Original Research Paper

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COMPARATIVE STUDY OF EPIDURAL 0.75% ROPIVACAINE WITH DEXMEDETOMIDINE AND 0.75% ROPIVACAINE ALONE IN ORTHOPAEDIC PATIENTS UNDERGOING LOWER LIMB SURGERIES (A STUDY OF 60 CASES)

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ABSTRACT **Background And Aims:** The aim of the study is to evaluate the effect of addition of Dexmedetomidine (0.6 ug/kg) to ropivacaine (0.75%) (20cc) plain for epidural anaesthesia & intraoperative and postoperative analgesia for lower limb surgery.

Materials & Method:

After institutional research ethical committee approval & obtaining an informed written consent, 60 patients were included in a double blind controlled comparative clinical study for planned lower limb surgeries in our hospital. All patients were divided into two groups-group RD(n=30) and Group R(n=30)

- Group R [n=30] - 20 ml of 0.75% ropivacaine [0.75% Ropivacaine in 20 ml ampule]
- Group RD [n=30] - 20 ml of 0.75% ropivacaine with 0.6microgram/kg dexmedetomidine [inj. Dexmedetomidine 1ml=100 microgram,]

Inclusion Criteria

1. Patients scheduled for lower limb surgeries.
2. ASA Physical status I to III
3. Age group 18 to 65 years
4. Willing to participate in study

Exclusion Criteria

1. Patients' refusal
2. Uncooperative patients / Not able to understand pain assessment test
3. Patients with history of drug allergy
4. Drug addict / Patient on long term steroid therapy
5. Patient in grade IV
6. Age group <18 and >65 years
7. Pregnancy

All patients were thoroughly assessed day before surgery and screened for any associated medical illness like hypertension, diabetes mellitus, asthma, ischemic heart disease, chronic obstructive pulmonary disease, epilepsy, any liver or renal disorder, major disease in past, any eventful previous anaesthesia exposure or post-operative anaesthetic complications, drug allergy, family history etc. Routine investigations like haemoglobin, blood sugar, serum creatinine, blood urea, bleeding time, clotting time, and electrocardiogram were carried out and documented. Statistical analysis was done by unpaired 't' test. P value of <0.05 is considered statistically Significant. **Results:** Demographics were comparable. Following laryngoscopy and intubation, heart rate (HR) systolic (SBP), diastolic (DBP) and mean arterial pressure (MAP) were markedly increased in the control group whereas in group D there was a fall in Heart rate (P<0.001 at 0, 1 & 5 mins and P<0.05 at 10 min), SBP (P<0.001 at 0, 1, 5 & 10 mins interval), DBP (P<0.001 at 0, 1, 5 & 10 mins interval), MAP (P<0.001 at 0, 1, 5 & 10 mins interval). **Conclusion:** Epidural dexmedetomidine as adjuvant to ropivacaine produces synergistic effects with earlier onset time of sensory block, earlier achievement of complete sensory and motor blockade, prolonged sensory and motor blockade and good intraoperative sedation. Dexmedetomidine in a dose of 0.6 g/kg is a safe and effective adjuvant to ropivacaine in epidural blockade in lower limb surgeries.

KEYWORDS : Dexmedetomidine, Ropivacaine, Epidural

INTRODUCTION:

The regional anaesthetic techniques considerably reduce post operative pain and systemic analgesic requirements. Sufficient post operative pain relief must be fundamental part of administration of anaesthesia. Insufficient post operative pain relief may end up in clinical and psychological changes that may escalate the morbidity as well as the financial burden as a whole also affecting the quality of life post-operatively.[1]

Surgical Anaesthesia and perioperative Analgesia delivered through an indwelling epidural catheter is a safe and effective method for management of perioperative pain.[2] Increasing the duration of local anaesthetic action is often desirable because it prolongs analgesia. Different additives have been used to prolong regional blockade.

Epidural anaesthesia for lower limb surgery is a well-accepted technique for various advantages such as better intra and post operative pain management and greater patient satisfaction. [3]

Ropivacaine, a new amide local anaesthetic, has minimal cardiovascular and central nervous system toxicity as well as lesser propensity of motor block during postoperative epidural analgesia compared to bupivacaine.[4]

The addition of opioid as an adjuvant provides a dose sparing effect of local anaesthetic and superior analgesia [5]. Dexmedetomidine, a new alpha 2 agonist, has evolved as a panacea for various applications and procedures in the perioperative and critical care settings.[6]

It acts on both pre and post synaptic sympathetic nerve terminal, thereby decreasing sympathetic outflow and norepinephrine release. This action is responsible for sedative, anxiolytic, sympatholytic and hemodynamic effects.[7]

Dexmedetomidine produces a manageable hypotension and bradycardia, but the striking feature of this drug is the lack of opioid related side effect such as respiratory, depression, pruritus, nausea, and vomiting. Dexmedetomidine has been evaluated epidurally without any report of neurological deficit in the human being.[8][9] It was found that dexmedetomidine produces prolonged post operative analgesia with minimal side effects when added to ropivacaine in epidural and caudal anaesthesia.[10]

METHODS:

After taking the Institutional Ethics Committee's approval (registration no. IEC/Certi/18/01/2021). After institutional research ethical committee approval & obtaining an informed written consent, 60 patients were included in a double blind controlled comparative clinical study for planned lower limb surgeries in our hospital. All patients were divided into two groups - Group RD (n=30) and Group R

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- Group R [n=30] - 20 ml of 0.75% ropivacaine [0.75% Ropivacaine in 20 ml ampule]
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5. Patient in grade IV
6. Age group <18 and >65 years
7. Pregnancy
8. Known case of TB/Peptic ulcer/Chronic inflammatory disease/ Obesity.

A day prior to the surgery, a preoperative visit was made and a detailed history and clinical examination of the patient was done.

All selected patients were explained about the purpose, procedure and side effects of the study drug and informed written consent was taken. They were also explained about assessment of pain with the help of Visual Analogue Scale. Patients were advised to stay nil by mouth for 8 hours on the day of surgery.

After giving sitting position, The back was prepared with an antiseptic solution and was draped with a sterile towel. After infiltration with Inj. Lignocaine 2% 2 cc Under all aseptic and antiseptic precautions lumbar epidural was performed with 18 G touhy epidural needle at the lumbar L3-L4 interspace using loss of resistance technique via a midline approach. Epidural catheter inserted through epidural needle after confirmation of epidural space. then epidural catheter fixed properly after giving test dose with 3 ml of 1.5% preservative free lidocaine with 1:200,000 epinephrine.

After that Patients were given bolus dose of drug via epidural catheter according to group allotment in supine position. Time when bolus dose given was recorded.

Patient's baseline Temperature, PR, RR, BP, VAS score, motor block, sensory block and SpO2 were recorded before premedication, Before induction, After induction ,After 5 min, After 10min,After 15 min, after 30 min and then every 30 min.

till the end of Surgery. Same parameters were recorded postoperatively at postop 30 min, At 1 hour, At 2 hour, At 4 hour and at 6 hour post-operatively. See for sensory block, Motor block, VAS Score, Duration of analgesia.

The incidence of perioperative complications like hypotension (arterial BP<20% of baseline), bradycardia (HR<50 beats/min), nausea, vomiting, respiratory difficulty, shivering, headache, backache, pruritus, dural tap /bloody tap, urinary retention and others were monitored and treated accordingly.

Statistical analysis was done using unpaired 't' Test to find P value. (p value >0.05 is considered Non significant, p value <0.05 is considered significant, p value <0.001 is considered Highly significant).

RESULTS:

Table 1 shows, the mean age of patient in group RD was 38.86 ± 10.23 years, in group R was 38.40 ± 13.14. This difference in age was statistically insignificant between the two groups.(p value >0.05)

The mean weight of patient in group RD was 62.66 ± 11.65 kilograms, in group R was 61.03 ± 5.44 kilograms. This difference in weight was statistically insignificant between the two groups.(p value >0.05)

Table 1 Comparison Between Of Demographic Data [age And Weight] Between Group RD And R

	GROUP RD	GROUP R	P VALUE	SIG
AGE	38.60+10.23	38.40+13.14	>0.05	NS
WEIGHT	62.66+11.65	61.03+5.44	>0.05	NS

Table 2 Comparison Of Heart In Two Groups Of Patients Study

TIME	GROUP RD MEAN +SD	GROUP R MEAN+SD	P VALUE	SIG
Before premedication	82.20+8.02	81.40+6.24	>0.05	NS
Before induction	81.93+8.29	82.00+6.74	>0.05	NS
After induction				
1 min	82.13+9.26	83.46+6.47	>0.05	NS
5 min	82.73+8.87	84.53+5.76	>0.05	NS
10 min	83.00+8.25	84.60+5.63	>0.05	NS
15 min	82.53+8.11	84.00+5.84	>0.05	NS
20 min	83.66+8.66	83.46+6.70	>0.05	NS
30 min	82.60+7.93	82.66+7.70	>0.05	NS
45 min	82.80+8.65	82.26+6.29	>0.05	NS
60 min	82.46+8.79	81.60+5.64	>0.05	NS
75 min	82.06+8.71	81.46+5.82	>0.05	NS
90 min	81.53+8.59	81.46+6.14	>0.05	NS
105 min	81.40+9.72	81.20+5.74	>0.05	NS
120 min	81.60+8.49	80.66+6.56	>0.05	NS

Table 3 Comparison Of Mean Aterial Pressure And Two Groups Of Patients Studied.

TIME	GROUP RD MEAN+SD	GROUP R MEAN+SD	P VALUE	SIG
Before premedication	91.93+4.74	90.30+5.03	>0.05	NS
Before induction	91.30+4.45	90.46+4.70	>0.05	NS
After induction				
1 min	90.33+4.31	87.93+4.99	>0.05	NS
5 min	89.03+4.78	87.50+4.50	>0.05	NS
10 min	88.33+4.52	87.70+4.33	>0.05	NS
15 min	87.66+4.33	87.23+4.14	>0.05	NS
20 min	87.33+4.06	87.33+3.78	>0.05	NS
30 min	87.50+4.04	87.03+3.84	>0.05	NS
45 min	87.26+4.24	87.53+4.08	>0.05	NS
60 min	87.20+4.54	87.33+3.82	>0.05	NS
75 min	87.46+3.97	87.50+3.85	>0.05	NS
90 min	87.83+3.89	87.70+3.87	>0.05	NS
105 min	88.20+4.67	88.06+4.04	>0.05	NS
120 min	88.86+4.57	88.33+4.00	>0.05	NS

Above Table and chart shows that MAP was comparable in both groups at all time before and after epidural anaesthesia, which was statistically not significant (p>0.05).

Table 4 Comparison Of Onset Of Sensory Block

Two segment regression time (minutes)		
	Group RD	Group R
Mean + SD	7.30 1.62	11.56 1.75
P value	<0.05	
Significance	Significant	

Above Table and chart shows that two segment regression time of sensory block that is T10-T12 is achieved early in group R - 11.56 ± 1.75 minutes as compared to group RD - 7.30 ± 1.62 minutes, which was statistically significant.

Table 5 Comparison Of Duration Of Sensory Block

Total duration of sensory block (minutes)		
	Group RD	Group R
Mean + SD	324.83+24.94	229.00+21.06
P value	<0.05	
significance	Significant	

Above Table and chart shows that Total duration of sensory block is achieved in group RD 324.83 ± 24.94 minutes as compared to group R - 229.00 ± 21.06 minutes, which was statistically significant.

Table 6 Comparison Of Onset Of Motor Block

Onset (minutes)		
	Group RD	Group R
Mean + SD	17.76+2.06	20.53+2.3
P value	<0.05	
Significance	Significant	

Above table chart shows the onset of motor block in group RD was 17.76 ± 2.06 Minutes and in group R it was 20.53 ± 2.30 Minutes which was statistically significant($p< 0.05$).

Table 7 Comparison Of Duration Of Motor Block.

Total duration of motor block (minutes)		
	Group RD	**Group R**
Mean + SD	303.00+14.89	216.66+18.63
P value	<0.05	
significance	Significant	

Above Table and chart shows total duration of motor block in group RD was 303.00 ± 14.89 min and group R was 216.66 ± 18.63 min which was statistically significant ($p<0.05$).

Table 8 Comparison Of Rescue Analgesia

	Group RD	**Group R**
Mean + SD	369.33 ± 17.00	278.66 ± 11.05
P value	<0.05	
significance	Significant	

Above Table and chart shows total Rescue Analgesia duration in group RD was 369.33 ± 17.00 min and group R was 278.66 ± 11.05 min which was statistically significant ($p<0.05$).

DISCUSSION:

The synergistic action of epidural local anesthetics and opioids is well established. The use of neuraxial opioid is associated with number of side effect, hence various other drugs including alpha 2 agonists are evaluated as an alternative to opioids as adjuvant to neuraxial block.

Injection ropivacaine when used alone is adequate for surgeries lasting 3-4hrs. hence, if we required regional anaesthesia for longer duration we used some additives. Addition also have advantage of providing post operative analgesia. A number of adjuvant have been studied prolong the effect of epidural anaesthesia. Dexmedetomidine is one among them.

Dexmedetomidine is a specific and selective alpha 2 adrenoceptor agonist. Activation of receptor in the brain and spinal cord inhibit neuronal firing and leads to sympatholytic effect, causing hypotension, bradycardia, sedation and analgesia.

In our study, majority of the patients were young age in both groups 30 patients from each group. The mean weight in both groups is also identical. These parameters were kept identical in both groups to avoid discrepancy in intraoperative and post operative outcome of patients.

ONSET OF SENSORY BLOCK

In our study, mean time of onset of sensory block at shin of tibia in group RD was 7.3 ± 1.62 minutes, in group R 11.56 ± 1.75 minutes which was significant statistically ($p<0.05$).

In 2019, Ashem Jack Meitei, studied comparison of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries. The onset of sensory block in RD group is 11.16 ± 2.135 minutes which was significantly shorter than R group 15.36 ± 2.481 minutes ($p = 0.00$).

In 2015, Bhawana Rastogi, studied dexmedetomidine as an adjuvant to epidural 0.75% ropivacaine in patients undergoing infraumbilical surgery, the onset of sensory block in RD group is 2.50 ± 0.877 minutes and in R group 7.00 ± 1.198 minutes with statistically highly significant difference ($p<0.001$).

In Bajwa et al., their study compared dexmedetomidine and clonidine as adjuvant to ropivacaine for epidural, the onset of sensory block in Rd group was 8.52 ± 2.36 minutes and in R group it was 9.72 ± 3.44 minutes which is statistically significant ($p<0.05$).

TOTAL DURATION OF SENSORY BLOCK

In our study, mean time for total duration of sensory block in group RD was 324.83 ± 24.94 minutes, in group R 229 ± 21.06 minutes which was significant statistically ($p<0.05$).

In 2019, Ashem Jack Meitei, studied comparison of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries. The total duration of sensory block in RD group is 529.36 ± 58.125 minutes which was significantly longer than R group 391.68 ± 33.404 minutes ($p = 0.00$).

In Kaur et al., comparative evaluation of ropivacaine versus dexmedetomidine and ropivacaine in epidural anaesthesia in lower limb orthopedic surgeries, the total duration of sensory block in RD group is 535.18±19.85 as compared to R group 375.20±15.97, which is statistically significant ($p=0.00$)

ONSET OF MOTOR BLOCKADE

In our study, mean time of onset of motor block in group RD was 17.76 ± 2.06 minutes, in group R 20.53 ± 2.3 minutes which was significant statistically ($p<0.05$).

In 2019, Ashem Jack Meitei, studied comparison of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries. The onset of motor block in RD group is 23.76 ± 3.908 minutes which was significantly shorter than R group 27.24 ± 3.126 minutes ($p = 0.00$).

In 2015, Bhawana Rastogi, studied dexmedetomidine as an adjuvant to epidural 0.75% ropivacaine in patients undergoing infraumbilical surgery, the onset of motor block in RD group is 17.20 ± 4.10 minutes and in R group 23.90 ± 3.57 minutes with statistically highly significant difference ($p<0.001$).

TOTAL DURATION OF MOTOR BLOCK

In our study, mean time for total duration of motor block in group RD was 303.00 ± 14.89 minutes, in group R 216.66 ± 18.63 minutes which was significant statistically ($p<0.05$).

In 2019, Ashem Jack Meitei, studied comparison of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries. The total duration of sensory block in RD group is 390.44 ± 37.994 minutes which was significantly longer than R group 264.96 ± 30.788 minutes ($p = 0.00$).

In 2015, Bhawana Rastogi, studied dexmedetomidine as an adjuvant to epidural 0.75% ropivacaine in patients undergoing infraumbilical surgery, the total duration of sensory block in RD group is 362.13 ± 72.985 minutes and in R group 185.38 ± 23.243 minutes with statistically highly significant difference ($p<0.0001$).

DURATION OF ANALGESIA

In our study, mean time of duration of analgesia in group RD was 369.33 ± 17.00 minutes, in group R 278.66 ± 11.05 minutes which was significant statistically ($p<0.05$).

In 2019, Ashem Jack Meitei, studied comparison of ropivacaine versus ropivacaine plus dexmedetomidine under epidural anaesthesia in lower limb surgeries. The duration of analgesia in RD group is 512.36 ± 55.815 minutes which was significantly shorter than R group 368.40 ± 52.366 minutes ($p = 0.00$).

In 2015, Bhawana Rastogi, studied dexmedetomidine as an adjuvant to epidural 0.75% ropivacaine in patients undergoing infraumbilical surgery, the duration of analgesia in RD group is 429.25 ± 90.444 minutes and in R group 216.58 ± 25.560 minutes with statistically highly significant difference ($p<0.001$).

In Bajwa et al., their study compared dexmedetomidine and clonidine as adjuvant to ropivacaine for epidural, the onset of sensory block in Rd group was 342 minutes and in R group it was 246.72 ± 30.46 minutes which is statistically significant ($p<0.05$).

Findings of the above all studies are comparable with the present study.

CONCLUSION:

Epidural dexmedetomidine as adjuvant to ropivacaine produces synergistic effects with earlier onset time of sensory block, earlier achievement of complete sensory and motor blockade, prolonged sensory and motor blockade and good intraoperative sedation. Dexmedetomidine in a dose of 0.6 g/kg is a safe and effective adjuvant to ropivacaine in epidural blockade in lower limb surgeries.

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