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Original Research Article

Clinical Characteristics of Individuals Having Spinal Anaesthesia with Intrathecal Bupivacaine and Clonidine, as well as Intrathecal Bupivacaine and Fentanyl

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Abstract

Aim: The aim of this study is to assess the clinical profile of patients undergoing spinal anesthesia with intrathecal bupivacaine with clonidine and intrathecal bupivacaine with fentanyl. **Methods:** A prospective double blind randomized controlled study was conducted in the Department of Anaesthesiology and Critical Care, Patna Medical College and Hospital, Patna, Bihar, India for a period of 1 year. 100 adult patients were randomly divided on an alternative basis into two groups of 50 each. Group **"**A**"**-Bupivacaine plus clonidine group. Group **"**B**"**- Bupivacaine plus fentanyl group. Patients with ASA grade 1and 2 and age group of 18–70yrs were included in the study. Those patients scheduled to undergo elective lower abdominal, lower extremity, gynaecological or urological surgeries under subarachnoid block were included in this study. Patients in group 'A' received 3 ml (15 mg) of hyperbaric bupivacaine 0.5% plus 1 $\mu g.kg^{-1}$ of clonidine. Patients in group 'B' received 3 ml (15 mg) of hyperbaric bupivacaine 0.5% plus (25 µg) of fentanyl. After injection, patient was immediately turned to supine position. **Results:** Majority of patients in both the groups belonged were in the age group of 35 to 45 years. The number of males was 45% and females 55%. Majority of female patients in the both the groups have the heights in the range of 160 to 170 cms and males 171 to 175 cms. Samples were height matched. 42 percent of the patients underwent gynaecological surgery followed by lower limb surgeries 34 percent and Lower Abdominal Surgeries 24 percent. **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 improvement in the post-operative pain and decrease the requirement of rescue analgesia.

Keywords: Spinal anesthesia, bupivacaine, Clonidine, fentanyl

Introduction

Spinal anaesthesia is often used for both elective and emergency caesarean section. However, one disadvantage of spinal anaesthesia with bupivacaine alone is its relatively short duration of action, and the need for early analgesic intervention in the post-operative period. The concept of co-induction of anesthesia has come forward by administering short acting lipophilic opioids like fentanyl and a selective Beta 2 agonist like clonidine so as to reduce the dose requirement of bupivacaine and its adverse effects and prolong analgesia in the post-operative period[1]. The clinical efficacy of intrathecal opioids to relieve visceral pain has also been demonstrated by several workers[2,3]. The addition of fentanyl 10 µg to hyperbaric bupivacaine 10.5-12.5 mg increases the intraoperative and early postoperative quality of subarachnoid block[2].

The technique of subarachnoid block is quite simple and single injection results in ideal operating conditions with complete analgesia, profound muscular relaxation, decreased blood loss and minimal ventilatory disturbances. Further, in a developing area like Bihar, non-availability of highly sophisticated anaesthetic equipment and compressed gases with their prohibitive cost makes spinal anaesthesia one of the major tools in the hands of an anesthesiologist. If we can extend its duration to include the postoperative period it will be unmatched. Reasons to achieve optimal postoperative pain relief than any other surgical patients and they also present with unique challenges. Post cesarean delivery patients are at higher risk for thromboembolic events which may also be precipitated by immobility from inadequate pain control[4,5] or excessive sedation from opioids. Moreover, these women need to ambulate, to be alert and energetic enough to care for, interact with and breastfeed their newborn. Early breastfeeding is important immediately after childbirth to promote and improve mother bonding and enhances puerperal changes to regain prepregnancy state[6,7]. With these goals in mind, the analgesic of choice requires minimal secretion in breast milk, little or no effect on neonates, minimal maternal side effects and minimal or no interference with caring for the newborn or discharge from hospital. The common modalities are systemic administration of opioids, either by intramuscular injection or i.v. injection, by patient-controlled analgesia or by neuraxial injection of opioids as part of regional anaesthesia for postoperative analgesia in cesarean delivery. Fentanyl is a synthetic primary µ-opioid agonist. Chemically it is N-phenyl-N-(1-phenethyl-4- piperadenyl) and was first synthesized by Dr.Paul Janssen in 1959. In 1960 fentanyl was introduced as an intravenous anaesthetic under the name of sublimaze. In Mid 1990, duragesic patch of fentanyl was introduced into clinical trial. Now fentanyl is given via various routes i.e. transdermal, i.v., i.m., oral, sublingual, buccal, intrathecal, epidural[8].

Materials and methods

A prospective double blind randomized controlled study was conducted in the Department of Anaesthesiology and Critical Care, Patna Medical College and Hospital, Patna, Bihar, India for 1 year, after taking the approval of the protocol review committee and institutional ethics committee.

100 adult patients were randomly divided on an alternative basis into two groups of 50 each. Group **"**A**"**-Bupivacaine plus clonidine group. Group **"**B**"**-Bupivacaine plus fentanyl group. Patients included in the study were ASA grade 1and 2 patients and in the age group of 18 –70 yrs. Those patients scheduled to undergo elective lower abdominal, lower extremity, gynaecological or urological surgeries under subarachnoid block were included in this study.

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 'A' received 3 ml (15 mg) of hyperbaric bupivacaine 0.5% plus 1 $\mu g.kg^{-1}$ of clonidine. Patients of group 'B' 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 injection mephenteramine 6 mg i.v. were given to maintain arterial blood pressure within 20% of baseline and injection 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 pricks 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

Table1: Age distribution of patients

Age	Gender		Total
	Female	Male	
Below 25	5	9	14
25-35	10	20	30
35-45	25	11	36
45-55	13	4	17
Above 55	2	1	3
Total	55	45	100

Majority of patients in the both the groups belonged to the group 35 to 45 years.

Table2: Gender distribution of patients

Gender	Number of patients	Percentage
Male	45	45%
Female	55	55%
Total	100	100%

The number of males 45% and females 55%

Table3: Height distribution of male and female

Height(cms)	Female	Male	Total
160-165	24	8	32
166-170	25	5	30
171-175	6	21	27
>176	0	11	11
Total	55	45	100

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

Type of surgery	Frequency=100	Percentage
Gynaecology	42	42%
Lower Abdominal Surgery	24	24%
Lower Limb Surgery	34	34%

Most of the patient's 42 percent from gynaecology surgery followed by lower limb surgery 34 percent and Lower Abdominal Surgery 24 percent.

Discussion

Clonidine, a selective partial agonist for α2 adrenoreceptors known to increase both sensory and motor block of local anaesthetics, after intrathecal administration exerts its analgesic effects through activation of post synaptic α2 receptors in substantia gelatinosa of spinal cord[9]. Fentanyl and bupivacaine co-administration have a synergistic inhibitory action on the Aδ and C- fiber conduction causing improved perioperative analgesia[10].

The use of neuraxial opioids have increased dramatically over the last few years. They improve the quality of intraoperative analgesia produced by local anaesthetics, by binding directly with spinal opiate receptors and prolong the duration of postoperative analgesia. Opioids administered in the subarachnoid space appear to act principally on μ-receptor in the substantia geletinosa of the dorsal horn of spinal cord by suppressing excitatory neuropeptide release from cfibers[11]. The combination of local anaesthetic and opioids, allow for a reduction in doses of both classes of drugs, thus lessening the side effects attributable to each. Fentanyl, a lipophilic opioid has rapid onset of action following intrathecal administration, provides better intraoperative analgesia and is a safer alternative than morphine for management of early post operative pain as it does not migrate to fourth ventricle in sufficient concentration to cause delayed respiratory depression when administered intrathecally[12].

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[13].

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[14].

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[15].

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[16,17].

Conclusion

The present study concluded that 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 improvement in the post operative pain and decrease the requirement of rescue analgesia.

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