Original Article

ISSN (0): 2456-7388; ISSN (P): 2617-5479

Clinical Comparative Study between Fentanyl and Dexmedetomidine with Bupivacaine for Lower Limb Surgery in Spinal Anaesthesia

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Abstract

Background: Spinal anesthesia is a preferred technique of choice in infra umbilical surgeries. The spinal anesthesia effect can be improved by adding various adjuvant like Fentanyl, clonidine, dexmedetomidine. Dexmedetomidine is a highly selective alpha 2 adrenergic agonists. The aim of study to compare efficacy and safety between Dexmedetomidine and Fentanyl with Bupivacaine. **Subjects and Methods:** A prospective randomized, double-blind study was conducted on 100 patient by dividing them into two groups. Group D: 2.5ml (12.5mg) of 0.5% hyperbaric bupivacaine with 5mcg (0.5ml) dexmedetomidine and Group F : 2.5ml(12.5mg) of 0.5% hyperbaric bupivacaine with 2 5mcg(0.5ml) fentanyl. The total volume injected intrathecally was 3.0ml in ASA I and II grade patient undergoing lower limb surgery. **Results:** Patients in dexmedetomidine group D had a significantly longer sensory and motor block time than patients in fentanyl group F. The mean time of sensory regression to level S1 was 306.00 ± 13 .32 in group D and 206.14± 16.69 in group F(P<0.001). The regression time of motor block to reach modified Bromage 0 was 257.70±14.61 in group D and 178.54±14.23 in group F (P<0.001). **Conclusion:** Intrathecal Dexmedetomidine is associated with prolonging motor and sensory block as compare to Fentanyl.

Keywords: Bupivacaine, Dexmedetomidine, Fentanyl, spinal anesthesia.

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Received: April 2020
Accepted: April 2020

Introduction

Spinal anaesthesia is most commonly used for infra umbilical surgeries. The spinal block has a rapid onset, deep block and cost-effectiveness. However, postoperative pain is an important problem as the use of the drug has limited duration of effect, so the administration of the postoperative analgesic is necessary.[1,2]

Administrating the combination of other classes of analgesics with local anaesthetics has used to increase the duration and reduce the side effects of analgesia.[3] Various additive drug have been tried with Bupivacaine for improvement in the quality and extending the duration of blockade like vasoconstrictors, opioid analogs, neostigmine, benzodiazepine, ketamine and α2 agonist etc.[4,5] Opioid analogs as an additive in spinal anaesthesia improve the onset of action to prolong the duration of block and to improve the quality of intraoperative and postoperative analgesia.[4-6] Dexmedetomidine belongs to the imidazole subclass of α2-receptor agonist similar to clonidine and FDA approved used as a sedative in ICU patients also used as anxiolysis, hypnosis, sympatholytic and adjunct analgesia.[7,8] Dexmedetomidine potentiates the effect of all intraoperative anesthetics regardless of method of administration(intravenous, volatile or even regional block.[9,10]

Fentanyl is a lipophilic opioid that has a rapid onset and short duration of action following intrathecal administration. It prolongs the duration and reduced analgesic requirements in the early postoperative period following spinal block.[4]

In this study our aim to compare the efficacy of dexmedetomidine and Fentanyl added to intrathecal Bupivacaine in terms of duration of block and analgesia in lower limb surgeries.

Subjects and Methods

After approval from the institutional ethical committee, 100 patients, aged 18 to 60 years, of either sex, undergoing lower limb surgery and belonging to American society of anesthesia (ASA) class 1 or 2, who visited the institution from November 2016 to October 2017 were screened for the study. A thorough pre-anesthetic checkup, including a detailed history and physical examination, was done. Patients having any major cardiovascular, neurological or respiratory illness were excluded from the study. Other exclusion criteria were any vertebral deformity or history of trauma to spine, skin infection at the site of lumbar puncture, any contraindication to spinal anaesthesia and patient's refusal for the procedure.

The patients were explained about the procedure and about

visual Analogue Scale (VAS). Informed consent was taken. The patients were kept fasting as per standard guidelines. They were premedicated with Alprazolam 0.25 mg and Ranitidine 150 mg orally the night before and on the morning of surgery.

The randomization was done using a computer-generated sequence of numbers and the sealed envelop technique. The 100 patients were randomly divided into two groups.Group D received 2.5ml hyperbaric bupivacaine 0.5% (12.5mg) with 5mcg (0.5ml) of inj. Dexmedetomidine (total volume 3.0ml). Group F received 2.5ml of hyperbaric bupivacaine 0.5% (12.5mg) with 25mcg (0.5ml) fentanyl (total volume 3ml). An independent anesthesiologist prepared the drug under all aseptic precaution in similar disposable syringes and was not involved in further management or observation of the patients. The person performing the spinal anesthesia had no knowledge about the content of the syringes.

In the operation room, standard monitoring includes 5 lead electrogram, noninvasive automated blood pressure and pulse oximetry done. Baseline heart rate, blood pressure, respiratory rate and hemoglobin oxygen saturation were recorded. An 18G cannula was secured into a peripheral vein and 15ml/kg body weight lactated Ringer solution was administered. The patient was placed in a sitting position on the operation table with stool provide as a footrest and pillow placed in the lap. An assistant maintained the patient in a vertical plane while flexing the patient's neck and arms over the pillow to open the lumber interspinous space. With full aseptic precaution, intervertebral space between L3-L4 vertebra was identified and a small skin wheal was raised with 3ml of lignocaine 2%. A 25G Quincke spinal needle was inserted, advanced and subarachnoid space recognized. The study drug was administered at a rate of 0.2ml/second. The patient was placed in a supine position until the maximum effect was achieved.

After assessing the time of onset of action of drug and level of blocked, the surgery was allowed. The level of sensory blockade was assessed by pinprick using a short bevel needle while the patient's eyes were covered. The parameters observed included time of onset of sensory blockade(time between administration of drug and onset of tingling and numbness in the lower limb), degree of motor blockade tested by James Modified Bromage score[11][0= unable to raise leg straight against resistance, 1=unable to raise leg straight but able to flex the knee, 2= unable to flex knee but with free movement of feet, 3= unable to move leg or feet], duration of analgesia(time from administration of an intrathecal drug to very first complain of pain). The heart rate, blood pressure, oxygen saturation and respiratory rate were also recorded. All the parameters were recorded just after giving spinal anaestyhesia (0 min), then at 5 min intervals till 15 minutes, after that 15 min intervals till 180 min. A drop in heart rate below 60 beats/min was managed with atropine 0.2mg increment iv was given, and a fall in blood pressure ≥20% of baseline was initially managed with a bolus of 5ml/kg of lactated Ringer solution, followed by inj. Ephedrine 6mg bolus increment iv. Oxygen 3-4 lit/min was given with face mask if spo2 fell below 94%. If the respiratory movement were paradoxical or the patient complained of dyspnoea and oxygen saturation could not be maintained with the above-mentioned measures, respiratory assistance was given with or without endotracheal intubation.

When the patients VAS score was >3, analgesia was supplemented with 1mg/kg of tramadol iv. Any side effects like sedation, respiratory depression, nausea, vomiting, pruritus, urinary retention were recorded.

Statistical Analysis

The statistical analysis was done using SPSS for window version 15.0 software. Data are presented as median, mean (±SD) or frequencies as appropriate. Statistical tests applied included student t-test, two-tailed Mann-Whitney u –test. P-value <0.05 was considered statistically significant.

Results

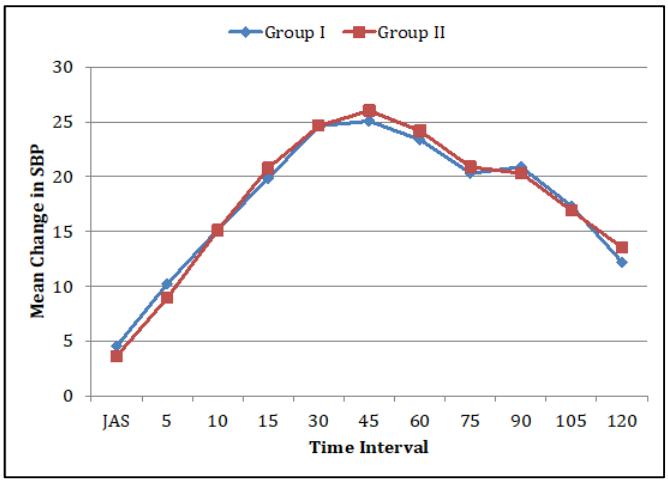

Figure 1: mean change in SBP in 2 groups

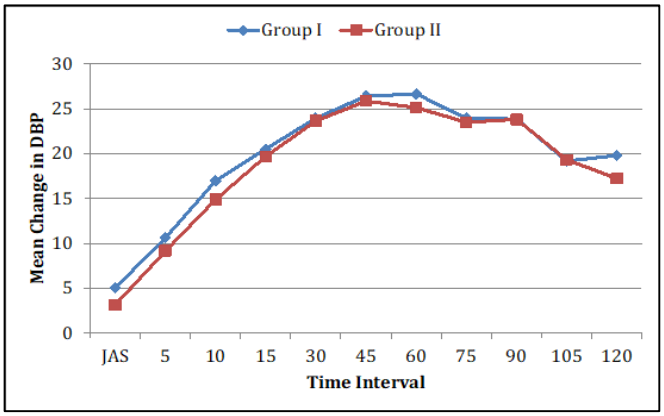

Figure 2: mean change in DBP in 2 groups

There was no significant differences between the two age group regarding age, weight, height and sex. There was no significant difference in the type and duration of surgery. Intraoperative systolic, diastolic and mean arterial blood pressure trends are shown in [Figure 1-3]. Heart rate trends are shown in [Figure 4].

Mean oxygen saturation in both groups shown in [Figure 5].

The following conclusions were drawn from the study. Meantime of onset of sensory block (T10) for group D and group F were 3.72±0.50 minutes and 3.80±0.53 minutes, respectively. The onset of sensory block was faster in group D. There for showing statistically significant intergroup difference (p<0.0 01) but no significant difference between

group D and F (p=0.440). The median level of sensory block was T6 in all two groups after 15 min of intrathecal injection of drugs. The mean time to achieve T6 sensory block was significantly lower in group D (<0.001). All patients achieved a maximum grade of motor blockade showing no significant difference between two-groups (p=1). Meantime to achieve grade III motor in group D 5.76±0.43 and group F were 5.80±0.40. The onset of motor block was faster in group D (P=<0.001), showing a statistically significant intergroup difference but no significant between study group D and F (>0.05). The time period for sensory regression to S1 level were 306.0±13.32, 206.14±16.69 minutes in study group D and F, respectively. Sensory block regression to S2 is faster in group F as compared to group D (p<0.001). The time period of recovery of motor block was more in group D 257.70±14.61 in comparison to group F 178±14.23 minutes. The mean duration of analgesia was in group D 373.0±16.26 and 302.40±16.01in group F minutes showing significant difference among two groups (p<0.001). Although the patients in both groups remained hemodynamically stable intraoperatively. No significant difference was observed among both groups for side effects. Sedation was more in group D. Hypotension and bradycardia more in group F followed by group D. No patients have nausea vomiting and respiratory depression in groups in both the group.

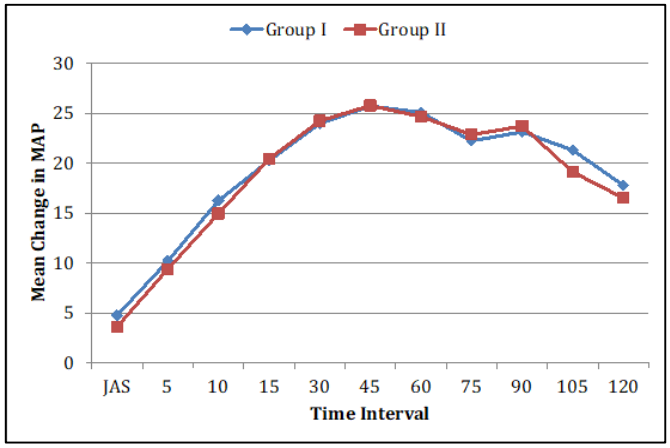

Figure 3: mean change in MAP in 2 groups

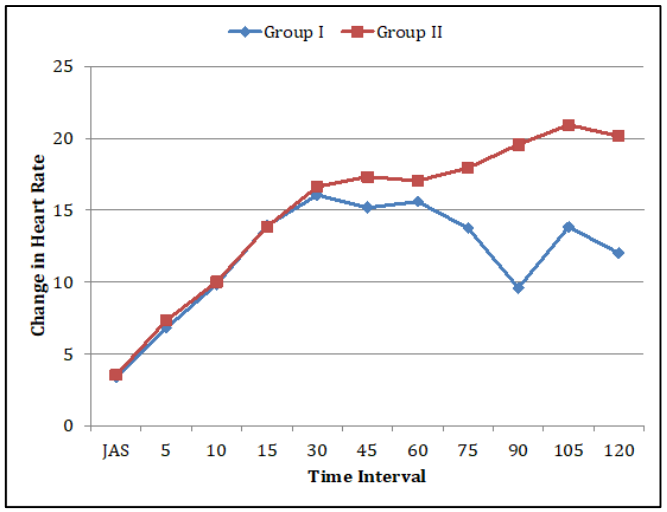

Figure 5: mean change in heart rate in 2 groups

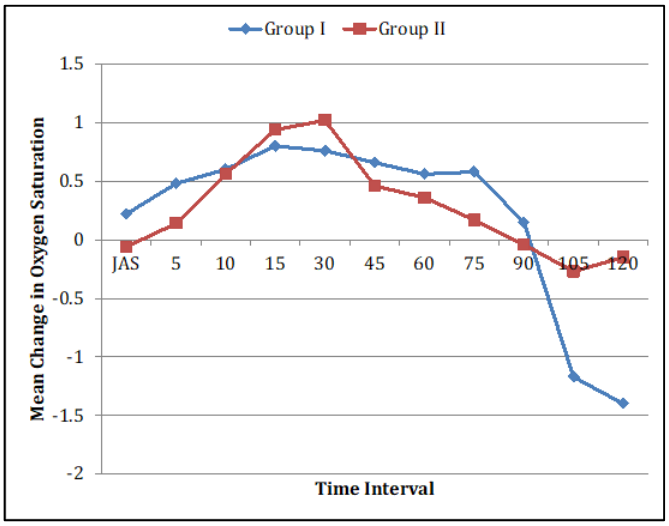

Figure 5: mean change in oxygen saturation in 2 groups

Discussion

The mechanism by which intrathecal α2 adrenoceptor agonists prolong the motor and sensory block of local anesthetic is not well known. They act by binding to presynaptic C- fibers and postsynaptic dorsal horn neurons. Their analgesic action is a result of depression of the release of C- fiber transmitter and hyperpolarisation of postsynaptic dorsal horn neurons.[12]

Alpha 2 adrenergic receptor agonists like clonidine and dexmedetomidine have been the focus of interest for their sedative, analgesic, sympatholytic and hemodynamic stabilizing properties. Clonidine has been used intrathecally to prolong the sensory and motor block and reduced tourniquet pain. It prolongs and intensified the effect of the spinal anesthetic by altering systemic resorption. Dexmedetomidine is a newer, highly selective drug in the same family, with a different, more favorable pharmacokinetic profile. The analgesic property of dexmedetomidine is 8-10 fold more than clonidine. It has been recently used as a systemic analgesia and regional anesthesia adjuvant, both intrathecal and epidural to intensify and prolong the action of analgesic and local anesthetics.[13-15]

Opioid analogs have been used as an additive in spinal anesthesia to improve the onset of action to prolong the duration of block and to improve the quality of intraoperative and postoperative analgesia.[4-6]

In the present study mean time to achieve sensory block, the duration of sensory block and the meantime is taken for regression to S1 segment was statistically significant with a p-value of <0.001 in group D in comparison to group F. Gupta et al,[15] who compared 5mcg Dexmedetomidine and 25mcg of fantasy with Bupivacaine intrathecally found a significant change in dexmedetomidine droup with regard to time of onset, duration, and time is taken for regression to S1 segment. Fyneface-Ogun et al,[16] used dexmedetomidine 2.5mcg intrathecally found significant change in time to achieve the highest sensory block and time taken for regression to S1 when compared to Fentanyl.

The mean time is taken for the onset of Bromage 3 in group D and group F were comparable. The mean time taken for

regression to Bromage 0 in group D was statically significant with a p-value of <0.001. Similar results were found in the study of Gupta et al.[15] Al-Mustafa et al,[17] who used varying doses of dexmedetomidine, found a statistically significant change in the onset of Bromage 0.

The duration of analgesia is prolonged in the dexmedetomidine group when compared to Fentanyl. The mean time for rescue analgesia was significantly higher with dexmedetomidine. There is a wide variation in time for first rescue analgesia in dexmedetomidine and fentanyl group in various studies of Gupta et al,[15] Eid et al,[18] and Jamliya et al.[19] But dexmedetomidine produced prolonged analgesia when compared to Fentanyl, which was statistically significant in all the studies.

Intrathecal Dexmedetomidine and Fentanyl with Bupivacaine did not have much effect on vital parameters except for a decrease in heart rate in the dexmedetomidine group. A similar observation was made by Mohammed et al.[20] Patients in both groups were hemodynamically stable as shown in the study of Gupta et al,[15] Al-Mustafa et al,[17] and Tarbeeh et al,[21] did not find much change between the groups.

No significant difference was observed among the different groups for the side effects sedation was more in groups D than groups F.

Conclusion

In our study comparing intrathecal Dexmedetomidine and intrathecal Fentanyl with Bupivacaine, the result indicate that dexmedetomidine provides mean time to achieve sensory and motor block was shorter in the dexmedetomidine groups. The median of the maximum level of sensory block was the same in both the groups. The sensory and motor block was more prolonged in dexmedetomidine groups than fentanyl groups showing a significant difference among the two groups (p<0.001). The overall duration of analgesia was significantly longer in dexmedetomidine groups than fentanyl groups showing a significant difference among the two groups (p<0.001).

We conclude that dexmedetomidine may find a place in regular clinical use as an intrathecal adjuvant with hyperbaric Bupivacaine due to its improved quality of sensory and motor block characteristics when compared to Fentanyl. Hence dexmedetomidine may be used as an alternate to Fentanyl for intrathecal use.

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How to cite this article: Vashishth T, Varun S. Clinical Comparative Study between Fentanyl and Dexmedetomedine with Bupivacaine for Lower Limb Surgery in Spinal Anaesthesia. Acad. Anesthesiol. Int. 2020;5(1):126-130.

DOI: dx.doi.org/10.21276/aan.2020.5.1.25

Source of Support: Nil, **Conflict of Interest:** None declared.