"A Comparative Study of Bupivacaine with Dexamethasone and Bupivacaine with Clonidine through Single Space Paravertebral Block for Post Operative Analgesia in Thoracic and Abdominal Surgeries"

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Abstract

Introduction: Regional anaesthesia using paravertebral block has been suggested as an ideal adjunct to general anaesthesia for thoracic and abdominal surgeries. The duration and efficacy of postoperative analgesia and hemodynamic stability of equal doses of Bupivacaine with Dexamethasone and 0.5% Bupivacaine with Clonidine through single space Para vertebral block in thoracic and abdominal surgeries was evaluated.

Materials and Methods: This study was a prospective, randomized, double blind and comparative study. 60 ASA I and II patients aged between 18-60 years undergoing elective thoracic and upper abdominal surgeries were randomly allocated into two groups of 30 each. GROUP C received Bupivacaine + Clonidine, Group D received Bupivacaine + Dexamethasone. Using VAS score, the analgesia was evaluated every hour for six hours and then every six hours till 48 hours.

Result: The duration of analgesia in group D was significantly longer when compared to group C. The mean duration of analgesia in group C was 353.60±52.03 minutes and in group D was 594.40±71.78 minute.

Keywords: Paravertabral Block, Bupivacaine, Dexamethasone, Clonidine.

I. Introduction

Surgical pain is a universal phenomenon affecting all patients in the intraoperative and postoperative period. Regional anaesthesia using paravertebral block has been suggested as an ideal adjunct to general anaesthesia for thoracic and abdominal surgeries. Benefits include a reduction in postoperative pain leading to reduced requirement of analgesics, thereby indirectly leading to a reduction of postoperative nausea and vomiting, prolonged postoperative pain relief and potential for early discharge. Thoracic paravertebral block involves injection of local anesthetic at the site where the spinal nerve emerges from the intervertebral foramina. Paravertebral block has been used to relieve acute chest wall pain from rib fractures, herpes zoster, pleurisy, to manage acute and chronic post thoracotomy pain and as an anesthetic technique for surgery of the chest and shoulder.

II. Objectives:

The aim of the study is to compare the following factors in two group’s i.e.

Group C – 0.125% BUPIVACAINE + CLONIDINE (1µg/kg).
Group D – 0.125% BUPIVACAINE + DEXAMETHASONE (4mg).

With respect to,
1. Onset and duration of Analgesia.
2. Quality of Postoperative analgesia, time to first pain medication.
3. Hemodynamic changes like heart rate and blood pressure.
4. Side effects/complications.

III. Materials And Methods

The study was conducted GGH, Guntur. Ethical Committee approval was obtained. Patients scheduled to undergo elective upper abdominal and thoracic surgeries under general anaesthesia were enrolled in this study.
Inclusion criteria:
1. Adult patients aged between 18-60 years of both sex.
2. Patients belonging to ASA Grade I and II. 
3. Emergency surgeries
4. ASA grade 3 and 4 patients
5. known case of hypersensitive reactions to local anesthetics.
6. Patients with coagulation disorders or on anticoagulant therapy.
7. Local infection at the site of proposed puncture for Paravertebral block.

Method:
After completion of surgeries under general anaesthesia using standard protocols patients were divided into two groups, Group C and Group D using double blind technique. An ipsilateral paravertebral block will be achieved under sterile conditions with the patient in the lateral position with block side up, at respected thoracic or lumbar vertebral level using an 18G tuohy needle by loss of resistance technique.

The onset of analgesia, duration, hemodynamic parameters and any side effects will be monitored. Sixty consecutive adult patients were studied. Written informed consent was obtained from all patients. The study population was randomized via sealed envelopes technique into two groups as Group C (n=30) - receiving paravertebral block with 0.125%bupivacaine + clonidine(1µg/kg). Group D (n=30) - receiving paravertebral block with 0.125% bupivacaine + dexamethasone(4mg).
The patients underwent postoperative assessment for pain, nausea and vomiting and hemodynamic changes at 1h(T1), 2h(T2), 3h(T3), 4h(T4), 5h(T5), 6h(T6), 12h(T12), 24h(T24) and 48h(T48) following surgery.

Method of Collection of Data
All patients underwent preoperative assessment prior to surgery. Standard institutional preoperative instructions were offered as per the hospital protocol. The patients were instructed on the use of the Visual Analogue Scale (VAS 0-10) and Numerical Rating Scale (NRS 0-4). Monitoring: NIBP, ECG,Sp02. Patient position: Lateral.

Procedure:
Part was cleaned and painted with antiseptic solution. Sterile drapes were placed. Planned needle insertion point was infiltrated with local anaesthetic. Tuohy's epidural needle was inserted perpendicular to the skin to contact transverse process at 2-4 cm depth. Syringe prefilled with air was connected to the Tuohy's epidural needle. Then the needle was manipulated to walk off the superior or inferior aspect of the transverse process, until loss of resistance to air could be elicited. Insertion was limited to less than 2 cm past the transverse process. Syringe was detached from the needle and epidural catheter was threaded in. Epidural needle was withdrawn over the catheter carefully. Catheter port was attached and catheter was fixed to skin using adhesive tapes. 12-15 ml of 0.125% bupivacaine along with either Dexamethsone (4mg) or Clonidine (1µg/kg). Dose used was 2-3 ml/dermatome level for multiple level block. Maximum dosage for bupivacaine used was 3 mg/kg of body weight. Patient was then made to lie down supine. Onset of sensory anaesthesia assessed 10-15 minutes after the injection.

Hemodynamic parameters were monitored. After surgery, patients were observed in the postoperative recovery room for one hour and then shifted to the postoperative ward. At1h(T1), 2h(T2), 3h(T3), 4h(T4), 5h(T5), 6h(T6), 12h(T12), 24h(T24) and 48h(T48) following surgery, level of postoperative pain was assessed using Visual Analogue Scale (VAS). The level of postoperative nausea & vomiting was assessed with Numerical Rating Scale (NRS). In patients of both groups, top up doses were administered via paravertebral catheter of 0.125% bupivacaine along with adjuvant based on VAS score. In both the groups, rescue analgesia was given with inj.Trimadol/inj.Diclofenac to patients with VAS scores of four or more. Ondansetron 0.1 mg/kg was given for anti emesis to patients with NRS score of two or more in both the groups.

Patients were observed for complications like
- Failure of paravertebral block.
- Pneumothorax.
- Hypotension.
- Dural puncture related complications such as intrathecal injection, and post dural puncture headache.
- Transient Horner's syndrome, ipsilateral or bilateral, caused by spread of anesthetic to stellate ganglion, or preganglionic high thoracic fibers.
IV. Results

Mean Onset Of Sensory Block

Table showing mean onset of sensory block

<table>
<thead>
<tr>
<th>Group</th>
<th>MEAN</th>
<th>SD</th>
<th>t* value</th>
<th>p' Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group C</td>
<td>8.20 ±2.84</td>
<td></td>
<td>2.517</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group D</td>
<td>6.60 ±2.38</td>
<td></td>
<td>13.33</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*Students unpaired t test

In this study the onset of sensory blockade was slightly earlier in the study group of dexamethasone having a mean onset time of 6.60±2.38 minutes in comparison with the clonidine group having a mean onset time of 8.20 ±2.84. The statistical analysis by student’s unpaired ‘t’ test was found to be statistically significant as the p value was 0.036 (p<0.05).

V. Mean Duration Of Block

<table>
<thead>
<tr>
<th>Group</th>
<th>Sensory Block</th>
<th>t* value</th>
<th>p' Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group C</td>
<td>331.20 ± 61.39</td>
<td>13.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group D</td>
<td>578.00 ± 69.22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Students unpaired t test

Patients of both groups were observed for up to 12 Hours. The mean duration of sensory block in group C was 331.20 ± 61.39 minutes and in group D was 578.00 ± 69.22 minutes. The duration of sensory block in group D was very highly significantly longer when compared to group C (p < 0.001).

Duration of Analgesia

<table>
<thead>
<tr>
<th>Group</th>
<th>Duration of Analgesia(In Minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group C</td>
<td>353.60 ±52.03</td>
</tr>
<tr>
<td>Group D</td>
<td>594.40 ±71.78</td>
</tr>
</tbody>
</table>

*Students unpaired t test

Patients of both groups were observed for up to 12 Hours. Time was noted when the patient asked for rescue analgesics. The mean duration of analgesia in group C was 353.60±52.03 minutes and in group D was 594.40±71.78 minutes. The duration of analgesia in group D was very highly significantly longer when compared to group C (p < .001).

Comparison Of Vas Score

Patients reporting a VAS score of four or more were provided rescue analgesia with Inj. Fentanyl (2.0 µg/kg body weight).

<table>
<thead>
<tr>
<th>VAS Score</th>
<th>Group D</th>
<th>Group C</th>
<th>SE</th>
<th>P value (Ranksum's test)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS (T1)</td>
<td>3.63</td>
<td>3.8</td>
<td>0.36</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T2)</td>
<td>0.8</td>
<td>4.1</td>
<td>0.53</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T3)</td>
<td>0.53</td>
<td>4.1</td>
<td>0.47</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T4)</td>
<td>3.4</td>
<td>2.97</td>
<td>2.01</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T6)</td>
<td>2.27</td>
<td>2.13</td>
<td>1.14</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T12)</td>
<td>1.7</td>
<td>1.74</td>
<td>0.29</td>
<td>&lt;0.0001 S</td>
</tr>
<tr>
<td>VAS (T24)</td>
<td>1.4</td>
<td>1.57</td>
<td>0.21</td>
<td>0.0003 S</td>
</tr>
<tr>
<td>VAS (T48)</td>
<td>0.99</td>
<td>0.16</td>
<td>0.14</td>
<td>0.0005 S</td>
</tr>
<tr>
<td></td>
<td>2.7</td>
<td>0.76</td>
<td>0.66</td>
<td>&lt;0.0001 S</td>
</tr>
</tbody>
</table>

S : Significant ; NS : Not significant
Comparison of NRS Score
The NRS scores of both the groups studied — Group D & Group C were compared. Observations were recorded in the postoperative period at 1st hour(T 1), 2nd hour(T 2), 3rd hour(T 3), 4th hour(T 4), 5th hour(T 5), 6th hour(T 6), 12th hour(T 12), 24th hour(T 24) and 48th hour(T 48). It was observed that the Group C had significantly higher NRS scores (mean INRS=8.33±2.47) in comparison to Group D (mean INRS=0.03±0.18).

<table>
<thead>
<tr>
<th>NRS SCORE</th>
<th>GROUP D</th>
<th>GROUP C</th>
<th>SE</th>
<th>P value</th>
<th>Inference</th>
</tr>
</thead>
<tbody>
<tr>
<td>NRS(T1)</td>
<td>MEAN</td>
<td>0.03</td>
<td>SD</td>
<td>0.18</td>
<td>1.73</td>
</tr>
<tr>
<td>NRS(T2)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>1.47</td>
</tr>
<tr>
<td>NRS(T3)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>1.40</td>
</tr>
<tr>
<td>NRS(T4)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>1.40</td>
</tr>
<tr>
<td>NRS(T5)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>0.97</td>
</tr>
<tr>
<td>NRS(T6)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>0.53</td>
</tr>
<tr>
<td>NRS(T12)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>0.53</td>
</tr>
<tr>
<td>NRS(T24)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>0.30</td>
</tr>
<tr>
<td>NRS(T48)</td>
<td>MEAN</td>
<td>0.00</td>
<td>SD</td>
<td>0.00</td>
<td>0.03</td>
</tr>
<tr>
<td>Cumulative</td>
<td>MEAN</td>
<td>0.03</td>
<td>SD</td>
<td>0.18</td>
<td>8.33</td>
</tr>
</tbody>
</table>

**Pulse Rate:**
In group C, the mean pulse rate ranged from 77± 6.0 to 78 ± 7.0 beats / min. In group D, the mean pulse rate ranged from 75 ± 7.0 to 77 ± 7.0 beats / min. The statistical analysis by student’s unpaired ‘t’ test showed that there was no significant difference in pulse rate between the two groups (p > 0.05).

**Systolic Blood Pressure:**
In group C, the mean systolic blood pressure ranged from 122.08±9.85 to 124.40±10.20 mm of Hg. In group D, the mean systolic blood pressure ranged from 122.4 ± 10.53 123.80 ± 11.19 mm of Hg. The statistical analysis by unpaired student’s ‘t’ test showed that there was no significant difference in systolic blood pressure between the two groups (p > 0.05).

**Diastolic Blood Pressure:**
In group C, the mean diastolic blood pressure ranged from 72.8 ± 6.9 to 74.8 ± 7.1 mm of Hg. In group D, the mean diastolic blood pressure ranged from 72.2 ± 6.6 to 73.24± 6.9 mm of Hg. The statistical analysis by student’s unpaired ‘t’ test showed that there was no significant difference in diastolic blood pressure between the two groups (p > 0.05).

**VI. Discussion**
Regional anaesthesia using paravertebral block (PVB) is an ideal alternative to general anaesthesia for thoracic and upper abdominal surgeries. The mechanism of action of paravertebral analgesia is by direct penetration of local anaesthetic into the intercostals nerve, including its dorsal ramus, the rami communicantes and the sympathetic chain. Benefits of paravertebral block include improved respiratory efforts, reduction in postoperative nausea and vomiting, prolonged postoperative pain relief and potential for early discharge. The study was a prospective, randomized, double blind study conducted at GGH/GMC, Guntur. Sixty patients belonging to ASA I and II physical status, scheduled to undergo upper abdominal and thoracic surgeries were enrolled in this study.

1. Onset of sensory block
In this study, it has been observed that the onset of sensory blockade was slightly earlier in the study group of dexamethasone having a mean onset time of 6.60±2.38 minutes in comparison with the clonidine group having a mean onset time of 8.20±2.84 minutes.

In a study conducted by Shrestha etal (2003)7 to compare the analgesic efficacy of local aesthetic with and without dexamethasone in supraclavicular brachial plexus block. Forty patients undergoing arm, forearm and hand surgeries were randomly selected. The forty patients were divided in two groups of 20 each. In-group one, a brachial plexus block was done with 40-50 ml of local anaesthetic with 1:200,000 adrenaline and in the other group the block was performed with the same amount of local anaesthetics with dexamethasone. The onset of action and duration of analgesia in the two groups were compared and any
complications of the procedure were noted. Onset of action was 18.15 ± 4.25 minutes in local anaesthetic group and 14.5 ± 2.10 minutes in the local anaesthetic + dexamethasone group. The two groups were comparable in respect to age, sex, and weight. There was significant faster onset of action and prolonged duration of analgesia in the dexamethasone group than in the other group, so the conclusion was addition of dexamethasone for brachial plexus block significantly quickens the onset of sensory block.

2. Duration of sensory block

Patients of both groups were observed for up to 48 Hours. The mean duration of sensory block in group C was 331.20 ± 61.39 minutes and in group D was 578.00 ± 69.22 minutes. This shows that addition of steroids prolongs the duration of sensory block. The prolongation of duration of block is the local effect of steroid than the systemic action. The effects are mainly mediated by glucocorticoid receptors. The blockade is not produced by the action of steroid alone. Hence it should be used in addition to a local anesthetic.

3. Duration of analgesia

In our study, Patients of both groups were observed for up to 48 Hours. Time was noted when the patient asked for rescue analgesics. The mean duration of analgesia in group C was 353.60±52.03 minutes and in group D was 578.00±69.22 minutes. The statistical analysis by students unpaired ‘t’ test showed that the duration of analgesia in group D was very highly significantly longer when compared to group C (p < .001).

Farzin Goravanchi et al (2012) did a case series of thoracic paravertebral blocks using a combination of ropivacaine, clonidine, epinephrine, and dexamethasone. Five patients who underwent surgery for breast cancer were followed for 6 days after placement of a multiple-injection, one-time paravertebral block. Data were collected on patient satisfaction, analgesic consumption, side effects, and complications. Ropivacaine as a sole agent in paravertebral blocks has a clinical duration of up to 6 hours. The addition of epinephrine, clonidine, and dexamethasone prolonged the clinical duration considerably.

1. Comparison of VAS and NRS scores

VAS scores of both the groups — Group C (bupivacaine + clonidine) and Group D (bupivacaine + dexamethasone) were compared. VAS scores were recorded in the postoperative period at 1st hour (T1), 2nd hour (T2), 3rd hour (T3), 4th hour (T4), 5th hour (T5), 6th hour (T6), 12th hour (T12), 24th hour (T24) and 48th hour (T48). Patients reporting a VAS score of four or more were provided rescue analgesia with Inj. Fentanyl (2.0 µg/kg body weight). VAS scores of Group D was found to be significantly lower (mean VAS =2.7±1.93) than group C (mean VAS =8.89±1.66).

The NRS scores of both the groups studied — Group D & Group C were compared. Observations were recorded in the postoperative period at 1st hour (T1), 2nd hour (T2), 3rd hour (T3), 4th hour (T4), 5th hour (T5), 6th hour (T6), 12th hour (T12), 24th hour (T24) and 48th hour (T48). It was observed that the Group C had significantly higher NRS scores (mean INRs =8.33±2.47) in comparison to Group D (mean INRs =0.03±0.18). Both, VAS and NRS scores were less in Group D compared to Group C.

Klein et al (2000) in their study including sixty patients, found that patients receiving PVB experienced statistically significant less pain at 30 min, 1 hr, 24 hr and 72 hr in comparison to patients receiving GA only.

2. Comparison of hemodynamic parameters

There was no statistically significant difference between hemodynamic parameters between the Dexamethasone group and Clonidine group. The use of dexamethasone or clonidine as adjuvants in paravertebral block did not cause any increase in the incidence of post operative nausea and vomiting.

VII. Conclusion

Based on this study, it can be safely concluded that
1. Paravertebral block with dexamethasone as adjuvant to bupivacaine provides superior analgesia in the postoperative period in comparison to clonidine.
2. Paravertebral block with dexamethasone as adjuvant to bupivacaine reduces incidence of postoperative nausea and vomiting in comparison clonidine.
3. Paravertebral block with dexamethasone as adjuvant to bupivacaine leads to significantly reduced consumption of opioids in the postoperative period in comparison to clonidine.
4. Paravertebral block with dexamethasone as adjuvant to bupivacaine leads to significantly reduced consumption of antiemetics in the postoperative period in comparison to clonidine.
5. Complication rates of paravertebral block with dexamethasone as adjuvant to bupivacaine are significantly low thereby proving it to be a relatively safe adjuvant.

Bibliography