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Original Research Paper

Anesthesiology

A PROSPECTIVE RANDOMIZED STUDY COMPARING THE EFFICACY AND CLINICAL PROFILE OF DEXMEDETOMIDINE AND FENTANYL AS AN ADJUVANT TO EPIDURAL ROPIVACAINE FOR POSTOPERATIVE PAIN RELIEF IN SPINE SURGERIES

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ABSTRACT

Background: Dexmedetomidine, is a new addition to the class of alpha-2 agonists, and a close congener of Clonidine, has been used for this purpose with many beneficial effects. Dexmedetomidine, is an imidazoline derivative, which is 1600 times more selective for alpha-2 receptors than alpha-1 receptors. It acts on both pre- synaptic and post- synaptic sympathetic nerve terminals and on the central nervous system thereby decreasing the sympathetic outflow and Norepinephrine release causing sedative, anti -anxiety, analgesic, sympatholytic effects. The anti nociceptive action is due to its effect at the spinal cord alpha -2 receptors

Methods: Study design: Prospective, randomized, double blinded study

Setting: Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Chennai.

STUDY POPULATION :60 Patients were selected and allocated in two groups

RESULTS: 1) The onset of sensory analgesia was earlier in Ropivacaine Dexmeditomidine (RD) group (5.93±0.700 min) than Ropivacaine Fentanyl (RF) group (7.67±0.702 min).

2) The peak effect of analgesia in our study was 12.07min. for RD group and 13.13min. for RF group which is statistically significant (Pvalue-0.1330).

3) The mean duration of analgesia as measured by the time taken for first rescue analgesic was significantly longer in RD group than RF group (349.80± 8.124min vs 298.20±4.77min).

4) Both the groups showed haemodynamic stability but the incidence of side effects such as hypotension and bradycardia were more in patients who received dexmedetomidine , which was managed easily with inj
Ephedrine 6mg and inj Atropine 0.6 mg.

5) Visual Analogue Scale score in group RD was 1.79 and 2.31 in group RF and it was found to be significant during the whole period of observation ($p<0.05$)

6) The rescue analgesic requirement was less with RD group when compared to RF group in the whole study period.

7) The administration of dexmedetomidine epiduraly produced sedation that was arousable, for many hours when compared to the plain ropivacaine group. The mean sedation score at various time intervals was significant between these two groups.

8) No episode of respiratory depression was noted in RD group compared to RF group.

CONCLUSION : It can be concluded from the study that epidural route provided adequate analgesia in spine surgeries in terms of VAS score in both the groups and analgesia was effective .However, Dexmedetomidine seems to be
a better alternative to fentanyl as an epidural adjuvant as it provides comparably stable hemodynamics, early onset and establishment of sensory anesthesia, prolonged analgesia in the post operative period, lesser consumption of post-operative rescue analgesics and much better sedation levels.

KEYWORDS :

INTRODUCTION

Spine surgeries are commonly associated with moderate to severe postoperative pain which is directly related to the invasiveness of the procedure. A large incision and manipulation of Multiple vertebrae in spine surgeries contribute postoperative pain which remains a great challenge for the anaesthesiologist to treat it. Multimodal analgesic techniques like parenteral analgesics or regional analgesia are commonly practised.

Conventional methods like intravenous or intramuscular analgesics are followed using opioid and non-steroidal anti-inflammatory drugs (NSAID's).The opioids, though potent analgesics, are associated with postoperative respiratory depression , nausea and vomiting, whereas less potent NSAIDs have limited use due to their renal and gastrointestinal side effects. The use of intrathecal opioids before surgical closure also provide effective postoperative analgesia without any major side effects .

The use of local anaesthetics with adjuvants like opioids and alpha agonists through an epidural catheter placed intraoperatively under direct vision at the end of the procedure, is an effective alternative method for controlling postoperative pain. This technique is relatively safe and effective in elective spine surgeries irrespective of age group. Good perioperative analgesia is important to attenuate the surgical stress response. Epidural analgesia reduces the adverse physiological responses to surgery like hyperactive autonomic nervous system response, cardiovascular stress response, tissue breakdown, high metabolic rate, pulmonary dysfunction and immune system dysfunction.

By placing a catheter in the epidural space, continuous anaesthesia can be maintained for a long period of time and long duration procedures can be performed. Epidural catheter can also be used to provide postoperative analgesia with lower concentrations of local anesthetic drugs alone or with adjuncts. Early postoperative mobilization and rehabilitation with minimal associated pain and discomfort is the most desirable feature in modern orthopedic surgeries(3). This can be done by using a local anesthetic with lesser propensity of motor block.

Ropivacaine, the newer amide local anesthetic with minimal cardiovascular, central nervous system toxicity as well as lesser propensity of motor block has been used in this study. Traditionally opioids have been used as adjuvant to achieve the desired anesthetic effect with a lower dose of local anesthetic and superior analgesia.

Dexmedetomidine, is a new addition to the class of alpha-2 agonists, and a close congener of Clonidine, has been used for this purpose with many beneficial effects. Dexmedetomidine, is an imidazoline derivative, which is 1600 times more selective for alpha-2 receptors than alpha-1 receptors. It acts on both pre- synaptic and

post- synaptic sympathetic nerve terminals and on the central nervous system thereby decreasing the sympathetic outflow and Norepinephrine release causing sedative, anti -anxiety, analgesic, sympatholytic effects. The anti nociceptive action is due to its effect at the spinal cord alpha -2 receptors.

This study was designed to compare the analgesic efficacy of Ropivacaine with Dexmedetomidine and Ropivacaine with Fentanyl by their epidural administration in patients undergoing elective spine surgeries.

Materials & methods

Study design: Prospective, randomized, double blinded study

Setting: Institute of Anaesthesiology and Critical Care, Rajiv Gandhi Government General Hospital, Chennai.

STUDY POPULATION

60 Patients were selected and allocated in two groups

ETHICAL CONSIDERATION

Approval was obtained from the Institutional ethics committee before the commencement of the study. Informed consent was obtained from all the patients participated in this study. All patients satisfying the inclusion criteria were included. Patients were interviewed by structured questionnaire.

Statistical analysis: Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test and categorical variables were analysed with the Chi-Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

INCLUSION CRITERIA

- Age : 20-65 years
- ASA : I & II
- Elective Surgeries
- Who have given valid informed consent.
- Lower thoracic below T8 and lumbosacral spine surgeries

EXCLUSION CRITERIA

- ASA III & IV
- Patients with heart block, Bradyarrthymia and Left ventricular failure
- Hematological disease, Bleeding or coagulation abnormalities
- Psychiatric diseases, TB spine and any other permanent neurological disorders

Group-1: (Ropivacaine + Dexmedetomidine (RD) (*n*=30); Ropivacaine 0.2% 15 ml plus dexmedetomidine 1 mcg/kg.
Group-2: (Ropivacaine + Fetanyl (RF) (*n*=30); Ropivacaine 0.2% 15ml plus Fentanyl 1 mcg/kg.

After administering the drug, the following parameters were recorded by the independent observer.

1) The pain score using Visual Analogue Scale (VAS) every 2 min for 30 min and then every 30 min until the need for next epidural top up.
2) Onset of analgesia (fall of VAS<4 after epidural drug).
3) Peak level of analgesia (achieving VAS score 0).
4) Duration of analgesia (starting from epidural drug administr ation to once the patient asks for additional rescue analgesia with VAS>4).
5) Monitoring of vital parameters such as NIBP, pulse rate, respiratory rate every 30 min.
6) Side-effects such as nausea, vomiting, respiratory depression, deep sedation (Ramsay sedation scale>3), shivering,dry mouth , bradycardia and hypotension and requirement for IV rescue analgesics (injection diclofenac).
7) Once the patient asked for additional epidural analgesia (VAS>4) for pain relief during the observation period, the study ended and the above mentioned parameters were noted.

RECORDING OF ADVERSE EFFECTS

Adverse events like hypotension, bradycardia, nausea, vomiting, dry mouth were noted. Hypotension (defined as systolic arterial pressure falling more than 20% from the pre-operative level) was treated with injection ephedrine 3-6 mg IV bolus and heart rate lessthan 50 beats/min was treated with 0.01 mg/kg of injection atropine. Post-operative maintenance IV fluids were given as per body weight. Nausea and vomiting were treated with 0.1 mg/kg of IV ondansetron.

OBSERVATION AND RESULTS

Descriptive statistics was done for all data and suitable statistical tests of comparison were done. Continuous variables were analysed with the unpaired t test and categorical variables were analysed with the Chi –Square Test and Fisher Exact Test. Statistical significance was taken as $P < 0.05$. The data was analysed using EpiInfo software (7.1.0.6 version; Center for disease control, USA) and Microsoft Excel 2010.

Table 1. Group distribution (n=60)

Groups	Group Names	Intervention Used	Procedure
RD	Ropivacaine + Dexmeditomidine.	Post- operative epidural block with Ropivacaine and Dexmeditomidine.	In post-operative patients who are undergoing elective spine surgeries
RF	Ropivacaine + Fentanyl.	Post- operative epidural block with Ropivacaine and Fentanyl.	

TABLE 2. SAMPLE SIZE CALCULATION

Sample size was determined based on

STUDY

A comparative study in the post -operative spine surgeries: Epidural ropivacaine with dexmedetomidine and ropivacaine with Fentanyl for post - operative analgesia, Authored by MS Saravana Babu et al .

PUBLISHED IN

Indian Journal of Anaesthesia | Vol. 57 | Issue 4 | Jul -Aug 2013.In this study the duration of analgesia has a mean difference of 62 minutes which is highly significant at 0.001.

DESCRIPTION

- The confidence level is estimated at 95%
- With a z value of 1.96
- The confidence interval or margin of error is estimated at +/ -12
- Assuming that the sample will have the specified attribute p% =62 and
- q%=38

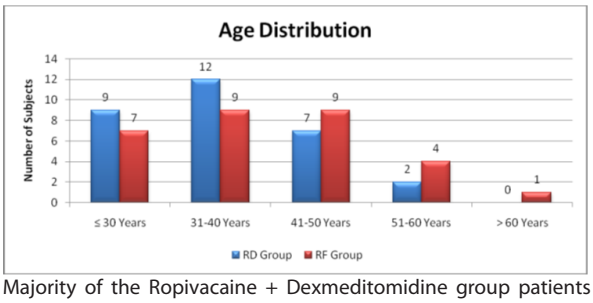
$n = p\% \times q\% \times [z/e\%]^2$
$n=62 \times 38 \times [1.96/15]^2$
$n= 40.23$

Therefore 40 is the minimum sample size required for the study. In our study we have taken 60 as the sample size.

Table-3: Age distribution (n=30 in Group RD and n=30 in Group RF)

Age Distribution	RD Group	%	RF Group	%
≤ 30 Years	9	30.00	7	23.33
31-40 Years	12	40.00	9	30.00
41-50 Years	7	23.33	9	30.00
51-60 Years	2	6.67	4	13.33
> 60 Years	0	0.00	1	3.33
Total	30	100	30	100

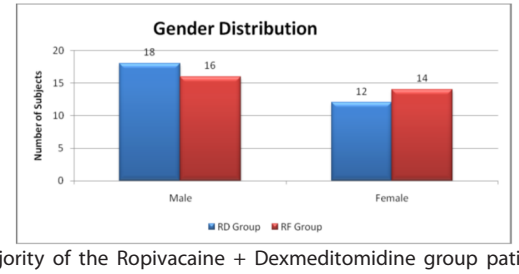
Age Distribution	RD Group	RF Group
N	30	30
Mean	36.10	39.50
SD	10.83	11.02
P value unpaired t test		0.233028



Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the 31-40 years age group (n=12, 40%) with a mean age of 36.10 years. In the Ropivacaine + Fentanyl group patients, majority belonged to the same age group as Ropivacaine + Dexmeditomidine group (n=9, 30%) with a mean age of 39.50 years. The association between the intervention groups and age distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

Table 4. Gender distribution

Gender Distribution	RD Group	%	RF Group	%
Male	**18**	**60.00**	**16**	**53.33**
Female	**12**	**40.00**	**14**	**46.67**
Total	**30**	**100**	**30**	**100**
P value Fishers Exact Test			0.7948	

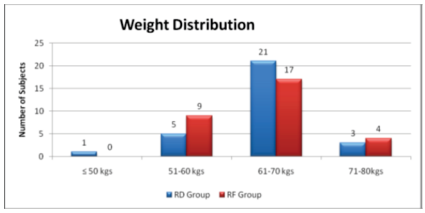


Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the male gender group (n=16, 60%). In the Ropivacaine + Fentanyl group patients, majority belonged to the male gender group (n=16, 53.33%). The ssociation between the intervention groups and gender distribution is considered to be not statistically significant since p > 0.05 as per fishers exact test.

Table 5. Weight distribution

Weight Distribution	RD Group	%	RF Group	%
≤ 50 kgs	1	3.33	0	0.0
51-60 kgs	5	16.67	9	30.00
61-70 kgs	21	70.00	17	56.67
71-80kgs	3	10.00	4	13.33
Total	**30**	**100**	**30**	**100**

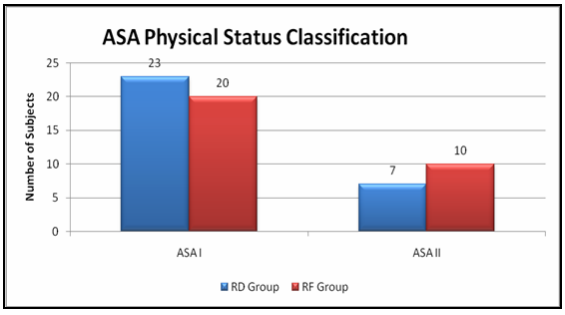
Weight Distribution	RD Group	RF Group
N	30	30
Mean	66.23	65.47
SD	5.77	6.41
P value unpaired t test		0.6282



Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the 61-70 kgs weight group (n=21, 70%) with a mean weight of 66.23 kgs. In the Ropivacaine + Fentanyl group patients, majority belonged to the same weight group as Ropivacaine + Dexmeditomidine group (n=17, 56.67%) with a mean weight of 65.47 years. The association between the intervention groups and weight distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

Table 6. ASA physical status classification

ASA Physical Status Classification	RD Group	%	RF Group	%
ASA I	23	76.67	20	66.67
ASA II	7	23.33	10	33.33
Total	30	100	30	100
P value Fishers Exact Test	0.5675			

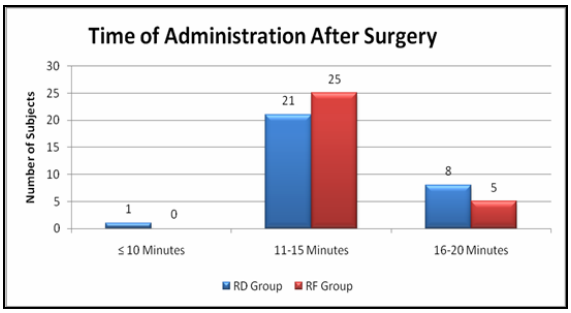


Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the ASA classification I group (n=23, 76.67%). In the Ropivacaine + Fentanyl group patients, majority belonged to the ASA classification I group (n=20, 66.67%). The asso ciation between the intervention groups and ASA physical status classification is considered to be not statistically significant since p > 0.05 as per fishers exact test.

Table 7.Time of administration of drug after surgery

Time of Administration of drug After Surgery	RD Group	%	RF Group	%
≤ 10 Minutes	1	3.33	0	0.00
11-15 Minutes	21	70.00	25	83.33
16-20 Minutes	8	26.67	5	16.67
Total	30	100	30	100

Time of Administration After Surgery	RD Group	RF Group
N	30	30
Mean	16.07	14.97
SD	2.63	2.04
P value Unaired t test		0.0756

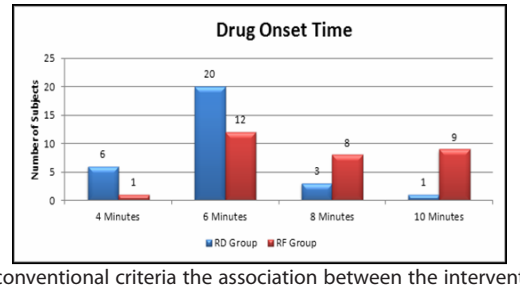


Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the 11-15 minutes after surgery drug administration time group (n=21, 70%) with a mean time of administration after surgery of 16.07 minutes. In the Ropivacaine + Fentanyl group patients, majo rity belonged to the same class interval as Ropivacaine + Dexmeditomidine group (n=25, 83.33%) with a mean time of administration after surgery of 14.97 minutes. The association between the intervention groups and time of administration after surgery distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

Table 8. Drug Onset Time

Drug Onset Time	RD Group	%	RF Group	%
4 Minutes	6	20.00	1	3.33
6 Minutes	20	66.67	12	40.00
8 Minutes	3	10.00	8	26.67
10 Minutes	1	3.33	9	30.00
Total	30	100	30	100

Drug Onset Time	RD Group	RF Group
N	30	30
Mean	5.93	7.67
SD	1.34	1.83
P value Unaired t test		0.0001

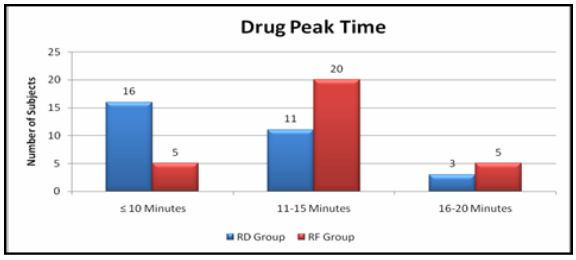


By conventional criteria the association between the intervention groups and drug onset time is considered to be statistically significant since p < 0.05 as per unpaired t test. In simple terms, Most of the Ropivacaine + Dexmeditomidine group patients belong to 6 minutes drug onset time class interval (n=20, 66.67%) with a mean drug onset time of 5.93 minutes. Similarly in the Ropivacaine + Fentanyl group majority of the patients belonged to the 6 minutes drug onset time class interval (n=12, 40%) with a mean drug onset time of 7.67 minutes. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0001. The mean drug onset time was meaningfully less in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 1.73 minutes. This significant difference of 23% reduction in mean drug onset time among patients belonging to Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance. In this study we can safely conclude that Post-operative epidural block with Ropivacaine + Dexmeditomidine results in significantly lowered drug onset time compared to Post-operative epidural block with Ropivacaine + Fentanyl when used In post-operative patients who are undergoing elective spine surgeries.

Table 9. Drug Peak Time

Drug Peak Time	RD Group	%	RF Group	%
≤ 10 Minutes	16	53.33	5	16.67
11-15 Minutes	11	36.67	20	66.67
16-20 Minutes	3	10.00	5	16.67
Total	30	100	30	100

Drug Peak Time	RD Group	RF Group
N	30	30
Mean	12.07	13.13
SD	3.08	2.27
P value Unaired t test		0.1330

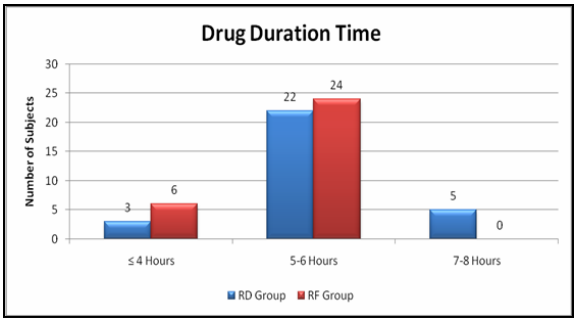


Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the ≤ 10 minutes drug peak time class interval (n=16, 53.33%) with a mean drug peak time of 12.07 seconds. In the Ropivacaine + Fentanyl group patients, majority belonged to 11 -15 minutes drug peak time class interval (n=20, 66.67%) with a mean drug peak time of 13.13 seconds. The association between the intervention groups and drug peak time distribution is considered to be not statistically significant since p > 0.05 as per unpaired t test.

Table 10. Drug Duration Time

Drug Duration Time	RD Group	%	RF Group	%
≤ 4 Hours	3	10.00	6	20.00
5-6 Hours	22	73.33	24	80.00
7-8 Hours	5	16.67	0	0.00
Total	30	100	30	100

Drug Duration Time	RD Group	RF Group
N	30	30
Mean	5.83	4.97
SD	0.99	0.72
P value Unaired t test		0.0003



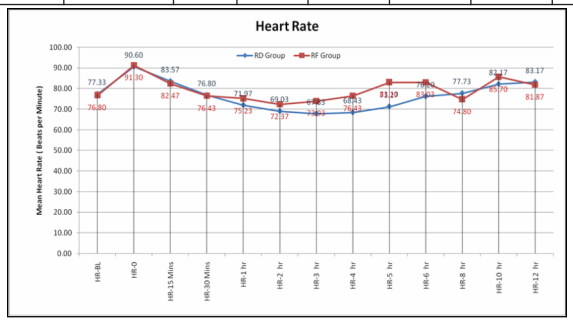
Majority of the Ropivacaine + Dexmeditomidine group patients belonged to the 5-6 hours drug duration time class interval (n=22, 73.33%) with a mean drug duration time of 5.83 hours. In the Ropivacaine + Fentanyl group patients, majority belonged to the same class interval as Ropivacaine + Dexmeditomidine group (n=24, 80%) with a mean drug duration time of 4.97 hours. The association between the intervention groups and drug duration time distribution is considered to be statistically significant since p < 0.05 as per unpaired t test.

By conventional criteria the association between the intervention groups and drug duration time is considered to be statistically significant since p < 0.05 as per unpaired t test. In simple terms, Majority of the Ropivacaine + Dexmeditomidine intervention group patients belonged to the 5-6 hours drug duration time class interval (n=22, 73.33%) with a mean drug duration time of 5.83 hours. In the Ropivacaine + Fentanyl group patients, majority belonged to the same class interval as Ropivacaine + Dexmeditomidine group (n=24, 80%) with a mean drug duration time of 4.97 hours. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0003. The mean drug duration time was meaningfully more in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 52.20 minutes. This significant difference of 1.17 times increase in mean drug onset time among patients belonging to Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine+Fentanyl

intervention group is true and has not occurred by chance. In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmeditomidine results in significantly longer drug onset time compared to Post- operative epidural block with Ropivacaine + Fentanyl when used In post-operative patients who are undergoing elective spine surgeries.

TABLE 11. HEART RATE

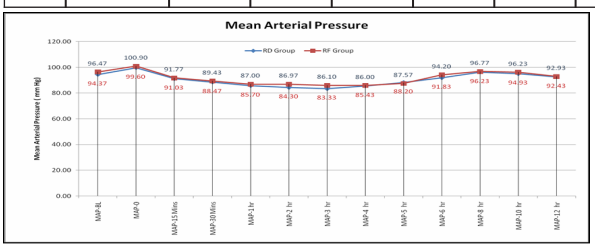
	Heart rate	HR-BL	HR-0	HR-15 Mins	HR-30 Mins	HR-1 hr	HR-2 hr	HR-3 hr	HR-4 hr	HR-5 hr	HR-6 hr	HR-8 hr	HR-10 hr	HR-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.33	90.60	83.57	76.80	71.97	69.03	67.83	68.43	71.27	76.20	77.73	82.17	83.17
	SD	5.96	7.56	6.65	6.25	6.97	8.05	8.36	8.37	8.98	9.46	6.80	7.46	6.66
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	76.80	91.30	82.47	76.43	75.23	72.37	73.93	76.43	83.10	83.03	74.80	85.70	81.87
	SD	6.93	6.78	5.14	7.14	6.82	6.40	6.79	7.52	9.56	8.80	9.98	9.72	8.34
	P value Unpaired t test	0.7505	0.7073	0.4768	0.8332	0.0716	0.0813	0.0030	0.0003	0.0000	0.0053	0.1893	0.1201	0.5076



By conventional criteria the association between the intervention groups and heart rate is considered to be statistically significant between 3 -6 hours since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmeditomidine intervention group, the heart rate is decreased to an average of 70.93 bpm in comparison with patients belonging to Ropivacaine + Fentanyl interventio n group in whom the heart rate is an average of 79.13 bpm. This indicates that there is a true difference among intervention groups and the difference is significant with a p -value of < 0.05 according to unpaired t-test. The heart rate was meaningfully less in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 8.19 bpm. This significant difference of 10% reduction in heart rate in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance. . In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmeditomidine results in significantly lower heart rate compared to Post- operative epidural block with Ropivacaine + Fentanyl when used In post- operative patients who are undergoing elective spine surgeries .

Table 12. Mean Arterial Pressure

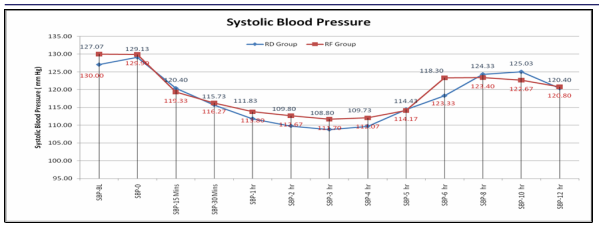
	Heart rate	HR-BL	HR-0	HR-15 Mins	HR-30 Mins	HR-1 hr	HR-2 hr	HR-3 hr	HR-4 hr	HR-5 hr	HR-6 hr	HR-8 hr	HR-10 hr	HR-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.33	90.60	83.57	76.80	71.97	69.03	67.83	68.43	71.27	76.20	77.73	82.17	83.17
	SD	5.96	7.56	6.65	6.25	6.97	8.05	8.36	8.37	8.98	9.46	6.80	7.46	6.66
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	76.80	91.30	82.47	76.43	75.23	72.37	73.93	76.43	83.10	83.03	74.80	85.70	81.87
	SD	6.93	6.78	5.14	7.14	6.82	6.40	6.79	7.52	9.56	8.80	9.98	9.72	8.34
	P value Unpaired t test	0.7505	0.7073	0.4768	0.8332	0.0716	0.0813	0.0030	0.0003	0.0000	0.0053	0.1893	0.1201	0.5076



Most of the Ropivacaine + Dexmeditomidine intervention group patients had mean MAP ranging from 94.37 mm Hg at baseline to 92.43 mm Hg at the end of 12 hours. Similarly the Ropivacaine + Fentanyl intervention group patients had mean MAP ranging from 96.47 mm Hg at baseline to 92.93 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and mean arterial pressure is considered to be not statistically significant sinc e $p > 0.05$ as per unpaired t test.

Table 13. Systolic Blood Pressure

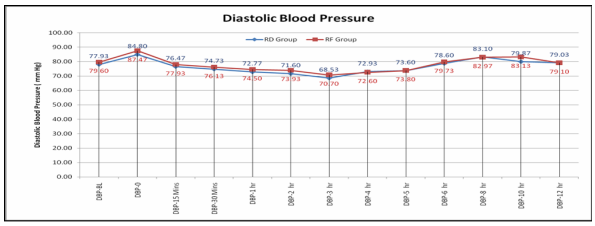
	Systolic Blood Pressure	SBP-BL	SBP-0	SBP-15 Mins	SBP-30 Mins	SBP-1 hr	SBP-2 hr	SBP-3 hr	SBP-4 hr	SBP-5 hr	SBP-6 hr	SBP-8 hr	SBP-10 hr	SBP-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	127.07	129.13	120.40	115.73	111.83	109.80	108.80	109.73	114.43	118.30	124.33	125.03	120.40
	SD	11.30	8.08	7.05	7.42	7.07	10.08	8.69	4.16	9.50	11.67	8.58	8.91	7.36
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	130.00	129.90	119.33	116.27	113.80	112.67	111.70	112.07	114.17	123.33	123.40	122.67	120.80
	SD	9.39	8.20	7.01	6.10	5.02	5.34	5.22	5.13	7.09	10.36	9.93	9.18	9.23
	P value Unpaired t test	0.2788	0.7166	0.5593	0.7622	0.2195	0.1756	0.1238	0.0581	0.9024	0.0826	0.6983	0.3150	0.8534



Most of the Ropivacaine + Dexmeditomidine intervention group patients had mean SBP ranging from 127.07 mm Hg at baseline to 120.40 mm Hg at the end of 12 hours. Similarly the Ropivacaine + Fentanyl intervention group patients had mean SBP ranging from 130.00 mm Hg at baseline to 120.80 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and systolic blood pressure is considered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 14. Diastolic Blood Pressure

Diastolic Blood Pressure		DBP-BL	DBP-0	DBP-15 Mins	DBP-30 Mins	DBP-1 hr	DBP-2 hr	DBP-3 hr	DBP-4 hr	DBP-5 hr	DBP-6 hr	DBP-8 hr	DBP-10 hr	DBP-12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	77.93	84.80	76.47	74.73	72.77	71.60	68.53	72.93	73.60	78.60	83.10	79.87	79.03
	SD	6.96	6.23	4.78	3.50	6.33	7.97	14.00	3.00	13.83	8.31	7.48	5.04	5.97
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	79.60	87.47	77.93	76.13	74.50	73.93	70.70	72.60	73.80	79.73	82.97	83.13	79.10
	SD	7.30	6.64	5.95	4.73	5.08	3.38	12.16	3.94	5.14	9.12	7.83	6.19	5.38
P value Unpaired t test		0.3691	0.1141	0.2971	0.1979	0.2474	0.1480	0.5247	0.7138	0.9412	0.6168	0.9465	0.2891	0.9639

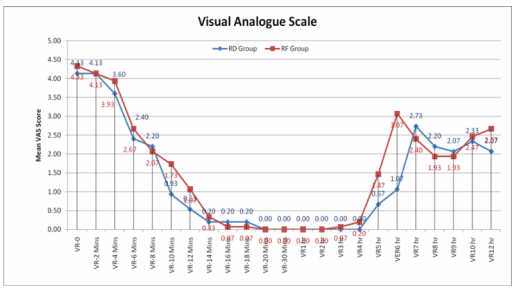


Most of the Ropivacaine + Dexmeditomidine intervention group patients had mean DBP ranging from 77.93 mm Hg at baseline to 79.03 mm Hg at the end of 12 hours. Similarly t he Ropivacaine + Fentanyl intervention group patients had mean DBP ranging from 79.60 mm Hg at baseline to 79.10 mm Hg at the end of 12 hours. By conventional criteria the association between the intervention groups and diastolic blood pressure is consi dered to be not statistically significant since $p > 0.05$ as per unpaired t test.

Table 15. Visual Analogue Scale

Visual Analogue Score		VR-0	VR-2 Mins	VR-4 Mins	VR-6 Mins	VR-8 Mins	VR-10 Mins	VR-12 Mins	VR-14 Mins	VR-16 Mins	VR-18 Mins	VR-20 Mins	VR-30 Mins
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	4.13	4.13	3.60	2.40	2.20	0.93	0.53	0.20	0.20	0.20	0.00	0.00
	SD	0.51	0.51	0.81	0.81	0.61	1.01	0.90	0.61	0.61	0.61	0.00	0.00
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	4.33	4.13	3.93	2.67	2.07	1.73	1.07	0.33	0.07	0.07	0.00	0.00
	SD	0.92	0.51	0.37	0.96	0.37	0.69	1.01	0.76	0.37	0.37	0.00	0.00
P value Unpaired t test		0.3036	1.0000	0.0472	0.0250	0.0309	0.0008	0.0355	0.4562	0.3097	0.3097	> 0.999	> 0.999

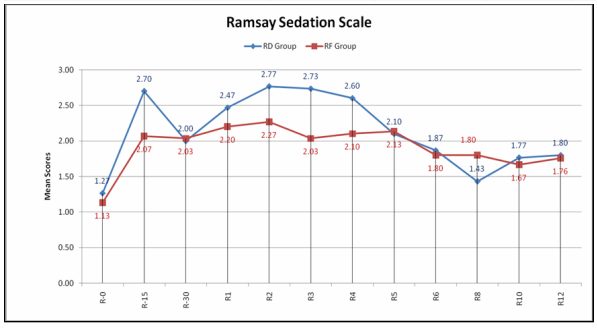
Visual Analogue Score		Vr1 hr	Vr2 hr	Vr3 hr	Vr4 hr	Vr5 hr	VER6 hr	Vr7 hr	Vr8 hr	Vr9 hr	Vr10 hr	Vr12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30
	Mean	0.00	0.00	0.00	0.00	0.67	1.07	2.73	2.20	2.07	2.33	2.07
	SD	0.00	0.00	0.00	0.00	1.60	1.64	1.53	0.81	0.37	0.76	0.37
RF Group	N	30	30	30	30	30	30	30	30	30	30	30
	Mean	0.00	0.00	0.07	0.20	1.47	3.07	2.40	1.93	1.93	2.47	2.67
	SD	0.00	0.00	0.37	0.81	1.48	1.26	0.81	0.64	0.64	0.86	0.96
P value Unpaired t test		> 0.999	> 0.999	0.3256	0.1841	0.0494	0.0000	0.2978	0.1611	0.0326	0.0268	0.0028



By conventional criteria the association between the intervention groups and VAS score is considered to be statistically significant between 4 - 12 minutes, 5-6 hours and 9-12 hours since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmeditomidine intervention group, the VAS score is decreased to an average of 1.79 in comparison with patients belonging to Ropivacaine + Fentanyl intervention group in whom the heart rate is an average of 2.31. This indicates that there is a true difference among intervention groups and the difference is significant with a p-value of < 0.05 according to unpaired t-test. The VAS score was meaningfully less in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 0.52. This significant difference of 23% reduction in VAS score in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance. . In this study we can safely conclude that Post - operative epidural block with Ropivacaine + Dexmeditomidine results in significantly lowered Visual Analogue Scale score compared to Post - operative epidural block with Ropivacaine + Fentanyl when used In post-operative patients who are undergoing elective spine surgeries.

Table 16. Ramsay Sedation Scale

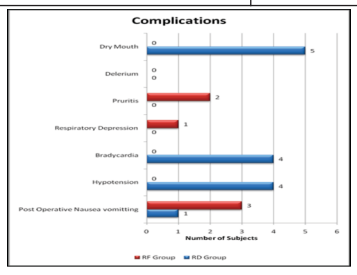
	Ramsay Sedation Scale	R-0	R-15 mins	R-30 mins	R1 hr	R2 hr	R3 hr	R4 hr	R5 hr	R6 hr	R8 hr	R10 hr	R12 hr
RD Group	N	30	30	30	30	30	30	30	30	30	30	30	30
	Mean	1.27	2.70	2.00	2.47	2.77	2.73	2.60	2.10	1.87	1.43	1.77	1.80
	SD	0.45	3.83	0.00	0.51	0.43	0.45	0.50	0.48	0.35	0.50	0.43	0.61
RF Group	N	30	30	30	30	30	30	30	30	30	30	30	29
	Mean	1.13	2.07	2.03	2.20	2.27	2.03	2.10	2.13	1.80	1.80	1.67	1.76
	SD	0.35	0.25	0.18	0.41	0.45	0.32	0.31	0.43	0.48	0.41	0.55	0.44
	P value Unpaired t test	0.2034	0.3740	0.3256	0.0287	0.0000	0.0000	0.0000	0.7791	0.5421	0.0030	0.4344	0.7649



80By conventional criteria the association between the intervention groups and RSS score is considered to be statistically significant between 1 -4 hours and 8th hour since $p < 0.05$ as per unpaired t test. In simple terms, in patients belonging to Ropivacaine + Dexmeditomidi ne intervention group, the RSS score is increased to an average of 2.40 in comparison with patients belonging to Ropivacaine + Fentanyl intervention group in whom the RSS score is an average of 2.08. This indicates that there is a true difference among intervention groups and the difference is significant with a p -value of < 0.05 according to unpaired t-test. The RSS score was meaningfully more in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean difference of 0.32. This significant difference of 1.15 times increase in RSS score in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group is true and has not occurred by chance. . In this study we can safely conclude that Post- operative epidural block with Ropivacaine + Dexmeditomidine results in significantly higher Ramsay Sedation Scale score compared to Post- operative epidural block with Ropivacaine + Fentanyl when used In post-operative patients who are undergoing elective spine surgeries.

Table 17.Complications

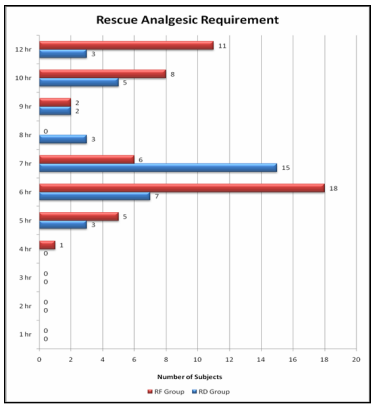
Complications	RD Group	%	RF Group	%	p value Fishers Exact Test
Post-Operative Nausea vomiting	1	7.14	3	50.00	0.6120
Hypotension	4	28.57	0	0.00	0.0562
Bradycardia	4	28.57	0	0.00	0.0562
Respiratory Depression	0	0.00	1	16.67	>0.9999
Pruritus	0	0.00	2	33.33	0.4915
Delirium	0	0.00	0	0.00	>0.9999
Dry Mouth	5	35.71	0	0.00	0.0522
Total	14	100	6	100	



Most of the Ropivacaine + Dexmeditomidine intervention group patients had dry mouth as the presenting complication (n=5. 35.71%) . Similarly the Ropivacaine + Fentanyl intervention group patients had pruritis as the presenting complication (n=2, 33.33%). By conventional criteria the association between the intervention groups an d complications is considered to be not statistically significant since $p > 0.05$ as per fishers exact test.

Table 18. Rescue Analgesic Requirement

Rescue Analgesic Requirement	RD Group	%	RF Group	%	P value Fishers Exact Test
1 hr	0	0.00	0	0.00	>0.9999
2 hr	0	0.00	0	0.00	>0.9999
3 hr	0	0.00	0	0.00	>0.9999
4 hr	0	0.00	1	1.96	>0.9999
5 hr	3	7.89	5	9.80	0.7065
6 hr	7	18.42	18	35.29	0.0082
7 hr	15	39.47	6	11.76	0.2921
8 hr	3	7.89	0	0.00	0.2373
9 hr	2	5.26	2	3.92	1.0000
10 hr	5	13.16	8	15.69	0.5321
12 hr	3	7.89	11	21.57	0.0303
Total	38	100.00	51	88	



By conventional criteria the association between the intervention groups and rescue analgesic requirement is considered to be statistically significant at 6th, 7th and 12th hour since $p < 0.05$ as per fishers exact test test. In simple terms, the rescue analgesic requirement at 6th hour was less in patients belonging to Ropivacaine + Dexmeditomidine intervention group(n=7, 18.42%) in comparison with patients belonging to Ropivacaine + Fentanyl intervention group (n=18, 35.29%) This indicates that there is a true difference among intervention groups and the differenceis significant with a p-value of 0.0082. The rescue analgesic requirement was meaningfully less in Ropivacaine + Dexmeditomidine intervention group at 6th hour compared to Ropivacaine + Fentanyl intervention group by a difference of 16.87 percentage points. This significant difference of 1.92 times increase in the rescue analgesic requirement in Ropivacaine + Fentanyl intervention group compared to Ropivacaine + Dexmeditomidine intervention group is true and has not occurred by chance.

Similarly the rescue analgesic requirement at 12th hour was less in patients belonging to Ropivacaine + Dexmeditomidine intervention group (n=3, 7.89%) in comparison with patients belonging to Ropivacaine + Fentanyl intervention group (n=11, 21.57%). This i ndicates that there is a true difference among intervention groups and the difference is significant with a p-value of 0.0303. The rescue analgesic requirement was meaningfully less in Ropivacaine + Dexmeditomidine intervention group at 12 th hour compared to Ropivacaine + Fentanyl intervention group by a difference of 13.67 percentage points. This significant difference of 2.73 times increase in the rescue analgesic requirement in Ropivacaine + Fentanyl intervention group compared to Ropivacaine + Dexmeditomidine intervention group is true and has not occurred by chance.

In this study we can safely conclude that Post - operative epidural block with Ropivacaine + Dexmeditomidine results in significantly lower rescue analgesic requirement compared to Post - operative epidural block with Ropivacaine + Fentanyl when used In post-operative patients who are undergoing elective spine surgeries.

DISCUSSION

Patients undergoing spinal surgeries experience severe pain in the postoperative period, which may increase the morbidity , incidence of complications and prolong postoperative rehabilitation. Postoperative pain therapy mainly consists of administration of oral or intravenous opioids in combination with non steroidal anti-inflammatory drugs, but it often results in insufficient pain control and side effects such as respiratory depression, nausea, and vomiting. Epidural anesthesia and analgesia have been shown to be superior to intravenous analgesia with respect to quality of pain relief, incidence of side effects, pulmonary, cardiac, and gastrointestinal dysfunction. Turner et al.(34), showed in an observational study that epidural catheters placed intraoperatively by the surgeon followed by infusion of local anesthetics with or without opioids were capable of providing good analgesia after posterior spinal fusion. Even when the epidural space was disrupted during surgery, local anesthetic that leaks out from epidural space acts like wound infiltration..A good cooperation and communication is needed with the respective surgeon , who places the epidural catheter directly into the surgical field. It is easy to understand that surgeons are afraid of development of any kind of infection of the wound or the epidural space, especially after spine surgery, because even small hematomas are an exce llent medium for bacteria. At first glance, a catheter directly placed in this area does not gain acceptance in the eyes of the surgeons, irrespective of the applied medication. Apart from dislodgement, the placement of an epidural catheter into a recently operated area in the vertebral column with epidural application of local anesthetics may include the problem of unpredictable absorption of the drug and motor blockade.

An ideal adjuvant should provide a longer duration of analgesia and better hemodynamic stability. There is a reduced requirement of analgesics with the use of an epidural adjuvant due to the property of augmentation of the local anaesthetic effects, thereby prolonging the duration of analgesia. To avoid neuraxial opioid induced adverse effects such as respiratory depression, nausea, vomiting, urinary retention and pruritus, α -2 agonists are being used as an alternative epidural adjuvants. Introduction of this newer agent dexmedetomidine has increased the scope of α-2 agonists usage in neuraxial blockade. Rapid onset of local anaesthetic action, longer period of analgesia and better cardiovascular parameters have widened the scope of usage of dexmedetomidine epidurally.

In our prospective randomized control study, we compared the analgesic efficacy of fentanyl 1µg/kg and dexmedetomidine 1µg/kg which were added to 15 ml 0.2% ropivacaine , by giving these drugs through an epidural catheter in 60 patients undergoing elective spine surgeries. The efficacy of dexmedetomidine verses fenta nyl as an adjuvant in epidural analgesia was studied. The patients in both the groups with respect to age, weight, ASA Physical status did not show a statistically significant difference.

ONSET OF ANALGESIA

The onset of sensory analgesia at T10 segment was earlier in RD group (5.93±0.700 min) than in the RF group (7.67±0.702 min). For onset of anaesthesia, the determinants are, diffusion through meningeal layers, penetration of neural tissue and distribution of the drug in various tissues. Dexmedetomidine being more lipophilic and having a favourable pKa produces an earlier onset of anagesia than fentanyl.

PEAK EFFECT OF ANALGESIA

The peak effect of analgesia in our study was at 12.07min. for RD group and at 13.13min. for RF group which is statistically significant (Pvalue- 0.1330)

DURATION OF ANALGESIA

In our study, the mean duration of analgesia as measured by the time taken for first rescue analgesic was significantly longer in RD group than RF group (349.80± 8.124min vs 298.20±4.77min). The mean durat ion time was meaningfully more in Ropivacaine + Dexmeditomidine intervention group compared to Ropivacaine + Fentanyl intervention group by a mean time of 52.20 minutes. This parameter show that the analgesic potentiating effect of dexmedetomidine is more than that offentanyl.

All these characteristics correlate with the study conducted by **sukhminder jit singh bajwa** *et al* [19]., in 100 patients undergoing elective lower limb orthopaedic surgeries under lumbar epidural with dexmedetomidine 1µg/kg and fentanyl 1µg/kg added to ropivacaine 0.75% as

the study drug. In his study the onset time to reachT10 sensory level, was significantly shorter in group RD (7.12 ±2.44mon.) as compared to group RF(9.146±2.94). The time to reach peak analgesia was significantly shorter in RD group (13.38±4.48)compared to RF group(16.61±4.36). The mean duration of analgesia was longer

(366.62±24.42min) in RD group than (242.16±3.86min) in the RF group thus promissing the superior block characteristics of RD group than RF group.

MS Saravana babu *et al*., (2014)[conducted a prospective randomized study in 60 patients to evaluate the efficacy and clinical profile of Dexmedetomidine and Clonidine as an adjuvant to Ropivacaine, in epidural analgesia in spine surgeries by giving 20 ml of 0.2% Ropivacaine and 1 µg/kg of Dexmedetomidine (group RD) or 20 ml of 0.2% Ropivacaine and 2 µg/kg of Clonidine (group RC

They observed that the addition of Dexmedetomidine to Ropivacaine as an adjuvant resulted in an earlier onset (7.33±1.76 min) of analgesia as compared to the addition of Clonidine (8.40±1.61 min). The duration of analgesia was also prolonged in Dexmedetomidine group (407.00±47.06 min) compared to Clonidine group (345.01±35.02)..These results correlate with our study.

Ravi Prakash, B.B.Kushwaha, Shashibhushan, V.K.Bhatia, Girish Chandra and B.P.Singh et al did a comparative study of Bupivacaine 0.25% alone and with Fentanyl or Dexmedetomidine for percutaneous nephrolithotomy (pcnl) under epidural anaesthesia. The study was conducted on 75 patients who were randomly allocated in to threegroups, Group A (n=25): patient receiving only 20 ml epidural 0.25% Bupivacaine. Group B (n=25): patient receiving 20 ml epidural0.25% Bupivacaine along with Fentanyl (1mcg/kg) and Group C (n=25): patient receiving 20 ml epidural 0.25% Bupivacaine along with Dexmedetomidine (1mcg/kg).They observed that addition of Fentanyl and Dexmedtomedine prolongs the duration of analgesia. Dexmedetomidine was more effective in this respect. Time for 2 segment regression was 86.52 ± 9.07minutes for Group A, 120.00 ± 5.95 minutes for . Group B and 135.40 ± 9.57 minutes for Group C.These results also correlate with our study that Dexmedetomidine is an better alternative adjuvant to Fentanyl, for epidural local anesthetics in prolonging the duration of anaesthesia with stable hemodynamics.

Ajay Kumar Anandan *et al*.,(2014)[30] conducted a study comparing Ropivacaine with Dexmeditomedine (RD) with Ropivacaine (R) in 30 patients and concluded that the onset was earlier i n RD (3.60min.) compared with R group (4.60 min.). and the duration of analgesia was prolonged in RD (289min.) compared to R group (243 min). this results were correlated with our study.

Mausumi Neogi *et al.*, [24] (2010) did a comparative study on paediatric patients undergoing elective inguinal herniotomy. They compared the efficacy of Clonidine 1 µg/kg and Dexmedetomidine 1 µg/kg as adjuvants to Ropivacaine for caudal analgesia.. They randomized the patients into 3 study groups, group R (Ropivacaine), group C (Ropivacaine+ Clonidine), group D (Ropivacaine + Dexmedetomidine) and observedthat, the mean duration of analgesia was 6.32±0.46 hours in group R, 13.17±0.68 hours in group C and15.26±0.86 hours in group D. Duration of analgesia was significantly prolonged in both group C and group D in comparison to group R but not between group C and group D. They concluded that the addition of both Clonidine and Dexmedetomidine with Ropivacaine administered caudally significantly increased the duration of analgesia. These results also correlate with our study.

Sarabjit Kaur et al.,[33] (2014) conducted a prospective, randomized double-blind study in 100 patients undergoing lower limb surgeries by randomly into groups receiving 150 mg of 0.75% Ropivacaine (Group A) and 150 mg of 0.75% Ropivacaine with Dexmedetomidine (1 µg/kg) (Group B). Two groups were compared with hemodynamic changes, block characteristics which included time to onset of analgesia at T10, maximum sensory analgesic level, time to maximum sensory and motor block, regression at S1 dermatome and time to the first dose of rescue analgesia. Significant difference was observed in relation to the duration of sensory block (375.20 ± 15.97 min. in Group A and 535.18 ± 19.85 min. in Group B [*P* - 0.000]), duration of motor block (259.80 ± 15.48 min in Group A and 385.92 ± 17.71 min in Group B [*P* - 0.000]), duration of post-operative analgesia (312.64 ± 16.21 min in Group A and 496.56 ± 16.08 min in Group B [*P* < 0.001]) and consequently low doses of rescue analgesia in Group B (1.44 ± 0.501) as compared to Group A (2.56 ± 0.67). They concluded that Epidural Dexmedetomidine as an adjuvant to Ropivacaine associated with prolonged sensory and motor block, hemodynamic stability, prolonged postoperative analgesia and reduced demand for rescue analgesics when compared to plain Ropivacaine. Thesestudy also concluded that addition of Dexmedetomidine to Epidural Ropivacaine prolongs the duration of action, and gives earlier onset of action of Ropivacaine.

HEMODYNAMIC PARAMETERS

In our study the mean Heart Rate(HR), Systolic blood pressure (SBP), Diastolic blood pressure(DBP) at varying time intervals showed significant difference between the groups RD and RF. Though there was decrease in HR ,fall in SBP,DBP in both the groups, the mean HR was maintained between 60-70/min (70.93) in RD group whereas it was maintained at 65 - 80/min(79.13) in RF group. The mean SBP range from 127.07 mm Hg at baseline to 120.40 mm Hg at the end of 12 hours in RD group and mean SBP ranging from 130.00 mm Hg at baseline to 120.80 mm Hg at the end of 12 hours in RF group. The mean DBP range from 77.93 mm Hg at baseline to 79.03 mm Hg at the end of 12 hours in RD group and mean DBP range from 79.60 mm Hg at baseline to 79.10 mm Hg at the end of 12 hours in RF group.

The study done by **sukhminder jit singh bajwa** et al[19]., showed hemodynamic stability with both RF and RD groups and there was no significant difference on statistical comparison. The mean dose of mephentermine required was 11.8mg in RD and 8.mg in RF group in their study. The better hemodynamic stability and longer duration of sensory analgesia by dexmedetomidine has also been shown in the study of **Gupta et al**[26]. They compared intrathecal administration of ropivacaine and ropivcaine/ dexmedetomidine and concluded that dexmedetomidine group has longer duration of analgesia with better hemodynamic stability.In A comparative study in the post-operative spine surgeries by epidural Ropivacaine with Dexmedetomidine andRropivacaine with Clonidine for post-operative analgesia conducted **by M S.SARANABABU** et al . There was no significant difference of heart rate and mean arterial blood pressure in both the groups at the time of administration of drugs, but it started to decrease as evident at 30 min post-injection, there was a fall in both groups. There was a decreasing trend of heart rate and mean arterial pressure post-injection in both groups and this decrease was significant in the RC group compared with RD group (*P*<0.05) but none of the patient showed bradycardia or hypotension at any time.

There was a decrease in mean respiratory rate in both the groups after giving the drug and the difference between the groups was statistically not significant (*P*>0.05) at different time intervals. None of the patient showed respiratory depression (<10/min) at any time. Our study results also correlate with this study in terms of hemodynamic stability.

VISUAL ANALOGUE SCORE

VAS score between group RD was 1.79 and 2.31 in group RF and found to be significant during the whole period of observation (p<0.05) which correlated with study done by **Gupta et al** [26]., which showed the maximum visual analogue scale score for pain was less in group RD (4.4±1.4) as compared to group R (6.8±2.2).

RESCUE ANALGESIC REQUIREMENT

In our study, the rescue analgesic requirement at the 6th hour was less in RD group(18.42%) compared to RF group (35.29%) . Similarly at 12th hour, it was 7.89% in RD group ompared to RF group (21.57%). I n the study conducted by Sarabjit kaur et al.,[25] there was

significant delayed requirement of rescue analgesia (496.56 ± 16.08 min in Group A and 312.64 ± 16.21 min in Group B) and also reduced 24 h analgesic requirement (1.44 ± 0.501 in Group B and 2.56 ± 0.67 in Group A) with 1 µ/kg Dexmedetom idine added to Ropivacaine, which supports the analgesic efficacy of Dexmedetomidine as an epidural adjuvant.

In the study conducted by **MS Saravana babu *et al***., (2014)[32] , they compared the efficacy of Ropivacaine and Dexmedetomidine with Ropivacaine and Clonidine. They concluded that the need for IV rescue analgesics in both the groups was nil throughout the study period. The mean VAS score was higher in the Clonidine group at each time interval. They concluded that, the epidural route provided adequat e analgesia in spine surgeries and Dexmedetomidine is a better neuraxial adjuvant to Ropivacaine for providing early onset and prolonged post -operative analgesia and stable cardiorespiratory parameters.

RAMSAY SEDATION SCORE

In our study, the mean sedation score at various time intervals was significant between these two groups. Majority of patients in RF group were sedated to score of 0,1 and 2 but in RD group the patients were sedated to a score of 2 and 3.This is correlated with the study conducted by **Sukhminder Jit singh Bajwa et al.[19],** sedation in RD group was 2 in 38% , 3 in 48% whereas RF group had sedation score of 2 in 16% and 3 in 2%. In this study we can safely conclude that RSS score was significantly higher in RD group than RF group.

***Oriol-Lopez et al*[24]** conducted an observational study to find out the anxiolytic and sedative property of dexmedetomidine. Epidural dexmedetomidine 1µg/kg was given with lignocaine in 40 patients who underwent various abdominal surgeries. They used Ramsay sedat ion score and concluded that 90% of the study group were sedated to a score of 3 and 4 from 15 to 90 minutes after drug administration.

COMPLICATIONS

In our study, the predominant side effect was dry mouth , bradycardia and hypotension in RD group whereas in RF group it was Nausea and vomiting. In the RD group, 35.71% had dry mouth, bradycardia and hypotension 28%. Similarly the RF group 50% had Nausea and vomiting pruritis 33% as the presenting complication. There was no respiratory depression in RD group but 16.67% in RF group. **Sukhminder jit singh bajwa et al.[19],** showed nausea and vomiting as the predominant side effect in RF group, nausea and dry mouth in RD group and none in both the groups had respiratory depression.

SUMMARY

In this prospective randomized study, the analgesic efficacy of dexmedetomidine 1µg/kg and fentanyl 1µg/kg which were added to 15 ml of0.2% ropivacaine were compared by giving these drugs through an epidural catheter in 60 patients undergoing elective spine surgeries. Th e efficacy of dexmedetomidine versus fentanyl as an adjuvant in epidural analgesia was studied.

The following observations were made:

1) The onset of sensory analgesia was earlier in Ropivacaine Dexmeditomidine (RD) group (5.93±0.700 min) than Ropivacaine Fentanyl (RF) group (7.67±0.702 min).
2) The peak effect of analgesia in our study was 12.07min. for RD group and 13.13min. for RF group which is statistically significant (Pvalue - 0.1330).
3) The mean duration of analgesia as measured by the time taken for first rescue analgesic was significantly longer in RD group than RF group (349.80± 8.124min vs 298.20±4.77min).
4) Both the groups showed haemodynamic stability but the incidence of side effects such as hypotension and bradycardia were more in patients who received dexmedetomidine , which was managed easily with inj Ephedrine 6mg and inj Atropine 0.6 mg.
5) Visual Analogue Scale score in group RD was 1.79 and 2.31 in group RF and it was found to be significant during the whole period of observation ($p<0.05$)
6) The rescue analgesic requirement was less with RD group when compared to RF group in the whole study period.
7) The administration of dexmedetomidine epiduraly produced sedation that was arousable, for many hours when compared to the plain ropivacaine group. The mean sedation score at various time intervals was significant between these two groups.
8) No episode of respiratory depression was noted in RD group compared to RF group.

CONCLUSION

It can be concluded from the study that epidural route provided adequate analgesia in spine surgeries in terms of VAS score in both thegroups and analgesia was effective . However, Dexmedetomidi ne seems to be a better alternative to fentanyl as an epidural adjuvant as it provides comparably stable hemodynamics, early onset and es tablishment of sensory anesthesia, prolonged analgesia in the post operative period, lesser consumption of post-operative rescue analgesics and much better sedation levels.

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