

A Clinical Comparative Study between Fentanyl and Dexmedetomidine as an Adjuvant with 0.75% Ropivacaine in Epidural Anaesthesia for Lower Limb Orthopaedic Surgery

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ABSTRACT

Introduction: Epidural anaesthesia is a common method for anaesthetic management after lower limb orthopaedic surgery. The aim is to study the anesthetic effects along with hemodynamics and adverse effects, if any when fentanyl and dexmedetomidine are used as an adjuvant to 0.75% Ropivacaine in epidural anaesthesia for major lower limb orthopaedic surgery.

Material and methods: The study included 100 cases classified randomly into two groups (each=50): Group RF: Patient receiving epidural anaesthesia with 15 ml of 0.75% Ropivacaine and 1microgram/kg Fentanyl. Group RD: Patients receiving epidural anaesthesia with 15 ml of 0.75% Ropivacaine and 1microgram/Kg of Dexmedetomidine.

Results: The quality of analgesia was better with dexmedetomidine than fentanyl group ($p<0.05$), and the requirement for first rescue top up was significantly latter with dexmedetomidine than fentanyl group ($p<0.05$). In our study while comparing the adverse effects between the two groups we did not find any significant difference between the two groups statistically. The incidence of nausea and vomiting was higher in fentanyl group while incidences of urinary retention, shivering and dry mouth was higher in dexmedetomidine group.

Conclusion: Dexmedetomidine is a better adjuvant to epidural ropivacaine compared to fentanyl for epidural anaesthesia in patients undergoing lower limb orthopaedic procedures.

Keywords: Dexmedetomidine, Fentanyl, Epidural Ropivacaine

many a time for achieving desired peri-operative anesthetic effect resulting in a higher risk of local anesthesia toxicity. Therefore, keeping in mind the numerous benefits of epidural technique and the new amide local anesthetic ropivacaine, having lesser systemic toxicity as well as lesser propensity of motor block during post operative period, the following study has been undertaken to search for a better and newer adjuvants (Fentanyl and Dexmedetomidine) giving superior quality of anesthesia with fewer adverse effects and stable haemodynamics. Fentanyl binds to mu opioid G-protein coupled receptors, which inhibits pain by release of neurotransmitter and also by decreasing intracellular Ca^{2+} levels. Fentanyl is 800 times more lipid soluble than Morphine and is rapidly absorbed from the epidural space and CSF. Analgesia is produced primarily through interaction with mu receptor at supraspinal site. It also binds to Kappa receptor, substansia gelatinosa of spinal cord. Fentanyl being a lipophilic opioid agonist, provides rapid onset, a dose sparing effect of local anesthesia and superior analgesia, reduced cephalic spread. Dexmedetomidine, a highly selective alpha-2 adrenergic receptor agonist with relative ratio of alpha2/alpha1 activity (1620:1), which is eight times higher than that of clonidine. It possesses all the properties of analgesic, peri operative sympatholysis, anxiolysis, effective sedation yet easily arousable and haemodynamic stabilizing properties.

Current research aimed to study the anesthetic effects along with hemodynamics and adverse effects, if any when fentanyl and dexmedetomidine are used as an adjuvant to 0.75% Ropivacaine in epidural anaesthesia for major lower limb orthopaedic surgery.

INTRODUCTION

Pain is a common human experience, a symptom frequently encountered in clinical practice. "Failure to relieve pain is morally and ethically unacceptable". Adequate pain relief could be considered as a basic human right. Various modalities for control of pain, peri-operatively and post-operatively has been tried, out of which spinal and epidural techniques which are regional anesthesia techniques has been very popular for lower limb and lower abdominal operations as it has many advantages over general anesthesia. Epidural technique is a versatile technique and has been widely used in anesthesia practice, as it has the benefit for not only providing peri-operative surgical anesthesia but post-operative analgesia in lower abdominal and lower limb surgeries, allowing early rehabilitation, facilitate rapid recovery, reduce morbidity and allow early discharge from hospital. Analgesia with pure local anesthesia without any adjuvant needs higher doses,

MATERIAL AND METHODS

After obtaining an approval of research and ethical

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committee of hospital and after having informed consent from each patients a prospective randomized clinical study was done for one year duration. 100 cases of adult patients in the age group 18-60 years from Orthopedics Department Assam Medical College and Hospital, Dibrugarh were taken up for study to undergo epidural anesthesia with fentanyl and dexmedetomidine as an adjuvant and 0.75% Ropivacaine as a local anaesthesia.

Inclusion criteria

- Patient aged between 18-60 years.
- Patient with ASA Grade I or II.
- Patient planned for elective orthopedic procedures of hip, femur, tibia, both bone leg and patella with approximate same duration of operation.

Exclusion criteria

ASA Grade \geq to III.

Known case of hypersensitive reactions to local anesthetics or adjuvants in the present study.

Patients with medical complications like anaemia, diabetes mellitus, cardiac disease, hypertension, chronic respiratory disease, hypovolemia, shock, septicemia, coagulation abnormalities or any anticoagulant therapy.

Patients with spinal deformity or vertebral anomaly.

Local infection at the site of proposed puncture for epidural anesthesia.

Emergency surgeries.

Plan of study

The study were carried out on total 100 patients. The total number of patients were randomly allocated into two groups and each group with 50 patients each, based on sequentially numbered opaque sealed envelope technique (SNOSE).¹⁵⁰

A. Group RF: Patient receiving epidural anesthesia with 15 ml of 0.75% Ropivacaine and 1microgram/kg Fentanyl.

B Group RD: Patients receiving epidural anesthesia with 15 ml of 0.75% Ropivacaine and 1microgram/Kg of Dexmedetomidine.

Both the groups received equal volume of the adjuvant diluted with normal saline whenever required to make the volume up to 2 ml.

All study solution were prepared aseptically in identical syringes and were administered at room temperature.

Methodology

All patients included in this study received tab Alprazolam 0.5 mg orally, the night before operation. In all patients IV line was established and inj Ranitidine 50 mg i.v was given and an infusion of 10 ml/kg of Ringers lactate was commenced. In the operating room standard monitoring was established (ECG, Non-invasive Blood pressure, pulse oximetry) and baseline measurements were recorded.

Lumbar epidural anesthesia was induced using 18 G Touhy needle with patients in the sitting position in L3-L4 interspace and location of epidural space was confirmed using loss of resistance technique. A test dose of 3 ml of 2% Lignocaine with adrenaline was administered into epidural space and thereafter epidural catheter was secured 3 to 5 cm into

epidural space and patient was placed in the supine position. The respective drugs depending on the group allocated were injected bolus slowly at the rate of 1ml/sec into the epidural space after confirmation of the correct placement of the epidural catheter.

Heart rate, Mean arterial pressure, SPO2 was recorded using standard monitors before epidural

injection and thereafter every 5 mins for the first 30 mins and then every 15 mins interval thereafter till 60 min and then at 30 min interval till 240 mins and then finally at 60 min interval till the time when pain reappeared. A decrease in Mean arterial pressure less than physiological limit of 65 mm of Hg were considered to be hypotensive and treated with IV fluids and 3mg/dose of intravenous ephedrine.

- A heart rate less than 50/min were considered to be bradycardia and were treated with 0.6mg intravenous atropine.

The degree of sensory block was assessed by Visual Analog Scale:

The patient was shown a scale of 10 cm length. 0 end of the scale was taken as "no pain" and 10 cm mark as "worst possible pain". Intensity of pain increases gradually from 0 to 10 and the patient was asked to grade accordingly to the intensity of pain.

Sensory block height:

It was assessed by loss of sensation to pin prick on the dependent side using a 22G blunt hypodermic needle in the midclavicular line at 1 min interval after injection for 5 min and then every 5 min interval, until 2 consecutive levels of sensory block were identical. Surgery was initiated once the level of sensory block reached T10 level. Assessment was continued every 30 mins after completion of surgery until regression to S1.

The degree of motor block was assessed by the Modified Bromage scale:

Motor blockade in the lower limbs was assessed using modified Bromage scale.

Bromage 0 – able to perform a full straight leg raise over the bed for 5 sec

Bromage 1 – unable to perform the leg raise but can flex the leg on the knee articulation

Bromage 2 – unable to flex the knee but can flex the ankle

Bromage 3 – unable to flex ankle but can move the toes

Bromage 4 – unable to move toes (total paralysis).

Assessment was done at 1 min interval after injection for the first 5 mins and then every 5 mins until maximum block was achieved and than surgery was commenced. Assessment of motor block was then done at 30 min interval till regression of motor block to Bromage 1.

Successful epidural anaesthesia was defined as surgical anaesthesia (loss of pin prick sensation at T10 and Bromage score 2 or 3).

The level of sedation was assessed by modified Ramsay sedation score:

Score response

S1 Anxious and agitated or restless, or both.

S2 - Co-operative, oriented, and calm.

S3 - Responsive to commands only.

S4 - Exhibiting brisk response to light glabellar tap or loud auditory stimulus.

S5 - Exhibiting a sluggish response to light glabellar tap or loud auditory stimulus.

S6 - Unresponsive.

Sedation scores was recorded just before initiation of surgery and then every 5 mins for the first 30 minutes and then 15 minutes interval for the next 30 min and there after at 30 min interval.

Time to first rescue top-up was interpreted as the time when the patient first complaint of pain and was recorded

Any adverse effects, intra operative or post operative was recorded.

After surgery the patient was transferred to the post operative monitoring room and was monitored accordingly.

The following parameters was observed immediately after the administration of epidural block:

1. **Motor Block:** The following parameters was assessed.
 - a. Time for onset of complete motor block.
 - b. Grade of motor blockade.
2. **Sensory Block:** The following parameters was assessed.
 - a. Time for onset of sensory analgesia at T10.
 - b. Maximum block height reached.
 - c. Time taken to reach maximum block level.
3. Ramsay Sedation Score.
4. Heart Rate, Mean Arterial Pressure and SpO₂
5. Adverse Effects.
6. Comparison of post operative block characteristics
 - a. Mean time for two segment dermatomal regression
 - b. Mean time for regression to Sacral level 1.
 - c. Mean time for regression to Bromage 1.
 - d. Time for first rescue top- up.

Equipments and Accessories used in the present study:

- A. Aseptic and sealed epidural set consisting of 18G tuohy needle, LOR syringe, epidural catheter with filter.
 - B. One sterilized drape sheet.
 - C. One pointed knife.
 - D. Syringes (one 5ml for test dose, two 10ml for LA, one 2ml for adjuvant and one 2ml for local injection of local anesthesia into the site of epidural injection).
 - E. Sterilized swabs with swab holding forcep.
 - F. Two gallipots (one for povidone iodine and another for rectified spirit)
 - G. Boyle's anesthetic machine containing oxygen and nitrous cylinders with vapourizers containing isoflurane as well as equipments for resuscitation (appropriate size endotracheal tubes, working laryngoscope with medium and large size blades, stylet and working suction apparatus) were kept ready before the procedure.
 - H. Adjustable operating table.
- Emergency drugs (atropine sulphate, ephedrine, adrenaline, dopamine) were kept ready with us.

STATISTICAL ANALYSIS

Appropriate statistical tools were applied to analyze the data.

Results were expressed as the means and standard deviation or as numbers and percentages. The comparison of normally distributed continuous variables between groups was performed by using one way analysis of variance (ANOVA). Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two groups.

Statistical analysis was done by applying Chi-square test, ANOVA test and students "t" test to analyze the data, p value was determined and a confidence interval of 95% was taken.

RESULTS

Most common operation performed in group RD is open reduction and internal fixation of tibia (24%) and femur (22%). In group RF the most operation performed was also open reduction and internal fixation of tibia (26%) and femur (24%). This is comparable in both the groups, other operations though less in number but they were also comparable in both the groups (table-1).

In our study we found the mean time for onset of sensory

Type of Surgery	Group RD		Group RF	
	No.	%	No.	%
HRA	5	10	5	10
DCS	3	6	3	6
DHS	7	14	6	12
A and R	1	2	1	2
ORIF, FEMUR	11	22	12	24
ORIF, TIBIA	12	24	13	26
IRF, FEMUR	1	2	1	2
IRF, TIBIA	1	2	2	4
EXFIX, FEMUR	1	2	1	2
EXFIX, TIBIA	3	6	1	2
TBW, PATELA	5	10	4	8
PATELECTOMY	0	0	1	2

Table-1: Types of surgery performed in each group

	Group – RD (Mean±SD)	Group– RF (MEAN±SD)	"p" value
Mean Time±SD (minutes)	8.02±0.734	12.14±1.49	<0.01

Table-2: Mean time of sensory onset at T10 level

	Group– RD (Mean±SD)	Group–RF (Mean±SD)	"p" value
Mean Time±SD (minutes)	14.88±0.87	18.98±1.03	<0.01

Table-3: Time for maximum level of sensory block attained

	Group–RD (Mean±SD)	Group – RF (Mean±SD)	"p" value
Mean Time±SD (minutes)	20.5 ±1.187	24.2±1.113	<0.01

Table-4: Time for complete motor block

Grade (bromage)	Group-RD		G -RF		p value
	NO.	%	NO	%	
0	0	0	0	0	0.5
1	0	0	0	0	
2	5	10	8	16	
3	45	90	42	84	

Table-5: Grade of motor block

	Group RD	Group RF	p value
Mean Time±SD	161.76±6.12	120.6±3.06	<0.01

Table-6: Mean time for two segmental dermatomal regression

	Group RD	Group RF	P value
Mean time ± SD	311.34± 23.6	224.06±24.47	<0.01

Table-7: Mean time for dermatomal regression to S1

	Group RD	Group RF	P value
Mean time ± SD	181.2±17.53	157.46±18.32	<0.01

Table-8: Mean time for regression to B1

Sedation score	Group RD		Group RF		p value
	NO	%	NO	%	
S1	0	0	17	34	0.01
S2	15	30	33	66	
S3	29	58	0	0	
S4	6	12	0	0	

Table-9: Intraoperative sedation score

	Group RD	Group RF	p value
Mean time ± SD	344 ± 23.03	255.5± 23.12	<0.01

Table-10: Time to first rescue top-up

Side effect	Group RD		Group RF		p value
	NO	%	NO	%	
Nausea and vomiting	2	4	8	16	0.09
Pruritis	0	0	0	0	0
Urinary retention	5	10	4	8	1.0
Shivering	3	6	2	4	1.0
Dry mouth	9	18	2	4	0.05
Others	0	0	0	0	0

Table-11: Comparison of adverse effects between two groups

block at T10 level for group RD to be 8.02 ± 0.73 and that of group RF to be 12.14 ± 1.49 . There is a highly significant difference ($p < 0.01$) between the study groups in respect to the time for onset of sensory block at T10 level (table-2).

In our study we found the mean time for maximum level of sensory block attained for group RD to be 14.88 ± 0.872 minutes and that of group RF to be 18.98 ± 1.039 and the "p" value < 0.01 , which is statistically highly significant (table-3). In our study we found the mean time for onset of motor block for Group-RD to be 20.5 ± 1.187 and that of group RF to be 24.2 ± 1.113 and the "p" value < 0.01 , which is statistically highly significant (table-4).

In our study we found that 90% of the patients were of Bromage 3 and 10% were of Bromage 2 in the group

Time (minutes)	Group - RD	Group - RF	p value
PRE - OP	83.3 ± 11.9	82.5 ± 4.3	0.65
5	83 ± 12.64	80.9 ± 12.5	0.34
10	81.2 ± 12	77.6 ± 11.8	0.13
15	77.18 ± 12.06	74 ± 11.6	0.11
20	74.7 ± 11.2	72 ± 10.8	0.22
25	70.7 ± 10.5	71.9 ± 11.3	0.58
30	64.54 ± 6.5	66.44 ± 5.8	0.13
45	63.54 ± 3.6	64.9 ± 4.6	0.10
60	69.4 ± 10.6	69.6 ± 10.3	0.92
90	69.2 ± 9.3	70.4 ± 11	0.55
120	69.2 ± 9.4	71.6 ± 9.9	0.21
150	70.5 ± 10	73.1 ± 9.9	0.19
180	71.2 ± 9.8	73.2 ± 9.5	0.30
210	72.8 ± 6.3	74.4 ± 3.5	0.12
240	74.1 ± 3.8	75.4 ± 3.3	0.06
300	75.8 ± 6.1	77.08 ± 3.9	0.21
360	78.24 ± 5.9	80 ± 5.20	0.11

Table-12: Comparison of heart rate

Time (minutes)	Group - RD	Group-RF	"p" value
PRE - OP	86.08 ± 8.09	89.6 ± 10.02	0.05
5	84.48 ± 8.15	87.94 ± 9.45	0.05
10	82.52 ± 8.12	85.86 ± 9.09	0.05
15	80.4 ± 8.36	83.78 ± 8.76	0.05
20	78.66 ± 8	81.48 ± 8.76	0.09
25	76.16 ± 7.05	79 ± 7.82	0.05
30	73.54 ± 6.43	75.86 ± 6.63	0.07
45	71.28 ± 5.77	73.1 ± 5.73	0.11
60	69.9 ± 5.65	72.88 ± 5.87	0.11
90	70.9 ± 5.51	72.92 ± 6.24	0.08
120	71.62 ± 6.26	73.88 ± 6.72	0.08
150	72.22 ± 6.22	74.7 ± 6.89	0.06
180	74.02 ± 6.27	76.48 ± 6.72	0.06
210	75.32 ± 6.29	77.62 ± 6.52	0.07
240	77.14 ± 6.52	79.64 ± 6.33	0.05
300	78.72 ± 6.36	81.08 ± 6.16	0.06
360	81.08 ± 6.36	83.18 ± 6.66	0.11

Table-13: Comparison of mean arterial pressure

RD, while that in the group RF 84% of the patients were of Bromage 3 and 16% of the patients were of Bromage 2 (table-5).

In our study we found the mean time for two segment dermatomal regression for the group RD to be 161.76 ± 6.12 and that of group RF to be 120.6 ± 3.06 and the "p" value < 0.01 , which is statistically highly significant (table-6).

In our study we found the mean time for two dermatomal regression to S1 for the group RD to be 311.34 ± 23.6 and that of group RF to be 224.06 ± 24.47 and the "p" value < 0.01 , which is statistically highly significant (table-7).

In our study we found the mean time for regression to B1 for the group RD to be 181.2 ± 17.53 and that of group RF to be 157.46 ± 18.32 and the "p" value < 0.01 , which is statistically highly significant (table-8).

In our study the highest sedation score in the group RD was S4 and the maximum number of patients were found to have a sedation score of S3 (58%) and that in the group RF, the

highest level of sedation score and also the maximum number was found in S2 (66%). There is statistically significant difference between the two groups ($p = 0.001$) (table-9).

In our study we found the time to first rescue top-up for the group RD to be 344 ± 23.03 and that of group RF to be 255.5 ± 23.12 and the “p” value <0.01 , which is statistically highly significant (table-10).

In our study while comparing the adverse effects between the two groups we did not find any significant difference between the two groups statistically (table-11).

In our study there was no significant difference between the patients of group RD and group RF as far as HR was concerned and the “p” value was not significant at any time in the study period (table-12).

In our study there was no significant difference between the patients of group RD and group RF and the “p” value was not significant as far as MAP was concerned at any time in the study period (table-13).

DISCUSSION

In our study, the demographic profiles (age, sex, weight, height), ASA status, Types of surgery and duration of surgery were comparable and statistically insignificant.

Sensory block

Onset

In our study we found the mean time for onset of sensory block at T10 level for group-RD to be 8.02 ± 0.73 and that of group RF to be 12.14 ± 1.49 . We found a highly significant difference ($p < 0.01$) between the study groups in respect to the time for onset of sensory block at T10 level.

In the study conducted by Bajwa et al.¹, they found that in elective lower limb orthopaedic procedures, by addition of dexmedetomidine (1mcg/kg) to 0.75% ropivacaine resulted in an earlier onset of analgesia at T10 level 7.12 ± 2.44 min in comparison to fentanyl (1mcg/kg) and 0.75% ropivacaine 9.14 ± 2.94 min which is statistically significant and is in accordance with our study.

Similar studies done by Selim MF et al.², with epidural dexmedetomidine and fentanyl with bupivacaine during labor found that the mean onset of analgesia was significantly earlier in the dexmedetomidine group compared to the fentanyl group.

Gupta et al.³ compared the adjuvant effects between dexmedetomidine and fentanyl with other local anaesthetics epidurally and found that the onset of sensory analgesia at T10 level was earlier in the dexmedetomidine group (7.25 ± 2.3 mins) compared to the fentanyl group (9.27 ± 2.79 mins) which are similar to our study.

Similar results were also observed by Han C et al.⁴ in their study. They conducted the study on sixty parturients scheduled for CS under epidural anesthesia and divided them into three groups; dexmedetomidine ropivacaine (RD), fentanyl ropivacaine (RF) and normal saline ropivacaine (RN). After identification of the epidural space 15ml of 0.75% ropivacaine was administered epidurally with 1mcg/kg of dexmedetomidine in RD group, 1mcg/kg of fentanyl in RF group and 2 ml of normal saline in RN group. They found

that the administration of dexmedetomidine combined with ropivacaine can provide early onset of sensory anesthesia which is similar to the findings of our study.

Our study does not agree with Salgado PFS et al.⁵ Their study was aimed to evaluate clinical characteristics of epidural anesthesia performed with 0.75% ropivacaine associated with Dexmedetomidine. Forty patients scheduled for hernia repair or varicose vein surgeries under epidural anesthesia participated in this study and they concluded that it did not affect onset time which is in contrast to our study. The reason for that, may be the lesser number of study population which is only forty, whereas it is hundred in our study.

Maximum level of sensory block attained and mean time to achieve that:

In our study we found that the maximum level of sensory block attained by the group dexmedetomidine ropivacaine (RD) was at the level of T4, which was 16% of the total patients and maximum no of patients 48% was found at the level of T5; while in the group fentanyl ropivacaine (RF) the maximum level of block attained was T5 and 16% of the total patients attained that level and maximum no of patients 60% attained the level of T6.

We also found that the mean time for maximum level of sensory block attained for group dexmedetomidine ropivacaine (RD) to be 14.88 ± 0.872 minutes and that of group fentanyl ropivacaine (RF) to be 18.98 ± 1.039 and the “p” value <0.01 , which is statistically highly significant.

Bajwa et al.¹ in their study found that, not only maximum level of sensory block level was attained by the group Ropivacaine Dexmedetomidine (T4-6) in comparison to the group Ropivacaine Fentanyl (T5-7) but also it was achieved earlier in the group Ropivacaine Dexmedetomidine (13.38 ± 4.48 min) in comparison to the group Ropivacaine Fentanyl (16.61 ± 4.36 min). Similarly in our study we found that the group RD attained higher level of sensory block and the time to receive the sensory level was earlier in dexmedetomidine group compared to the fentanyl group.

Similarly Gupta et al.³ found in their study that when dexmedetomidine was compared with fentanyl as adjuvant, the median maximal sensory level attained with dexmedetomidine was T6 and the time taken to achieve maximum sensory block was 21.37 ± 4.3 min in comparison to the group RF with median maximal sensory level T7 and the time taken to achieve maximum sensory block 27.7 ± 3.1 min, which is comparable to our study.

Mean time for two segment dermatomal regression and regression to S1:

In our study we found the mean time for two segment dermatomal regression was prolonged for the group Ropivacaine Dexmedetomidine 161.76 ± 6.12 compared to that of group Ropivacaine Fentanyl 120.6 ± 3.06 and the “p” value <0.01 , which is statistically highly significant. Also the mean time for dermatomal regression to S1 for the group Ropivacaine Dexmedetomidine was prolonged (311.34 ± 23.6 mins) in comparison to that of group Ropivacaine Fentanyl (224.06 ± 24.47 mins) also the “p” value was

<0.01, which is statistically highly significant.

Salgado PFS et al.⁵ in their study found that epidural dexmedetomidine with 0.75% ropivacaine did not affect upper level of anaesthesia which is in contrast to our study and the reason for that may be due to the lesser number of study population, which was only 20 in the ropivacaine dexmedetomidine group.

However, despite having a smaller study group, Salgado PFS et al.⁵ found that epidural dexmedetomidine with 0.75% ropivacaine provided a prolonged duration of sensory blockade which is in accordance with our study, and the reason for that may be due to the higher doses of ropivacaine (20ml) and dexmedetomidine (1mg/kg) used in their study. Similar to our study Bajwa et al.¹ found that though both the adjuvants provided a smooth and prolonged post operative analgesia but the effects of dexmedetomidine were more significant on statistical comparison as compared to fentanyl. They found that the dexmedetomidine ropivacaine group had prolonged time to two segmental dermatomal regression (140.32±10.21min) in comparison to the fentanyl group (110.84±9.48min). Also the mean time for regression to S1 was (328.28±28.14min) for the dexmedetomidine ropivacaine group and (204.64±26.38 min) for the RF group; which is in accordance with our study and corroborates our study.

Similar results were observed by Selim MF et al.² In their study they found that dexmedetomidine as an adjuvant provided longer duration of sensory analgesia (155.6±28.1min) in comparison to fentanyl (129±18.7min) when combined with bupivacaine.

Also Gupta et al.⁶ in their study found that the total duration of sensory analgesia was longer in the dexmedetomidine group (187.7±6.9) compared to fentanyl group (146.7±8.3) when combined with levobupivacaine also.

Similarly Attri et al.⁶ in their study with 1mcg/kg of dexmedetomidine and 150 mg of 0.75% ropivacaine in epidural anesthesia for lower limb orthopedic surgeries found that it provided prolonged sensory analgesia.

MOTOR BLOCK (Mean time for complete motor block and grade of motor block):

In our study the mean time for complete motor block for RD group was 20.5±1.18 min and that of RF group to be 24.2±1.11 min and the “p” value <0.01, which is statistically highly significant. Also in our study we found that 90% of the patient were of Bromage 3 and 10% were of Bromage 2 in the group RD, while that in the group RF 84% of the patients were of Bromage 3 and 16% of the patients were of Bromage 2. In both the groups none of the patients were of Bromage 2. The difference between the two groups in regard to grade of motor block was not statistically significant. Also in our study we found that the mean time for regression to B1 for the RD group was 181.2 ±17.53 min and that for the group RF was. 157.46 ± 18.32 min and the “p” value <0.01, which is statistically highly significant.

Similar to our study Salgado PFS et al.⁵ (2008), found in their study that epidural dexmedetomidine with 0.75%

ropivacaine prolonged the motor block duration time and also resulted in a more intense motor block.

Also Carreon Jet al.⁷ in their study comparing dexmedetomidine and fentanyl as adjuvants in epidural anaesthesia for open elective abdominal surgery concluded that there was no significant differences between Dexmedetomidine and Fentanyl when compared in terms of motor blockade, when administered in the epidural space. This is in contrast to our study, and the reason for that may be due to the higher doses of fentanyl 100mcg/kg taken for their study in comparison to our study which was 1mcg/kg fentanyl.

Bajwa et al.⁸ in their study found that epidural dexmedetomidine provided an early onset of complete motor block as well as prolonged duration of motor block. The mean time for complete motor block for the group RD was 18.16 ±4.52 min and that for the group RF was 22.98±4.78 min. And the mean time for regression to B1 for the group RD was 259.62 ± 21.38 min and that for the group RF was 178.52 ± 23.29 min, which is similar to our study.

Also Gupta et al.⁹ found that, epidural dexmedetomidine and fentanyl when compared as an adjuvants with other local anaesthesia like 0.5% levobupivacaine, the time taken to reach complete motor block is early and duration of motor block (167.4 ± 21 min) is prolonged in the dexmedetomidine group than the fentanyl group, (125.6±36 min) which is statistically significant. So all of the above studies found that the time taken for complete motor block in the dexmedetomidine group was earlier in comparison to the fentanyl group. Also the time taken for regression of motor block to B1 was prolonged in the dexmedetomidine group as compared to the fentanyl group which corroborates our study.

However Selim MF et al.² in their study of comparative evaluation of epidural bupivacaine dexmedetomidine and bupivacaine fentanyl found that no cases showed Bromage score of greater than 2 which is in contrast to our study.

Intra operative sedation score

In our study patients were calm and compose in both the groups throughout the surgery, although dexmedetomidine showed superior sedation score during the intra-operative period. In our study the highest sedation score in the group RD was S4 (12%) and the maximum number of patients were found to have a sedation score of S3 (58%). While in the group RF, the highest level of sedation score as well as the maximum number of patients were found in S2 (66%). We found a statistically significant difference between the two groups (p=0.001), with dexmedetomidine showing higher Ramsay sedation scores than fentanyl.

Similar findings were observed by Benzon HT et al.¹⁰ in their study. They found that the degree of sedation was less in patients receiving epidural fentanyl which corroborates with our findings.

Also Carreon J et al.⁷ in their study found that higher ramsay scores were evident after giving epidural injection of dexmedetomidine when compared with fentanyl.

Similar studies comparing the sedative property of dexmedetomidine and fentanyl with local anaesthetics other than ropivacaine such as that done by ElKahim M, et al.¹¹ where they found that the use of epidural dexmedetomidine 1mcg/kg with bupivacaine prevents intra operative awareness.

Similarly Bajwa SJ et al.⁸ in their study while comparing the sedation level of both epidural dexmedetomidine and fentanyl with 0.75% ropivacaine found that, in the dexmedetomidine group 38% and 42% of patients exhibited grade 2 and grade 3 sedation as compared to 16% and 2% in the fentanyl group. Only 12% of the patients in the dexmedetomidine group had sedation score of 1 as compared to 82% wide and wake patients in the fentanyl group which is comparable to our findings.

In the study conducted by Wang Zhi-li.¹² to study the influence of epidural dexmedetomidine on intra operative awareness in thoracic surgery with one lung ventilation concluded that epidural dexmedetomidine provides good sedation and prevents intra operative awareness which is similar to our findings.

Similar findings were also observed by Jain D, et al.¹³ where they found that dexmedetomidine when given epidurally, the majority of the patients were sedated, yet arousable, by verbal commands or light tactile stimulus (sedation scale 3-4) 10+5 minutes following administration of dexmedetomidine in the epidural space.

Also Selim MF, et al.² in their study did a comparative evaluation of epidural dexmedetomidine and fentanyl with bupivacaine and found that the number of patients with a sedation score of 2 was significantly higher in the dexmedetomidine group compared with the fentanyl group. Similarly Gupta et al.⁹ in their comparative study between adjuvants dexmedetomidine and fentanyl with epidural 0.5% levobupivacaine for vaginal hysterectomy found that, the maximum Ramsay sedation score was higher (>3) in the patients belonging to the dexmedetomidine group, while it was less than 2 in the fentanyl group. Similar results were also found in our study, with dexmedetomidine group showing higher Ramsay sedation scores >2 than fentanyl ≤2. Also Negi S et al.¹⁴ and Han C et al.¹⁴⁸ in their study found that, dexmedetomidine-based anaesthetic regimen in comparison to the fentanyl-based anaesthesia provided appropriate anxiolysis and sedation, similar to our findings.

Hemodynamic changes and spo2

In our study hemodynamic stability was one of the important features with adjuvants dexmedetomidine and fentanyl with local anaesthesia, through epidural route. Table 19 and 20 shows the hemodynamic parameters of heart rate (HR) and mean arterial pressure (MAP) of both the groups. In our study both the groups showed a decreasing trend in the HR and MAP in the intra-operative period. Opioids negative chronotropic effect is a known fact, but in our study decrease in heart rate was also seen in dexmedetomidine group similarly. The maximum fall in the heart rate was seen during 30-60 minutes after epidural injection of the drugs

intraoperatively, thereafter the heart rate remain stable in the range of 60-80/min. Similarly a decreasing trend was observed in the MAP and the maximum decline was seen during 30-60 minutes after epidural injection of the drugs, but it never went below acceptable physiological limit of 65 mm Hg during the study period. In the post operative period both the HR and the MAP was stable. In our study the incidence of hypotension was 14% and bradycardia 12% in the dexmedetomidine group, were as 10% and 4% in the fentanyl group which is statistically not significant.

Similar to our study, Oriol Lopez SA et al.¹⁵ in their study found that after epidural blockade with dexmedetomidine 1mcg/kg to local anaesthesia, produces hemodynamic stability.

J. Carreon, et al.⁷ in their study compared the adjuvants effects of epidural dexmedetomidine 1mcg/kg and fentanyl 100mcg/kg with local anaesthesia for open elective abdominal surgery and found that the mean heart rate was lower in the dexmedetomidine group that needed treatment with atropine in comparison to the fentanyl group. But in contrast to it, in our study we found that the mean heart rate declined in both the groups at 30-50 mins that did not needed treatment with atropine except a very few patients in both the groups which was not statistically significant. However in their study they did not found any significant differences in the mean arterial pressure between the two groups which is similar to our study.

Also Bajwa SJ et al.⁸ in their study, compared the haemodynamic effects of both epidural dexmedetomidine and fentanyl with 0.75% ropivacaine and found that there was decline in the heart rate and mean arterial pressure in both the groups and maximum decline was seen at 30-50 mins. The decrease in the heart rate and mean arterial pressure between the two groups was not statistically significant. These findings are similar to our study which corroborates our study.

In contrast to our study Selim MF et al.² their study, found that significant hypotension and bradycardia occurred with epidural dexmedetomidine when compared with fentanyl. The reason for the significant hypotension in their study could have been due to the study population which included pregnant patient, in contrast to our study population which included lower limb orthopedic procedures. Also the local anaesthesia used in their study was bupivacaine which is more potent than ropivacaine.

Also, Gupta et al.⁹ in their comparative study of both epidural dexmedetomidine and fentanyl for vaginal hysterectomy, found that there was decline in the heart rate and mean arterial pressure in both the groups and maximum decline was seen at 30-35 mins. And they concluded that hemodynamic stability was one of the most remarkable features with addition of dexmedetomidine and fentanyl which we also found in our study.

Similarly Attri et al.⁶ in their study with 1mcg/kg of dexmedetomidine and 150 mg of 0.75% ropivacaine in epidural anaesthesia for lower limb orthopedic surgeries found that patients remained hemodynamically stable and

incidence of bradycardia and hypotension was comparable at all measured intervals, which is similar to our findings.

Similar to our findings, Negi S et al.¹⁴ also found stable hemodynamic parameters in their study.

Bamne et al.¹⁶ in their study with 0.75% ropivacaine and dexmedetomidine for lower limb surgery, concluded that the hemodynamic parameters such as heart rate and blood pressure remained stable throughout the intraoperative period, which we also found in our study

In our study stable spo2 without any respiratory depression was one of the important features with adjuvants dexmedetomidine and fentanyl with 0.75% ropivacaine through epidural route. Table 21 shows the spo2 of both the groups. Appropriate statistical test shows that there was no significant difference in the above parameter in the two study groups, which corroborates with the findings of Oriol Lopez SA et al.¹⁵, J. Carreon, et al.⁷, Bajwa et al.⁸, Yongxin Liang, et al.¹⁹, Selim MF et al.², Gupta et al.⁹, Negi S et al.¹⁴ and Bamne et al.¹⁶

Side effects

In our study of side effect profiles comparing the two groups, we found that the incidence of nausea and vomiting was more in the RF group 16% in comparison to the RD group 4%. And the incidence of dry mouth was higher in the dexmedetomidine group 18% compared to fentanyl group 4% but was statistically not significant. In our study we did not find any statistical difference in the incidence of urinary retention in both the groups although it is a known side effect of opioids. Also the incidence of shivering was less in both the groups and was statistically not significant. There was no incidence of pruritus in both the groups and no other side effect was seen in both the groups.

Similar findings were observed by Bajwa et al.¹ were they found the incidence of nausea and vomiting to be higher in the fentanyl group. In contrast to our study they found the incidence of urinary retention to be higher in the dexmedetomidine group compared to the fentanyl group.

Also Bajwa et al.⁸ and Kamal, M. M. and Talaat, S. M.¹⁷ found in their study that dry mouth was more common with epidural dexmedetomidine which we also found in our study. Also Selim MF et al.² and Gupta et al.⁹ in their study found that the incidence of nausea and vomiting was higher in the fentanyl group than dexmedetomidine group, when given epidural injection which is in accordance to our findings.

Similarly, Hanoura S, Hassanin R and Singh R.¹⁸ and Bamne et al.¹⁶ in their study did not find any significant side effects by the addition of epidural dexmedetomidine and fentanyl.

In contrast to our findings Benzon HT, et al.¹⁰, Selim MF et al.² and Gupta K et al in their study found that pruritus was frequent with epidural fentanyl which we did not find in any of the study population.

In the post operative period we found that the time for rescue top-up was prolonged in the dexmedetomidine group 344 ± 23.03 in comparison to that of fentanyl group 255.5 ± 23.12 and the "p" value <0.01 , which is statistically highly significant. Also none of the patients in both the groups

required any additional top-up or rescue analgesia with other pain relieving drugs during the entire peri-operative period and the quality of surgical anaesthesia was also excellent in both the groups. Also visual analog scale for assessment of pain showed 0 scores during the entire surgical period in both the groups. Similar findings were observed by Bajwa et al.⁸ and Attri et al.⁶ in their study.

CONCLUSION

The conclusion, from the present study of epidural anaesthesia with ropivacaine 0.75% along with adjuvants Dexmedetomidine 1 microgm/kg (RD group) and Fentanyl 1 microgm/kg (RF group) in lower limb orthopaedic procedure is that, dexmedetomidine (1 microgm/kg) is a better adjuvant than fentanyl (1 microgm/kg), as it provides early onset and longer duration of sensory and motor blockade, providing prolonged post operative analgesia, thus requiring lesser post operative analgesic drugs, comparatively stable haemodynamics with high grade sedation level without any respiratory depression and lesser side effects.

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