A study to evaluate the effect of low dose Intrathecal dexmedetomidine as adjuvant to low dose bupivacaine (H) Spinal Anaesthesia in elderly patients undergoing Infrabulimal Surgery

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Abstract

Background: Elderly patients pose a serious challenge to anaesthesia not only because of associated co-morbidities but also due to physiological changes during aging. Therefore lower doses of local anaesthetics along with Intrathecal α2-adrenoceptor agonists have been shown to decrease the required doses of local anaesthetics and are devoid of major side effects. Hence this study evaluates spinal anaesthesia characteristics in elderly patients.

Methods: 120 Patients aged more than 60 years belonging to ASA I,II and III physical status and posted for infrabulimal surgeries were randomized into 2 groups, Group B(Bupivacaine) and Group BD (Bupivacaine + Dexmedetomidine). Under aseptic conditions lumbar puncture was performed in sitting position at L3/4 interspace and 2.1 ml of study agents were administered. Group B received 10mg of 0.5% hyperbaric Bupivacaine and Group BD received 10mg of 0.5% hyperbaric Bupivacaine and 5mcg of Dexmedetomidine. In all cases monitoring of Blood pressure, ECG, Oxygen saturation and Respiratory rate was done at regular intervals intra-operatively. Sensory block and motor blocks were assessed periodically.

Results: There were no clinically and statistically significant changes in heart rate and blood pressure and the mean max fall in HR, SBP, DBP and MAP. However, it was observed that there was a statistically significant (P<0.001) decrease in the time of onset of sensory block and motor block in Group BD(1.68±0.96 and 2.42±1.12) when compared to Group B(2.24±0.81 and 3.33±1.06). Duration of analgesia and the time for first rescue analgesia was prolonged in Group BD (P<0.001). There were no side effects except for mild sedation in Group BD.

Conclusion: Addition of Dexmedetomidine 5 mcg to intrathecal Bupivacaine(H) in elderly patients causes minimum hemodynamic changes, prolongs sensory and motor block.

Keywords: spinal anaesthesia, dexmedetomidine, bupivacaine, intrathecal

Introduction

Aging is an irreversible and progressive physiological phenomena characterized by degenerative changes in the structure and functional reserve of organs and tissue. In almost every country, the proportion of people aged over 65 years is growing faster than any other age Group, as a result of both longer life expectancy and declining fertility rates. By the year 2040, persons aged 65 years or older are expected to comprise 24% of the population and account for 50% of health care expenditures. With the rising longevity and 1/3rd of the surgical patients being elderly, geriatric anaesthesia has come into prominence. Elderly patients pose a serious challenge to anaesthesia not only due to associated co-morbidities but also due to natural changes during aging. Both the peripheral and central nervous system degenerate with advancing age. A reduction in the number of neurons within the spinal cord, deterioration of myelin sheaths and connective tissue barriers and slowing of the conduction velocity in peripheral nerves, especially the motor nerves, all these changes contribute to altered nerve block characteristics (dose-response relationship). Thus reduction in the intrathecal dose (fixed volume and concentration) of local anaesthetic may prevent major changes in the vital parameters and further modification of the given dose by use of spinal adjuvants like Dexmedetomidine may be rewarding.

Dexmedetomidine by acting on the alpha-2 adrenoreceptors located on the primary afferent terminals of neurons in spinal cord, brain stem and peripheral tissue, will exhibit synergistic
effects with Local anaesthetics and will also produce analgesic effects [6]. In this background we undertake to evaluate spinal anaesthesia characteristics in elderly patients due to the effect of 5mcg of Dexmedetomidine as an adjuvant to low dose Bupivacaine (H) 10mg. Our aim was to evaluate the effect of low dose intrathecal Dexmedetomidine (5mcg) as an adjuvant to Bupivacaine (H) (10mg) in Elderly regarding,

1. Hemodynamic stability
2. Time of onset of sensory and motor block
3. Duration of Sensory and Motor block
4. Time for first rescue analgesia
5. Side effects if any

Materials and Method
Following ethics committee approval, informed consent was obtained from the patients. Detailed pre-anesthetic evaluation was done. Patient aged more than 60 years of either sex who are fit for spinal anaesthesia undergoing Infra umbilical surgeries belonging to ASA physical status I, II and III were included in the study. Those patients with bleeding diathesis and coagulopathy, Severe hepatic failure, Heart blocks, dysrhythmias, ASA IV patients, having Infection at the site of spinal anaesthesia and Known allergy to local anaesthesia or Dexmedetomidine were excluded from the study.

Sample size was calculated based on the study by Seop Chang Y et al (2015) and considering the mean difference 6.1mmHg and SD 11.7 in mean blood pressure between study and control Group, with 95% CI and 80% power, sample size will be 43 in each Group1. Considering the nonresponsive rate of 20% We have included 60 patients in each Group. Hence 120 Patients were randomly allocated to 2 Groups of 60 each by computer generated randomization table. Group B (Bupivacaine) and Group BD (Bupivacaine + Dexmedetomidine). Under aseptic conditions lumbar puncture was performed in sitting position at L3-4 / L4-5 interspace using a para- median approach with a 25-G Quincke spinal needle and 2.1 ml of study agents were administered. Group B received 10mg of 0.5% hyperbaric Bupivacaine and Group BD received 10mg of 0.5% hyperbaric Bupivacaine and 5mcg of Dexmedetomidine. The solution was injected over 6 seconds with no barbotage followed by immediate placing the patient in supine position with the operating table in neutral position.

In all cases monitoring of Blood pressure, ECG, Oxygen Saturation and Respiratory rate was done at regular intervals intra-operatively. Sensory block and motor blocks were assessed periodically. Intraoperative fluid requirement was managed taking into account the cardiopulmonary status of the patients. Hypotension was defined as a decrease in Systolic blood pressure (SBP) of >20% of the Basal SBP and was initially treated with crystalloids and if necessary Vasopressors. Bradycardia defined as a decrease in heart rate of > 20% of the Basal value and was treated with intravenous atropine (0.6mg). At 10 mnts after spinal injection, the inability to reach a sensory block at T12 and a Modified Bromage Score of 0 was considered as a block failure and was excluded from further study. In case of intra-operative discomfort or pain patients were administered appropriate anaesthesia based on the patients physical status and was excluded from the study.

At the end of surgery patients were shifted to post-anesthesia care unit. The duration of analgesia was considered as the period from the injection of the study drug to patient perceiving sensation and time for first rescue analgesia was considered as period from the injection of the study drug to the first request made by the patient for analgesics. For rescue analgesia intravenous infusion of Diclofenac 75 mg was given, which was repeated after 12 hours, if needed.

Vital signs (ECG, Pulse rate, NIBP, Respiratory rate, SpO2) were recorded at intervals of 2, 4, 6, 8, 10, 15, 20, 30, 40, 50, 60, 75 and 90 minutes. Onset of sensory and motor blockade, Duration of analgesia and motor block, Time to first rescue analgesic (Diclofenac), VAS at 4th and 8th hour post operatively and adverse effects like Bradycardia, Hypotension/Hypertension, sedation, Nausea/vomiting, Desaturation, Dry mouth and Others were monitored.

Descriptive statistics done for all data and suitable statistical tests of comparison were applied. Data was entered in MS Excel and analysed in SPSS v20. Continuous variables were summarised as mean or median with standard deviation (SD) or interquartile range (IQR). Categorical variables were expressed as percentages with 95% confidence interval (95% CI). T test was used to test the statistical significance of difference between the groups in continuous variables. Two way ANOVA was used to test the statistical significance of difference in variation of heart rate, systolic, diastolic, and mean arterial blood pressure. Chi square test was used test the statistical significance of deference in distribution of categorical variable. P value less than 0.05 was considered as statistically significance.

Results
All the patients included in the study received the assigned intervention and were followed up till the end of study. Patient demographic characteristics were comparable in both groups (age, gender, BMI).

Table 1: Distribution of anthropometric parameters

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N</th>
<th>Group B</th>
<th></th>
<th>Group BD</th>
<th></th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mean</td>
<td>±S.D</td>
<td>Mean</td>
<td>±S.D</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>60</td>
<td>68.08</td>
<td>4.91</td>
<td>69.3</td>
<td>5.75</td>
<td>0.4</td>
</tr>
<tr>
<td>Height (cms)</td>
<td>60</td>
<td>166.58</td>
<td>5.15</td>
<td>160.95</td>
<td>8.30</td>
<td>0.1</td>
</tr>
<tr>
<td>Weight (kgs)</td>
<td>60</td>
<td>64.26</td>
<td>5.10</td>
<td>61.50</td>
<td>7.31</td>
<td>0.3</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>60</td>
<td>23.16</td>
<td>1.69</td>
<td>23.78</td>
<td>2.88</td>
<td>0.9</td>
</tr>
</tbody>
</table>

In Group B the mean basal HR was 79.43±8.74 bpm and at 90th minute was 71.58±7.20 bpm with a difference of 7.85. In Group BD the mean basal HR was 78.75±11.15 bpm and at 90th minute was 70.38±7.75 bpm with mean difference of 8.37. The mean difference in the HR between Group B and Group BD was statistically insignificant (P= 0.067).
In Group B the mean basal SBP was 138.53±13.45 mm hg and at 90th minute was 121.15 ±7.133. In Group BD the mean basal SBP was 139.73±15.61 mm hg and at 90th minute was 123.53±11.587. Even though there was a statistically significant fall in SBP from the baseline value to the 90th minute in both the Groups, the mean difference in the fall of SBP was statistically insignificant (P value =0.601).

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Fig 3: Graph showing comparison of mean DBP between the Groups at various time intervals

In Group B the mean basal MAP was 99.51±8.28mm hg and at 90th minute was 90.08 ±5.29. In Group BD the mean basal MAP was 102.02±9.87mm hg and at 90th minute was 89.76± 6.83. Even though there was a statistically significant fall in MAP, the mean difference in the fall of MAP from the basal to the 90th minute between the two Groups was statistically insignificant (P=0.30).

Fig 4: Graph comparing mean of the MAP between the Groups at various time intervals

The mean time of onset of sensory block (TOSB) was 2.24 ±0.81 minutes in Group B and 1.68 ± 0.96 minutes in Group BD and was statistically significant with a P value of < 0.001. The mean time of onset of motor block (TOMB) was 3.33 ±1.06 minutes in Group B and 2.42 ± 1.12 minutes in Group BD and was statistically significant with a P value of < 0.001. The total duration of motor block (TDMB) was 299.56 ±59.66 minutes in Group B and 416.30 ± 79.61 minutes in Group BD and was statistically significant with a P value of < 0.001. The total duration of analgesia (TDA) was 323.61±59.87 minutes in Group B and 457.23 ± 77.31 minutes in Group BD and was statistically significant with a P value of < 0.001. The time for first rescue analgesia (TRA) was 377.60±56.37 minutes in Group B and 520.85± 87.93 minutes in Group BD and was statistically significant with a P value of < 0.001.
Table 2: Characteristics of sensory and motor block of the studied Groups (minutes).

<table>
<thead>
<tr>
<th></th>
<th>Group B Mean ±S.D</th>
<th>Group BD Mean ±S.D</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TOSB</td>
<td>2.24 ± 0.81</td>
<td>1.68 ± 0.96</td>
<td>&lt;0.0001</td>
</tr>
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</tr>
<tr>
<td>TRA</td>
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<td>520.85 ± 87.93</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

The VAS score after 4 hours of surgery in Group B was 3.26 ± 2.34 and that of Group BD was 2.01 ± 1.34. The VAS score after 8 hours of surgery in Group B was 5.98 ± 2.16 and that of Group BD was 2.56 ± 1.82.

Three patients in Group B and Five patients in Group BD had bradycardia which required treatment with atropine 0.6mg iv. And 9 patients in Group B and 12 in Group BD had hypotension and required injection mephenetermine in addition to iv fluids.

Discussion

Elderly patients pose a serious challenge to anaesthesia not only due to associated co-morbidities but also due to natural changes during aging. Thus reduction in the intrathecal dose (fixed volume and concentration) of local anaesthetic may prevent major changes in the vital parameters. Low-dose local anesthetics can limit the block level and induce rapid recovery from anaesthesia. Hence lower doses of local anesthetics along with an adjuvant are preferred for spinal anesthesia in elderly patients [8]. Various adjuvants are frequently co-administered with local anesthetics to improve the anesthetic quality and postoperative analgesia and to reduce the incidence of hypotension after spinal anaesthesia. Adjuvants like intrathecal opioids can cause several problems, including respiratory depression, pruritus, and central nervous system excitation. Intrathecal a2-adrenoceptor agonists as adjuvant drugs have been shown to decrease the required doses of local anesthetics and are devoid of these side effects [9].

We conducted a study to assess the effect of dexmedetomidine with bupivaine for spinal anaesthesia and found that there were no significant change in hemodynamic parameters. But the mean time of onset of sensory and motor block were faster in group BD. The duration of motor block was longer in group BD, and the requirement of rescue analgesics were comparable among Groups. Duration of motor block was longer in group BD. The VAS score after 4 hours of surgery in Group B was 3.26 ± 2.34 and that of Group BD was 2.01 ± 1.34. The VAS score after 8 hours of surgery in Group B was 5.98 ± 2.16 and that of Group BD was 2.56 ± 1.82.

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not be studied; United State Food and Drug Administration has no approval for perineural application of Dexmedetomidine. Also a lower dose of Bupivacaine (H) and Dexmedetomidine as adjuvant could have been studied.

References