A STUDY TO COMPARE THE EFFECT OF DEXMEDETOMIDINE AND CLONIDINE AS AN ADJUVANT TO ROPIVACAINE FOR EPIDURAL ANESTHESIA IN INFRAUMBILICAL SURGERIES

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Abstract

Background: Alpha-2 adrenergic agonists have both analgesic and sedative properties and can be used as an effective adjuvant in epidural anaesthesia. The aim of our study to compare the efficacy and clinical profile of α-2 adrenergic agonists dexmedetomidine and clonidine, when used as adjuvants in epidural anaesthesia in patients undergoing infraumbilical surgeries with special emphasis on their sedative properties and ability to provide smooth intra-operative and post-operative analgesia.

Methods: This Hospital Based, double blind, randomized, comparative, interventional Study was carried out in 60 patients undergoing infra umbilical surgeries. After obtaining permission from Institutional Ethics Committee and Research Review Board. All patients randomly allocated in two groups of 30 patients in each group. Group A patient received 15 ml 0.75 % ropivacaine + 1 microgram/kg dexmedetomidine, Group B received 15 ml 0.75 % ropivacaine + 1 microgram/kg clonidine.

Results: The time of onset of sensory block with dexmedetomidine was earlier compared to clonidine (8.3±1.26 min versus 11.6±1.81min). Mean time to attain highest sensory level was 13.3± 1.4 minutes in group A and 17.6± 1.9 minutes in group B. Mean duration of sensory block was 306.1 ± 8.32 minutes in group A and 285.2 ± 17.4 minutes in group B. Mean time to motor onset was 17.7±3.3 minutes in group A and 18.8±2.9 minutes in group B. Mean duration of motor block was 241.1 ± 4.81 minutes in group A and 216.9± 7.17minutes in group B. There was no significant difference in VAS score till half an hour and after one hour we got significant difference in both groups.

Conclusion: We concluded that when used with ropivacaine (0.75%) as an adjuvant dexmedetomidine (1microgram/kg) and clonidine (1microgram/kg) shortens the onset of sensory block, prolongs the duration of sensory and motor blockade and provides the effective and prolonged post operative analgesia with adequate sedation and without major adverse effects and hemodynamic changes.

Keywords: Clonidine, dexmedetomidine, epidural, ropivacaine.
INTRODUCTION:

Epidural anaesthesia is commonly used technique for providing surgical anaesthesia with post-operative analgesia in lower abdominal and limb surgeries\(^\text{[1]}\). The most sought requirement in present day’s infraumbilical surgeries, are early postoperative mobilization and rehabilitation with minimally associated pain and discomfort\(^\text{[2-4]}\). Many local anaesthetic drugs are available for epidural anaesthesia including Bupivacaine that is still popular among anaesthetists due to its desirable clinical profile, but carries inherent risk of cardiac toxicity of variable degree depending upon dosages and patient factors.

The newer amide local anaesthetic ropivacaine, shares many physiochemical properties with Bupivacaine but with less systemic toxicity and greater margin of safety than other local anaesthetic agents of similar duration of action. The safety of ropivacaine is due to its availability in pure S-enantiomer form. It has less neurotoxic and cardiotoxic potential and preferentially blocks sensory fibres to greater degree than the motor fibers.

Recent clinical data have shown that ropivacaine is safe and effective for regional anaesthetic techniques. Early recovery of motor function in comparison to Bupivacaine is associated with decreased venous thromboembolism and shorter hospitalization\(^\text{[5,6]}\). It has always been a matter of research to find out drugs or techniques to potentiate the quality of central neuraxial blocks.

A variety of drugs, such as opioids, midazolam and alpha-2 agonists, were tried as an adjuvant with ropivacaine to prolong the duration of intraoperative and postoperative analgesia with variable results.

Alpha-2 adrenergic agonists have both analgesic and sedative properties and can be used as an effective adjuvant in epidural anaesthesia\(^\text{[7]}\). Dexmedetomidine, alpha-2 agonist, is made up of medetomidine’s dextrogyrous enantiomer and considered as a super selective alpha-2 adrenergic agonist’s prototype \(^\text{[8]}\). It is reported to have synergistic effect with ropivacaine for epidural anaesthesia. Clonidine, is an \(\alpha_2\) adrenergic agonist, offers several benefits in children when added to local anaesthetics either neuraxially\(^\text{[9-10]}\) or peripherally\(^\text{[11]}\). It increases the duration of nerve blockade, and produces mild sedation for 1 to 3 hours postoperatively (which does not preclude hospital discharge).

With this background information, after the approval of ethical committee we have done a prospective clinical study at our institute with the aim to compare the efficacy and clinical profile of \(\alpha_2\) adrenergic agonists dexmedetomidine and clonidine, when used as adjuvants in epidural anaesthesia in patients undergoing infraumbilical surgeries with special emphasis on their sedative properties and ability to provide smooth intra-operative and postoperative analgesia.

MATERIALS AND METHODS

This Hospital Based, double blind, randomized, comparative, interventional Study was carried out in 60 patients undergoing infra umbilical surgeries in Department of Anaesthesiology, S.M.S. Medical College and Attached Group of Hospitals, Jaipur after obtaining permission from Institutional Ethics Committee and Research Review Board. Informed consent was obtained from all patients for performance of epidural anaesthesia after explaining them in detail about the study protocol, side effects of study drug and procedure.

Inclusion Criteria
1. ASA grade I, II
2. Age 20-60 years.
3. Patient Ht. >145cm
4. Patients undergoing infra umbilical surgeries
5. Patient wt 45 – 85 Kg

Exclusion Criteria
1. Patient refusal
2. Patient having contraindications for epidural anaesthesia (infection at the site of injection, spine deformity, patient receiving antiplatelet drugs such as aspirin, clopidogrel, patient receiving heparin,
3. Pre-existing neurological defects, bleeding disorders, coagulation diathesis), endocrinial disease.
4. Patient with chronic history of headache & backache.
5. Any contraindication to study drug.
6. Known hepatic, renal, cardiac, neurological, psychiatric, metabolic or respiratory disease.
7. Evidence of gross radiological and anatomical abnormality in lumbar region.
8. Surgery extended to more than 2 hrs.

Data collection: The present study titled “A study to compare the effect of dexmedetomidine and clonidine as an adjuvant to ropivacaine for epidural anaesthesia in infraumbilical surgeries” included sixty patients of 20-60 year age with ASA grade I, II and weighing 45 -85 kg undergoing infraumbilical surgeries under epidural anaesthesia in SMS medical college and attached hospital, Jaipur after written and informed consent.

All patients randomly allocated in two groups of 30 patients in each group by computer generated random number table and procedure also blinded to study drugs by constant volume of drug in both groups. Group A patient received 15 ml 0.75 % ropivacaine + 1 microgram/kg dexmedetomidine, Group B received 15 ml 0.75 % ropivacaine + 1 microgram/kg clonidine.

Observations regarding the demographic data , preoperative vitals, sensory blockade(onset, level and duration ), motor blockade(onset, duration), two segment regression time, duration of analgesia, sedation, VAS score effect on vitals and intraoperative & postoperative adverse effects have been recorded.

Statistical Analysis: Statistical analysis was performed with the SPSS, version 21 for Windows statistical software package (SPSS inc., Chicago, IL, USA). The Categorical data was presented as numbers (percent) and were compared among groups using Chi square test. The quantitative data was presented as mean and standard deviation and were compared by student t-test. Probability was considered to be significant if less than 0.05.

RESULTS

Table 1: Socio-demographic variable

<table>
<thead>
<tr>
<th>Socio-demographic variable</th>
<th>Group A</th>
<th>Group B</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (Yrs)</td>
<td>39.0±11.8</td>
<td>42.6±10.6</td>
<td>0.224</td>
</tr>
<tr>
<td>Male: Female</td>
<td>21:9</td>
<td>20:10</td>
<td>0.99</td>
</tr>
<tr>
<td>Weight</td>
<td>65.6±12.5</td>
<td>62.8±10.2</td>
<td>0.345</td>
</tr>
<tr>
<td>ASA grade I:II</td>
<td>22:8</td>
<td>24:06</td>
<td>0.760</td>
</tr>
</tbody>
</table>

The two groups were comparable as there was no significant difference between the two groups in respect to age and sex distribution, height and weight characteristics. The distribution of the type of surgery and the duration of surgery were also found to be comparable.

Table 2: Study variable

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A</th>
<th>Group B</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean time to sensory onset (min)</td>
<td>8.3±1.3</td>
<td>11.6±1.8</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean time to attain highest sensory level (min)</td>
<td>13.3±1.4</td>
<td>17.6±1.9</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean duration of sensory block (min)</td>
<td>306.1±8.32</td>
<td>285.2±17.32</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean time to 2 segment regression (min)</td>
<td>160.5±12.4</td>
<td>139.9±11.7</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean time to motor onset (min)</td>
<td>17.7±3.3</td>
<td>18.8±2.9</td>
<td>0.267</td>
</tr>
<tr>
<td>Mean duration of motor block (min)</td>
<td>241.2±4.81</td>
<td>216.9±7.17</td>
<td>0.001</td>
</tr>
<tr>
<td>Mean total duration of analgesia (min)</td>
<td>316.6±31.9</td>
<td>280.9±30.4</td>
<td>0.001</td>
</tr>
</tbody>
</table>
The difference was highly significant between two groups for sensory onset that is p<0.001. Onset time is more in B group as compared to A group. There was statistically significant difference in highest level of sensory block among both study groups (p <0.001). Mean time was more in B group as compare to A group. There was statistically significant difference in mean duration of sensory block among both study groups (p <0.001). Duration of sensory block was more in A group as compared to B group. Difference was highly significant between two groups for mean time to 2 segment regression that is p<0.001. Two segment regressions is fast in group B as compare to group A. There was statistically no significant difference in mean time to motor onset in both groups (p value is 0.167). Both groups are comparable in motor onset. There was statistically significant difference in mean duration of motor block in both groups (p <0.001). Duration of block is more in group A as compare to group B. Difference was significant between two groups for mean total duration of analgesia that is p value is < 0.001.

Significant difference was observed in sedation score at 10 minutes and end of surgery among both study groups (p value <0.001). There was no significant difference in frequency of complications among both groups.

**DISCUSSION**

In recent years there is wide use of the epidural technique not only during surgery to provide anaesthesia and analgesia but also for obstetric and trauma as well as acute, chronic and cancer pain states. Epidural nerve block is central neuraxial anaesthesia and analgesia technique. Retrospective, prospective and metaanalysis studies have demonstrated an improvement in surgical outcome through beneficial effect on perioperative pulmonary function, blunting surgical stress response and improved analgesia.

The procedure is commonly performed as a sole anaesthetic or in combination with spinal or general anaesthetic. The duration of anaesthesia or analgesia is prolonged with use of catheter. Because of lidocaine induced transient neurological symptoms and cauda equina syndrome, it was replaced by bupivacaine in last few years. It was noted that bupivacaine is cardiotoxic and neurotoxic so ropivacaine, a new local anaesthetic got attention. It is considered to be less cardiotoxic. DA McNamee et al compared plain ropivacaine with bupivacaine (17.5mg) for major orthopaedic surgeries. They considered that ropivacaine offered a reliable
motor block with predictable and rapid return of motor function after surgery.

For control of pain, patient controlled epidural analgesia (PCEA) used in similar manner to that of intravenous patient controlled analgesia (IV PCA) by its actions on spinal cord and reduction in NMDA mediated effect.

Epidural block do not alter the course of underlying process, but may offer effective pain relief, performed in the spinal region including cervical, thoracic, lumbar and sacral regions.

Variety of drugs used with local anaesthetic agents, to improve the speed of the onset and duration of analgesia and counteract the disadvantage of the local anaesthetic.

By adding of these adjuvants, dose of local anaesthetics like bupivaine can be reduced and its side effects also reduced like myocardial depression, hypotension, bradycardia, heart block and ventricular arrhythmias.

In our study the mean time to onset of surgery block up to T10 dermatome in group dexmedetomidine was 8.3± 1.3min and in clonidine group was 11.6± 1.8 min that was highly statistically significant between the groups (P value <0.001).Result of our study was similar to Bajwa SJ et al13 study in which they conclude that onset of sensory block with dexmedetomidine given with bupivacaine was faster than clonidine with bupivacaine. MS Saravana Babu et al14 also evaluated that sensory onset was earlier in dexmedetomidine group as compare to clonidine when used with ropivacaine.

The mean time to achieve highest level of sensory block was higher in clonidine group 17.6±1.9 minutes as compare to group A 13.3±1.4minutes. It takes low time to attain highest sensory level in dexmedetomidine group. Our results were similar to study of SJS Bajwa et al13 and SM Channabasappa et al15.

The time taken for two segment regression of sensory block by two dermatome in group A 160.5± 12.4minutes and in group B 139.9± 11.7minutes (P value <0.001) that is statistically significant. Result of our study were similar to study of SM Channabasappa et al15 and Safiya I Shaikh et al16.

Dexmetomidine results in delayed regression time up to L1 resulting in prolonged duration of sensory block as compare to clonidine .The mean duration of sensory block was in group A 306.1±8.32 minutes as compare to clonidine group 285.2±22.5 minutes which was comparable and significantly prolonged.

Result of our study was supported by VR Hemant Kumar et al17 and Bajwa et al13, they concluded that duration of sensory blockage were found to be significantly better in dexmetomidine group.

In our study the mean time of total duration of motor block was 241.2±4.81 minutes in group A and 216.9± 7.17 minutes was in group B. The difference in total duration of motor block was highly significant (P value <0.001). Results of our study were consistent with Pramila Soni et al18 who concluded that duration of motor and sensory block was prolonged in dexmetomidine group.

VAS score was used to assess the analgesia in patient post operatively. The addition of alpha 2 agonist to local anaesthetic improves the post operative analgesia.

Post operative VAS score at different time interval were non-significant before 1 hour and significant after 1 hour.

Our result were in accordance with study conducted by Safiya et al16 who conclude that time to rescue analgesia was prolonged in dexmetomidine group compare to clonidine with bupivacaine.

In our study, there was highly significant difference in sedation score at 30 minutes and at the end of surgery between the groups. Sedation score was 3.4 ± 2.1 in A and 2.4 ± 1.8 in B group at 30 minutes, while sedation score was 3.1 ± 1.5 in A group and 2.1 ± 1.5 B in group at end of surgery.
Similar study was done by Shobna Gupta et al\textsuperscript{19} with low dose 0.2 % Ropivacaine and higher alpha 2 agonist doses in caudal anaesthesia and found no statistically significant difference post operatively in sedation score.

Result of our study supported by Vijay G Anand et al\textsuperscript{20} study, the difference from our study may be due to high dose of alpha 2 agonist drugs.

**CONCLUSION**

We concluded that when used with ropivacaine (0.75%) as an adjuvant dexmedetomidine (1microgram/kg) and clonidine (1microgram/kg) shortens the onset of sensory block, prolongs the duration of sensory and motor blockade and provides the effective and prolonged post operative analgesia with adequate sedation and without major adverse effects and hemodynamic changes. Dexmedetomidine is more potent adjuvant as compare to clonidine in all above respects.

**BIBLIOGRAPHY**


