Original Research Paper

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COMPARATIVE STUDY OF THE ANALGESIC EFFECT OF EPIDURAL DEXMEDETOMIDINE AND FENTANYL IN LOWER LIMB ORTHOPAEDIC SURGERIES

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ABSTRACT

INTRODUCTION : Epidural anaesthesia is one of the most commonly used procedure to provide analgesia and anaesthesia for lower abdominal,perineal,lower limb surgeries.opiods have been used as an adjuvant to local anaesthetics for a longer time. Recently α-2 agonists are being used as an adjuvant to provide superior analgesia with minimal side effect

AIMS: The present study aims at comparing the hemodynamic,sedative and analgesic potentiating effects of epidurally administered fentanyl and dexmedetimidine when combined with ropivacaine.

METHODS: 60 patients of ASA1&2 undergoing lower limb orthopaedic surgeries were randomly allocated to two groups ,RD and RF, with 25 patients in each group. Group RD received 15ml of 0.75%ropivacaine with 1µg/kg of dexmedetomidine and RF received 15ml of 0.75%ropivacaine with 1µg/kg of fentanyl. Various parameters like Heart rate,blood pressure,sedation scores at every 30 minutes,onset of sensory analgesia at T10,Time for peak sensory analgesia,onset of complete motor block,time for two segmental r egression,time for return of motor activity to bromage1,duration of analgesia were recored in both groups and compared with the help of statistical tools like chi.square test, paired t-test.

RESULTS: Both the study were comparable in their demographic profile,duration of surgery.onset of sensory analgesia at T10,maximum sensory analgesia and time taken to reach that level,onset of complete motor block were earlier in RD group than RF group.Duration of analgesia was also longer in RD group. patients in RD were much better sedated than RF group .Incidence of shivering,nausea was much higher in RF group while incidence of dry mouth wae higher in RD group.

CONCLUSION: Thus dexmedetomidine seems to a better alternative

KEYWORDS : dexmedetomodine, epidural anaesthesia, fentanyl.ropivacaine

INTRODUCTION

Epidural anaesthesia is one of the most commonly used technique in modern anesthesiology. It provides not only perioperative surgical anaesthesia but also postoperative analgesia in surgeries involving the lower limbs, pelvis, perineum and lower abdomen .Good perioperative analgesia is an important avenue to attenuate the surgical stress response .Epidural reduces the adverse physiological response to surgery like autonomic hyperactivity, cardiovascular stress, tissue breakdown, increased metabolic rate, pulmonary dysfunction and immune system dysfunction.

By placing a catheter in epidural space, continuous anaesthesia can be maintained for a long period, thus making it suitable for procedures of long duration. This feature also enables the use of this technique for postoperative analgesia, using lower concentrations of local anaesthetic drugs alone or with adjuncts. Early postoperative mobilization and rehabilitation with minimally associated pain and discomfort is most desirable feature in modern orthopaedic surgeries[2].This can be done by placing an epidural catheter in lumbar space and using a drug with lesser propensity of motor block.

Ropivacaine,the newer amide local anaesthetic has minimal cardiovascular and central nervous system toxicity as well as a lesser propensity of motor block has been used in this study.

Dexmedetomidine,new addition to the class of alpha-2 agonist, and a close congener to clonidine, has been used for this purpose with many beneficial effects.It acts on both presynaptic and postsynaptic sympathetic nerve terminals and central nervous system thereby decreasing the sympathetic outflow and norepinephrine release causing sedative,antianxiety,analgesic,sympatholytic and hemodynamic effects .Its primary site of antinociceptive action appears to be at the spinal level. Alpha - 2 receptors at the spinal cord level are thought to be responsible for the analgesic properties of α2-adrenergic agonists (10,11).

This study was designed to evaluate the analgesic efficacy of ropivacaine dexmedetomidine mixture by comparing with ropivacaine fentanyl mixture by giving these drugs through lumbar epidural route in patiens undergoing elective lower limb orthopaedic surgeries.

MATERIALS AND METHODS

Patient selection:

The study population consist of ASA I & ASA II patients in the age group of 21 years to 65 years admitted to undergo elective orthopaedic lower limb surgeries at Govt tanjavur medical college. After getting approval by the institutional ethical committee and after obtaining written informed consent from each patient ,the study was conducted.

Inclusion criteria:

1. Age Group 21-56 years
2. ASA I and ASA II
3. Elective orthopaedic lower limb surgeries

Exclusion criteria:

1. Patient refusal
2. diabetes mellitus
3. hypertension
4. chronic obstructive respiratory disease
5. cardiac disease
6. coagulation abnormalities.
7. spinal deformities
8. patients allergic to local anaesthetics
9. preoperative hypotension

Preoperative assessment:

- Routine clinical examination
- Biochemical investigations,
- Electrocardiogram and chest x-ray were examined thoroughly for the conduct of anaesthesia.

Conduct of anaesthesia:

After obtaining witten informed consent Patients were allocated randomly into two equal groups Group RD and group RF by using lots.Since randomization was done by using lots each patient has equal chance of being selected in either of the group.

Group RD (n =25) received 15ml of 0.75% ropivacaine with 1 µg/kg of dexmedetomidine

Group RF (n=25) received 15ml of 0.75% ropivacaine with 1µg/kg of fentanyl.

METHODS

All patients were fasted for eight hours . Oral T.ranitidine 150mg was given as a premedication 2 hrs before surgery with sips of water. On arrival in the operating room, baseline cardiorespiratory parameters viz., Heart Rate(HR), Systolic blood pressure(SBP), Diastolic blood

pressure(DBP),Mean arterial pressure(MAP) and Respiratory rate(RR) were recorded.

A good intravenous access was established using 18G IV cannula. Preloading was done with ringer lactate(10 ml/kg).

With the patient in sitting posture, after informing the procedure to the patient & under strict aseptic precautions, epidural space was identified at L3-L4 interspace using 16G Tuohy needle by loss of resistance technique. 19G epidural catheter was threaded in a cephalad direction & 5 cm catheter length was kept inside the epidural space. A test dose of 3 cc of 1.5 % lignocaine with adrenaline (5 µg/ml) was given. After confirming negative result for test dose, epidural catheter was fixed and secured with tapes. Bolus drugs of either drugs prepared were given. Vital parameters were continuously monitored and recorded every 5 minutes for the first 30 minutes, then every 30 minutes upto1hour, and every 15 minutes from 1 to 2 hours. Intravenous fluids and blood transfusion were given based on surgical requirement and mean arterial pressure.

All patients were given oxygen supplementation (4-5L/min)through Hudson's facemask. No intravenous opiod analgesics were supplemented during the study.

Hypotension[4] (SBP < 100 mmHg) was treated with Ephedrine 6mg i.v. Bradycardia[4] (HR<60 beats/minute) was treated with atropine 0.3mg i.v. Respiratory depression (RR< 8 breaths/min or SpO2 < 90%) was managed with intermittent positive pressure ventilation with 100% O2..Nausea or vomiting was treated with Ondansetron 4mg i.v.

Sensory level of block was assessed bilaterally by pin prick method in the midclavicular line from distal to proximal dermatome level.

Motor level of block was assessed by **Modified Bromage Scale**

SCALE	MOTOR BLOCK
1	Full flexion of knees and feet possible
2	Just able to flex knees, full flexion of feet possible
3	Unable to flex knees, full flexion of feet possible
4	Unable to move legs and feet

Sedation was assessed every 30 minutes using subjective sedation score

SCORE	
0	awake, conscious, nose dation, to slightly restless
1	calm and compose
2	awake on verbal command
3	awake on gentle tactile stimulation
4	awake on vigorous shaking
5	unarousable

The following details were noted after epidural drug administration .

1. Time to reach sensory block of T10 level
2. Peak sensory level
3. Time to reach peak sensory level
4. Time to reach complete motor block
5. Duration of analgesia.

At the end of surgery patients were shifted to the recovery room and subsequently to the post operative ward. The patients were instructed to inform the onset of incisional discomfort to the post operative ward nurse who was blinded to the study. Duration of analgesia was recorded from the onset of block to the time of incisional discomfort as reported by the patient.

Epidural top up of 8 ml of 0.2% ropivacaine was given as rescue analgesia when the patient reported of incisional discomfort.

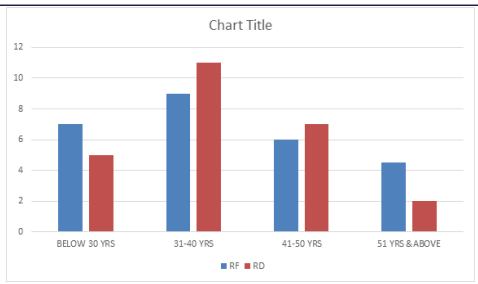
Side effects like shivering, dryness of mouth, nausea, vomiting, urinary retention and respiratory depression were noted

OBSERVATIONS AND RESULTS

Both the groups were comparable with respect to demographic profiles like age, sex, height, weight.

Table-1:Comparison of age

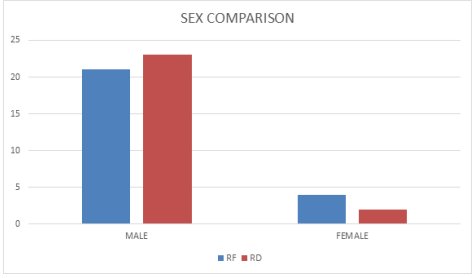
Group	Mean	S.D	Statistical inference
age			
RF Group (n=25)	36.72	9.458	T=-1.259 Df=48
RD Group (n=25)	39.72	7.237	



Persons aged 21yrs to 56yr were included in this study. The mean age is 36.72 in RF group and 39.72 in RD group .there is no statistical difference in the age comparison of the two groups.

Table 2: SEX DISTRIBUTION

Sex	RF Group (n=25)	RD Group (n=25)	Total (n=50)	Statisticial inference
Male	21(84%)	23(92%)	44(88%)	X^2=.758 Df=1 .384>0.05 Not Signficant
Female	4(16%)	2(8%)	6(12%)	



92%in RD group are males,84%in RF group are males.16% in RF group are females,2%in RD are females. the p value is 0.384>o.o5,there is no statistical difference in sex comparison between two groups.

Table 3:comparison Of Heart Rate Changes

Time in minutes	GROUP RF		GROUP RD		Statistical inference
	mean	S.D	Mean	S.D	
0	91.64	10.590	89.04	10.722	.393>0.05 Not Significant
10	96.04	12.889	79.32	8.693	.000<0.05 Significant
20	92.60	13.940	74.28	7.115	.000<0.05 Significant
30	86.36	9.814	70.20	6.042	.000<0.05 Significant
40	83.80	6.325	68.28	5.038	.000<0.05 Significant
50	81.12	7.715	67.96	5.820	.000<0.05 Significant
60	82.44	5.665	67.16	6.026	.000<0.05 Significant
70	83.12	7.230	67.52	5.455	.000<0.05 Significant
80	83.88	4.604	67.24	5.652	.000<0.05 Significant
90	82.40	5.362	66.96	5.412	.000<0.05 Significant
100	83.08	6.701	67.44	5.253	.000<0.05 Significant
110	74.36	28.625	61.36	19.170	.065>0.05 Not Significant
120	63.52	37.027	58.28	22.369	.548>0.05 Not Significant
130	52.84	40.960	55.20	24.865	.807>0.05 Not Significant
140	35.04	40.790	47.92	30.655	.213>0.05 Not Significant
150	26.92	40.449	34.32	33.755	.486>0.05 Not Significant

There was significant statistical difference in the mean heart rate at various intervals. the heart rate decreased in both groups but the mean heart rate was between 60-75 in RD group,70-85 in RF group.

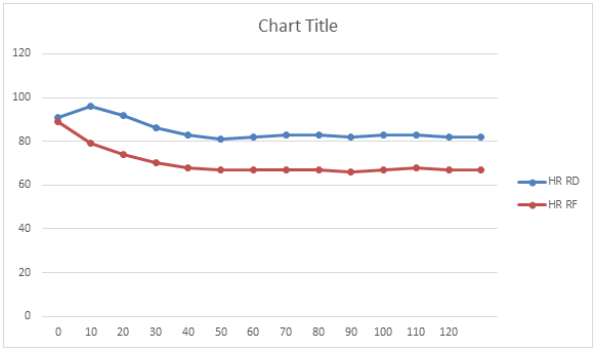
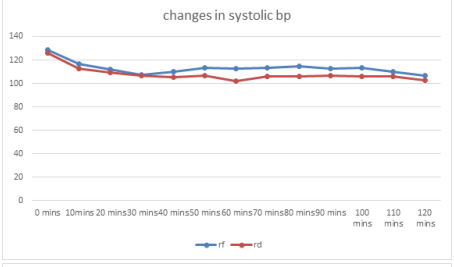
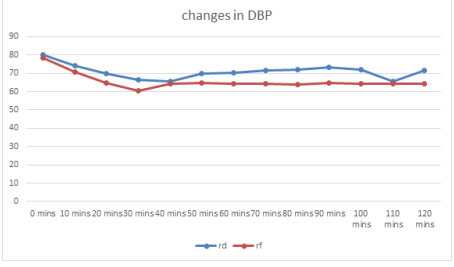


Table 4: Comparison Of Blood Pressure Changes

Time in minutes	RF GROUP				RD GROUP				Statistical inference	
	SBP		DBP		SBP		DBP		SBP	DBP
	Mean	S.D	Mean	S.D	Mean	S.D	Mean	S.D		
0	128.80	10.484	80.00	60583	121.08	8.366	78.56	6.318	NOT SIGNIFICANT	NOT SIGNIFICANNT
10	116.72	9.007	74.12	5.278	112.76	7.178	70.80	6.258	NOT SIGNIFICANT	SIGNIFICANT
20	112.08	7.308	69.84	4.947	109.04	6.052	64.84	6.980	NOT SIGNIFICANT	SIGNIFICANT
30	107.16	7.782	66.32	3.602	106.72	4.118	60.36	7.577	NOT SIGNIFICANT	SIGNIFICANT
40	109.96	8.687	65.80	6.298	105.68	3.902	64.24	3.677	SIGNIFICANT	SIGNIFICANT
50	113.08	8.784	69.68	6.619	106.64	3.999	64.56	4.583	SIGNIFICANT	SIGNIFICANT
60	112.72	8.122	70.48	6.239	102.20	21.731	64.20	3.819	SIGNIFICANT	SIGNIFICANT
70	113.40	9.156	71.40	7.360	106.12	3.586	64.20	4.113	SIGNIFICANT	SIGNIFICANT
80	114.60	8.874	72.04	7.657	106.36	4.009	64.08	3.696	SIGNIFICANT	SIGNIFICANT
90	112.80	6.813	73.28	6.889	107.00	3.894	64.64	3.026	SIGNIFICANT	NOTSIGNIFICANT
100	113.60	5.568	71.96	5.473	105.80	3.240	64.44	3.852	SIGNIFICANT	SIGNIFICANT
110	109.96	8.687	65.80	6.298	105.81	3.902	64.24	3.677	SIGNIFICANT	SIGNIFICANT
120	106.69	9.156	71.40	7.360	103.02	3.586	64.20	4.113	SIGNIFICANT	SIGNIFICANT

Changes in blood pressure





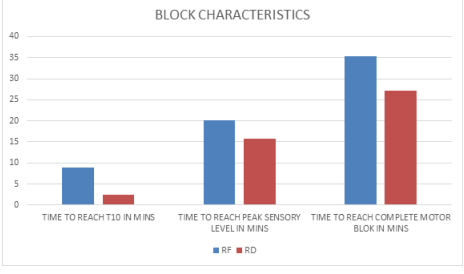


Table 5:COMPARISON OF BLOCK CHARACTERISTICs

parameters	RF GROUP		RD GROUP		Statistical inference
	Mean	S.D	Mean	S. D	
Time to reach T10 sensory level in minutes	8.92	0.702	5.64	0.700	T=16.538 Df=48 0.000<0.05 significant
Time to peak sensory level in minutes	20.08	1.498	15.68	1.030	T=12.104 DF=48 0.000<0.05 significant
Time to reach complete motor block in minutes	35.40	1.443	27.24	1.363	T=20.555 Df=48 0.000<0.05 significant

Table 6: Comparison Of Block Regression Characteristics

Parameters in minute	RF GROUP		RD GROUP		Statistical inference
	mean	S.D	mean	S.D	
Time to two segmental regression	117.20	4.103	149.60	10.985	T=-13.815 DF=48 0.000<0.05 SIGNIFICANT
Timeforregression to bromage 1	176.60	6.72	238.00	7.071	T=-31.456 DF=48 0.000<0.05 SIGNIFICANT
Time for first rescue analgesia	215.80	4.717	339.20	8.124	T=-65.679 DF=48 0.000<0.05 SIGNIFICANT

Table -9 Sedation Characteristics

Time in min	Subjective sedation score(percentage of cases)												Statistical inference
	Group RF						Group RD						
	0	1	2	3	4	5	0	1	2	3	4	5	
30	84	16	-	-	-	-	-	100	-	-	-	-	X^2=50.000 Df =1 .000<0.05 significant
60	-	100	-	-	-	-	-	-	100	-	-	-	X^2 =50.000 Df=1 0.000<0.05 significant
90	-	100	-	-	-	-	-	-	100	-	-	-	X^2=50.000 Df=1 .000<0.05 significant
120	12	56	32	-	-	-	-	-	64	36	-	-	X^2=39.400 Df=3 .001<0.05 significant

84%of patients had sedation of 0 at 30mts in RF group,100%of patients had sedation score 1 in RD group.

Table -10 Peak Sensory Level

Level of sensory	RF Group (n=25)	RD Group (n=25)	Total (n=50)	Statisticial inference
T2	0	2(8%)	2(4%)	X^2=50.000 Df=5 .000<0.05 Significant
T3	0	10(40%)	10(20%)	
T4	0	13(52%)	13(26%)	
T5	11(44%)	0	11(22%)	
T6	11(44%)	0	11(22%)	
T7	3(12%)	0	3(6%)	

In RD group 52% patients had sensory segmental level of T4 40%of patients had T3 whereas in RF majority of patients had sensory segmental level of T5(44%),T6(40%),only 1 patient (4%) had T4 level which is statistically significant.

Table 11- Comparison of side efffects

adverse effects	RF Group (n=25)	RD Group (n=25)	Total (n=50)	Statisticial inference
Drymouth	-	3(12%)	3(6%)	X^2=11.009 Df=4 .026<0.05 Siginficant
Nausea	2(8%)	1(4%)	3(6%)	
Shivering	6(24%)	-	6(12%)	
Vomiting	1(4%)	-	1(2%)	

DISCUSSION:

A number of clinical trials have been conducted to prove the efficacy of anti- nociceptive effect of α_2 agonists using different techniques and different types of drugs with conflicting results. The use of epidural techniques also offer the advantage of effective prolonged postoperative analgesia as compared to nerve blocks and local infiltration.Sopoids have been used long as an adjuvant to local anaesthetics.clonidine is the pioneer of α2 agonists and dexmedetomidine is the new congener. The sedative effect of dexmedetomidine has been well established in the literature but the analgesic potency has not been clearly established. The epidural effect is dose dependent and superior than IV due to its high affinity for α_2 adrenergic receptors in spinal cord.The anti-nociceptive effect dexmedetomidine is dose dependent and is primarily related to its affinity ofα_2 receptors in spinal cord.Prolonged analgesic action of LA is probably due to reduced systemic absorption caused by local vasoconstriction mediated by α_{2C} in smooth muscle of epidural venous plexus.Dexmedetomidine cause more sensory than motor block duration mediated by binding to α_{2A} receptors in locus caeruleus diminishing the release of norepinephrine .

During epidural administration cephalad spread into meninges may be responsible for sedation.The side effect is bradycardia occurs in epidural if the level is higher.The incidence of shivering due to central inhibition of thermoregulatory. In this prospective randomized study, we compared the analgesic efficacy of fentanyl 1µg/kg and dexmedetomidine 1µg/kg added to ropivacaine 0.75% 15ml by giving these drugs through lumbar epidural in 50 patients undergoing elective orthopaedic lower limb surgeries. Both the study groups were comparable in their demographic profile and physical parameters like age, sex, height, weight. The time taken to reach peak sensory level was(15.68±1.030) in RD group much earlier than fentanyl group(20.08±1.The onset of sensory analgesia at T10 was earlier in RD group(5.64±0.700) than RF group(8.92±0.702) .Dexmedetomidine being more lipophilic and having a favourable pKa produces earlier onset than fentanyl.The peak sensory level attained in our study was at T2 to T4 in RDgroup and T4-T6 in RFgroup.The mean duration of analgesia as measured by the time for first rescue analgesia was significantly longer in RD group than RF group(339.20± 8.124 vs 215.80±4.77) .The mean duration of analgesia (366.62±24.42) in RD group and (242.163.86) in RF group.The peak sensory level attained was at T4toT6 in RD group T5toT7 in RFgroup.The higher sensory level attained in our study could be due to attributed to the different demographic profiles of these patients.Time for two segmental regression was earlier in RFgroup117.20 4.108 than RD group149.60 10.985which is statistically significant.The time for complete motor blockade was in RDand RF group.In the study done by kilzilarslan et all (2008) to compare the analgesic efficacy of adding clonidine75µg and fentanyl 50µg to 0.125%bupivacaine in pregnant patients showed that the duration of analgesia was longer with clonidine than fentanyl group and much lower consumption of local anaesthetic in clonidine group than fentanyl group.

The mean HR,SBP,DBP at varying time intervals showed significant difference between these groups.Though there was decrease in HR ,fall in SBP,DBP in both the groups, the mean HR was maintained between 60-70 in RD group slightly lower than RF group. But none of our patients received ephedrine during the study The mean sedation score at various time intervals was significant between these two groups.

The predominant side effect was drymouth and nausea in RD group whereas shivering in RF group. Only 1 patient had vomiting in RFgroup ,none in RD group had vomiting and there was no respiratory depression in both the groups.