4 pt in group I and 12pt in group T II, with p value 0.0198.

Table 1: Demographic profile of the patient in both groups.

variables		Group – I (N=30)	Group – II (N=30)	P value
Age (yrs)		45.70±12.67	46.50±9.77	0.394983
Sex	M	22	20	Chi square state =0.3175
F	8	10		P=0.573138
Weight(kg)		66.56±9.311	68.03	0.180312
Height(cm)		163.87±10.115	166.69±10.19	0.134916
ASA	I	20	18	Chi square state =0.2871
	II	10	12	P value 0.592097
Duration of Surgery(min)		106.42±12.48	108.32±10.36	0.86448

Table 2: Hemodynamic parameters

Variables	Group – I (mean)	Group – II (mean)	P value
SBP(mm of Hg)	123.83±7.23	121.43±6.82	0.412834
DBP(mm of Hg)	77.80±4.89	78.13±4.60	0.764
RR(per min)	24.03±4.97	23.42±3.85	0.380934
HR(per min)	82.44±6.93	80.46±7.36	0.2872
SpO_2 (%)	99±0	99±0	1

Table 3: Sensory and motor block characteristics of two groups.

Variables	Group – I	Group – II	P value
Time of onset of sensory block(min)	3.71±0.6	4.94±1.12	0.01862
Maximum sensory level achieved	T7 dermatomes	T6 dermatomes	0.0001
Time for maximum sensory level(min)	12.6±1.96	11.62±1.8	0.204
Time for two segment regression	114.68±16.24	72.42±8.94	0.00001
Time to regression to S2 dermatome.	435.64±34.28	259.46±26.45	0.00001
Time to complete motor block	26.82±6.21	25.34±2.8	0.1436
Total duration of motor block	278.46±24.62	210.46±42.68	0.00001
Time of first dose of rescue analgesia	462.364±20.42	268.42±32.486	0.0001

Table 4: Analgesia requirement

Drug	Group – I (number)	Group – II (number)	P value
Diclofenac	30	30	1.0
Tramadole	4/26	12/8	0.0/98

Table 5: Adverse effects

Advise effect	Group - 1	Group – 11
Hypertension	6	4
Bradycardia	1	1
Vomiting	2	4
sedation level	1	1

As per table 5 out of 30 patient 6 patients develop hypotension in group I but only 4 pts. in group II developed hypotension, sedation score was same in both group. Two patients in group II have vomiting.

Discussion

Dexmedetomidine is a α2A receptor agonist, and highly lipophilic, it binds to α-2A receptor in spinal cord and produces analgesia, It prolongs the duration of both sensory and motor blocked induced by local anaesthetics [10,11]. Clinical studies of Lawhead R G et al. and Elhakim et al and by various author suggests that dexmedetomidine potentiate local anaesthetic and improves quality of block [12,13].

In present study the demographic profile and basal hemodynamic parameters are comparable to each other, with p value more than 0.05. The time of onset of sensory block was significantly early in group I then group II (3.71±0.6 vs 4.94±1.12) which is not supported by the work of Rajni gupta et al., [14] but this finding corroborate with the finding of Sargado et al. [15]. The maximum sensory level achieved in group I was higher than group II which is supported by the work of Bajwa at al. [16].

The time for maximum sensory level in group I was not significantly different than group II both are comparable to each other (126+1.96 vs 11.62+1.8) which is supported by the finding of sarabjit et al. [17].

Time for two segment regression was significantly longer in group I then group II, which is supported by the work of Rajni gupta et al and sarabjit et al. [14,17].

Time to regression to S2dermatome was longer in dexmedetomidine group then ropivacaine done group (435.64+34.20 VS 259.46+26.45) with p value 0.00001. This finding corroborates with the work of De Kock M et al. [18]. In our study the time to complete motor block was statistically comparable to each other with p value 0.1436 but the duration of block that is regression to Bromage 0 was longer in dexmedetomidine adjuvant group and was significant statistically, this corroborates with the study of salgado of et al. [15].

Dexmedetomidine and ropivacaine is associated with significant prolongation in requirement of first dose of rescue analgesia, in comparison to ropivacaine alone. Dexmedetomidine by acting on α2A receptor decreases the release of C- fibre transmitters and by hyperpolarising dorsal horn cells potentiate ropivacaine, this is corroborated with the finding of, salgado et al and, Eisanachijc et al. [15,19]. Requirement of analgesia was also significantly low in dexmedetomidine group then, ropivacaine group.

Regarding adverse effect six patient out of thirty in group I have hypotension which higher then ropivacaine but not significant statistically which corroborates with the finding of Bajwa et al and Pramila soni et al.[16,20].

Conclusion

We would like to conclude that five micro gram of dexmedetomidine when added to ropivacaine is associated with faster onset and longer duration of sensory blocked, haemodynamic stability, absence of sedation and reduced need for analgesia in first 24 hour.

References

1. Liu SS, Strodtbeck WM, Richman JM, Wu CL. A comparison of regional versus general anesthesia for ambulatory anesthesia:a meta-analysis of randomized controlled trials. Anesth Analg 2005;101:1634–42.
2. Amlan Swain, Deb Sanjay Nag, Seelora Sahu, and Devi Prasad Samaddar, Adjuvants to local anesthetics: Current understanding and future trends, World J Clin Cases. 2017 Aug 16;5(8):307–23.
3. Finucane BT, Ganapathy S, Carli F, Pridham JN, Ong BY, Shukla RC, Kristoffersson AH, Huizar KM, Nevin K, Ahlén KG; Canadian Ropivacaine Research Group. Prolonged epidural infusions of ropivacaine (2 mg/mL) after colonic surgery: the impact of adding fentanyl. Anesth Analg. 2001;92:1276–85.
4. S Kurdi Madhuri and Kumari. B Anjali, Use of Ropivacaine intrathecally, J Anaesthesiol Clin Pharmacol. 2010 Oct-Dec;26(4):564.

5. Cemile Oztin Ogun, et al. The comparison of intrathecal isobaric ropivacaine & isobaric ropivacaine-clonidine for cesarean delivery. The Internet Journal of Anaesthesiology. 2007;15(1).
6. Hunter JC, Fontana DJ, Hedley LR, Jasper JR, Lewis R, Link RE, Secchi R, Sutton J, Eglen RM. Assessment of the role of alpha 2-adrenoceptor subtypes in the antinociceptive, sedative and hypothermic action of dexmedetomidine in transgenic mice. Br J Pharmacol. 1997;122:1339–44.
7. K Sudheesh, SS Harsoor, Dexmedetomidine in anaesthesia practice: A wonder drug? Indian Journal of Anaesthesia, Year : 2011;4(55):323-24.
8. Bromage PR. Epidural Analgesia. Philadelphia: WB Saunders; 1978.p.144.
9. Katz J, Melzack R. Measurement of pain. Surg Clin North Am 1999;79:231–52.
10. Schnaider TB, Vieira AM, Brandao AC, Lobo MV. Intraoperative analgesic effect of epidural ketamine, clonidine or dexmedetomidine for upper abdominal surgery. Rev Bras Anestesiol. 2005;55:525–31.
11. Manpreet Kaur and P. M. SinghCurrent role of dexmedetomidine in clinical anesthesia and intensive care, Anesth Essays Res. 2011 Jul-Dec; 5(2):128–33.
12. Lawhead RG, Blaxall HS, Bylund DB. Alpha-2A is the predominant alpha-2 adrenergic receptor subtype in human spinal cord. Anesthesiology. 1992;77:983–91.
13. Elhakim M, Abdelhamid D, Abdelfattach H, Magdy H, Elsayed A, Elshafei M. Effect of epidural dexmedetomidine on intraoperative awareness and post-operative pain after one-lung ventilation. Acta Anaesthesiol Scand. 2010;54:703–9.
14. Rajni Gupta, Jaishri Bogra, Reetu Verma, Monica Kohli, Jitendra Kumar Kushwaha, and Sanjiv Kumar. Dexmedetomidine as an intrathecal adjuvant for postoperative analgesiaIndian J Anaesth. 2011 Jul-Aug; 55(4):347–51.
15. Salgado PF, Sabbag AT, Silva PC, Brienze SL, Dalto HP, Módolo NS, et al. Synergistic effect between dexmedetomidine and 0.75% ropivacaine in epidural anesthesia. Rev Assoc Med Bras. 2008;54:110–5.
16. Bajwa SJ, Arora V, Kaur J, Singh A, Parmar SS. Comparative evaluation of dexmedetomidine and fentanyl for epidural analgesia in lower limb orthopedic surgeries. Saudi J Anaesth. 2011;5:365–70.
17. Sarabjit Kaur, Joginder Pal Attri, Gagandeep Kaur, and Tejinder Pal Singh, Comparative evaluation of ropivacaine versus dexmedetomidine and ropivacaine in epidural anesthesia in lower limb orthopedic surgeries, Saudi J Anaesth. 2014 Oct-Dec;8(4):463–469.
18. De Kock M, Gautier P, Fanard L, Hody JL, Lavand' homme P. Intrathecal Ropivacaine and clonidine for ambulatory Knee arthroscopy. A dose response study. Anesthesiology. 2001;94:574–8.
19. Eisanach JC, De Kock M, Klimscha W. α2 adrenergic agonists for regional anesthesia. Anesthesiology. 1996;85:655–74.
20. Pramila Soni, Comparative study for better adjuvant with ropivacaine in epidural anesthesia.Anesth Essays Res. 2016 May-Aug;10(2):218–22.

Instructions to Authors

Submission to the journal must comply with the Guidelines for Authors. Non-compliant submission will be returned to the author for correction.

To access the online submission system and for the most up-to-date version of the Guide for Authors please visit:

http://www.rfppl.co.in

Technical problems or general questions on publishing with **IJEM** are supported by Red Flower Publication Pvt. Ltd's Author Support team (http://rfppl.co.in/article_submission_system.php?mid=5#)

Alternatively, please contact the Journal's Editorial Office for further assistance.

Editorial Manager
Red Flower Publication Pvt. Ltd.
48/41-42, DSIDC, Pocket-II
Mayur Vihar Phase-I
Delhi - 110 091(India)
Mobile: 9821671871, Phone: 91-11-22754205, 45796900, 22756995
E-mail: author@rfppl.co.in