A COMPARATIVE STUDY OF EPIDURAL 0.5% LEVOBUPIVACAINE VERSUS EPIDURAL 0.5% LEVOBUPIVACAINE WITH DEXMEDETOMEDINE ON ANALGESIA AND HAEMODYNAMICS

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ABSTRACT: BACKGROUND: Levobupivacaine, the pure S enantiomer of bupivacaine has emerged as a safe local anaesthetic than its racemic counterpart. Dexmedetomidine the novel selective alpha 2 adrenergic agonist has several advantages when given through epidural route as an adjuvant. AIM: To compare plain 0.5% levobupivacaine with dexmedetomidine and 0.5% levobupivacaine epidurally for analgesia and haemodynamics. METHODOLOGY: 60 patients undergoing infraumbilical and lower limb surgeries were randomized to two groups. Group A (n=30) received only levobupivacaine 0.5% 20ml epidurally. Group B (n=30) received 50mcg of dexmedetomidine with levobupivacaine 0.5% 20ml epidurally. The time of onset of analgesia, duration of analgesia, the need for rescue analgesia and its effect on haemodynamic parameters and any adverse outcome were noted. Statistical work done by student t test and chi square test and p<0.05% were taken to be significant. RESULTS: Dexmedetomedine fastens the onset of analgesia and prolongs the duration of analgesia without any disturbance in haemodynamic parameters and nil significant adverse effects. CONCLUSION: We conclude that dexmedetomedine can be used as an adjuvant to levobupivacaine which fastens the onset and prolong the duration of analgesia without any alteration in haemodynamics.

KEYWORDS: Levobupivacaine, Dexmedetomidine, Analgesia, Haemodynamics.

INTRODUCTION: Regional anaesthesia came popular from the time of Sir August Bier in 1898.¹ Intrathecal anaesthesia and epidural anaesthesia are the most popular regional anaesthesia techniques used for lower abdominal & lower limb surgeries. Epidural anesthesia reduces the perioperative stress response to surgery and improves surgical outcome Epidural anaesthesia and analgesia has become one among the best accepted techniques for lower abdominal & lower limb surgeries as it provides good sensory and motor blockade with contracted bowels retaining adequate spontaneous respiration, hemodynamic stability and also an indwelling epidural catheter facilitates further administration of analgesic doses for the postoperative period.² Epidural anaesthesia reduces the incidence of hemodynamic changes due to sympathetic blockade as it produces segmental anaesthesia unlike subarachnoid block, provides effective surgical anaesthesia as compared to subarachnoid block even for prolonged procedures, incidence of postdural puncture headache is not encountered as dura is not pierced and provides prolonged postoperative analgesia.³,4 The S (−)-enantiomer of bupivacaine, levobupivacaine has advantages of decreased cardiovascular toxicity and there is also a relatively decreased motor nerve fiber penetration and block, thereby a decreased post-operative motor blockade and thus early ambulation of the patients can be achieved compared to the former bupivacaine.⁵,6,7 The addition of adjunctive agents (Opioids & alpha 2 agonists) to local anaesthetics via epidural and intrathecal routes may provide a dose sparing effect and increase the duration and quality of analgesia.
Opioids like fentanyl have been used traditionally as an adjunct for epidural administration in combination with lower dose of local anaesthetic to achieve the desired anaesthetic effect. The addition of opioid does provide a dose sparing effect of local anaesthetic and superior analgesia but there is always a possibility of an increased incidence of pruritis, urinary retention, nausea, vomiting and respiratory depression. Dexmedetomidine is a highly selective alpha 2 adrenergic agonist with greater receptor affinity than clonidine. In addition it also has hemodynamic stabilizing effects and reduction of anaesthetic drug requirements. Epidural dexmedetomidine does cause a manageable hypotension & bradycardia but the striking feature of this drug is its lack of opioid related side effects like respiratory depression, pruritis, nausea and vomiting.

Hence the present study is to evaluate the effects of addition of dexmedetomidine to epidural 0.5% levobupivacaine on analgesia and haemodynamic parameters in infraumbilical and lower limb surgeries.

**AIM OF THE STUDY:** To evaluate the effect of addition of Dexmedetomidine to epidural 0.5% Levobupivacaine solution on the duration of analgesia and haemodynamic changes in pulse rate and blood pressure compared to plain 0.5% epidural levobupivacaine.

**METHODOLOGY:** After getting approval from the institutional ethical committee 60 adult patients of either sex belonging to the age group 20-50 years weighing between 50-75kg with BMI ranging between 19-24, undergoing elective infraumbilical 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.

**GROUP A:** 30 patients who received 20ml of epidural 0.5% Levobupivacaine with 0.5ml distilled water.

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

Patients not willing for the study, pregnant women, ASA III & ASA IV patients, patients who are known allergic to study drugs, patients in sepsis, patients undergoing emergency surgeries, patients having infection at the site of injection, coagulopathy or other bleeding diathesis were excluded from the study.

After included in the study, the patients were explained about the procedure and shifted to the operation theatre where a good 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 standard premedication. All 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 2ml. L2-L3/L3-L4 interspaces were selected and epidural space identified using 18G Tuohy needles, midline approach, using loss of resistance technique with air. After exclusion of blood in the needle with negative aspiration, 2ml of 0.5% levobupivacaine was injected to exclude intrathecal placement of the needle. After which epidural catheter was inserted and fixed 5cm inside. Now patients in group A received 18ml of 0.5% Levobupivacaine with 0.5ml distilled water and group B received 18ml of 0.5% Levobupivacaine plus
0.5ml of Dexmedetomidine containing 50µg epidurally. Baseline pulse rate, SpO₂ at room air, noninvasive blood pressure was recorded. Cardio respiratory parameters were monitored continuously and recordings were made every 5 minutes until 30 minutes and at 10 minute interval for the first 2 hours and thereafter for every hour till 6 hours. Intraoperatively, incidence of bradycardia (Heart rate<50beats per minute) will be treated with 0.6mg of injection atropine i.v and hypotension (Systolic blood pressure falling more than 20% from the baseline value) will be treated with injection ephedrine 6 mg IV. Duration of analgesia was recorded as 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 >3. Procedure was explained and the patients were taught to assess the onset of pain using the visual analogue scale (VAS). In the visual analogue scale the patients were shown a 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:** Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD and results on categorical measurements are presented in percentage (%). Chi-square test has been used to find the significance of study parameters on categorical scale between two 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 was used for data analysis.

**RESULTS:** All the 60 patients completed the study protocol. There were no significant differences in the age, sex, ASA physical status, height and weight as mentioned in Table 1.

| VARIABLE         | GROUP A           | GROUP B           |
|------------------|-------------------|-------------------|
| AGE (YRS)        | 35.17± 4.969      | 34.63±5.147       |
| GENDER(N)        |                   |                   |
| MALE             | 22                | 22                |
| FEMALE           | 8                 | 8                 |
| ASA              |                   |                   |
| 1                | 25                | 25                |
| 2                | 5                 | 5                 |
| WEIGHT(KGS)      | 61.77±5.250       | 61.20±4.290       |

Table 1: Demographic Characteristics

There was no statistically significant difference between the two groups in the duration of surgery with P value being 0.856.

| DURATION OF SURGERY (IN MINUTES) | GROUP | MEAN | STANDARD DEVIATION | p-VALUE |
|----------------------------------|-------|------|--------------------|---------|
|                                  | A     | 85.67| 15.241             | 0.856   |
|                                  | B     | 86.60| 19.963             |         |

Table 2: Duration of surgery by group
The duration of analgesia is prolonged with group B (477.83 minutes) when compared to group A (351.67 minutes) which shows statistical significance with p value of 0.000.

**Table 3: Duration of analgesia**

| GROUP | MEAN   | STANDARD DEVIATION | p-VALUE |
|-------|--------|---------------------|---------|
| A     | 351.67 | 54.730              | 0.000   |
| B     | 477.83 | 44.580              |         |

The heart rate recorded between 30 to 100 minutes was found to be statistically significant between the 2 groups.
| TIME INTERVAL (MINUTES) | GROUP | MEAN HEART RATE (BEATS/MINUTE) | STANDARD DEVIATION | p-VALUE |
|------------------------|-------|--------------------------------|--------------------|---------|
| Basal                  | A     | 83.73                          | 6.384              | 0.061   |
|                        | B     | 87.20                          | 7.622              |         |
| 1                      | A     | 86.60                          | 6.871              | 0.056   |
|                        | B     | 89.93                          | 6.357              |         |
| 5                      | A     | 83.10                          | 7.355              | 0.068   |
|                        | B     | 86.73                          | 7.763              |         |
| 10                     | A     | 81.40                          | 6.371              | 0.600   |
|                        | B     | 82.27                          | 6.362              |         |
| 15                     | A     | 79.13                          | 6.678              | 0.439   |
|                        | B     | 77.67                          | 7.845              |         |
| 25                     | A     | 76.20                          | 5.616              | 0.029   |
|                        | B     | 72.20                          | 8.006              |         |
| 30                     | A     | 74.87                          | 5.625              | 0.000   |
|                        | B     | 68.60                          | 7.185              |         |
| 40                     | A     | 73.53                          | 6.616              | 0.000   |
|                        | B     | 65.13                          | 7.514              |         |
| 50                     | A     | 72.93                          | 6.074              | 0.000   |
|                        | B     | 62.33                          | 7.685              |         |
| 60                     | A     | 71.47                          | 5.823              | 0.000   |
|                        | B     | 62.07                          | 6.918              |         |
| 70                     | A     | 72.00                          | 4.751              | 0.000   |
|                        | B     | 62.64                          | 5.813              |         |
| 80                     | A     | 71.50                          | 4.628              | 0.000   |
|                        | B     | 62.59                          | 6.073              |         |
| 90                     | A     | 71.41                          | 3.519              | 0.000   |
|                        | B     | 61.00                          | 3.658              |         |
| 100                    | A     | 70.25                          | 5.175              | 0.000   |
|                        | B     | 62.00                          | 3.225              |         |
| 110                    | A     | 68.50                          | 4.726              | 0.156   |
|                        | B     | 63.20                          | 5.215              |         |
| 120                    | A     | 70.00                          | 2.000              | 0.025   |
|                        | B     | 62.67                          | 3.055              |         |

Table 4: Haemodynamic changes- Heart Rate
Mean arterial blood pressure recorded at 5, 10, 15, 20, 25, 30, 40, 50, 60 minutes were found to be statistically significant.

| TIME INTERVAL (MINUTES) | GROUP | MEAN OF MEAN ARTERIAL BLOOD PRESSURE (MM HG) | STANDARD DEVIATION | p-VALUE |
|-------------------------|-------|---------------------------------------------|-------------------|---------|
| Basal                   | A     | 90.97                                      | 5.327             | 0.787   |
|                         | B     | 90.60                                      | 5.143             |         |
| 1                       | A     | 90.73                                      | 5.105             | 0.316   |
|                         | B     | 89.27                                      | 6.085             |         |
| 5                       | A     | 87.83                                      | 5.497             | 0.008   |
|                         | B     | 83.47                                      | 6.816             |         |
| 10                      | A     | 85.33                                      | 4.751             | 0.002   |
|                         | B     | 79.60                                      | 8.067             |         |
| 15                      | A     | 83.03                                      | 4.664             | 0.000   |
|                         | B     | 77.10                                      | 6.989             |         |
| 20                      | A     | 81.73                                      | 5.977             | 0.002   |
|                         | B     | 75.67                                      | 8.049             |         |
| 25                      | A     | 81.20                                      | 6.718             | 0.000   |
|                         | B     | 74.40                                      | 7.403             |         |
| 30                      | A     | 79.50                                      | 7.385             | 0.019   |
|                         | B     | 74.70                                      | 8.014             |         |
| 40                      | A     | 79.57                                      | 6.831             | 0.005   |
|                         | B     | 73.27                                      | 9.791             |         |
There was no significant difference between the two groups with regards to oxygen saturation.

| TIME INTERVAL (MINUTES) | GROUP | MEAN OF SpO₂ (%) | STANDARD DEVIATION | p-VALUE |
|-------------------------|-------|------------------|--------------------|---------|
| Basal                   | A     | 98.67            | 0.661              | 0.676   |
|                         | B     | 98.60            | 0.563              |         |
| 1                       | A     | 90.00            | 0.651              | 0.831   |
|                         | B     | 98.67            | 0.547              |         |
| 5                       | A     | 98.70            | 0.535              | 0.221   |
|                         | B     | 98.53            | 0.507              |         |
|   |   | A     | B     | Pr  | P   |
|---|---|-------|-------|-----|-----|
| 10|   | 98.63 | 98.37 | 0.556 | 0.490 | 0.054 |
| 15|   | 98.60 | 98.57 | 0.675 | 0.504 | 0.829 |
| 20|   | 98.60 | 98.47 | 0.563 | 0.507 | 0.339 |
| 25|   | 98.70 | 98.47 | 0.596 | 0.507 | 0.108 |
| 30|   | 98.70 | 98.50 | 0.651 | 0.509 | 0.190 |
| 40|   | 98.53 | 98.53 | 0.571 | 0.571 | 0.001 |
| 50|   | 98.43 | 98.50 | 0.504 | 0.572 | 0.634 |
| 60|   | 98.57 | 98.50 | 0.626 | 0.509 | 0.652 |
| 70|   | 98.53 | 98.33 | 0.507 | 0.479 | 0.122 |
| 80|   | 98.83 | 98.53 | 0.648 | 0.571 | 0.062 |
| 90|   | 98.50 | 98.47 | 0.572 | 0.507 | 0.812 |
| 100|   | 98.60 | 98.40 | 0.621 | 0.498 | 0.174 |
| 110|   | 98.50 | 98.40 | 0.572 | 0.498 | 0.473 |
| 120|   | 98.67 | 98.43 | 0.606 | 0.504 | 0.111 |

**Table 6: Oxygen saturation**

![Figure 5: Oxygen saturation](image)

**Figure 5: Oxygen saturation**
Adverse effects were reported in 16.7% of patients in group A and 30% of patients in group B. But hypotension/bradycardia (fall of >20% from the baseline) requiring treatment with Inj. Ephedrine/Inj. Atropine were found to be statistically insignificant while comparing the two groups.

| ADVERSE EFFECTS     | GROUP | \( \text{Count} \) | \( \% \text{ within Group} \) | \( \% \) |
|---------------------|-------|--------------------|-------------------------------|--------|
| Dry Mouth           | Group A | -                 | -                             | -      |
|                     | Group B | 1                 | 3.33%                         | 3.33%  |
| Nausea Vomiting     | Group A | 1                 | 3.33%                         | 1      |
|                     | Group B | 1                 | 3.33%                         | 3.33%  |
| Shivering           | Group A | -                 | -                             | -      |
|                     | Group B | 2                 | 6.67%                         | 6.67%  |
| Urinary Retention   | Group A | 2                 | 6.67%                         | 2      |
|                     | Group B | -                 | -                             | -      |
| Hypotension         | Group A | 2                 | 6.67%                         | 2      |
|                     | Group B | 3                 | 10%                           | 3      |
| Bradycardia         | Group A | -                 | -                             | -      |
|                     | Group B | 2                 | 6.67%                         | 2      |

Table 7: Distribution of adverse effects

| Group | Yes | \( \% \) | No | \( \% \) |
|-------|-----|----------|----|--------|
| A     | 5   | 16.67    | 25 | 83.3   |
| B     | 9   | 30       | 21 | 70.0   |
| Total | 14  | 23.33    | 46 | 75.40  |

Table 8: Overall distribution of adverse effects

p-value- 0.3598

Figure 6: Distribution of adverse effects
DISCUSSION: This study compared the effects of addition of epidural dexmedetomidine (50 micrograms) to epidural 0.5% levobupivacaine 20ml. Demographic parameters such as age, sex, height & weight have no statistical difference between the two groups. Distribution of ASA status was also similar in both groups.

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 Mana13 Kopacz14 and Saurav15 et al.

The fall in heart rate in group B was maximum between 30 mins to 100 mins which showed statistical significance compared to group A which were comparable to Carpenter and Hell et al16,17 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 Wang18 Elhakim19 and Orial20,21 et al. Similarly fall in systolic, diastolic & mean arterial blood pressure in group B was maximum from 5 to 70 mins with statistical significance compared to group A. But the fall in systolic blood pressure >20% from baseline or less than 90 mm Hg which necessitated treatment with ephedrine was found in 7 patients in group B patients as compared to 1 patient in group A which is also statistically non-significant. Though there was fall in systolic blood pressure <90mm Hg in 7 out of 30 patients in group B patients, their MAP never went below 60mm Hg which correlates with the study conducted by Bajwa et al22,23 and Ralli et al24 with the use of epidural Dexmedetomidine. Also postoperatively, heart rate & blood pressure remained stable in both the groups. The stable hemodynamics can be explained on the basis of the concentration of Levobupivacaine used and the selection of suitable dose of Dexmedetomidine.

Adverse effects were noted only in 5 out of 30 patients in group A and in 9 patients in group B which is statistically non-significant. Among group B patients, dry mouth was reported in 2 patients. Shivering in 2 patients, urinary retention, nausea & vomiting were observed one in each of the patients. Only 13% of the patients in group B experienced adverse effects which are statistically non-significant compared to group A patients. These findings correlate well with the study conducted by Neal et al14 and Ralli et al,24 where similar adverse effects experienced were reported to be only mildly discomforting to the patients. None of the patients in group B had profound deep sedation or respiratory depression.

CONCLUSION: This study concludes that combining Dexmedetomidine 50 micrograms 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 & 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 Dexmedetomidine when given epidurally.
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