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Original Research Article

To Compare the Effect of Dexmedetomidine, Clonidine and Fentanyl in Epidural Anaesthesia in Lower Limb Orthopaedic Surgeries When Given as an Adjuvant to 0.75% Ropivacaine.

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Abstract

Background & Methods: The aim of the study is to compare the effect of, Dexmedetomidine, Clonidine and Fentanyl in epidural anaesthesia in lower limb orthopaedic surgeries when given as an adjuvant to 0.75% Ropivacaine. 90 patients of ASA class I and II, aged between 20-60 years, of either sex (M & F), scheduled for elective lower limb orthopaedic surgeries were included in this study.

Results: Time of onset of sensory block was minimum in Dexmedetomidine group i.e. 8.24±0.38 minutes followed by fentanyl group (8.52±0.27 minutes) and clonidine group (9.45±0.18 minutes) with statistically highly significant difference in onset of sensory blockade amongst three groups ($p<0.0001$). Time of onset of motor blockade in present study was minimum (12.25±0.77 minutes) in group A followed by Group B and Group C i.e. (14.09±0.78 and 16.23±0.35 minutes) respectively and the difference was statistically highly significant ($p<0.001$). Intergroup analysis of difference of onset of motor block was observed to be highly significant between group A& B, Group A & C as well as Group B & C ($p<0.001$).

Conclusion: We conclude that the addition of 1.5mcg/kg Dexmedetomidine as an adjuvant to 0.75% Ropivacaine (P) for epidural block in lower limb orthopaedic surgeries, causes an early onset and prolonged duration of motor blockade and analgesia in comparison to 2mcg/kg Clonidine and 1mcg/kg Fentanyl as adjuvants.

Keywords: Dexmedetomidine, Clonidine, Fentanyl, anaesthesia & orthopaedic.
Study Design: Comparative Study.

1. Introduction

Intrathecal anaesthesia and epidural anaesthesia are the most popular regional anaesthesia techniques used for lower limb surgeries[1].

The advantages of epidural anaesthesia[2] includes effective surgical anaesthesia and fulfilment of extended duration of surgical needs, provides prolonged post-operative analgesia to the patient, reduces the incidence of hemodynamic changes and decreases the requirement of opioid analgesics.

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Ropivacaine[3] is a new amide local anaesthetic. It has been shown to have an increased therapeutic index in human volunteer studies. In several studies it was concluded that ropivacaine was less cardiac depressant[4,5], less arrhythmogenic and less neurotoxic than bupivacaine[6.]

Dexmedetomidine[7] is a relatively selective alpha2-adrenergic agonist which decreases sympathetic tone and also attenuates the stress response to anaesthesia and surgery, along with sedation and analgesia. Most of the patients receiving dexmedetomidine were effectively sedated but easily arousable which is a unique feature of dexmedetomidine, not observed with other sedatives.

Clonidine, an alpha 2 adrenoceptor agonist has antihypertensive properties, which when administered epidurally has good analgesic action that is mediated via alpha 2 adreno receptors in dorsal horn cell of spinal cord[8].

Fentanyl[9] a commonly known opioid, has been used traditionally as an adjunct to local anaesthetic for epidural administration to achieve the desired anaesthetic effect. It provides a dose sparing effect of local anaesthetic and high grade analgesia but there is a possibility of an increased incidence of side effects like pruritus, urinary retention, nausea, vomiting and respiratory depression. Also, the incidence of motor block after epidural analgesia with amide local anaesthetics (LA) and opioids is approximately 4-12% which itself defeats the novel purpose of early rehabilitation.

2. Material and Methods

The present study was carried out in the Department of Anaesthesiology, Gandhi Medical College & associated Hamidia hospital Bhopal, during period from January 2018 to July 2019.

90 patients of ASA class I and II, aged between 20-60 years, of either sex (M & F), scheduled for elective lower limb orthopaedic surgeries were included in this study. All the patients were subjected to detailed pre-anaesthetic evaluation with clinical history, thorough physical and systemic examination, routine investigation which include complete blood count, urine (routine and microscopy), blood sugar, renal function test, serum electrolytes, X-ray chest PA view, ECG and any special investigation if required was done for the study. An informed written consent was taken from all the patients after explaining every patient in detail regarding nature and purpose of the study and for the possible risks and complications.

Group A	Ropivacaine 0.75% (17ml)	1.5mcg/kg Dexmedetomidine
Group B	Ropivacaine 0.75% (17ml)	2mcg/kg Clonidine
Group C	Ropivacaine 0.75% (17ml)	1mcg/kg Fentanyl

Inclusion Criteria-

1. After obtaining approval from institutional ethics committee and informed written consent from patients. 90 patients of either sex of ASA Grade I and II, age ranging from 20 to 60 years scheduled for lower limb orthopaedic surgeries under epidural block were enrolled in this study.

Exclusion Criteria-

1. Patient refusal.
2. ASA grade III and IV.
3. Patients on alpha-2 antagonist treatment.
4. Patients with infection at the site of injection.

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5. Patients with coagulopathy.
   90 patients were divided into 3 equal groups of 30 patients each.

3. Result

Table 1- DEMOGRAPHIC PROFILE OF PATIENTS IN THREE DIFFERENT GROUPS

Demographic Variables	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Age (years)	47.2	7.78	47.13	7.52	46.97	7.93	0.99
Height (cm)	158.23	11.15	159.23	10.76	160.17	10.85	0.79
Weight (kg)	59.2	10.41	59.27	10.5	59.87	11.01	0.96

All the patients included were in the range of 21 to 60 years. Mean age of patients of group A, B and C was 47.2±7.78, 47.13±7.52and 46.97±7.92 respectively. Mean height and weight in group A was 158.23±11.15 cm and 59.2±10.41 kg; in group B, it was 159.23±10.76 cm and 59.27±10.5 kg respectively. Mean height in group C was 160.17±10.85 and mean weight was 59.87±11.01 kg. The three groups were comparable (using ANOVA test) in demographic variables ($p>0.05$).

Table 2- DISTRIBUTION OF PATIENTS IN THREE DIFFERENT GROUPS ACCORDING TO ASA GRADE

ASA Grade	Group A (RD)		Group B (RC)		Group C (RF)		P value
	n	%	n	%	N	%	
I	16	53.3	16	53.3	15	50	0.96
II	14	46.7	14	46.7	15	50	
Total	30	100	30	100	30	100	

Above table represents distribution of patients according to ASA grade. In present study, 53.3%, 53.3% and 50% patients belonged to grade I in group A, B and C respectively. The distribution according to ASA grade was comparable (chi square test) between three groups ($p=0.96$).

Table 3- COMPARISION OF ONSET OF SENSORY BLOCKADE (MIN.) IN THREE DIFFERENT GROUPS.

Parameters	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Onset Of sensory blockade (min)	8.24	0.38	9.45	0.18	8.52	0.27	0.0001

Time of onset of sensory block was minimum in Group A i.e. 8.24±0.38 minutes followed by Group C (8.52±0.27 minutes) and Group B (9.45±0.18 minutes). Test of significance (ANOVA) identified statistically highly significant difference in onset of sensory blockade amongst three groups ($p<0.0001$)

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Table 4- COMPARISION OF ONSET OF MOTOR BLOCKADE (MIN.) IN THREE DIFFERENT GROUPS

Parameters	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Onset of Motor blockade (min)	12.25	0.77	14.09	0.78	16.23	0.35	0.001

Time of onset of motor blockade was 12.25±0.77 minutes in group A which was minimum followed by Group B and Group C i.e. 14.09 ±0.78 and 16.23±0.35 minutes respectively. Test of significance identified statistically significant difference in onset of motor blockade duration amongst three groups ($p<0.001$).

Table 5- COMPARISION OF DURATION OF MOTOR BLOCK (MIN) IN THREE GROUPS

Parameters	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Duration of Motor blockade (min)	373.33	45.21	340.67	19.64	310.83	21.14	0.001

Duration of motor block was maximum in group A 373.33±45.21 minutes, 340±19.64 in group B and minimum in Group C 310.83±21.14 minutes. Test of significance observed statistically significant difference in duration of motor block among three groups ($p<0.001$).

Table 6- COMPARISION OF DURATION OF ANALGESIA IN THREE GROUPS

Parameters	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Duration of analgesia (min)	461.17	120.35	365.0	43.92	222.33	16.12	0.001

Duration of analgesia was maximum in group A= 461.17±120.35 min followed by Group B= 365±43.92 min and Group C= 222.33±16.12 min respectively and the difference observed (using ANOVA) was statistically significant ($p<0.001$).

Table 7- COMPARISON OF REQUIREMENT OF FIRST RESCUE ANALGESIA IN THREE GROUPS

Parameters	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Duration of rescue analgesia requirement (min)	431.17	74.34	381.67	37.15	261.33	17.95	0.001

Duration of rescue analgesia requirement was maximum in group A (431.17±74.34 minutes) followed by Group B (381.67±37.15 minutes) and Group C (261.33±17.95 minutes) respectively and the difference observed was statistically significant ($p<0.001$). Rescue analgesia was provided with epidural supplementation with 8ml of 0.75% Ropivacaine over 5 minutes.

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Table 8- COMPARISON OF INCIDENCE OF SIDE EFFECTS IN THREE GROUPS

Side effects	Group A (RD)		Group B (RC)		Group C (RF)		P value
	n	%	n	%	N	%	
Nausea	5	16.7	9	30	14	46.7	0.04
Vomiting	4	13.3	7	23.3	13	43.3	0.03
Shivering	0	0	0	0	3	10	NA
Pruritis	0	0	0	0	6	20	NA
Bradycardia	6	20	15	50	8	14.6	0.03
Hypotension	4	13.3	13	43.3	6	20	0.02
Dry Mouth	1	3.3	3	10	2	6.7	0.58
Respiratory depression	0	0	0	0	0	0	NA
Urinary retention	3	10	4	13.3	4	13.3	0.21

Incidence of nausea (46.7%) and vomiting (43.3%) was maximum in Group C(n=9) whereas incidence of bradycardia (50%, n=15) and hypotension (43.3%, n=13) was maximum in Group B. Pruritis was significant in group C in 6 patients. Urinary retention was noted equally significant in all three groups(n=4). Test of significance identified statistically significant difference for the incidence of nausea, vomiting, bradycardia and hypotension among the participants of three groups ($p<0.05$).

TABLE 9- COMPARISON OF POST OPERATIVE PAIN IN THREE GROUPS AS PER VAS PAIN SCALE (0-10)

Median post op VAS score	Group A (RD)		Group B (RC)		Group C (RF)		P value
	Mean	SD	Mean	SD	Mean	SD	
Immediate	0.00	0.00	0.00	0.00	0.00	0.00	NA
1 hour	0.00	0.00	0.00	0.00	0.00	0.00	NA
2 hour	0.00	0.00	0.00	0.00	0.00	0.00	NA
3 hour	0.00	0.00	0.00	0.00	0.00	0.00	NA
4 hour	0.00	0.00	0.00	0.00	0.00	0.00	NA
5 hour	0.00	0.00	0.03	0.18	0.07	0.25	0.36
6 hour	0.27	0.45	0.78	1.58	0.93	0.17	0.15
7 hour	2.67	1.12	4.93	0.82	4.80	1.09	0.001
8 hour	5.10	1.37	6.47	1.31	7.13	1.51	0.004
9 hour	6.13	1.01	8.40	0.67	8.27	0.78	0.004
10 hour	6.87	0.97	9.20	0.71	9.23	0.43	0.003
11 hour	9.93	2.54	10.0	0.0	10.0	0.0	0.132
12 hour	10.0	0.0	10.0	0.0	10.0	0.0	1.0

Post-operative pain was calculated using VAS scale. Pain was not observed in any of the group till 4 hours following surgery (VAS=0). Patients in group B and group C complained of pain after 5th hour. Test of significance observed no statistical difference in pain till 6 hours ($p>0.05$) whereas from 7 hour onwards, a significant difference in VAS score>5 was observed between the three groups ($p<0.05$). Pain was observed earlier in group C followed by Group B and Group A.

4. Discussion

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In present study, time of onset of sensory block was minimum in Dexmedetomidine group i.e. 8.24±0.38 minutes followed by fentanyl group (8.52±0.27 minutes) and clonidine group (9.45±0.18 minutes) with statistically highly significant difference in onset of sensory blockade amongst three groups ($p<0.0001$). Intergroup analysis of onset of sensory blockade in present study was observed to be highly significant between group A& B, Group A &C as well as Group B & C ($p<0.001$).

Bajwa s et al (2011)[10] observed early onset of sensory anesthesia at T10 level in group RD was 8.52±2.36 min compared to group RC in which it was 9.72±3.44 min.

Kaur S et al (2014) observed that onset of sensory blockade to T10 dermatome was 14.18±6.02 min in R group and 12.53±4.17 min in Group RD.

Singh Rashpal et al (2015) noted time taken for onset of sensory block at T10 was earlier i.e. 8.62±1.32 min in Group RD and 11.94±1.07 min in Group RF, which related to our study.

Vashisht R et al (2016)[11] observed early onset of sensory block at T10 level in Group RD(9.22±0.86 min) as compared to RF which was (11.30±0.99 min).

Paul A et al (2015) in his study observed onset of sensory block was fastest in dexmedetomidine group as compared to fentanyl group.The findings of our study correlated with the findings of Kaur S et al(2014), George M et al(2014), Singh rashpal et al(2015), Agarwal S et al (2016).

Motor blockade was assessed using Modified Bromage scale. Score of 1 for motor block was observed in 53.3% patients in group A at 5 minutes, whereas in group B and C, score 1 was achieved in only 23.3% and 10% patients respectively. According to Modified Bromage grade, the difference in motor block was statistically significant at 5 minutes ($p=0.01$) and 10 minutes ($p=0.002$).Time of onset of motor blockade in present study was minimum (12.25±0.77 minutes) in group A followed by Group B and Group C i.e. 14.09±0.78 and 16.23±0.35 minutes respectively which was statistically highly significant ($p<0.001$). Intergroup analysis of difference of onset of motor block was observed to be highly significant between group A& B, Group A & C as well as Group B & C ($p<0.001$). It has been postulated that it is due to depression of the release of C-fiber transmitters and hyperpolarization of postsynaptic dorsal horn neurons.

El Attar et al (2015)[12] in their study also observed statistically faster motor onset in dexmedetomidine group as compared to the fentanyl group (F) and the bupivacaine group (B) ($P = 0.0001$).

Soni P et al(2012)[13] observed early onset of motor blockade of grade 1 in group RD i.e. 11.3±1.69 min as compared to 20.6±3.8 min in group ropivacaine with NS

Vasupalli Ret al(2016)[14] observed that the onset of motor blockade (bromage 3) in Group RD was 11.22±2.61mins as compared to 15.36±3.28 min in Group RF.

Mahendru V et al (2013) observed no statistical difference in onset of motor block among 4 groups ($p=0.08$).

Routray SS et al (2017) also observed no statistical difference in onset of motor block between fentanyl and clonidine group.

The onset of motor block was earlier in our study as the dose and concentration used was more in our study as compared to above studies.

Duration of motor block was maximum in group A(RD) 373.33±45.21 minutes followed by group B(RC) (340.67±19.64 minutes) whereas minimum in Group C(RF) 310.83±21.14 minutes ($p<0.001$). There was highly significant difference between group A& B, Group A & C as well as Group B & C ($p<0.001$).

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Our study concurs with the study conducted by J Bajwa SJ, Arora V, Kaur J et al who observed the mean duration of analgesia to be 366.62±24.42 mins in group RD compared to 242.16±23.86 mins within group RF which is highly significant.
Balgur S et al[15] (2015) observed total duration of motor block was significantly prolonged in Group RF(261.20±10.33 min) compared to Group R(229.30±13.79 min) and Group RC(240.0±10.4 min).
Vasupalli R et al[14] (2016) observed total duration of motor block was significantly prolonged in Group RD (233.70±15.36 min) compared to Group RF (149.0±21 min).The total duration of motor block for Group RD was shorter in Vasupalli R et al as the concentration of dexmedetomidine was less(0.6mcg/kg) as compared to 1.5 mcg/kg in our study.

5. Conclusion

We conclude that the addition of 1.5mcg/kg Dexmedetomidine as an adjuvant to 0.75% Ropivacaine (P) for epidural block in lower limb orthopaedic surgeries, causes an early onset and prolonged duration of motor blockade and analgesia in comparison to 2mcg/kg Clonidine and 1mcg/kg Fentanyl as adjuvants.

Epidural dexmedetomidine causes prolonged sedation as compared to Clonidine/Fentanyl with longer duration of post op analgesia and least hemodynamic changes and minimal side effects.

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