A COMPARATIVE STUDY OF DEXMEDETOMIDINE AND BUPRENORPHINE AS AN ADJUVANT WITH ROPIVACAINE FOR SPINAL ANESTHESIA IN INFRA-UMBILICAL SURGERIES

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Abstract

Background: For lower abdominal surgeries, spinal anesthesia is the preferred option due to its quick onset, better blockade, lower risk of infection in the surgical site, cerebrospinal fluid and epidural. lower failure rates, and cost-effectiveness. However, it has the disadvantages of a shorter duration and less postoperative analgesia. In spinal anaesthesia, a variety of adjuvants have been combined with local anaesthetics to reduce intraoperative visceral and somatic pain and to provide prolonged postoperative analgesia. Recently dexmedetomidine, an alpha2 - agonist is used as a neuraxial adjuvant for effective analgesia. Objectives: The main aim of the study is to compare the spinal block characteristics of dexmedetomidine with buprenorphine as an adjuvant to hyperbaric ropivacaine in spinal anaesthesia in patients undergoing infra-umbilical surgeries. Materials and Methods: This randomised controlled trail study was conducted at Department of Anesthesia in SRM medical college, Trichy. A total of seventy participants were randomly allocated into two groups, 35 participants each. Group A participants were given intrathecal 3ml 0.75% ropivacaine with Buprenorphine (30µg) in 0.2 ml normal saline and Group B participants were given intrathecal 3ml 0.75% ropivacaine with dexmedetomidine (15µg) diluted in 0.2 ml normal saline. Data regarding the time of onset of sensory block, time for maximum level of sensory blockade, time of onset of motor block, duration of sensory block, duration of motor block, time of two segment regression of sensory blockade, time of first analgesic request, incidence of side effects and the hemodynamic parameters such as heart rate, systolic & diastolic blood pressure and mean arterial pressure were recorded. Data collected were entered in Microsoft Excel and analysed in SPSS version 21.0. Data analysis was done using SPSS and continuous variables and categorical variables were interpreted using frequencies (mean±SD) and proportions (%). Results: The duration of sensory and motor block is significantly lesser in buprenorphine group with 323.67 and 297.13 mins where as in it is higher in Dexmedetomidine group with 503.21 and 441.73 mins respectively. The time two segments of sensory segments in buprenorphine group is 271.51 mins where as in Dexmedetomidine group it is 399.7 mins and the results were significant. Time to sensory regression is much longer in Dexmedetomidine group. Conclusion: The addition of Dexmedetomidine as an adjuvant to 0.75% hyperbaric ropivacaine in spinal anaesthesia produces longer duration of sensory and motor block as compared to Buprenorphine with fewer side effects.
INTRODUCTION
For lower abdominal and lower limb procedures, central neuraxial blocking in the form of spinal/epidural anesthesia is highly popular since it avoids the drawbacks of general anaesthesia, such as airway manipulation, polypharmacy, and other unfavourable outcomes like postoperative nausea and vomiting, as well as the need for additional intravenous analgesics.[1] The management of postoperative pain is a significant challenge because spinal anaesthesia produced by local anaesthetics alone has short duration of action, necessitating early analgesic intervention. To enhance the quality of intraoperative analgesic and lengthen it in the postoperative period, numerous adjuvants to local anaesthetics have been used intrathecally.[2]

Opioids are frequently used as intrathecal adjuvants because they don’t significantly inhibit motor or autonomic functions. But side effects like pruritus, nausea, vomiting, urinary retention, and delayed respiratory depression have prompted more research into non-opioid analgesics with less negative side effects.[3,4]

Buprenorphine, a μ receptor partial agonist centrally acting lipid soluble analogue has been safely used as an adjuvant for spinal anaesthesia. It has low intrinsic activity and its lipophilicity and high molecular weight prevents it from spreading rostrally and does not cause respiratory depression unlike the other hydrophilic opioid.[5]

New neuraxial adjuvants called 2-adrenergic agonists like dexmedetomidine, clonidine are used recently to enhance the efficacy of subarachnoid blockade in terms of both sensory and motor blockades.[6] Their primary mechanism of action is that at the level of spinal cord which includes pre- and postsynaptic sites of action. Pre-synaptically, α2-receptor activation inhibits release of substance P from afferent “c” fibers within dorsal horn. Postsynaptically, it inhibits the development and subsequent transmission of integrated pain signals within second-order neurons of the substantia gelatinosa.[7]

Dexmedetomidine is a highly selective, α2 adreno-receptor agonist with alpha-2: alpha-1 binding ratio of 1620:1 that provides sedation, hypnosis, analgesia and sympatholysis without any respiratory depressive action. Dexmedetomidine is a significantly more potent sedative and analgesic drug than clonidine because of its high specificity for the α2 subtype and eight times greater α2:α1 selectivity.[8,9]

Ropivacaine is an amide local anesthetic, safe and effective for regional anesthetic procedures such as epidural and brachial plexus block, according to extensive clinical data.[10] Few studies have shown that dexmedetomidine administered intrathecally as an adjuvant with ropivacaine produces significantly prolonged postoperative analgesia with minimal side effects. Hence we proposed this study.

Objectives
- To compare the spinal block characteristics of dexmedetomidine with buprenorphine as an adjuvant to ropivacaine in spinal anesthesia in patients undergoing infra-umbilical surgeries such as Onset of sensory blockade, Maximum level of sensory blockade attained and the time taken for the same, Time for two-segment sensory regression, Onset and duration of motor blockade & Total duration of analgesia.
- To compare the hemodynamic stability, time to rescue analgesia and postoperative analgesic consumption with the two adjuvants in patients.

MATERIALS AND METHODS

Study Design
- A Comparative study.
- Study area
  - Department of Anesthesia, Trichy SRM medical college hospital & research Centre.
- Study duration
  - Three months
- Study population
  - Patients posted for lower abdominal surgeries.

Inclusion criteria
- Patients belonging to ASA grade I & II.
- Patients with age between 18-60yrs
- Both sex.
- Scheduled for elective infra umbilical surgery, requiring spinal anaesthesia.

Exclusion criteria
- Participants not willing to give consent
- Patients belonging to ASA grade III and IV
- Pregnant and Lactating patients
- Patient refusal for neuraxial anesthesia
- Patients having
  - raised intracranial pressure
  - severe hypovolemia
  - bleeding coagulopathy
  - local infection
  - uncontrolled hypertension/ diabetes mellitus
  - neurological disorder rand deformities of spine
  - cardiac disease
  - hepatic disease
- Allergy to local anaesthetics, Buprenorphine and dexmedetomidine
- surgery duration more than 3 hours or surgery requires both combined spinal and epidural anesthesia.

Sampling Technique
- Convenient sampling
- Sample size: 70

Operational definition
- Onset of sensory blockade - The time from administration of intrathecal injection of the study drug to the time to achieve loss of pin prick sensation at T10 level.
Time taken for maximum sensory blockade - The time taken to achieve the highest level of sensory block from the time of injection.

Duration of two-segment sensory regression- The time interval between administration of the intrathecal injection of the study drug to regression of sensory block by two segments from the maximum sensory block height.

Onset of motor blockade- The time from the intrathecal injection of study drug to the time to achieve complete motor block i.e. grade 3 by using Modified Bromage scale:0 = no block, 1 = able to flex knees with free movement of feet, 2 = unable to flex knees but able to move feet, 3 =complete block

Duration of motor blockade - The time from the administration of the intrathecal injection of study drug until the patient recovers to Bromage score 0.

Duration of analgesia - The time interval between block onset and the requisition of first analgesic.

Rescue analgesia was provided with intravenous paracetamol 15-30mg/kg when the Visual analogue Scale (VAS) score was 4 or more.

Hypotension - The reduction of SBP of more than 30% from the baseline value or SBP <90 mmHg, and it was treated with an increased rate of intravenous fluids and vasopressors in the form of Inj.Ephedrine 6mg intravenously (was repeated if necessary).

Bradycardia - The reduction in heart rate of more than 30% from the baseline or HR <50 bpm, and was treated with injection atropine 0.3mg increments or injection glycolpyrolate 0.02 – 0.04mcg/kg

Adverse effects- Patients were monitored for adverse effects such as nausea, vomiting, pruritus, respiratory depression.

Data Collection
Data was collected in Department of Anesthesia in Trichy SRM medical college hospital and research center. This study was conducted among 70 patients who were posted for infra-umbilical surgeries. After getting informed written consent they were randomly allocated into two groups (Group A and Group B) consisting of 35 participants each. Group A participants were given intrathecal 3ml 0.75% ropivacaine with Buprenorphine (30µg) in 0.2 ml normal saline and Group B participants were given intrathecal 3ml 0.75% ropivacaine with dexmedetomidine (15µg) in 0.2ml normal saline. During pre-operative evaluation, weight, basal heart rate, and blood pressure were recorded. The duration of analgesia, onset, and duration of sensory block, onset and duration of motor block, heart rate, and blood pressure were recorded at the 0 min to 90 mins with 5 mins interval after completion of injection.

Scoring was used to assess sensory effect as 0 = no block, 1 = touch sensation (analgiesia) and 2 = no sensation (anesthesia). The motor block was assessed according to the modified Bromage scale (0–3). The onset of motor block (time to reach Bromage score 3) and duration of motor block (time to regression of Bromage score 0) were recorded. Based on the visual analogue scale, pain score assessed and the administration of first analgesia time were noted.

Data was entered in Microsoft excel 2019 and analysed using software SPSS (Statistical Package of Social Sciences) version 21. Continuous variables and categorical variables were interpreted using frequencies (mean±SD) and proportions (%).Chi-square test and student t test was used to determine statistical difference between the study groups in the parameters measured. P less than 0.05 were considered as statistically significant.

Ethical issues
- Participants were informed about the study and informed consent was obtained
- This study was presented to Institutional Ethical Committee of Trichy SRM Medical College Hospital& research center.

RESULTS

The results of the present study are described as follows

<table>
<thead>
<tr>
<th>Table 1: Comparison of study variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parameters</td>
</tr>
<tr>
<td>----------------------------------</td>
</tr>
<tr>
<td>Age in years</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Weight in kg</td>
</tr>
<tr>
<td>Height in cm</td>
</tr>
<tr>
<td>BMI in kg/m²</td>
</tr>
</tbody>
</table>
ASA class
I 22 (62.8%)
II 13 (37.2%)

Duration of surgery(mins)
124+/- 16.12
126.14+/- 14.24

*p test used to compare means and chi square to compare proportions
The age in Group A is 41.33 years and in group B is 42.59 years. The gender, age, weight, height, BMI and ASA class distribution is not different between two groups as the results were non-significant making both groups comparable.

Table 2: Comparison of sensory and motor block parameters

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group A BUPRENORPHINE</th>
<th>Group B DEXMEDETOMIDINE</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time of onset of sensory block in mins</td>
<td>3.33+/-.603</td>
<td>2.42+/-.512</td>
<td>0.341</td>
</tr>
<tr>
<td>Time for maximum level of sensory blockade in mins</td>
<td>4.56+/-.1.24</td>
<td>5.46+/-.2.14</td>
<td>0.0349</td>
</tr>
<tr>
<td>Time of onset of motor block in mins</td>
<td>4.21+/-.8.93</td>
<td>3.92+/-.7.87</td>
<td>0.465</td>
</tr>
<tr>
<td>Duration of sensory block in mins</td>
<td>323.67+/-.19.6</td>
<td>503.21+/-.13.91</td>
<td>0.001</td>
</tr>
<tr>
<td>Duration of motor block in mins</td>
<td>297.13+/-.16.78</td>
<td>441.73+/-.13.94</td>
<td>0.001</td>
</tr>
<tr>
<td>Time of two segment regression of sensory block in mins</td>
<td>115.24+/-.8.9</td>
<td>103.58+/-.11.25</td>
<td>0.001</td>
</tr>
<tr>
<td>Time of first analgesic request in mins.</td>
<td>428.66+/-.123.74</td>
<td>453.23+/-.133.34</td>
<td>0.417</td>
</tr>
</tbody>
</table>

The time of onset of sensory block and motor block has significant difference between two groups which showed earlier onset in dexmedetomidine group compared to Buprenorphine group. The duration of sensory and motor block is significantly lesser in buprenorphine group with 323.67 and 297.13 mins where as in it is higher in Dexametomidine group with 503.21 and 441.73 mins respectively.
The time of regression of two segments of sensory block in buprenorphine group is 271.51 mins where as in Dexametomidine group it is 399.7 mins and the results were significant. Time to sensory regression is much longer in Dexametomidine group.

Table 3: Adverse effects

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Group A BUPRENORPHINE</th>
<th>Group B DEXMEDETOMIDINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>7</td>
<td>0</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>Nausea and vomiting</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Rigors/chills</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Total no of cases with adverse effects</td>
<td>17</td>
<td>2</td>
</tr>
</tbody>
</table>

The adverse effects are observed in buprenorphine (group A) such as hypotension in n=7(20%), Bradycardia in n=6,(17.1%), Nausea and vomiting n=3(8.5%), rigors and chills n=2(5.7%), totally n=17(48.5%), dexametomidine (group B) hypotension n=0 (nil), bradycardia n=1(2.7%),
nausea and vomiting n=0(nil), rigors and chills n=1(2.7%) totally n=2(5.7%), which shows higher number of incidence of adverse effects in group A compared to group B.

![Figure 3: Incidence of adverse effect](image)

The incidence of adverse effects such as hypotension, bradycardia, nausea & vomiting, rigors, chills are significantly lower in Dexmedetomidine group.

**DISCUSSION**

In the present study the two adjuvants buprenorphine and dexmedetomidine were considered and compared their benefits and side effects as adjuvants to ropivacaine for infraumbilical surgeries. From our study we found that dexmedetomidine was found effective than buprenorphine in case of the duration of sensory and motor block and it was statistically significant.

In the present study it was found that the mean duration of onset of sensory blockade and motor blockade is higher in dexmedetomidine group with 503.21 and 441.73 mins than in buprenorphine group with 323.67 and 297.13 mins with statistically significant.

A study conducted by Deepa et al. also found that the mean duration of sensory block in dexmedetomidine group is approximately 51% longer than buprenorphine group. The mean duration of motor block was shorter in buprenorphine group (298.63 ± 35.79) when compared with dexmedetomidine group (432.33 ± 12.74) which is similar to our study report. Another study by Ganesh et al. also showed a statistically significant difference in mean duration of sensory blockade between dexmedetomidine group, clonidine group and buprenorphine group and concluded that highest duration of sensory blockade was seen in buprenorphine group and lowest in dexmedetomidine group which is also comparable to our study report.

In a study by Akhila et al also stated that the two segment regression was significantly slower with dexmedetomidine (330±68min) compared to buprenorphine (225±58min) which is comparable to our study report in which the mean duration of sensory regression in dexmedetomidine group is 399.78+/−16.99 when compared to buprenorphine group is 271.51+/−16.38 mins. Another study by Gupta et al also found that The mean time of sensory regression to S1 was 476±23 min in dexmedetomidine group and 187±12 min in buprenorphine group with P<0.001 which is also similar to our study report.

Another study by Bansal et al. also found that the duration of analgesia was compared in both the groups; Group B (buprenorphine) (295.547 ±45.1462 mins) and Group D(dexmedetomidine ) (581.933 ±122.0251 mins) with a statistical difference of p < 0.001 and concluded that duration of analgesia in Group D was far longer as compared to Group B which is in consistent with our study report.

In the present study it was found that there were no significant difference with respect to hemodynamic parameters (heart rate, systolic and diastolic BP and mean arterial pressure) among the groups, which is comparable to a study conducted by Amitha S et al also found that there is no statistical significance in hemodynamic parameters among the study group.

In our study it was also found that the incidence of side effects is less in dexmedetomidine group which is comparable to a study Deepa et al also found that side effects are less in Group D than group B.

**CONCLUSION**

During spinal anesthesia use of adjuvants enables the use of less local anaesthetics and increases the duration and quality of analgesia. Our study concluded that addition of dexmedetomidine as an adjuvant to 0.75% hyperbaric ropivacaine in spinal anesthesia produces longer duration of sensory and motor block but takes slightly more time to attain complete motor block as compared to Buprenorphine. Dexmedetomidine as an intrathecal adjuvant results in hemodynamic stability that is comparable to buprenorphine without producing excessive sedation or respiratory depression and with fewer side effects.

**Limitations**

Small sample size and a single centre study.

**Conflict of interest**

Nil.

**REFERENCES**