Original article:

Comparative Study Of Dexmedetomidine And Fentanyl As An Adjuvant To Intrathecal 0.5% Hyperbaric Bupivacaine In Infraumbilical Surgeries

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Abstract:

Introduction: Spinal anaesthesia is administered by using Bupivacaine routinely for lower abdominal and lower limb surgeries.When a patient is going to receive spinal anaesthesia, with local anaesthesia agents like Bupivacaine, addition of an adjuvant drugs intrathecally will increase the efficacy of neuraxial block is a logical choice.

Aims and objectives: To observe the effect of addition of intrathecal Fentanyl and Dexmedetomidine on the quality of spinal anaesthesia ,post-operative analgesia and to study the effect of combination with local anaesthetic on hemodynamic and vital parameters.

Material & Methods: 60 patients of ASA grade I and II were included between age 20 to 60, who were undergoing infra umbilical surgeries. 60 patients were randomized into two groups, 30 patients each. Group D received 2.5 mL volume of 0.5% hyperbaric Bupivacaine and 5 µgDexmedetomidine in 0.5 mL of normal saline intrathecal. Group F received2.5 mL volume of 0.5% hyperbaric Bupivacaine with 25 µg Fentanyl intrathecal.The onset and duration of sensory and motor block, the hemodynamic effects, the duration of analgesia and the occurrence of side effects were noted.

Results: Onset of sensory and motor blockade was shorter in group F compared to group D. Duration of analgesia was significantly longer in group D. Mean blood pressure and heart rate were significantly lower in group D as compared to group F.

Conclusion: we concluded that use of 5mcg Dexmedetomidine as an adjuvant to Bupivacaine heavy in spinal anaesthesia is beneficial regarding longer duration of action, safety and better pain relief.

Key words : Dexmedetomidine,Fentanyl ,Spinal Anaesthesia,Bupivacaine.

Introduction

Spinal anaesthesia is administered by using Bupivacaine routinely for lower abdominal and lower limb surgeries. The resulting nerve block is sufficient to ensure patient's wellbeing, while motor block facilitates the surgeon's work. It also provides effective pain relief in the initial post-operative period. When a patient is going to receive spinal anaesthesia, with local anaesthesia agents like Bupivacaine, addition of an adjuvant drug intrathecally that will increase the efficacy of neuraxial block is a logical choice. Predictably, thus, a number of adjuvants have been added to spinal local anesthetics e.g., opioids like morphine, buprenorphine, pethidine, hydromorphone, Fentanyl, sufentanil, and tramadol. [1] Other adjuvants like clonidine, ketamine, Dexmedetomidine and neostigmine have been introduced recently. [2] Various studies have shown that intrathecalDexmedetomidine and intrathecal

Fentanyl produces prolongation of spinal anaesthesia and reduces the need of post-operative analgesic requirement. [5-7]

Fentanyl exhibits close structural similarities to local anesthetics and has demonstrable local anesthetic effect on sensory C primary afferent nerve fibers, which may facilitate analgesic effects.[3,4] Furthermore, Fentanyl is the most frequent intrathecal lipophilic opioid used as analgesic agent with minimal cephalad spread making it the least likely of all the intrathecal opioids to cause delayed respiratory depression.[4]

Dexmedetomidine, a new highly selective α2-agonist, is under evaluation as a neuraxial adjuvant as it provides stable hemodynamic conditions, good quality

of intraoperative and prolonged postoperative analgesia with minimal side effects.[5-7] Dexmedetomidine has been approved by Food and Drug Administration (FDA) as a short-term sedative for mechanically ventilated intensive care unit (ICU) patients. Based on earlier human studies, it is hypothesized that intrathecal 5 μgDexmedetomidine would produce more postoperative analgesic effect with hyperbaric Bupivacaine in spinal anaesthesia with minimal side effects.[5-7]

This would be beneficial in surgeries of long duration also. By using low dose Dexmedetomidine and Fentanyl the incidence of adverse effects of these drugs also could be reduced. Therefore, we have observed the effect of addition of intrathecal Fentanyl and intrathecalDexmedetomidine on the quality of spinal anaesthesia and post-operative analgesia and study the effect of combination with local anaesthetic on hemodynamic and vital parameters.

Materials and Methods: In this observational analytical randomized study, 60 patients, between 20-60 years of age, of either sex, of ASA grade I and II who were undergoing infra umbilical surgeries were selected in order to study the quality of subarachnoid block and post-operative analgesia produced by a combination of Bupivacaine and Dexmedetomidine in comparison with Bupivacaine and Fentanyl. After obtaining approval from the institutional ethics committee and ascertaining selection criteria, informed, valid written consent was obtained from each of the patients for participation in the study. Exclusion criteria were: Patient refusal, patient on chronic analgesic therapy, patient with gross spinal deformity, patient with peripheral neuropathy, patient taking sympathomimetics or sympatholytic drugs, known allergy to local anesthetics, history of chronic headache or backache, local infection at the site, coagulation disorder, ASA Grade III, IV, V, and history of alcohol or drug abuse. Preoperative evaluation was carried out in all patients with detailed history, general physical examination including height, weight, evidence of any spinal deformity or any neurological disease and mental status of the patient. Vital parameters [pulse, blood pressure, oxygen saturation in room air, respiratory rate] were noted and systemic examination was performed. The patients were randomly divided in two groups of 30 each using a computer generated random number list: Group D:2.5 mL volume of 0.5% hyperbaric Bupivacaine and 5 μgDexmedetomidine in 0.5 mL of normal saline intrathecal. Group F:2.5 mL volume of 0.5% hyperbaric Bupivacaine with 25 μg Fentanyl intrathecal. The total volume of solution in both the groups was 3.0 ml.Preoperatively adequate fasting was confirmed and baseline heart rate, blood pressure, ECG and spo2 were recorded. A peripheral venous access was secured on non-dominant hand with 18 gauge cannula and preloading with lactated Ringer's solution was initiated at the rate of 10 ml/kg, 15 min prior to

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subarachnoid block. No sedatives or analgesics were administered preoperatively. Subarachnoid blockade was performed in sitting position with midline approach with strict aseptic precautions using 25 G Quincke needle. Patients were immediately placed in supine position supporting the head and shoulders. The operation table was kept horizontal to the floor after institution of spinal block. Oxygen face mask was applied with flow rates 5 L/min. The highest level of sensory block was checked by pin prick method, caudal to cephalad direction every 2 min after the procedure of the subarachnoid was complete and the time taken to achieve this was noted. Motor block was assessed by Modified Bromage scale (0: No motor block, 1: Inability to raise extended leg; able to move knees and feet, 2: Inability to raise extended leg and move knee; able to move feet, 3: Complete block of motor limb). Intraoperative sedation score was graded (0: Wide awake. 1: Sleeping comfortably but responding to verbal commands. 2: Deep sleep but arousable. 3: Not arousable.) Vital parameters like heart rate, arterial blood pressure and peripheral oxygenation saturation were noted immediately after injection and thereafter every 2 min for first 10 min, every 5 min for next 10 min, every 10 min for next 50 min, every 30 min for next 2 h, every 60 min for next 3 h and then at 12 h. Surgery was allowed after satisfactory subarachnoid block was established. Satisfactory block was defined as a sensory level of T8 and Modified Bromage score of 3. Duration of surgery was noted. At the end of surgery, no prophylactic pain relief was given and patients were transferred to post anaesthesia care unit and monitoring was continued for vital parameters. Sedation score, level of sensory block, motor block and visual analogue scale (VAS), which were explained to patient prior, were noted every 15 min for the first 2 h, every 30 min for the next 4 h and thereafter every 6 h interval until 24 h. Duration of sensory block was defined as: From time of injection of subarachnoid drug till the level of regression to L5 - S1 level assessed by reappearance of sensation on heel and sole of foot. Duration of motor block was defined as: from the time of injection of subarachnoid drug until the time the patient was able to flex hip, knee and ankle (Modified Bromage scale 1). Both the durations were noted. Post operative pain was assessed by Visual Analogue Scale (VAS) using a plain scale measuring 10 cms with 1 mm markings. Duration of analgesia was considered as interval from time of intrathecal injection to the time of first analgesic demanded post-operatively or when VAS score was >5 whichever was first. We chose VAS score of 5 since, it depicts moderate pain and we wanted to asses till how long can the patient be comfortable only by virtue of neuraxial blockade. Injection Tramadol i.v. 100 mg was used as rescue analgesic. At that point, study was terminated with respect to analgesia. All the patients were observed for any side effects or complications in the post-operative period for 24 hours.

The primary outcome variable was duration of analgesia and hemodynamic changes. The data obtained was statistically analysed using the following tests: Unpaired student's *t*-test. Average % change in data over baseline values to detect trends. A '*P*' value of < 0.05 was considered to be statistically significant.

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Results:

Sixty patients were included and randomly assigned to their treatment groups.There were no significant differences in age, height, and weight among the two groups. The duration of surgery was also similar.

	Group D	*Group F*
Age	37.5±12.2	39.3±11.6
Height	151±5	154±4
Weight	52.6±8.8	51.8±9.4

The mean onset of sensory block was compared in group D and group F. Group B had faster onset of sensory blockade as compared to group D.(P=0.08) The mean onset of motor block was compared in group D and group F. The mean onset of motor blockade in group F was faster than group D. (P=0.09)

Onset Time (Mins.)	Group D	Group F
Sensory Block	2.45±1.44	2.16±1.03
Motor Block	3.22±2.25	3.07±2.90

The mean duration of sensory block in group D was longer than group F. The difference between groups D versus group F was significant. The mean duration of motor blockade time was significantly longer in group D than group F.

Duration Time (Mins)	Group D	Group F
Sensory Block	197.4±28.5	142.2±14.7
Motor Block	206.6±38.6	166.2±15.8

The duration of anaesthesia in group D was longer compared to group F. The patients who were given Dexmedetomidine had a significantly prolonged duration of anaesthesia compared with Fentanyl group. As to the duration of anaesthesia, the mean time to first analgesic request was also significantly longer in group D than in group F. This difference between group D versus group F was significant. Total analgesic consumption during 24 hours after surgery failed to demonstrate a significant difference between D and F groups.

The mean variation of mean arterial pressure (MAP) was significant between group D and F. The mean variation of heart rate (HR) was significant between group D and F.

The two groups were found to have no significant difference in terms of other intraoperative and postoperative side effects including nausea, vomiting, shivering and respiratory depression, although shivering is less in Group D. The two groups were found to have significant difference in terms of sedation.

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Side Effects	Group D (No. of patients)	Group F (No. of patients)
Nausea - Vomiting	4	3
Sedation	12	5
Shivering	17	24
Respiratory Depression	0	0

Discussion:

Spinal anaesthesia is a popular anaesthesia technique for lower abdominal surgeries. Though it provides effective analgesia in initial postoperative period, this effect is very short lasting.In the context of "Augmentation strategies" for intrathecal analgesia, the discovery of opioid receptors and the subsequent development of the technique of epidural and intrathecal opioid administration is undoubtedly one of the most significant advances in pain management in the last three decades.

Plethora of studies has shown that intrathecal opioids can provide profound post-operative analgesia with fewer central and systemic adverse effects than with opioids administered systemically. A wide variety of non-opioids have also been used in epidural or subarachnoid space to achieve pain relief without the risk of respiratory depression. [8-10] Time of onset of sensory and motor blockade was comparable in both groups group F being faster than group D. Time taken for segment regression and recovery of motor blockade was significantly prolonged in group D. Hemodynamicallybradycardia and hypotension were more in group D but could be controlled by drugs.

The duration of analgesia in group D was significantly higher. Thus, patients receiving Dexmedetomidine as adjuvant to Bupivacaine were pain free and comfortable for longer duration after surgery compared to patients receiving Bupivacaine and Fentanyl combination.

In our study, we observed that, in both the groups all patients were calm, sleeping comfortably. Mild sedation was observed in patients with group D, no excessive sedation or respiratory depression was noted in this study. This underlies the safety of low dose intrathecal Dexmedetomidine and Fentanyl.

The hemodynamic parameters viz. Heart rate and blood pressure were monitored perioperatively. There was slight reduction in blood pressure and heart rate at 5-30 min after subarachnoid block in group D, they responded to standard doses of mephentermine and atropine respectively.

Time of onset of sensory and motor blockade was comparable in both groups Fentanyl being faster than Dexmedetomidine. There was no significant change in peripheral oxygen saturation from baseline in both the groups ($P > 0.05$), and supplemental oxygen or any other form of airway management was not needed.

Conclusion:

Thus we can conclude that use of 5mcg Dexmedetomidine as an adjuvant to Bupivacaine in spinal anaesthesia is beneficial regarding longer duration of action, safety and better pain relief.

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