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Comparison Of Ropivacaine Hydrochloride With Two Doses Of Clonidine Hydrochloride Under Spinal Anaesthesia In Anorectal Surgeries

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ABSTRACT

Background: Addition of clonidine to ropivacaine intrathecally has been found to improve quality and duration of sensory and motor blockade alongwith improvement in postoperative analgesia. In our study we compared ropivacaine alone and in combination with different doses of clonidine.

Material and Methods: The randomised doubleblind study was conducted on 90 patients aged 20-65years withASA grade I-III posted for elective anorectal surgeries of duration less than 90 minutes under spinal anaesthesia.Patients were randomly divided into three groupsof 30 each. Group I received (18.75 mg)plain ropivacaine. Group II received 18.75 mg ropivacaine and 50 µg clonidine and Group III received 18.75 mg ropivacaine and 75 µg clonidine. Onset and duration of sensory and motor blockade, haemodynamic changes, postoperative analgesia, sedation score and side effects were compared between the groups.

Results: The time of request of first analgesia was longest in group III(611.33 minutes) which was significantly greater than group II (426.96 minutes) and group I (220 minutes).The difference in the sedation score between group I and group II was statistically non-significant and difference between group I and III and group II and III was highly significant. There was no incidence of delayed micturition in group I, 4(13,33%) in group II and 6(20%) in group III

ConclusionAddition of both 50 and 75µg of clonidine to ropivacine significantly prolonged duration of analgesia with lesser number of rescue analgesia and reduced VAS score but there were more incidence of sedation, hypotension and delayed micturition with 75 µg of clonidine.

Keywords: spinal anaesthesia, ropivacaine, clonidine

INTRODUCTION: Perioperative pain causes several adverse effects like decreased pulmonary compliance, inability to cough, tachycardia and increased cardiac work due to sympathetic stimulation, risk of deep vein thrombosis due to immobility of the limb, nausea, vomiting and greater endocrine metabolic stress response to surgery resulting in a catabolic state.[1,2]

Various surgeries are associated with different grades of pain. The prevalence of anorectal diseases is 4-5% of general population. Haemorrhoids, which are one of the commonest afflictions of mankind from time immemorial, is estimated to affect 40% of the entire population and is the most common anorectal disease.[3]

Out of the various options available for the treatment of haemorrhoids, haemorrhoidectomy is considered one of the best as it treats the disease and recurrence rate is also very low with it. A scalpel is used during surgery to cut out the haemorrhoids which is relatively painful and recovery is even

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more painful than the haemorrhoids themselves, 2-3 weeks are taken before returning to normal activity. Therefore post operative pain relief is one of the major concerns in haemorrhoidectomy .[4]

Ropivacaine is the recent longacting local anaesthetic of amide group which was first introduced to decrease the cardiotoxicity and neurotoxicity produced by bupivacaine. [5,6]In an attempt to further minimise the adverse effects of local anaesthetics and prolong the duration of post operative analgesia, various adjuvants like vasoconstrictors, analgesics, opioids, α2 agonists etc have been used.[7]Intrathecal clonidine has been extensively evaluated as an alternative to neuraxial opioids for control of pain and has proven to be a potent analgesic, free of at least some of the opioid related side effects.[8.9,10]

As haemmorhoids is a very painful condition and requires excellent post operative analgesia, we were in need of a dose that fulfilled the criteria of providing adequate sensory anaesthesia in the intraoperative period with longer lasting post operative pain relief but not at the expense of early ambulation. Keeping this in mind, we did this study to compare the effects of adding two different doses of clonidine i.e 50 and 75 µg to 18.75 mg of 0.75 % ropivacaine hydrochloride with respect to onset and duration of sensory and motor block, postoperative pain, haemodynamic parameters and side effects and complications in spinal anaesthesia foranorectal surgeries.

MATERIAL AND METHODS: After approval of the protocol from the institutional ethics committee, this randomised doubleblind study included 90 patients in the age group of 20-65 years of either sex of American Society of Anaesthesiologists (ASA) grade I, II and III scheduled for elective anorectal surgeries of duration less than 90 minutes under spinal anaesthesia after obtaining written informed consent.

Patients were randomly divided into three groups of 30 each. In Group I, 30 patients received 2.5cc of 0.75% isobaric ropivacaine, in Group II: 30 patients received 2.5cc of 0.75% isobaric ropivacaine and 50 µg of clonidine and in Group III: 30 patients received 2.5cc of 0.75% isobaric ropivacaine and 75 µg of clonidine. Appropriate dilution with normal saline was made to make the total volume of 3 cc. The patient having the following conditions were excluded from the study: Patient's refusal, neurological disorders, coagulation disorders, allergy to study drug, life threatening disease, any signs of sepsis, previous injury, deformity or previous surgery of spine.

All the patients were given; Tab.Alprazolam 0.25 mg a night before surgery, Inj. Glycopyrrolate 0.2 mg intramuscular route 45 minutes before operation. Intravenous line was secured with 18 G intracath and the patients were preloaded with 10 ml/kg body weight of ringer lactate solution over 15-20 minutes. Multiparameter monitor will be attached and baseline heart rate, respiratory rate, non - invasive blood pressure (NIBP), oxygen saturation and electrocardiography were recorded. Inj. Midazolam 0.04 mg/kg body weight was given just before the procedure in all the groups. The patients were placed in the lateral decubitus position. L3-4 intervertebral space or L4-L5 intervertebral space was located. Skin wheal was raised by 26 gauze needle with 2% xylocaine. Spinal needle No. 25, Quincke was introduced into subarachnoid space using a midline approach. After aspiration of CSF, the patient was given one of the study drugs intrathecally according to the random number chart. Study drug was prepared by another investigator to facilitate double blinding. After administering the drug, spinal needle was taken out and the patients were made supine immediately and were given 5L/ min of O2 via a face mask. The anaesthesiologists performing the technique recorded the intra operative data and followed the patient postoperatively until discharged from post anaesthesia care unit.

Continuous multiparameter monitoring of was done for hemodynamic response. Readings were recorded preoperatively, then intra operatively every 2 minutes for the first 10 minutes, thereafter every 5 minutes till 30 minutes and then every 15 minutes till the end of surgery in all the three groups. Bradycardia (defined as heart rate less than 60 beats per minute) was treated by Injection Atropine sulphate as required. Hypotension (defined as decrease in systolic blood pressure by more than 20% of the base value) was treated by additional Ringer lactate and if systolic blood pressure falls by more than 30%, injection ephedrine was used as per required.

In all groups I, II and III sensory and motor(using modified bromage scale) blockade was checked every 2 minutes for first 10 minutes, then every 5 minutes till 30 minutes by pinprick method using 27G needle and then every 15 minutes till the end of surgery. Thereafter, post operatively

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sensory blockade was checked every half an hour for the next three hours, every hourly for the next nine hours and then every three hour till 24 hours.

Supplementation of following drugs were noted during surgery: Analgesics, sedatives, antiemetic, vasopressors or any other drug. Following side effects and complications were note: Hypotension, bradycardia, headache, nausea, vomiting local anaesthetic toxicity, total spinal, urinary retention, neurological changes, backache. Other complications, if any. The time to first rescue analgesia was noted which was given if the VAS>3. Drugs preferred were NSAIDS (Inj. Diclofenac). Second line of drug were opioids (Inj Tramadol hydrochloride). The data from the present study was systematically collected, compiled and statistically analysed using ANOVA and post hoc power analysis.

RESULTS: All patients in group I, II and III were comparable w.r.t age, sex, weight, ASA grading, duration of surgery and baseline haemodynamics as shown in table I.

The mean onset of sensory block to T12 was 3.67±1.44 minutes in group I, 3.30 minutes in group II and 3.43 ±1.38 minutes in group III. The median maximum sensory level reached in group I was T8 whereas the median maximum sensory level reached in group II and III was T7. The time taken for maximum sensory level of T8 in group I was 10.13±3.267 minutes. The time taken to achieve a maximum sensory block in group II and group III was 8.17±2.506 minutes and 7.70±2.120 minutes respectively which is statistically insignificant as shown in table 2.

The mean time for regression to S2 in group I was 221.72±28.103 minutes, in group II was 266.17±27.627 minutes and group III was 332.33±30.898 minutes which was highly significant among all the three groups as shown in table 2.

The maximum motor block achieved in all the three groups was bromage grade 3 which was comparable and statistically insignificant. The time taken to achieve maximum motor block of bromage 3 in group I, II and III was 12.40±3.68, 10.93±4.18 and 9.63±4.48 minutes respectively. The results were comparable among the three groups and was found to be statistically insignificant. The mean duration of motor block in group I, II and III was 187, 202 and 256 minutes respectively. The duration of motor block was greater in high dose clonidine group (group III) than group II and group I and was statistically significant among all the three groups as shown in table 2.

In group I, II sedation score in intraoperative period remained 2. In group III sedation score intraoperatively. up to 20 minutes remained 2 and then it started increasing at 30 minutes from 2.00 to 2.45±0.50 up to 60 minutes The difference in the sedation score between group I and group II was statistically non significant(p value> 0.05) and difference between group I and III and group II and III was highly significant(p value<0.001) as shown in table3.

Post operative VAS scores at different time intervals were significantly lower in groupIIIas compared to group II and group I indicating superior analgesia. The time of request of first analgesia was longest in group III which was 611.33 minutes which was significantly greater than group II 426.96 minutes and group I 220 minutes. A dose dependent reduction in rescue analgesia requirements was noted in our study as shown in table 4.

Three patients (10%) in group III and only one patient (3.33%) in group II developed bradycardia which was corrected by inj. Atropine andiv fluids. The fall in systolic pressure was easily corrected by i.v fluids with only one patient in group III requiring inj. Ephedrine 10 mg. Relative fall in diastolic blood pressure was observed in group III which was again easily corrected by i.v fluids and inj. Ephedrine.

There was no incidence of delayed micturition in group I. The incidence of delayed micturition was four (13.3%) in group II and six(20%) in group III as shown in table 5. Two (6.67%) patients in group III had urinary retention till 24 hours and required urinary cathetrisation.

TABLE 1: Demographic Parameters

	Group	Group	Group	Group I vs	Group I vs	Group II vs

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	I(n= 30)	II(n=30)	III(n=30)	II pvalue with significance	III pvalue with significance	III pvalue with significance
Age(years) Mean±SD	42.76±13.96	41.67±13.72	40.13±13.31	0.94(NS)	0.77(NS)	0.90(NS)
Weight(kg) Mean±SD	67.40±9.40	68.36±5.13	67.83±7.67	0.8(NS)	0.9(NS)	0.7(NS)
SEX Male Female Total	 23(76.67%) 7 (23.33%) 30 (100%)	 22(73.33%) 8(26.67%) 30	 23(76.67%) 7 (23.33%) 30 (100%)	0.76 (NS)	1.00(NS)	0.76(NS)
Duration of surgery(minutes)	47.67±7.95	50.67± 10.96	50.33±10.08	0.46(NS)	0.54(NS)	0.99(NS)

S-significant(p <0.05),NS-non significant(p> 0.05), HS-highly significant(p<0.001)

TABLE 2: Spinal Efficacy Parameters

	Group I (n= 30)	Group II (n= 30)	GroupIII (n= 30)	P value Gp I vs Gp II	p value GpI vs III	P value Gp II vs III
Onset of sensory block to T12(min)	3.67±1.44	3.30±120	3.43±1.38	0.54(NS)	0.78(NS)	0.92(NS)
Max sensory level	T8	T7	T7	0.54(NS)	0.54 (NS)	1.00(NS)
Time to max sensory level(min)	9.03±2.38	8.17± 2.50	7.70±2.12	0.32(NS)	0.07(NS)	0.72(NS)
Time to regression to S2(min)	221.72±28.10	266.17±27.62	332.33±30.89	0.000(HS)	0.000(HS)	0.000(HS)
Max motor block(Bromage Score)	3	3	3	>0.05(NS)	>0.05(NS)	>0.05(NS)
Time to complete motor blockade(min)	11.40±4.67	10.93±4.03	9.63±2.25	0.68(NS)	0.18(NS)	0.38(NS)
Total duration of motor blockade(min)	187.00±29.26	202.83±33.00	256.17±26.48	0.10(NS)	0.000HS)	0.000(HS)

S-significant(p <0.05),NS-non significant(p> 0.05), HS-highly significant(p<0.001)

TABLE 3: Sedation Score

Time	Group I (n= 30)	GroupII (n= 30)	GroupIII (n= 30)	Gp I vs II p value with significance	Gp value with significance p I vs III	Gp II vs IIIp value with significance
0 min	2.00±0.00	2.00±0.00	2.00±0.00	1.00(NS)	1.00(NS)	1.00(NS)
10 min	2.00±0.00	2.00±0.00	2.00±0.00	1.00(NS)	1.00(NS)	1.00(NS)
20 min	2.00±0.00	2.00±0.00	2.00±0.00	1.00(NS)	1.00(NS)	1.00(NS)
30 min	2.00±0.00	2.00±0.00	2.45±0.50	1.00(NS)	0.001(HS)	0.001(HS)
60 min	2.00±0.00	2.00±0.00	2.45±0.50	1.00(NS)	0.001(HS)	0.001(HS)

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120 min	1.86±0.22	2.00±0.00	2.45±0.22	0.16(NS)	0.001(HS)	0.001(HS)
4 hr	1.30±0.10	1.54±0.10	2.45±0.10	0.12(NS)	0.001(HS)	0.001(HS)
6-10 hr	1.20±0.24	1.50±0.20	1.50±0.10	0.08(NS)	0.08(NS)	0.99(NS)

S-significant(p <0.05),NS-non significant(p> 0.05), HS-highly significant(p<0.001)

TABLE 4: Rescue Analgesia

	Group I (n= 30)	Group II (n= 30)	Group III (n= 30)	P value
Time of request for rescue analgesia(min)	290.66±41.76	449.00±60.81	549.33±44.92	0.06(NS)
No of injections/24 hours	3.4±0.49	2.9±0.40	2.06±0.24	0.06(NS)

S-significant (p <0.05),NS-non significant(p> 0.05), HS-highly significant(p<0.001)

TABLE 5: Side Effects And Complications

	Group I	Group II	Group III	Gp I vs II p value with significance	Gp I vs III p value with significance	Gp II vs III p value with significance
Hypotension	4(13%)	8(26%)	10(33%)	0.31(NS)	0.03(S)	0.26(NS)
Bradycardia	0	1(3.33%)	3(10%)	0.31(NS)	0.76(NS)	0.30(NS)
Nausea	0	1(3.33%)	3(10%)	0.31(NS)	0.76(NS)	0.30(NS)
Vomiting	0	0	0	-	-	-
Total spinal	0	0	0	-	-	-
Urinary retention	0	4 (6.67%)	6(20%)	• 0.038(S)	0.02(S)	0.48(NS)

S-significant(p <0.05),NS-non significant(p> 0.05), HS-highly significant

TABLE 6: Showing Percentage Fall In Systolic Blood Pressure Among Three Groups At Various Time Intervals In The Intraoperative Period

Time Interval	Group – I (n=30)	Group – II (n=30)	Group- III (n=30)	P valueGp I vs II	P value Gp I vs III	P value Gp II vs III
2 minutes	2.88±1.52	2.71±1.34	2.78±1.70	0.67(NS)	0.939(NS)	0.92(NS)
4 minutes	4.37±1.92	5.97±1.77	5.99±3.06	0.20(NS)	0.30(NS)	0.90(NS)
6 minutes	5.77±3.86	8.34±2.78	8.40±3.23	0.13(NS)	0.21(NS)	0.90(NS)
8 minutes	6.97±4.01	9.93±3.09	9.65±3.40	0.07(NS)	0.84(NS)	0.97(NS)
10 minutes	7.23±6.82	9.36±4.12	9.62±4.69	0.14(NS)	0.83(NS)	0.62(NS)
15 minutes	7.61±7.26	10.85±5.88	11.40±8.27	0.03(S)	0.02(S)	0.99(NS)
20 minutes	5.77±6.71	11.40±8.27	15.22±7.84	0.04(S)	0.02(S)	0.04(S)
25 minutes	5.98±6.71	8.72±6.35	10.17±6.82	0.03(S)	0.08(NS)	0.73(NS)
30 minutes	4.66±6.80	7.97±5.30	6.61±6.75	0.09(NS)	0.90(NS)	0.99(NS)

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45 minutes	3.48±6.38	5.69±5.60	5.12±6.03	0.37(NS)	0.939(NS)	0.932(NS)
60 minutes	5.42±7.19	5.32±5.40	4.92±6.94	0.32(NS)	0.40(NS)	0.13(NS)

S-significant($p < 0.05$),NS-non significant($p > 0.05$), HS-highly significant

DISCUSSION: Optimal pain relief following surgery cannot be achieved by a single drug or method. Multimodal or balanced analgesia is defined as use of two or more analgesic drugs or techniques in combination. The rationale of balanced analgesic approach is achievement of sufficient analgesia due to additive or synergestic effects between different analgesics with concomitant reduction of side effects. [11]

Malinovsky et al found that intrathecal clonidine alone could not provide surgical anaesthesia in humans. Large doses of clonidine (upto 450µg) provided sedation and longlasting analgesia but not surgical anaesthesia.[12]For this reason, clonidine has been used as an adjuvant to local anesthetics, rather than alone.

In our study, we used clonidine as an adjuvant to ropivacaine with an aim to prolong post operative pain relief and note the common complications of clonidine as hypotension, sedation and bradycardia. The fall in systolic blood pressure was less than 20% in 4(13%) patients in group I, 8(26%) patients in group II and 10(33%) patients in group III which was corrected by intravenous fluids. The fall in systolic blood pressure was >30% in two (6.67%0 patients in group III which was corrected by inj. Ephedrine hydrochloride 10 mg and intravenous fluids. In the study done by De kock et al on 120 patients undergoing knee arthroscopy, it was observed that mean arterial blood pressure was significantly lower ($P < 0.05$) in patients in groups 3 and 4(8 mg ropivacaine and 45 and 75 µg clonidine) as compared to group 1 and 2(8 mg ropivacaine alone and with 15µg clonidine). Relative hypotension was seen in group 4 with 75µg clonidine. [13]This is in accordance with our study where we observed significant fall in systolic blood pressure in group II and group III at 15, 20 and 25 minute interval.

The mean onset of sensory block to T12 dermatome was 3.67±1.44 minutes in group I, 3.30 ±1.20 minutes in group II and 3.43 ±1.38 minutes in group III. Similarly Chan-Jong Chung et al in their study where hyperbaric Ropivacaine 18 mg was used had a sensory onset to T10 dermatome at 3.2±1.2 minutes.[14]This is nearly in accordance with our study in group I.

The median maximum sensory level reached in group I was T8 and the median maximum sensory level reached in group II and III was T7. In another study by De Kock et al where 8 mg of ropivacaine was added to 45 µg and 75 µg clonidine in patients undergoing ambulatory knee surgery, peak dermatome reached in both groups was T8 and T6 respectively which is nearly in accordance with our study. [13]

The mean time for regression to S2 in group I was 221.72±28.103 minutes, in group II was 266.17±27.627 minutes and group III was 332.33±30.898 minutes which was highly significant among the three groups and it was prolonged in group III as compared to group I and group II.

McNamee DA et al in his study on hundred and four patients undergoing total hip arthroplasty under spinal anaesthesia, found that time for regression to T10 dermatome was 3 hrs with Ropivacaine 18.75 mg, this is nearly consistent with our study group I.[15]

In a study done by De Kock et al, it was observed that sensory block was prolonged by 1.38 times on addition of 45µg clonidine to 8 mg of ropivacaine. De Kock et al concluded that duration of prolongation of sensory blockade by clonidine is dose dependent. [13]

The mean duration of motor block in group I, II and III was 187±29.26 minutes, 202±33.00 minutes and 256±26.48 minutes respectively. The duration of motor block was greater in high dose clonidine group (group III) than group II and group I and was statistically significant amongall the three groups. These findings are in accordance with those of Bonnet et al who also demostrated a dose dependant prolongation of motor block using 75 and 100 µg clonidine with hyperbaric tetracaine.[16] Significant prolongation of motor block with the addition of clonidine was also demonstrated by kulkarni et al.[17]

Post operative VAS scores at different time intervals were significantly lower in group III as compared to group II and group I indicating superior analgesia. The time of request of first analgesia was longest in group III which was 594.33±44.92 minutes which was significantly greater than group II in which it was 449.00±60.81 minutes and in group I in which it was 290.66±41.76 minutes. A dose dependent

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reduction in rescue analgesia requirements was noted in our study. It was highly significant among the three groups.

Number of injections of rescue analgesia in the three groups was 3.4±0.49 in group I, 2.9±0.40 in group II and 2.06±0.24 in group III. It was highly significant when group I was compared with group II and III.

Our results are in accordance with the study conducted by Filos et al who evaluated the dose dependent haemodynamic and analgesic profile of intrathecal clonidine by administering 150,300 and 450 µg clonidine and reported a significantly prolonged duration of analgesia with the higher doses.[18]They also noticed a dose dependent reduction of post operative pain scores.

In a study done by Kulkarni et al, it was concluded that addition of 45µg clonidine to 10 mg of ropivacaine in lower limb orthopaedic surgeries caused prolongation of time of request of first post operative analgesic in hours which was 3.92±0.66 hours and 1.84±1.30 hours in ropivacaine and ropivacaine- clonidine group respectively.[17]

In another study by Strebel et al conducted in eighty patients undergoing orthopaedic surgery under spinal anaesthesia with 18 mg bupivacaine with three doses of clonidine (37.5µg, 75µg and 150µg), it was observed that VAS scores were significantly reduced in clonidine groups with prolongation of time interval to first request for supplemental analgesia: 295±80 minute(bupivacaine alone), 343±75 minutes (bupivacaine with 37.5µg clonidine), 381±117 minutes (bupivacaine with 75µg clonidine) and 445±136 minutes (bupivacaine with 150µg clonidine). All these studies are in accordance with our study which also showed prolongation of time of request for supplemental analgesia and reduction of VAS scores with clonidine.[19]

Sedation score was comparable in all the three groups till 30 minutes intraoperatively but after that significant sedation was observed in group III as compared to group I and group II. In the post operative period also, sedation was seen in group III patients till 3 hours after surgery. The patients were easily arousable on verbal commands. Thereafter, patients were alert and cooperative in the post operative period.

De kock et al also concluded in its study that the dose of 75 µg clonidine when added to 8 mg of ropivacaine hydrochloride was associated with significant sedation. This is in accordance with our study group III.[13]

There was no incidence of delayed micturition in group I. The incidence of delayed micturitionwas 2 (6.67%) patients in group II and 6(20%) patients in group III. 2(6.67%) patients in group IIIhad urinary retention till 24 hours in the post operative period and required urinary catheterization in our study

Hence in our study we found that 18.75 mg of isobaric 0.75% ropivacaine alone and with addition of 50µg and 75µg clonidine provided effective surgical anaesthesia in intraoperative period. 50µg and 75µg clonidine when added to 18.75 mg ropivacaine hydrochloride solution significantly prolonged duration of analgesia with lesser number of rescue analgesia and reduced VAS score. But more patient with 75 µgclonidine added to ropivacainehave delayed micturition. Also more sedation and hypotension incidence occurred with 75µg clonidine as compared to plain ropivacaine alone and also as compared to 50µgclonidine when added to ropivacaine.

CONCLUSION: Addition of both 50 and 75µg of clonidine to ropivacine significantly prolonged duration of analgesia with lesser number of rescue analgesia and reduced VAS scorebut there were more incidence of sedation ,hypotension and delayed micturition with 75 µg of clonidine.

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