Clinical profile of patients undergoing spinal Anesthesia with intrathecal bupivacaine with clonidine and intrathecal bupivacaine with fentanyl

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Abstract
Intrathecal clonidine is being extensively evaluated as an alternative to neuraxial opioids for control of pain and has been proven to be a potent analgesic. It is used in combination with opioids and local anesthetics in labour analgesia and orthopaedic surgery. However, there is still dearth of studies for using intrathecal clonidine for postoperative analgesia in lower abdominal surgeries. Pre anaesthetic check-up was carried out pre operatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done. The number of males and females in each group was same (n=30) and samples in both groups were matched with respect to sex. Majority of female patients in the both the groups belonged to the group 26 to 55 years. Samples were age matched. The number of males and females in each group was same (n=30) and samples in both groups were matched with respect to sex. Majority of female patients in the both the groups belonged to the group 160 to 170 cms and males 171 to 175 cms. Samples were height matched.

Keywords: Spinal anesthesia, bupivacaine, clinical profile

Introduction
Spinal anesthesia results from the delivery of the anesthetic agents into the subarachnoid space. It is one of the simplest regional aesthetic techniques to perform. Safe practice of spinal anaesthesia includes properly selecting and preparing the patient, accessing the CSF, administering appropriate anesthetic drugs and adjuvants, managing physiologic side effects and monitoring the patient throughout the procedure as well as in the early recovery process [1].

Spinal anesthesia with hyperbaric bupivacaine 0.5% is a popular method. The main reasons for the popularity of spinal block are that the block has well defined end points and the anesthesiologist can produce the blocks reliably with a single injection. The versatility of spinal anesthesia is afforded by a wide range of local anesthetics and additives that allow control over the level, the time of onset and the duration of spinal anesthesia. The distribution of local anesthetic solutions within the subarachnoid space determines the extent of the neural blockade produced by spinal anesthesia [2].

August Bier performed the first spinal anesthetic more than a century ago, by injecting cocaine into the cerebrospinal fluid of a patient. For most of the subsequent hundred years, local anesthetics were the only substances used for neuraxial blockade. This changed with the discovery of opioid receptors in the spinal cord in the 1970s, intrathecal and epidural opioid administration alone or in combination with local anesthetics became widespread. Since then driven by the ongoing discovery of multiple spinal transmitter and receptors like cholinergic, opioid, NMDA, GABA, benzodiazepam receptors triggered the usage of many diverse groups of pharmacological agents such as neostigmine, opioids, ketamine, midazolam for synergistic effect with hyperbaric bupivacaine (0.5%) in prolonging the duration of analgesia. However, each drug has its own limitations and a need for alternative method or drug always exists [3].

Fentanyl, a highly lipophilic opioid, has rapid onset of action following intrathecal administration. It has become very popular additive to hyperbaric bupivacaine in recent times and is a established technique now. However, fentanyl has side effects like pruritus, nausea and vomiting [4].

Intrathecal clonidine is being extensively evaluated as an alternative to neuraxial opioids for control of pain and has been proven to be a potent analgesic. It is used in combination with opioids and local anesthetics in labour analgesia and orthopaedic surgery. However there is
still dearth of studies for using intrathecal clonidine for postoperative analgesia in lower abdominal surgeries [5].

Methodology
After approval from the hospital ethical committee, a prospective double blind randomized controlled study was carried out on 60 adult patients. Patients were randomly divided on an alternative basis into two groups of 30 each.

Group “C” - Bupivacaine plus clonidine group.

Group “F” - Bupivacaine plus fentanyl group.

Inclusion criteria
- ASA grade 1 and 2 patients.
- Age group of 18–60 yrs.
- Patients giving valid informed consent.
- Those patients scheduled to undergo elective lower abdominal, lower extremity, gynaecological or urological surgeries under subarachnoid block.

Method of study
Pre anaesthetic check up was carried out pre operatively with a detailed history, general physical examination and systemic examination. Airway assessment and spinal column examination were done. In the pre operative room, intravenous line was secured and the patients were preloaded with 15 ml / kg Ringer’s lactate, 30 minutes prior to spinal anaesthesia.

In each case, spinal anaesthesia was performed under strict aseptic precautions by inserting 25 gauge Quincke’s spinal needle into subarachnoid space at L2-3 or L3-4 interspace with patient in lateral position and the study solution was injected over 15-20 seconds.

Patients belonging to group ‘C’ received 3 ml (15 mg) of hyperbaric bupivacaine 0.5% plus 1 µg.kg⁻¹ of clonidine. Patients of group ‘F’ received 3 ml (15 mg) of hyperbaric bupivacaine 0.5% plus (25 µg) of fentanyl. After injection, patient was immediately turned to supine position.

Standard monitoring was carried out in the form of pulse oximetry, ECG and non invasive arterial blood pressure monitoring. Pulse rate, respiratory rate, arterial blood pressure and oxygen saturation were recorded every 3mins for first 10 mins, every 5 mins for next half an hour and then every 10 mins intra operatively. Bolus doses of inj mepheneteramine 6 mg i.v. were given to maintain arterial blood pressure within 20% of baseline and inj atropine 0.6 mg i.v. was given when the patient developed bradycardia (PR< 50 beats/min). No other sedative or analgesic was given in the study period. Sensory block was assessed by pin prick in mid clavicular line bilaterally using 25 guage hypodermic needle. The onset of sensory block was considered as the time taken from intrathecal injection to the highest level of the sensory block. The duration of sensory block was taken from the time of intrathecal injection to regression of the level of sensory block to L₁ dermatome. Duration of motor block was recorded from onset time to time when the patient was able to lift the extended leg.

Modified Bromage Scale
Grade 0 - Full flexion of knees and feet.
Grade 1 - Just able to flex knees, full flexion of feet.
Grade 2 - Unable to flex knees, but some flexion of feet possible.
Grade 3 - Unable to move legs or feet.

The duration of complete analgesia was taken from the time of intrathecal drug administration to the first report of pain. The duration of effective analgesia was taken from the time of intrathecal drug administration to the time of first supplementation with rescue analgesic. Injection diclofenac sodium 1.0 mg / kg intramuscular was the rescue analgesic given if VAS was found to be 5 or more.

Sedation scores were assessed every 15 minutes both intra and post operatively using a four point score described by Chernik et al.

Grade 0 – patient wide awake.
Grade 1 – patient is sleeping comfortably, but responding to verbal commands.
Grade 2 – deep sleep but arousable.
Grade 3 – deep sleep, unarousable.

Post operatively, monitoring of vital signs, VAS scores and sedation scores was continued every 30 minutes until the time of regression of sensory block to L₁ dermatome. The incidence of hypotension (arterial blood pressure < 20% of baseline), bradycardia (heart rate <50beats/min), pruritus, nausea, vomiting and urinary retention were monitored in the recovery room and then shifted to the ward.

Results

Table 1: Age distribution

<table>
<thead>
<tr>
<th>Age</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>15-25</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>26-35</td>
<td>4</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>36-45</td>
<td>17</td>
<td>5</td>
<td>22</td>
</tr>
<tr>
<td>46-55</td>
<td>7</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>&gt;55</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>30</td>
<td>60</td>
</tr>
</tbody>
</table>

Majority of patients in the both the groups belonged to the group 26 to 55 years. Samples were age matched.

Table 2: Sex distribution

<table>
<thead>
<tr>
<th>Sex</th>
<th>Number of patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>30</td>
<td>50.0</td>
</tr>
<tr>
<td>Female</td>
<td>30</td>
<td>50.0</td>
</tr>
<tr>
<td>Total</td>
<td>60</td>
<td>100.0</td>
</tr>
</tbody>
</table>

The number of males and females in each group was same (n=30) and samples in both groups were matched with respect to sex.

Table 3: Height distribution

<table>
<thead>
<tr>
<th>Height (cms)</th>
<th>Female</th>
<th>Male</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>160-165</td>
<td>14</td>
<td>3</td>
<td>17</td>
</tr>
<tr>
<td>166-170</td>
<td>14</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>171-175</td>
<td>2</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>&gt;176</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>30</td>
<td>60</td>
</tr>
</tbody>
</table>

Majority of female patients in the both the groups belonged to the group 160 to 170 cms and males 171 to 175 cms. Samples were height matched.

Table 4: Type of surgery

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynaecology</td>
<td>25</td>
<td>41.7</td>
</tr>
<tr>
<td>Lower Abdominal Surgery</td>
<td>16</td>
<td>26.7</td>
</tr>
<tr>
<td>Lower Limb Surgery</td>
<td>19</td>
<td>31.7</td>
</tr>
</tbody>
</table>
Discussion
The first neuraxial block was performed 8 months after the demonstration in Heidelberg of the local anaesthetic properties of cocaine. James Leonard Corning (1855-1923), a neurologist in New York City on October 12, 1885 injected a total of 120 mg of cocaine between the T11 and T12 spinous process in a 45 year old man and obtained loss of sensation of the legs and perineum. He concluded that this proved action of cocaine on spinal cord and suggested its use in certain cases of spinal spasticity and for operations on the genito-urinary system [6].

On August 15, 1898, August Bier and August Hildebrandt, surgeons at Kiel University, Germany used the Quincke method of entering the intrathecal space and injected between 5mg and 15 mg of cocaine to produce spinal anaesthesia in six cases for operations on lower part of the body. They also reported the results of spinal anaesthesia given to each other in what has become one of the classic clinical papers in the medical literature [7].

The scientific study of spinal anaesthesia began within a few years after its introduction. Investigations were undertaken by Arthur E Barker (1850-1916) to determine the factors involved in spread of local anaesthetics within the subarachnoid space. His emphasis on gravity as an essential determinant of local anaesthetic spread remains an important facet of spinal anaesthesia technique today [8].

Post spinal headache was an annoying problem for the first practitioners and their patients. However, study by Leroy Vandam and Robert Dripps confirmed Bier’s original suggestion that CSF leakage through the dural rent was the causative factor. The use of small diameter spinal needles has decreased the incidence of post spinal headache. An innovative treatment of headache after dural puncture, epidural blood patch, was suggested by James B Gormley in 1960 and further described by Anthony J Digiovanni and Burdett S Dunbar in 1970 [9, 10].

Conclusion
The administration of local anaesthetics in combination with opioids intrathecally is an established technique for managing postoperative pain following abdominal, pelvic, thoracic or orthopaedic procedures on lower extremities. Local anaesthetics with opioids demonstrate significant synergy. They provide excellent analgesia with fewer drug requirements and decreased side effects.

References