A Comparative Study of Epidual Levobupivacaine Versus Epidural Levobupivacaine with Dexmedetomedine on Analgesia and Haemodynamics

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ABSTRACT

Introduction: Levobupivacaine is the S enantiomer of bupivacaine has emerged as a safe local anaesthetic than its racemic mixture counterpart bupivacaine. Dexmedetomedine is the novel selective alpha 2 agonist, Dexmedetomedine has several advantages when given through epidural route as an adjuvant therapy. Our main objective of this study was to compare plain levobupivacaine with dexmedetomedine and levobupivacaine epidurally for analgesia and haemodynamics.

Material and methods: 60 patients undergoing infraumblical and lower limb surgeries were randomized to two different groups. Group A (n=30) received only levobupivacaine 0.5% 20 ml epidurally. Group B (n=30) received 50 milli gram of dexmedetomedine with levobupivacaine 0.5% 20 ml epidurally administered. The duration of analgesia, The time of onset of analgesia, the need for rescue analgesia and its effect on haemodynamic parameters and any adverse outcome were noted randomly in this study.

Results: in this study, Dexmedetomedine prolongs the duration of analgesia without any changes in haemodynamic parameters, increases the onset of analgesia and nil significant adverse effects.

Conclusion: In our study, We are concluding that the dexmedetomedine can be used as an adjuvant therapy to levobupivacaine which increases the onset and prolong the duration of analgesia without any alteration in haemodynamic parameters.

Keywords: Rescue Analgesia, Haemodynamics, Levobupivacaine, Dexmedetomidine, Analgesia

INTRODUCTION

Intrathecal anaesthesia and epidural anaesthesia are the most popular in india as regional anaesthesia techniques used for lower abdominal and lower limb surgeries. Epidural anesthesia reduces the perioperative stress response to surgery and improves surgical outcome Epidural anaesthesia and analgesia has become one of the best accepted techniques for lower abdominal and lower limb surgeries as it offers good sensory and motor blockade with contracted bowels retaining adequate spontaneous respiration, hemodynamic stability and also an excellent indwelling epidural catheter facilitates further administration of analgesic doses for the postoperative period.[2]

Opioids drugs like Fentanyl mostly used traditionally as a adjunct therapy for epidural administration in combination with lower dosage of local anesthetics to achieve the desired anaesthetic effect.[8,9] The insertion of opioid analgesics does providing the dose sparing effect of local anaesthetic and increased analgesia but there is always a possibility of the increased incidence of side effects pruritis, urinary retention, nausea, vomiting and respiratory depression.[9] Dexmedetomidine is a highly selective alpha 2 adrenergic agonist with greater receptor affinity than clonidine.[10] apart from this, it also has the hemodynamic stabilizing effects and reduction of anaesthetic drug requirements Epidural dexmedetomidine does cause a manageable hypotension and bradycardia but The important point of this drug is its lack of opioid related side effects like vomiting, respiratory depression, pruritis.[10]

So in our present study is to evaluate the effects of incorporation of dexmedetomidine to epidural levobupivacaine on analgesia and haemodynamic changes in infraumbilical and lower limb surgeries.

Study aimed to evaluate the effect of incorporation of Dexmedetomidine to epidural Levobupivacaine on the duration of analgesia and haemodynamic parameter changes in pulse rate and blood pressure compared to plain epidural levobupivacaine.

MATERIAL AND METHODS

This study was conducted for the period of 1 year 6 months (May 2015 to November 2017) at Department of Surgery, MNR Medical College, Hyderabad. 60 adult patients of male and female belonging to the age group 20-50 years weighing between 50-75kg with BMI ranging between 19-24, undergoing elective infraumblical and lower limb surgeries with site of incision below T10 level were identified and randomly allocated to two groups through lots after getting written informed consent from the patients.

Group A: 30 patients were received 20ml of epidural 0.5% Levobupivacaine with 0.5ml of distilled water.

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Group B: 30 patients who were received 20ml of epidural 0.5% Levobupivacaine with 0.5ml of Dexmedetomidine containing 50µg.

Due to health issues, Patients who were not interested for the study, pregnant women, ASA III and ASA IV patients, patients who are known allergic to these study drugs, patients in sepsis, patients undergoing emergency surgeries in the past, patients having infection at the site of injection, coagulopathy or other bleeding diathesis were excluded from the present study.

After inclusion of patients in to the study, the patients were explained about the procedures and shifted to the operation theatre where a excellent peripheral intravenous access was secured using 18 gauge cannula and baseline non-invasive blood pressure, ECG, pulse rate and Spo2 were recorded. Injection Midazolam 0.03mg/kg IV was given as a standard premedication. All the patients received Ringer lactate solution 20ml/kg as preloading solution before the block. Intravenous fluids were given as per body weight and operative loss requirement. Patients were put in right lateral position and skin over the desired site was infiltrated with 1% lignocaine 2 ml. L2-L3/L3-L4 interspaces are selected and epidural space also identified using 18G Tuohy needles, midline approach, using loss of resistance technique with air. After the exclusion of blood in the needle with negative aspiration, 2 ml of 0.5% levobupivacaine was injected to exclude intrathecal placement of the needle. After that epidural catheter was inserted and fixed 5cm inside.

Patients in group A received 18 ml of 0.5% Levobupivacaine with 0.5 ml distilled water and group B received 18 ml of 0.5% Levobupivacaine plus 0.5ml of Dexmedetomidine containing 50µg epidurally. Baseline pulse rate, SpO2 at room air, noninvasive blood pressure was recorded effectively. Cardio respiratory parameters was monitored continuously and recordings were made every 5 minutes until 30 minutes and at 10 minute interval for the first 120 minutes(2 Hours) and thereafter for every hour till 6 hours. Intraoperatively, incidence of bradycardia will be treated with 0.6 mg of injection atropine i.v and hypotension (Systolic blood pressure falling more than 20% from the baseline value) will treated with ephedrine 6 mg IV injection. Duration of analgesia was recorded as a time interval from the completion of administration of anaesthetic agent to the time when the patient complains of pain at the surgical incision site with VAS score greater than 3. Procedure was explained and the patients were taught to assess the onset of pain using the visual analogue scale (VAS). In the VAS the patients were shown scale of 10 cm length. Zero end of the scale was taken as 'No pain' and 10 cm mark as 'Maximum pain'. Intensity of pain increases gradually from '0' to '10'. VAS score was assessed hourly from the time of completion of surgery. Patients were instructed to point the onset of pain on the scale when VAS score >3. During surgical procedure adverse effects like nausea, vomiting, dry mouth, dizziness, headache, respiratory depression, pruritis and shivering were recorded. Any postoperative untoward side effects were noted for 48 hours.

STATISTICAL ANALYSIS

In present study descriptive statistical analysis has been carried out. Results was represented as Mean ± Standard deviation and results on categorical measurements are

Characteristics	Group A	Group B
Age (years)	35.18 ±4.902	33.64±5.136
Gender (N) Male Female	 22 8	 22 8
ASA Values 1 2	 25 5	 25 5
Body Weight (Kgs)	61.66 ±5.260	61.08±4.450

Table-1: Demographic Characteristics

Duration of surgery (in minutes)			
Group	**Mean**	**SD**	**P value**
A	85.67	15.241	0.886
B	86.60	19.963	

Table-2: Duration of surgery by group.

Group	Time interval minutes	Mean heart rate Beats/min	SD
A	Basal	83.73	6.324
B		86.20	7.622
A	1	86.60	6.871
B		89.73	6.357
A	5	83.10	7.345
B		86.53	7.763
A	10	81.40	6.371
B		82.27	6.362
A	15	79.19	6.678
B		77.67	7.845
A	25	76.10	5.616
B		72.20	8.006
A	30	74.27	5.625
B		68.60	7.185
A	40	73.53	6.616
B		65.13	7.514
A	50	72.93	6.074
B		62.33	7.685
A	60	71.47	5.823
B		62.07	6.918
A	70	72.00	4.751
B		62.64	5.813
A	80	71.50	4.628
B		62.59	6.073
A	90	71.41	3.519
B		61.00	3.658
A	100	70.25	5.175
B		62.00	3.225
A	110	68.50	4.726
B		63.20	5.215
A	120	70.00	2.000
B		62.67	3.055

Table-3: Haemodynamic Changes of Heart

Group	Time interval minutes	Mean arterial blood pressure Mm hg	SD
A	Basal	90.69	5.527
B		90.91	5.142
A	1	90.72	5.105
B		89.26	6.085
A	5	87.83	5.497
B		83.46	6.816
A	10	85.33	4.752
B		79.60	8.049
A	15	83.03	4.664
B		77.11	6.989
A	20	81.73	5.977
B		75.67	8.049
A	25	81.20	6.718
B		74.40	7.403
A	30	79.50	7.386
B		74.70	8.014
A	40	79.57	6.831
B		73.27	9.791
A	50	79.17	7.527
B		73.13	8.402
A	60	77.53	7.682
B		73.32	7.453
A	70	77.46	6.265
B		75.23	6.324
A	80	78.98	7.307
B		76.41	7.985
A	90	80.47	7.383
B		76.93	8.204
A	100	81.62	5.829
B		78.55	8.745
A	110	80.55	6.856
B		80.00	9.798
A	120	77.67	3.055
B		76.33	4.041

Table-3: Mean arterial blood pressure of Heart

Group	Time interval minutes	Mean of SPo2	SD
A	Basal	98.65	0.661
B		98.60	0.563
A	1	90.01	0.652
B		98.67	0.547
A	5	98.70	0.536
B		98.54	0.507
A	10	98.63	0.556
B		98.37	0.490
A	15	98.60	0.675
B		98.57	0.504
A	20	98.60	0.563
B		98.47	0.507
A	25	98.70	0.596
B		98.50	0.507
A	30	90.90	0.751
B		98.50	0.629
A	40	97.40	0.571
B		96.49	0.587
A	50	95.28	0.324
B		98.50	0.262
A	60	98.57	0.626
B		98.50	0.509
A	70	98.53	0.507
B		98.33	0.479
A	80	98.83	0.648
B		98.53	0.571
A	90	98.50	0.572
B		98.47	0.507
A	100	97.40	0.321
B		96.20	0.328
A	110	97.40	0.642
B		96.30	0.668
A	120	97.57	0.676
B		96.23	0.904

Table-4: oxygen saturation levels

presented in percentage (%). Chi-square test, two way analysis of variance has been used to find the significance of study parameters on categorical scale between two different groups. Student't' test has been used to determine the significance between two group means. All analyses were two tailed and p <0.05 was considered significant. SPSS version 16.0 software was used for statistical data analysis.

RESULTS

In our study, 60 patients completed the study protocol. There was no significant differences in the age, sex, ASA physical status, height and weight as mentioned in Table 1.

No statistically significant difference was observed between the two groups in the duration of surgery with P value being 0.886 (table 1).

The duration of analgesia is extensively prolonged with group B (477 minutes) when compared to group A (351 minutes) which shows statistical significance with p value of 0.001.

The heart rate recorded between 30 to 100 minutes was found to be statistically significant between the 2 groups (table 2).

Mean arterial blood pressure recorded at 5, 10, 15, 20, 25, 30, 40, 50, 60 minutes were found to be statistically significant (table 3).

There was no significant difference between the two groups with regards to oxygen saturation (table 4).

Adverse effects reported in 16.8%. In group A, 30% of patients In group B. But hypotension/bradycardia requiring treatment with Inj. Ephedrine/Inj. Atropine was found to be statistically insignificant while comparing the two treatment groups.

DISCUSSION

In our present study we have compared the addition of dexmedetomidine to epidural 0.5% levobupivacaine 20 ml. Demographic parameters like age, sex, height and weight have no statistical difference between the two different groups.[6-8]

The results of our study demonstrates that adding

dexmedetomedine to 0.5% Levobupivacaine increases the duration of analgesia compared to plain Levobupivacaine. Timing of rescue analgesia was noted in both the groups and the mean duration of analgesia was found to be highly significant in group B (Mean time- 477.83 mins) with p value of 0.000 in comparison with group A (Mean time- 351.67 mins) which was comparable to study conducted by Morrison et al.[8]

The fall in heart rate in group B was more between 30 mins to 95 mins which showed statistical significance when compared to group A which were comparable But decrease in heart rate more than 20% from the baseline or less than 50 beats/min which needed treatment with atropine was found in 2 out of 30 patients in group B and was not found in any of the group A patients which is statistically insignificant which were comparable to studies by Wang, Elhakim and Orial. Similarly fall in systolic, diastolic and mean arterial blood pressure in group B was maximum from 5 to 70 mins with statistical significance compared to group A.[7]

5 patients out of 30 patients were experiences adverse effects in group A and in 9 patients in group B which is a statistically non-significant. In group B patients, 2 patients experienced dry mouth. Tremors in 2 patients, urinary retention, nausea and vomiting were observed one in each of the patients. In group B Only 13% of the patients experienced adverse effects which are statistically non-significant compared to A group patients.[8-10]

CONCLUSION

This study concludes that combining Dexmedetomidine 50 micro grams with 0.5% Levobupivacaine epidurally helps in prolonging the duration of analgesia and decreases the need for rescue analgesia. Changes in hemodynamic parameters (Blood pressure and Heart rate) were very minimal in the Dexmedetomidine group. Adverse effects encountered with Dexmedetomidine were also acceptable with only mild discomfort to the patients. Absence of respiratory depression is a remarkable feature of the Dexmedetomidine when it is given epidurally.

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