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Research Article

A comparative study on effects of intrathecal ropivacaine plus dexmedetomidine versus ropivacaine plus clonidine

Shweta Kujur[1*], K. K. Arora[2], Madhumita G. Murthy[3], Jyoti Prakash Samuel Ekka[4]

[1]Senior Resident, [3]Associate Professor, Department of Anaesthesiology and ICU, Chhattisgarh Institute of Medical Science, Bilaspur (C.G.), India
[2]Professor, Department of Anaesthesiology, S.S. Medical College, Rewa (M.P.), India
[4]Demonstrator, Department of Pharmacology, Chhattisgarh Institute of Medical Science, Bilaspur (C.G.), India

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***Correspondence:**
Dr. Shweta Kujur,
E-mail: shwetakujur08@gmail.com

ABSTRACT

Background: Subarachnoid block is a safe and effective alternative to general anaesthesia when surgical site is located on the lower extremities, perineum or lower body wall. Spinal anaesthesia produces intense sensory and motor blockade as well as sympathetic blockade. Intrathecal α-2-agonists are used as adjuvant drugs to local anaesthetics successfully over the last decade .They potentiate the effect of local anaesthetic and decrease the required doses. Clonidine is a partial α-2-adrenorecptor agonist used intrathecally, with a well- established record of efficacy and safety. Its addition to local anaesthetics prolongs the duration of both motor and sensory spinal blockade. Dexmedetomidine is an α-2-adrenorecptor agonist. It has α-2/α1 selectivity ratio which is eight times higher than that of Clonidine. With this background, this study was conducted to compare the effects of intrathecal Ropivacaine plus Dexmedetomidine versus Ropivacaine plus Clonidine during procedures.

Methods: The present prospective study was carried out in the Department of Anaesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore (M.P.), India. Study period was from June 2011 to July 2012. Patient were randomly allocated to one of the following three group in a double blinded fashion based on computer generated code: Ropivacaine (R), Ropivacaine + Dexmedetomidine (D); Ropivacaine + Clonidine (C). Nominal categorical data between study groups were compared using the Chi – squared test or Fisher's exact test as appropriate. $p<0.05$ was considered to be significant.

Results: In all age groups patients were equally distributed in three Groups. Mean time taken for the onset of sensory and motor block was quite low in group D patients. Thereby showing statistically highly significant difference in onset of sensory and motor blocks ($P<0.001$). Whereas mean duration of sensory and motor block was also quite prolonged in group D patients. ($p<0.001$) There is significant difference between all the three groups.

Conclusion: In conclusion our study shows that intrathecal Dexmedetomidine or Clonidine added with isobaric Ropivacaine produces rapid and prolonged sensory and motor block as compared to plain Ropivacaine.

Keywords: Subarachnoid block, Ropivacaine, Dexmedetomidine, Clonidine

INTRODUCTION

Subarachnoid block is a safe and effective alternative to general anaesthesia when surgical site is located on the lower extremities, perineum or lower body wall. Spinal anaesthesia produces intense sensory and motor blockade as well as sympathetic blockade. Spinal anaesthesia has progressed greatly since 1885 and is used successfully in a number of clinical situations after the administration of spinal analgesia in 1885 by Leonard Corning, a neurologist in New York for the first time.

The first planned spinal anaesthesia for surgery in man was administered by August Bier on 16 August 1898, when he injected 3 ml of 0.5% cocaine solution into a 34 year old labourer. Since then spinal anaesthesia faced many changes. Many drugs have been used and studied. With discovery of amide local anaesthetic agents, spinal anaesthesia has been a revolution. Lignocaine Since 1949 had been the main agent. But it became less popular after reporting of Cauda Equina Syndrome. Bupivacaine is a well established and most widely used long –acting regional anaesthetic; which like all amide anaesthetics has been associated with cardio toxicity when used in high concentration or when accidentally administered intravascularly.

This led to the discovery of Ropivacaine in 1996, which is a long acting regional anaesthetic that is structurally related to Bupivacaine It presented as a single s-enantiomer and has been used extensively for epidural and peripheral nerve blocks.

Ropivacaine was approved for a new route of administration, the intrathecal route, in the European Union in February 2004. The efficacy and tolerability of Ropivacaine for spinal anaesthesia in orthopaedic surgery have been demonstrated in several studies.[1] It has shown to produce sufficient surgical anaesthesia and analgesia and consistently shown, reduced side effect profile. However, Ropivacaine is overall less potent than Bupivacaine. Its action is slower in onset and short- lived. To overcome this, many adjuvants have been added to Ropivacaine intrathecally, all having their own side effects.[2,3,4]

Intrathecal α-2-agonists are used as adjuvant drugs to local anaesthetics.[5,6,7] They potentiate the effect of local anaesthetic and allow a decrease in the required doses.[7,8] The efficacy and safety of Clonidine, which is a partial α-2-adrenorecptor agonist, when used intrathecally is well-established.[9]

Its addition to local anaesthetics prolongs the duration of both motor and sensory spinal blockade.[10] Dexmedetomidine is an α-2-adrenorecptor agonist that is approved as an intravenous sedation and co analgesic drug. Its selectivity ratio for α-2/α1 receptor is eight times higher than that of Clonidine.[11]

With this background, the present study was conducted to compare the effects of intrathecal Ropivacaine plus Dexmedetomidine versus Ropivacaine plus Clonidine during procedures.

METHODS

The present prospective study was carried out in the Department of Anaesthesiology, M.G.M. Medical College and M.Y. Hospital, Indore (M.P.), India, from June 2011 to July 2012. Ethical considerations were met through intuitional ethical committee. Each patient was informed and written consent was taken. 75 such patients of ASA (American Society of Anaesthesiologist) grade I &II between the ages of 20-50 yrs of either sex were included for the study, who underwent routine orthopaedic lower limb surgeries.

Exclusion criteria

Age less than 20 years, Height less than 150 cm ,Weight more than 120 kg, Known hypertensive or diabetic, Patient taking ACE Inhibitors, calcium channel blocker, α-2-receptor blocker. Patient with hypovolemia or hypotension, Patients with pre-existing severe bradycardia, or ejection fraction <30%, Patient with arrhythmias on ECG or Cardiac block, Allergic to any drug to be used, any other contraindication for spinal anaesthesia

All patients were thoroughly examined during preoperative check up and investigated. History suggestive of any medical illness like diabetes mellitus, hypertension, jaundice, ischemic heart disease, stroke, bronchial asthma was asked.

Routine investigations were done in all patients. Specific investigations like Echocardiography, X-ray chest, liver function test were done whenever necessary. Patient were randomly allocated to one of the following three groups in a double blinded fashion based on computer generated code: Ropivacaine (R); Ropivacaine+ Dexmeditomidine (D); Ropivacaine +Clonidine (C). All patients received inj. Glycopyrolate 0.2 mg intramuscularly half an hour before surgery. In the operating room ,monitoring devices were attached which included heart rate, electrocardiograph (ECG),pulse oximetry (SpO_2), non-invasive blood pressure (NIBP) respiratory rate and the baseline parameters were recorded, a good intravenous line was secured and preloading was done with 500ml of ringer lactate solution. Inj Ondansetron 4 mg and inj. Ranitidine 50 mg was given to all patients intravenously. Lumbar puncture was performed in sitting position using 23 - gauge Quincke type spinal needle, under full aseptic precautions, via median approach.

Pt. allocated to Group	Received drug
R	3.2 ml of Ropivacaine plain, 0.75% with 0.3ml of normal saline
D	3.2 ml of Ropivacaine plain, 0.75% with 3 mcg of inj. Dexmedetomidine (diluted with 0.3 ml of normal saline)
C	3.2 ml of Ropivacaine plain, 0.75% with 30 mcg of inj. Clonidine (diluted with 0.3 ml of normal saline)

Utmost care was taken to avoid any leakage of these drugs. The spinal needle was removed and patient was immediately turned to supine position. To avoid any rostral spread of the drugs, head low position was avoided, after the drug was injected.

Onset of sensory block	Was tested by pin prick method. The time taken from injection of drug to absence of response to pinprick at T 10 Level was recorded as time of onset of sensory block.
Onset of motor block	It was taken as the time elapsing from injection to failure to raise the lower limb on command.
Level of sensory block	Maximum level at which patient could not feel pin prick sensation was taken as the level of sensory block.
Degree of motor block	This was tested using Bromage scale. 0 -Full flexion of knees and feet. 1 -Just able to flex knees, full flexion of feet. 2 -Unable to flex knees, but some flexion of feet possible. 3 -Unable to move legs or feet.

All patients were monitored with automated non-invasive BP, pulse oximetry and ECG. PR and BP were recorded preoperatively, immediately after injection, every 10 minutes till 30 minutes then half hourly till the end of surgery .PR < 60 per minute was graded bradycardia. PR > 100 per minute was graded as tachycardia. 0.6 mg Atropine was kept ready if needed in any episode of bradycardia. Blood pressure – Variations in BP were observed and hypotension was recorded. *"If Blood pressure falls more than 20% from the baseline, it was treated by injection Mephentermine Sulphate 0.4 mg/kg."* Ramsay Sedation Scale was used to test sedation. All the parameters from the pre-operative readings were recorded in the Proforma. All the parameters PR,BP etc were recorded after spinal injection and during surgery were compared with baseline (pre operative).Changes in these parameters were recorded and mean changes in each group at different periods of observation were calculated for inter group comparison.

Efficacy of analgesia was labelled as

Good	If no extra analgesics were required throughout surgery.
Fair	If Some discomfort were there but surgery lasted with small dose of sedative.
Poor	When Increase in pain was there and supplementary analgesia was given, either high dose of narcotic (Fentanyl or Pentazocine) or gas: Oxygen, Nitrous mixture via face mask.
Failed	Converted to General Anaesthesia

Duration of surgery in this study was taken as time from the injection to skin closure. Surgeons were allowed to start the operation once the level of sensory block was confirmed by pinprick method. Duration of sensory block: was recorded as time from injection to appearance of response to pin prick at L1 dermatome level. Duration of motor block: was recorded as time from onset of motor blockade to the time when patient is able to move legs. Patients were also monitored for any side effect like nausea, vomiting, and itching, respiratory depression etc. Postoperatively strict instruction were given to avoid Narcotics, Analgesic and low head position. Patients were monitored every 15 minutes for 1st hour followed by hourly monitoring till complete regression of block postoperatively. A ten point visual scale was used for assessment of pain in this study. Results are expressed as the mean and standard deviations, medians & ranges, or numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using one-way analysis of variance(ANOVA) and if appropriate, followed by the Bonferroni test for post hoc –analysis. Nominal categorical data between study groups were compared using the Chi – squared test or Fisher's exact test as appropriate. $P<0.05$ was considered to be significant.

RESULTS

In all age groups patients were almost equally distributed in three Groups. So age structure was comparable between Group R, D and C. In group R there were 15 male patients while in group D and group C there were 16 and 17 males patients respectively. Number of Female in Group R was 10 and in Group D and Group C was 9 and 8 respectively [Table-1].

Mean time taken for the onset of sensory and motor block was quite low in group D patients. Thereby showing statistically highly significant difference in onset of sensory and motor blocks ($P<0.001$). Whereas mean duration of sensory and motor block was also quite prolonged in group D patients. The results were statistically highly significant ($P<0.001$) There is

significant difference between all the three groups [Table-2].

Table 1: Age and Sex Wise Distribution of Study Subjects allocated in different groups.

Age	Group R		Group D		Group C	
	No.	%	No.	%	No	%
21-30 yrs	10	40	9	36	9	36
31-40 yrs	8	32	10	40	8	32
41-50 yrs	7	28	6	24	8	32
Sex						
Male	15		16		17	
Female	10		9		8	

Table 2: Mean onset and duration of Sensory and Motor Block among study subjects allocated in different groups.

	Group R	Group D	Group C	P Value
Mean Onset (in seconds)				
Sensory Block	726±32.08	112±34.77	369±38.51	<0.001
Motor Block	763±137	163.28±54.62	448±46.63	<0.001
Mean duration (in minutes)				
Sensory Block	117±23.8	225±26.9	183±30	<0.001
Motor Block	110±23.8	220±35.4	175±13	<0.001

The means of MAP, pulse rate, respiratory rate, mean of VAS and mean of Ramsay Scores between all the three groups were almost similar and statistically not significant [Table-3].

Table 3: Variation in Mean Arterial Pressure, Pulse Rate, Respiratory Rate and Visual Analogue Scale Scores with the Passage of Time among Study Subjects Allocated In Different Groups.

Time of Observation	Group R		Group D		Group C		P-Value
	Mean	S.D.	Mean	S.D.	Mean	S.D	
Mean Arterial Pressure							
0 min.	74.5	10.4	69.0	5.1	84.9	10.4	>0.005
10 min.	70.5	4.65	68.0	3.7	72.4	8.2	>0.005
20 min.	69.1	6.05	70.4	5.2	69.7	7.7	>0.005
30 min.	74.1	8.97	70.5	3.9	69.1	4.9	>0.005
1 hours	76.0	12	82.0	10.4	70.0	4.0	>0.005
4 hours	81.0	9.6	74.6	7.3	74.9	6.3	>0.005
6 hours	90.6	10.8	76.2	8.9	80.4	3.5	>0.005
Pulse rate							
0 min	87.68	8.83	85.32	10.88	89.20	2.77	>0.005
10 min	89.40	5.01	84.96	12.06	90.00	4.48	>0.005
20 min	87.60	3.61	87.96	7.62	87.12	4.12	>0.005
30 min	81.96	3.72	84.52	5.61	81.64	4.01	>0.005
1 hour	80.64	4.63	80.68	5.41	81.16	3.73	>0.005
4 hours	80.64	4.62	80.76	4.60	81.08	4.56	>0.005
6 hours	84.12	5.09	80.76	4.25	85.84	3.99	>0.005
Respiratory rates							
0 min	18.64	2.27	19.04	2.92	18.52	2.10	>0.005
10 min	17.32	2.14	16.96	1.97	17.52	2.10	>0.005
20 min	16.44	1.69	16.80	1.35	16.48	2.04	>0.005
30 min	16.84	1.65	16.96	1.55	16.96	1.88	>0.005
1 hour	16.56	1.66	16.52	1.48	16.56	2.18	>0.005
4 hours	16.16	1.40	16.36	1.38	16.20	1.35	>0.005
6 hours	16.48	1.71	16.72	1.49	16.64	1.96	>0.005
Visual Analogue Scale Scores							
0 min	2.22	0.68	1.96	0.85	1.90	0.74	>0.005
15 min	0.28	0.46	0.68	0.56	0.52	0.51	>0.005
30 min	0.20	0.41	0.24	0.44	0.52	0.51	>0.005
1 hour	0.20	0.41	0.20	0.41	0.52	0.51	>0.005
4 hours	1.68	0.45	2.04	2.17	2.10	0.74	>0.005
6 hours	2.80	0.43	2.04	0.79	2.54	0.58	>0.005
Sedation Level (Ramsay Scores)							
0 min	1.80	0.58	2.20	0.58	1.76	0.60	>0.005
15 min	2.76	0.44	2.52	0.51	2.56	0.51	>0.005
30 min	2.76	0.44	2.68	0.48	2.60	0.50	>0.005
1 hour	2.32	0.48	2.80	0.41	2.28	0.46	>0.005
4 hours	2.00	0.00	2.00	0.00	2.00	0.00	>0.005
6 hours	1.88	0.44	2.04	0.20	1.96	0.45	>0.005

Side effects observed in this study, were almost similar in all the three groups [Table-4].

Table 4: Side Effects of drugs observed in study subjects allocated in different groups.

Side Effects	Group R	Group D	Group C
Nausea-Vomiting	1	1	2
Bradycardia	-	-	-
Hypotension	2	1	-
Sedation	-	-	-
Itching	-	-	-
Respiratory depression	-	-	-
Dry mouth	1	-	2
Shivering	**1**	-	**1**

DISCUSSION

Ropivacaine is well approved for intrathecal route but its potency is considered lower than Bupivacaine and onset of block is slower. Since hemodynamic parameters are well maintained after Ropivacaine intrathecal injection and it is quite safer than the older drugs, it is been studied with interest worldwide. Clonidine is a partial α2 adrenoreceptor agonist used intrathecally along with local anaesthetics, prolongs the duration of both motor and sensory spinal blocked.[6]

Studies using a combination of intrathecal dexmedetomidine and local anaesthetics are lacking. The intrathecal dose and safety of dexmedetomidine was based on previous animal study.[12,13,14,15]

Al-Ghanem et al[16] concluded that 5 mcg Dexmedetomidine is a good adjuvant to spinal Bupivacaine, to produce prolonged block and excellent quality analgesia with minimal side effects. De Kock et al[17] concluded that small doses of Clonidine (15 & 45 mcg) given intrathecally significantly improve the quality

of spinal anaesthesia. From these studies, we concluded that 3 mcg Dexmedetomidine and 30 mcg of Clonidine would be safe and appropriate for this study.

The mean onset of sensory block was significantly shorter in group D (112±34.2 sec) and group C (369±38.3 sec) than in group R (726±32.06 sec), P<0.001. These values also significantly differ between group D and group C, P<0.001. Onset was shorter in group D than group C. Highest level of sensory block achieved was up to T 10 in group R, T8 in group D while up to T 7 in group C patients. Present study concurs with the study by Gonul Sagiroglu et al,[18] who observed highest sensory block up to T 7 for those patients receiving 30 mcg Clonidine plus ropivacaine. The mean onset of Motor block was significantly shorter in group D (163±54.62 sec) and group C (448±46.6 sec) than in group R (763±137 sec).Values also significantly differ between group D and group C, P value <0.001, onset shorter in group D than group C. Onset of sensory block at T10 level & Motor block was rapid in group D & C than group R And even rapid in group D than group C. The sensory block lasted significantly longer in group D & C averaging 252 ± 26.9 & 183± 30 min respectively as compared to 117± 23.8 min in group R (p< 0.001).

The motor block lasted significantly longer in group D (220 ± 35.4 min) & group C (175.4 ± 30 min) as compared to group R (110± 23.8 min) (P < 0.001). In all three groups Bromage III motor block could be achieved:

Duration of motor block and sensory block was longest in group D, then in group C, shortest in group R.

No patient needed additional analgesic or sedative in any group.

The result of current study is comparable with different studies who added either 30mcg of clonidine or 5 mcg of dexmeditomidine with Ropivacaine Gonul Sagiroglu et al [18] Rajni Gupta et al [19] Dan Benhamou et al.[20] In almost all the studies conducted by different authors, the mean duration of sensory and motor block has been longer with Clonidine or Dexmedetomidine added to Ropivacaine.

HR, BP, and RR were monitored up to 6 hrs after injection of drugs. The pre operative parameters were comparable in all the three groups. There was no significant difference in pulse rate in all three groups in this study. Intrathecal Dexmedetomidine or Clonidine did not cause any significant alteration in pulse rate as compared to Ropivacaine alone. The reason may be, we had used small doses of intrathecal dexmedetomidine (3 µg) in our study which was supported by Al-Ghanem et al.[16]

Both systolic and diastolic blood pressures were monitored in this study. There was no significant difference in findings in all the three groups. BP was well maintained in all the three groups throughout surgeries and postoperatively.

No significant difference was seen in any of the groups and no respiratory depression was seen in any patient in the current study. No patient in any group was deeply sedated. Addition of Dexmedetomidine or Clonidine via intrathecal route does not seem to alter consciousness of the patient. Intrathecally administered α-2-agonist have a dose-dependent sedative effect. (D' Angelo R et al).[21]

The dose of Clonidine & Dexmedetomidine selected in our study was at the lower end of the dosing spectrum which explains the lack of sedation in group D & C. No significant side effect like nausea, vomiting, sedation, respiratory depression, itching, shivering etc. were seen in any group in the current study.

CONCLUSION

In conclusion our study shows that intrathecal Dexmedetomidine or Clonidine given along with isobaric Ropivacaine produces rapid and prolonged sensory and motor block as compared to plain Ropivacaine. With dexmedetomidine sensory and motor block was more rapid and prolonged than clonidine. Both dexmedetomidine 3mcg or Clonidine 30mcg did not produces any significant hemodynamic instability or sedation. The findings of the present study will be useful for anaesthesiologist to choose appropriate combination of drugs during the procedure for effective outcome.

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