

A prospective randomized comparative study on the effectiveness of intrathecal dexmedetomidine and fentanyl as adjuvants to 0.5% hyperbaric bupivacaine in spinal anaesthesia

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Abstract

Background: Improvements in perioperative pain management for lower abdominal operations have been revealed to decrease morbidity, stimulate untimely ambulation, and progress patients' long-term outcomes. Dexmedetomidine, a selective alpha-2 agonist, has newly been used intrathecally as adjuvant to spinal anesthesia to extend its effectiveness. We compared different adjuvants they are dexmedetomidine and fentanyl added to hyperbaric bupivacaine for spinal anesthesia. The main endpoints were the time of onset and duration of sensory and motor block, Two segment sensory regression time, and duration of analgesia and occurrence of side effects **Method:** A total of 60 patients, aged 20-45 years old of physical status of ASA grade I,II, assigned to have elective lower limb surgeries under spinal anesthesia were divided into two equally sized groups (Group 1 and Group 2) in a randomized, fashion. The Group 1 was intrathecally administered 15mg hyperbaric bupivacaine with 25µg fentanyl in 0.5ml of normal saline and the group 2 group 15mg bupivacaine with 10µg dexmedetomidine in 0.5ml of normal saline. For each patient, sensory and motor block onset times, and the duration of two segment sensory regression time, sensory, motor blockade and duration of effective postoperative analgesia, were recorded. **Results and Conclusion:** The time of onset and duration of sensory and motor blockade and the duration of two segment sensory regression time of effective postoperative analgesia was statistically significant in dexmedetomidine (group 2) compared to fentanyl (group 1). The make use of 10µg dexmedetomidine with hyperbaric bupivacaine compared to intrathecal Fentanyl to adjuvant hyperbaric bupivacaine seems to be more efficiently hastens the onset and prolongs the time of sensory and motor blockade. Intraoperatively, there were fewer occurrences of side effects with intrathecal dexmedetomidine when compared to intrathecal fentanyl and reduces the requirement of rescue analgesic in the postoperative period in patients undergoing elective lower limb surgeries.

Key Words: Dexmedetomidine, Anaesthesia, adjuvant, bupivacaine, Fentanyl.

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INTRODUCTION

Spinal anaesthesia is a straightforward practice which is easier to execute with quick onset of anaesthesia, provided that sufficient analgesia mutually intra operatively and post operatively.¹ Spinal anaesthesia can be provided with a extensive variety of local anesthetics and additives that tolerate direct over the level, time of onset and duration of spinal anaesthesia.² Postoperative pain control is a most important difficulty, as by means of only local anesthetics is related with moderately small

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interval of action and consequently early analgesic interference is required in the postoperative stage³. A number of adjuvants, such as clonidine, midazolam, and others have been considered to make longer the outcome of spinal anesthesia⁴. Opioids generate severe and extended analgesic action without gross autonomic changes, loss of motor power or impairment of awareness other than pain when injected into subarachnoid space. Fentanyl particularly lipophilic opioid has rapid onset of action and minor side effects⁵. Duration of possessions of intrathecal fentanyl is dose independent. Side effects contain pruritus, nausea and vomiting and rarely serotonin syndrome⁶. In recent time's intrathecal administration of α_2 adrenoreceptor agonist as adjuvant to local anaesthetics has revealed to have soothing, analgesic, hemodynamic stabilizing effect with extended period of spinal block⁷. It is particularly precise, careful α_2 adrenoreceptor agonist with 8 times more similarity for α_2 adrenoreceptors than clonidine⁷. Based on previous individual studies, it was hypothesized that intrathecal 10 μ g dexmedetomidine would turn out more postoperative analgesic consequence with hyperbaric bupivacaine in spinal anaesthesia with very less side effects⁸. Till date, fewer studies done that evaluate the effects of adding of 10 μ g dexmedetomidine to hyperbaric bupivacaine and 25 μ g fentanyl to hyperbaric bupivacaine.

METHODOLOGY

The study protocol of this prospective, randomized study conducted at Department of Anaesthesia, NRI Institute of Medical Sciences, Visakhapatnam the study was approved by the Institutional Ethics Committee. All participants gave written informed consent. 60 patients were elected for lower limb procedure. Inclusion criteria were ASA physical status I-II, 18 years of age or older, weighing between 30-80 kg undergoing surgery of the lower limb, were recruited. Excluded from the study were patient for whom subarachnoid block is contraindicated, with uncontrolled, labile hypertension, uncontrolled diabetes, with history of allergy to study drug, patient with communication complicated that would prevent reliable post operative evaluation, with mental illness,

poly trauma patients, patients who are previously on alpha 2 agonists. After obtaining confirmation regarding recommended NBM status the patients were wheeled in to the operating theatres. All the patients were given anti emetics and H2 prophylaxis. No sedative or analgesic premedication was administered. Patients were briefed about the procedure and the visual analogue pain scale (VAS: 0-No pain, 10-worst pain ever) throughout the pre anaesthetic checkup and also in the operating room preoperatively. Under all aseptic safety measures, venous access is obtained in the dorm of the non-dominant hand with 18G cannula and infusion of crystalloid was commenced. The patient was then placed in the sitting position with some flexion to open the intervertebral spaces. Using 25G quincke spinal needle, spinal block was performed at level of L3-L4 through a midline approach and patient put to supine position. Patients in group D received 3ml of 0.5% hyperbaric bupivacaine with 10mcg dexmedetomidine. Patients in group F received 3ml of 0.5% hyperbaric bupivacaine with 25mcg fentanyl. The time at intrathecal injection was measured as 0 and the following parameters were experiential, time of the height of sensory blockade, onset of sensory blockade, motor blockade as per Bromage scale. Entire period of sensory blockade, superiority of analgesia, two segment sensory drop time, need for rescue analgesia when patient complains of pain and occurrence of side effects. Statistical analysis: A Comparative two group randomised clinical study with total 60 patients with 30 patients in group A(Fentanyl) and 30 patients in group B(Dexmedetomidine) were compared between the two groups. Statistical analysis of the data collected was done by chi square test and t-test using the computer online software www.epi.com. P values <0.05 was considered as statistically significant.

RESULTS

A total of 67 patients were chosen for the study. 7 patients were disqualified from the study; the data collected from all the 60 patients incorporated in the study were analyzed. There were no differences between the two groups regarding age, and weight distribution (Table1)

Table 1: Demographic Data

Data	Group1	Group2	P Value
Age in Years	30.89±15.10	31.05±12.31	>0.05
Weight in KG	56.92±16.37	57.01±13.56	>0.05

Table 2: Comparison of Time of Injection to T10, Highest sensory level, onset of Bromage 3 and regression to Bromage 0

	Group1(n30)		Group2(n30)		P Value
	Mean	SD	Mean	SD	
Time from injection to T10 (min)	3.33	0.67	2.75	0.59	<0.001
Time from injection to maximum sensory block (min)	11.29	1.63	11.96	1.61	0.325
Onset of Bromage 3 (min)	798.2	378.5	679.3	354.5	0.069
Regression to bromage 0 (min)	153.01	7.99	420.06	17.06	<0.001

Time from injection to T10: the time taken from injection to reach T10 in fentanyl (group1) is 3.33 ± 0.67 minutes, where as Dexmedetomidine (group2) was 2.75 ± 0.59 Minutes and 279.95 ± 50.23 seconds in group 1. Group 2 and 1 are statistically Significant with p-value<0.001. Regression to Bromage 0: The time take to regression level to bromage 0 in group 1 is 153.01 ± 7.99 minutes, where as 420 ± 17.06 minutes in group 2. Group 2 and 1 was statistically Significant with p-value<0.001.

Table3: Side Effects of the patients in fentanyl (group1) Vs Dexmedetomidine (group2)

Side effects	Group 1(%)	Group 2(%)
Hypotension	4(13)	8(27%)
Bradycardia	0(0)	4(13%)

All through the practice we observed bradycardia in dexmedetomidine group 4 patients (13%) and was effectively treated with vagolytic agents. while in Group 2 it was observed that there was hypotension in 14 patients (28%) and was effectively treated with vasopressors. Intraoperatively sedation score was assessed using modified Ramsay Sedation Scale and there was elevated frequency of sedation with dexmedetomidine group. Regression of motor block to Bromage 0 was practical and the occasion to regression was extensively prolonged to 420.06 ± 17.06 in the Dexmedetomidine group though it was 153.01 ± 7.91 in the Fentanyl group.

DISCUSSION

The method by which intrathecal alpha-2 adrenoreceptor agonists prolong the motor and sensory block of local anaesthetics is not well known. They proceed by necessary to presynaptic C-fibres and post synaptic dorsal horn neurons. Their analgesic action is an outcome of depression of the release of C-fibres transmitters and hyperpolarization of postsynaptic dorsal horn neurons. Local anaesthetics act by blocking sodium channels⁹. The continuation of effect may result from the necessary of alpha-2 adrenoreceptor agonists have been establish to have antinociceptive action for both somatic and visceral pain¹⁰. Studies using a combination of intrathecal dexmedetomidine and local anaesthetics are lacking. In our, the intrathecal use of dexmedetomidine preferred was based on earlier studies. A study by You HJ et.al 2016, reported that 2 and 4 µg dexmedetomidine supplementary to 15 mg bupivacaine produced similar analgesia in patients undergoing inguinal surgeries¹¹.

Sudheesh K et.al 2015 stated that in a contrast with 5 and 10 µg intrathecal dexmedetomidine for lower limb surgeries, 10 µg gave earlier onset and longer duration of block as well as postoperative analgesia¹². Rai A et.al 2017 reported that elevated doses of 15 and 20 µg of dexmedetomidine were initiate to turn out hypotension and bradycardia¹³. In the present study, revealed that the adding of 10 µg dexmedetomidine with hyperbaric bupivacaine extensively prolongs both sensory and motor block. Dexamethasone was more effective in adjuvant to provided superior quality intraoperative analgesia and hemodynamic constancy. Lower doses of intrathecal dexmedetomidine 3µg used in mixture with bupivacaine in humans have revealed to condense the onset of motor block and extend the duration of motor and sensory block with hemodynamic constancy and lack of sedation. DasA et.al 2015 had studied the consequence of adding of 5µg dexmedetomidine or 25µg fentanyl intrathecal to 10mg isobaric bupivacaine in vaginal hysterectomy and outcome was that 5 µg dexmedetomidine produces additional prolonged motor and sensory block as compared among 25µg plain bupivacaine. This study was also explains, the dexmedetomidine group we initiate longer time of both motor and sensory blockade, constant haemodynamic state and fine patient contentment.

CONCLUSION

The make use of of 10µg dexmedetomidine with hyperbaric bupivacaine compared to intrathecal Fentanyl to adjuvant hyperbaric bupivacaine seems to be more efficiently hastens the onset and prolongs the time of sensory and motor blockade. Intraoperatively, there were fewer occurrences of side effects with intrathecal

dexmedetomidine when compared to intrathecal fentanyl and reduces the requirement of rescue analgesic in the postoperative period in patients undergoing elective Spinal Anaesthesia.

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