Section: Anaesthesia

Original Research Article

TO STUDY AND COMPARE THE EFFECT OF FENTANYL AND DEXMEDETOMIDINE IN EPIDURAL ANAESTHESIA IN LOWER LIMB ORTHOPAEDIC SURGERIES WHEN GIVEN AS AN ADJUVANT TO 0.5% BUPIVACAINE

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Abstract

Background: In order to achieve the necessary peri-operative anaesthetic effect with pure local anaesthesia alone, greater doses are frequently required, which increases risk of local anaesthesia toxicity. Opioids can be added to local anaesthetics for reducing local anaesthetic dosage, and additionally provide enhanced dynamic pain relief, as well as, less regression of sensory blockage. The following study was carried out to look for newer and better adjuvants such as Dexmedetomidine and Fentanyl that could provide fewer side effects, stable haemodynamics and a superior quality of anaesthesia with the epidural technique using bupivacaine, in lower limb orthopaedic surgeries. **Materials and Methods:** This prospective observational study was carried out in the Department of Anaesthesia, Chirayu Medical College and Hospital, Bhopal, among 80 consented patients allocated into 2 groups of 40 each: Group BD [epidural study solution=38 ml bupivacaine hydrochloride (0.25%) + 1 ml dexmedetomidine (100 µg) + 1 ml Normal Saline] and Group BF [epidural study solution=38 ml bupivacaine hydrochloride (0.25%) + 2 ml fentanyl (100 µg) posted for lower limb orthopaedic surgeries, using a proforma, pre-anaesthetic evaluation, investigations followed by induction of anaesthesia and administration of test drug. Data was collected, compiled and analysed using SPSS 22.0 (trial version). **Result:** Most participants in Group BD (37.5%) and Group BF (37.5%) belonged to 31-40 and 41-50 years age group, respectively. Males (Group BD=67.5%; Group BF=60%), those of 51-70 kg weight band (Group BD=85%; Group BF=80%) and ASA Grade 1 (Group BD=57.5%, Group K=55%) constituted majority. Time taken for onset of sensory block, achieve its maximum level and attain complete motor blockade was significantly lesser in Group BD (p-value<0.0001; 0.001). Time taken for two-segment regression, duration of motor block and analgesia was significantly prolonged in Group BD (p-value<0.0001). Group BD had higher maximal Ramsey sedation score (p-value<0.0001). Incidence of bradycardia in Group BD was significantly higher (p-value=0.025). After 10 minutes of epidural, mean heart rate in Group BD was significantly lower (p-value=0.0004). After 10 minutes, MAP in BD group was significantly lower (p-value<0.0001). **Conclusion:** Dexmedetomidine is a superior alternative for fentanyl when used for epidural anaesthesia in combination with bupivacaine, the reason being quicker onset of sensory block along with shorter time required to reach the maximum sensory level, prolonged analgesia, and longer duration of motor block with a higher property of sedation.

INTRODUCTION

Epidural injections were first documented in 1885 when American neurologist James Corning of Acorn Hall in Morristown, New Jersey, utilised the procedure to complete a neuraxial blockage. The first description of the intentional epidural drug administration method was made in 1921 by the Spanish military surgeon Fidel Pagés.[1]

The epidural technique is being utilised extensively in anaesthetic practise for delivering perioperative surgical anaesthesia with the added advantage of providing post-operative analgesia in lower limb and lower abdominal procedures, allowing early mobilization and rehabilitation with minimally accompanying pain and suffering, hence lowering the likelihood of thromboembolic events, facilitating rapid recovery, reducing morbidity, and permitting early discharge from the hospital.[2] For a prolonged intervention, epidural anaesthesia also offers the flexibility to titrate the desired degree of anaesthetic and prolong the block time.[3]

The choice of medication for epidural anaesthesia mostly depends on how long the intended duration of anaesthesia is. Bupivacaine has an extended duration of action, and is a preferred anaesthetic for inpatient surgeries.[3] In order to achieve the necessary peri-operative anaesthetic effect with pure local anaesthesia alone, greater doses are frequently required, which increases the risk of local anaesthesia toxicity.[2] Opioids can be added to local anaesthetics for reducing the local anaesthetic dosage, and additionally provide enhanced dynamic pain relief, as well as, less regression of sensory blockage. Fentanyl is a lipophilic opioid with central action, which is used more frequently than hydrophilic opioids because it has a quicker onset of action, rapid clearance, and doesn't cause prolonged respiratory depression.[4] It has enhanced spinal anaesthesia and minimised adverse effects of anaesthetic medications, such as nausea, vomiting and pruritis.[5] Dexmedetomidine is a highly selective α2-adrenoceptor agonist with potent effects on the central nervous system. It provides sedative, anti-anxiety, analgesic, neuroprotective, and anesthetic-sparing properties. Dexmedetomidine has been used in conjunction with other medications to extend the analgesic effects of epidural blocks.[5]

The following study, was therefore carried out to look for newer and better adjuvants such as Dexmedetomidine and Fentanyl that could provide fewer side effects, stable haemodynamics and a superior quality of anaesthesia with the epidural technique using bupivacaine, in lower limb orthopaedic surgeries.

MATERIALS AND METHODS

This prospective observational study was carried out in the Department of Anaesthesia, Chirayu Medical College and Hospital, Bhopal, after approval by Institutional Ethics Committee. 80 consented patients of age group 18 – 65 years belonging to American Society of Anaesthesiologists (ASA) class I or II and posted for lower limb orthopaedic surgeries under epidural anaesthesia were included in the study.

All those with known hypersensitivity or allergy to study drug; cardio-pulmonary, renal or hepatic impairment; known history of substance or alcohol abuse; patients who received any pre-medication; with an initial core temperature >37.5˚C or <35.5˚C; requiring blood transfusion during surgery; hypo- or hyperthyroidism; diabetes mellitus, hypertension; chronic respiratory disease; anaemia, hypovolaemia, shock; septicaemia; abnormalities of coagulation or on any anticoagulant therapy; convulsions or psychiatric disorders; refusal; pregnant and lactating women; skin infection locally along the lumbar spine; chronic backache; spinal deformity; and headache were excluded from the study.

This sample size was calculated based on the pilot study and statistical reports of previous studies. The group sizes (n=40) were calculated to find out the efficiency of study drugs in prevention of shivering with a power of 95% [assuming a variability (S.D.) of ±10%] and a significance level of 0.05. The patients were randomly allocated into 2 groups of 40 each and were named as Group BD [epidural study solution=38 ml bupivacaine hydrochloride (0.25%) + 1 ml dexmedetomidine (100 µg) + 1 ml Normal Saline] and Group BF [epidural study solution=38 ml bupivacaine hydrochloride (0.25%) + 2 ml fentanyl (100 µg).

Pre-anaesthetic evaluation was done one day before the surgery, recording a detailed history and performing a complete physical examination. Basic routine investigations were carried out. Prior to surgery i.e. night before the operation, patients were givenTab. Alprazolam 0.5mg orally; I.V. line was secured; injected Ranitidine 50mg I.V.; infused 10ml/kg of Ringer's Lactate and instructed to fast for 6–8 hours. Pre-operative vital parameters such as pulse oximetry, blood pressure (non-invasive) and ECG (electrocardiography) were recorded on entering the operation theatre, on the day of surgery. Before induction of anaesthesia, each patient was catheterized using Foley's catheter, and a bupivacaine hydrochloride sensitivity test was carried out. Vital signs were recorded.

Under strict aseptic precautions, local infiltration of 2 cc of 1% lignocaine was carried out with a 26 gauge needle with the patient in sitting position. Using the technique of 'loss-of-resistance', Tuohy's needle (18-gauge) was inserted at the L3-L4 interlumbar space into the epidural space, with its bevel facing cephalad. An epidural catheter was introduced and secured 5 cm into the epidural space, and its position checked by aspiration of CSF (cerebrospinal fluid) or blood. A test dose containing 60 mg lignocaine + 1:200,000 epinephrine was administered so as to identify IV or intrathecal administration. The patients were then asked to lay in supine position and after 3 minutes, the drug solution under study was

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injected into the epidural catheter at a rate of 1 ml/3 second.Successful epidural anaesthesia was considered when loss of the pin-prick sensation was achieved at T10 and Bromage score of 2 or 3 was achieved.

Intraoperatively, supplemental oxygen via face mask at 5L/min was provided. Patient's baseline Heart rate, Blood pressure, Temperature and SpO2 were monitored for every 5 minutes till 30 minutes, then every 15 minutes till 60 minutes, every 30 minutes till 240 minutes and thereafter every 60 minutes till pain reappeared.

Hypotension was described as decrease in SBP (systolic blood pressure) of >20% baseline value or <100 mmHg, this was treated with I.V. fluids and/or 3mg/dose of intravenous ephedrine. Bradycardia was described as HR (heart rate) < 50/min and was treated with o.6mg I.V. Atropine.

Assessment of sensory blockade:A 3-point scale was used to assess the sensory blockade onset with maximum cephalic spread using a 26-gauge hypodermic needle (short-beveled) along the midclavicular line by the bilateral pin-prick method.

The scale is as follows:

0 = normal sensation
1 = analgesia i.e.loss of sensation of pin prick, and
2 = anesthesia i.e.loss of sensation of touch.

Assessment of motor blockade: Bromage 3-point score was used to assess the blockade of motor activity in the lower extremity. The scale is as follows:

0 = no impairment of motor activity (is able to move ankle, knee and hip joints)
1 = inability to raise either extended leg (is able to move ankle and knee joints)
2 = inability to raise extended leg and flex knee (is able to move ankle joint)
3 = inability to move the knee and foot.

Assessment of sedation: Ramsay Sedation Scale was used to grade the sedation which was recorded before initiation of surgery and thereafter every 20 minutes during the surgery. The scale is as follows:

1 = no sedation, conscious and awake
2 = calm, composed
3 = awakened on verbal command
4 = brisk response on gentle tactile stimulation
5 = awakened on shaking vigorously
6 = unarousable

Following properties of the block were observed and noted:

1. Onset of the sensory blockade
2. Maximum level of sensory blockade
3. Time taken to attain maximum sensory level
4. Time taken to complete motor blockade
5. Time taken for two segment regression
6. Duration of analgesia
7. Duration of the motor blockade
8. Postoperative pain assessed using a 10 point NRS (numerical rating scale) i.e. 0 = no pain and 10 = worst pain imaginable
9. Grading of sedation and maximum sedation score.

Statistical Analysis

Data was collected, compiled and analysed using SPSS 22.0 (trial version). Results were expressed as the means and standard deviation or as numbers and percentages. Statistical analysis was done by applying Chi-square test and unpaired "t" test. The level of significance was fixed at 95%. P-value < 0.05 was considered statistically significant.

RESULTS

[Table 1] displays the socio-demographic data of the study participants. Most of the study participants in Group BD (37.5%) and Group BF (37.5%) belonged to the age group of 31-40 years and 41-50 years, respectively. Males (Group BD=67.5%; Group BF=60%), those belonging to 51-70 kg weight band (Group BD=85%; Group BF=80%) and ASA Grade 1 (Group BD=57.5%, Group K=55%) constituted the majority. The mean height in Group BD and BF was 153.3±7.01 and 151.7±5.09 cm respectively. The mean duration of the procedure was 119.45±14.32 and 123.36±15.98 minutes respectively.

Table 1: Distribution of study participants on the basis of socio-demographic variables

Socio demographic variables		Group BD		Group BF		p-values
		No.	%	No.	%	
Age group	20-30 years	09	22.5	10	25.0	0.553
	31-40 years	15	37.5	13	32.5	
	41-50 years	11	27.5	15	37.5	
	51-60 years	5	12.5	2	5.0	
	Total	40	100	40	100	
	Mean±SD (years)	36.51±3.95		36.0±3.99		
Gender	Female	13	32.5	16	40.0	0.485
	Male	27	67.5	24	60.0	
	Total	40	100	40	100	
Weight	31-50 Kg	4	10.0	7	17.5	0.546
	51-70 Kg	34	85.0	32	80.0	
	>70 Kg	2	5.0	1	2.5	
	Total	40	100	40	100	
	Mean±SD (kg)	27.8±2.42		28.67±2.26		
Height	Mean±SD(cm)	153.3±7.01		151.7±5.09		0.246
ASA Grade	1	23	57.5	22	55.0	0.8228
	2	17	42.5	18	45.0	

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	Total	40	100	40	100	
Mean duration of procedure		119.45±14.32		123.36±15.98		0.253

Chi-square and unpaired t-test applied as per data. P-values insignificant.

Table 2: Comparison on the basis of various parameters related to blockade

Parameters	Group BD	Group BF	p-value
Onset of sensory block (min)	7.2±1.21	8.6±1.53	<0.0001*
Time to attain maximum sensory level (min)	14.8±1.97	17.1±2.23	<0.0001*
Maximum level of sensory blockade	T5	T6	0.07
Time to attain complete motor block (min)	18.45±3.45	21.1±3.51	0.001*
Time for two-segment regression (min)	165.2±15.29	137.5±10.54	<0.0001*
Duration of analgesia (min)	371.3±32.25	318.28±25.37	<0.0001*
Duration of motor block (min)	245.89±33.94	216.35±23.84	<0.0001*

As shown in [Table 2], the time taken for onset of sensory block, to achieve its maximum level and also to attain complete motor blockade was significantly lesser in Group BD as compared to Group BF (p-value<0.0001; 0.001) i.e. it was earlier in Group BD. The maximum level of sensory blockade achieved was T5 and T6 in Group BD and BF respectively. The time taken for two-segment regression was significantly prolonged in Group BD in comparison to Group BF with a p-value of <0.0001. The duration of motor block and analgesia was significantly prolonged in Group BD than Group BF (p-value<0.0001).

Table 3: Comparison on the basis of duration of postoperative visual analog scale

Post-operative time	Group BD	Group BF	p-value
6th hour	0.19±0.38	0.31±0.43	0.189
12th hour	2.23±0.45	2.68±0.57	0.0002*
18th hour	3.29±0.76	4.0±0.81	0.0001*
24th hour	4.10±0.71	4.74±0.62	<0.0001*

Unpaired t-test applied. P-value <0.05 considered significant

At 12, 18, and 24 hours following surgery, the postoperative NRS in Group BD significantly decreased (p-value=0.0002; 0.0001 and <0.0001), as depicted in [Table 3 & Figure 2].

Table 4: Comparison on the basis of sedation score

Sedation Score	Group BD	Group BF	p-value
1	1 (2.5%)	12 (30.0%)	<0.0001*
2	13 (32.5%)	27 (67.5%)	
3	21 (52.5%)	1 (2.5%)	
4	5 (12.5%)	0	

Chi-square test applied. P-value is significant

[Table 4 & Figure 3] shows that Group BD had significantly higher maximal Ramsey sedation scores than Group BF (p-value<0.0001).

Table 5: Comparison on the basis of side effects

Side effects	Group BD	Group BF	p-value
Bradycardia	12 (30.0%)	4 (10.0%)	0.025*
Hypotension	7 (7.5%)	5 (12.5%)	0.531
Nausea and vomiting	3 (7.5%)	9 (22.5%)	0.060
Pruritis	0	0	0
Urinary retention	6 (15.0%)	5 (12.5%)	0.745
Shivering	3 (7.5%)	1 (2.5%)	0.305
Dry mouth	11 (27.5%)	6 (15.0%)	0.172
Others	0	0	0

Chi-square test applied. P-value <0.05 considered significant

While some adverse effects were witnessed in both the groups, incidence of bradycardia in Group BD was significantly higher as compared to Group BF (p-value=0.025). Pruritis was not found in any group and there was no statistically significant difference between the two groups regarding remaining side effects, as has been depicted in [Table 5 and Figure 4].

Table 6: Comparison on the basis of vitals in both groups

Vital parameters	Group BD	Group BF	p-value
HR- before epidural injection	84.1±7.1	81.2±7.8	0.086
HR- After 10 minutes	67.6±8.7	74.3±7.3	0.0004*
HR- After 45 minutes	81.4±6.8	78.5±7.1	0.066
MAP- before epidural injection	93.1±4.0	94.6±3.1	0.065
MAP- After 10 minutes	75.6±3.1	82.7±2.5	<0.0001*

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MAP- After 45 minutes	87.2±3.4	88.6±3.2	0.062

Unpaired t-test applied. P-value <0.05 considered significant

[Table 6] shows that after 10 minutes of epidural anaesthesia injection, the mean heart rate in Group BD (67.6±8.7) was significantly lower than that in Group BF (74.3±7.3) with a p-value of 0.0004. After 45 minutes, the mean heart rate of Group BF (78.5±7.1) was lower than that of Group BD (81.4±6.8). On evaluating the mean arterial pressure, it was noted that after 10 minutes, MAP in the BD group (75.6±3.1) was significantly lower than that in the BF group (82.7±2.5) with a p-value<0.0001. At 45 minutes, there was no statistically significant difference between MAP in the two groups.

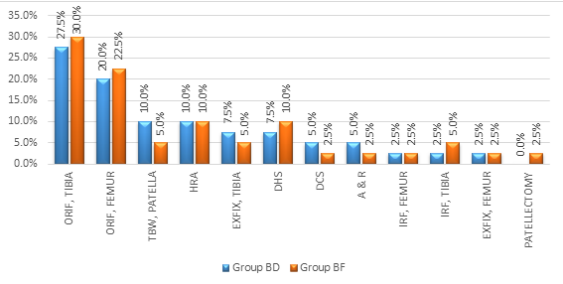

Figure 1: Distribution of study participants on the basis of diagnosis among the two groups

[Figure 1] shows distribution of diagnosis among the two groups. Most patients in Group BD and Group BF were those that underwent ORIF Tibia (27.5% and 30% respectively).

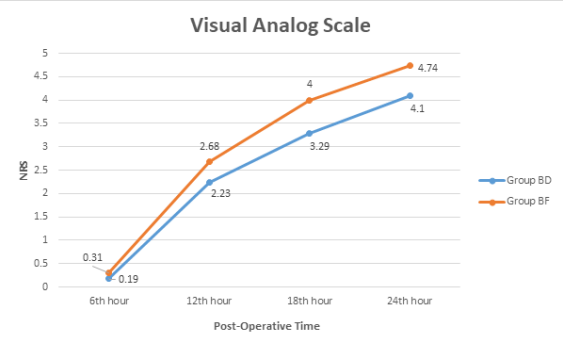

Figure 2: Comparison on the basis of duration of postoperative visual analog scale

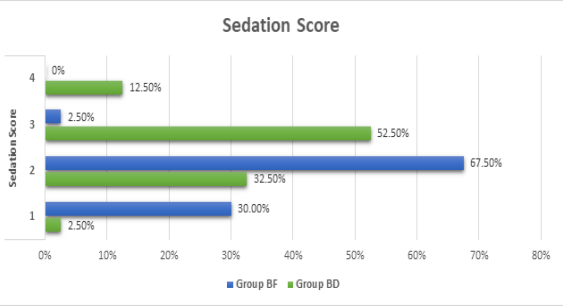

Figure 3: Comparison of two groups on the basis of sedation score

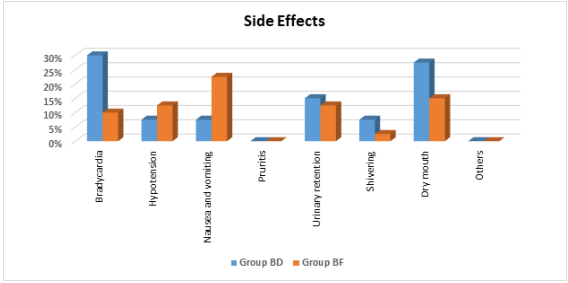

Figure 4: Comparison of both groups on the basis of side effects

DISCUSSION

In the present study, we compared the effects of adding fentanyl or dexmedetomidine to epidural bupivacaine among patients who underwent lower limb orthopaedic surgeries. Most of the study participants in Group BD and BF belonged to the age group of 31-40 years and 41-50 years, respectively. Males, those belonging to 51-70 kg weight band and ASA Grade 1 constituted the majority. The mean height in Group BD and BF was 153.3±7.01 and 151.7±5.09 cm respectively. The mean duration of the procedure was 119.45±14.32 and 123.36±15.98 minutes respectively. All the data was comparable in both the groups and p-values obtained were insignificant.

In the present study it was observed that the sensory anaesthesia induced by dexmedetomidine had a significantly early onset, and the postoperative analgesia lasted substantially longer i.e. it was prolonged, as compared to fentanyl. The mean time of onset of the sensory block was 7.2±1.21 minutes in dexmedetomidine group and 8.6±1.53 minutes in fentanyl group (p-value=<0.0001). The time taken to attain maximum sensory level was significantly lesser in dexmedetomidine group (14.8±1.97 minutes; p-value=<0.0001). Duration of analgesia, as well as, motor block was noted and it was significantly longer in those given dexmedetomidine (p-value=<0.0001). Similar results were obtained by Saikia A et al,[2] and Paul A et al,[6] in their study. Another study conducted by Kumari V et al,[4] and Bajwa SJ et al,[7] found similar results when dexmedetomidine was combined with ropivacaine among patients of lower limb orthopaedic surgeries. The findings of Gupta K et al,[8] among patients of vaginal hysterectomy induced epidurally with a combination of levobupivacaine and dexmedetomidine were concordant with those of our study as well. Another research by Selim MF et al,[9] using epidural dexmedetomidine and fentanyl with bupivacaine during labour indicated that the mean time to analgesia start was considerably earlier in the dexmedetomidine group compared to the fentanyl group. Gill et al,[13] also noted that the dexmedetomidine group's onset time was shorter than the fentanyl group's.

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It was observed in the present study that at 12, 18, and 24 hours following surgery, the postoperative NRS in Group BD significantly decreased (p-value=0.0002; 0.0001 and <0.0001 respectively). Our findings are concordant with the findings of Paul A et al,[6] who conducted the study among patients undergoing lower limb orthopaedic surgeries and induced with combination of bupivacaine with dexmedetomidine and fentanyl. Soliman R et al,[10] who conducted a similar study among patients undergoing total knee replacement observed similar results. Dexmedetomidine, they concluded, offered improved postoperative analgesia and lowered the need for postoperative opioids.

Group BD, in the present study, had significantly higher maximal Ramsey sedation scores than Group BF (p-value<0.0001). Our findings were supported by studies conducted by Paul A et al,[6] and Salgado et al,[11] Saikia A et al,[2] found that during the intraoperative time, dexmedetomidine had a higher sedation score. The difference between the two groups was statistically significant (p=0.001). Kumari V et al,[4] reported that more patients among the dexmedetomidine group had experienced sedation but maximum sedation achieved was not significantly different between the two groups. In their study, Benzon HT et al,[14] reported that patients receiving epidural fentanyl experienced reduced sedation, which is consistent with our findings.

As observed in the present study, while some adverse effects were witnessed in both the groups, incidence of bradycardia in Group BD was significantly higher as compared to Group BF (p-value=0.025). Pruritis was not found in any group and there was no statistically significant difference between the two groups regarding remaining side effects. Saikia A et al,[2] observed that bradycardia and hypotension was more in dexmedetomidine group, however the difference between the two groups was insignificant. Findings of Paul A et al,[6] were similar to our study and they reported that bradycardia was found more in Group BD. Similarly, Kumari V et al,[4] reported occurrence of bradycardia, as well as, hypotension to be higher in dexmedetomidine group, that required treatment with Inj Atropine (0.4mg) and Inj Mephentermine (6mg). However, they also reported higher incidence of pruritis in fentanyl group, though there was no significant difference between the two groups in terms of side effects statistically. Soliman R et al,[10] observed incidence of bradycardia and hypotension to be more in Group BD compared to Group BF.

It was noted in the present study that after 10 minutes of epidural anaesthesia injection, the mean heart rate in Group BD (67.6±8.7) was significantly lower than that in Group BF (74.3±7.3) with a p-value of 0.0004. After 45 minutes, the mean heart rate of Group BF (78.5±7.1) was lower than that of Group BD (81.4±6.8). On evaluating the mean arterial pressure, it was noted that after 10 minutes, MAP in the BD group (75.6±3.1) was significantly lower than that in the BF group (82.7±2.5) with a p-value<0.0001. At 45 minutes, there was no statistically significant difference between MAP in the two groups. Kumari V et al,[4] reported findings concordant to ours, when dexmedetomidine and fentanyl were combined with ropivacaine. In a study by Eskandar M et al,[12] heart rate was found to have decreased significantly in the BD group, however, the difference in MAP between both the groups was not significant. Akin et al,[14] reported that the blood pressure and mean heart rate was significantly lower in dexmedetomidine group. In another study by Bajwa SJ et al,[7] no significant difference in heart rate and MAP was observed in both the groups induced by combination of ropivacaine and dexmedotimidine/ fentanyl.

CONCLUSION

It was concluded from the present study that dexmedetomidine is a superior alternative for fentanyl when used for epidural anaesthesia in combination with bupivacaine, the reason being quicker onset of sensory block along with shorter time required to reach the maximum sensory level, prolonged analgesia, and longer duration of motor block with a higher property of sedation.

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