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Original Article

A Comparative Study between Dexmedetomidine and Fentanyl as Intrathecal Adjuvants to Bupivacaine for Lower Abdominal Surgery

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Abstract
Aims and Objectives: *Many adjuvants have been used with local anaesthetics in spinal subarachnoid block for better intraoperative and prolonged postoperative analgesia. The aim of this study is to compare the effects of dexmedetomidine and fentanyl as intrathecal adjuvant to hyperbaric bupivacaine on the onset and duration of sensory and motor block in lower abdominal surgeries.*
Materials and Method-*Ninety patients of ASA status I and II posted for lower abdominal surgery were randomly divided into two groups. Group D was administered hyperbaric bupivacaine 2.5ml + dexmedetomidine 5µg in 0.5 ml normal saline and group F was administered hyperbaric bupivacaine 2.5ml + fentanyl 25 µg in 0.5 ml normal saline . Duration and quality of sensory and motor block were assessed.*
Results-*Sensory and motor block in group D patients were longer than group F patients. Time taken for sensory blockade regression to S2 level was longer in D(396.67±24.12 min) group than F(190.60±26.12min) group which was statistically significant. Time taken for motor block regression to bromage 0 is longer in D(388.5±21.24min) group than F(134.8±19.76min) group which was also statistically significant.*
Conclusion- *Intrathecal dexmedetomidine when added as adjuvant to bupivacaine heavy (0.5%) provided better and prolonged analgesia in comparison to intrathecal fentanyl.*
Keyword- *Fentanyl, Bupivacaine, Intrathecal, Dexmedetomidine.*

INTRODUCTION

Spinal anaesthesia is the most commonly used technique for lower abdominal surgeries as it is very cost effective and easy to administer besides its other merits. Hyperbaric bupivacaine is the most common local anaesthetic used intrathecally.[1]

However, postoperative pain management is a major problem because spinal anaesthesia using only local anaesthetics is associated with

relatively shorter duration of action and thus early rescue analgesic is needed in the postoperative period. A number of adjuvants, such as dexemedetomidine, clonidine, opioids and midazolam, and others have been studied to prolong the effect of spinal anaesthesia for postoperative pain management [2].

Fentanyl, in recent years, has emerged as a useful intrathecal adjuvant for prolonging the effect of local anaesthetic in spinal anaesthesia. Intrathecal fentanyl when added to spinal local anaesthetics reduces visceral and somatic pain and this analgesic effect has been proved by many studies[3]. Although it is one of the most widely used intrathecal adjuvant in the present scenario, its intrathecal use has been shown to be associated with major side effects like respiratory depression, nausea, vomiting and pruritus. Dexmedetomidine, a new highly selective α2-agonist, has been used as a neuraxial adjuvant as it provides stable hemodynamic, good quality of intraoperative and prolonged postoperative analgesia with minimal side effects[4]. By virtue of its effect on spinal α-2 receptors, dexmedetomidine mediates its analgesic effects. Dexmedetomidine has been found to prolong analgesia when used as an adjuvant to local anaesthetics in subarachnoid block, epidural and caudal epidural blocks which has been well studied [5]. Previous studies have shown that a low dose (5 µg) of dexmedetomidine provides prolonged anaesthesia and quality post operative analgesia when used as an intrathecal adjuvant to hyperbaric bupivacaine with minimal effects on the hemodynamic status of the patient [6].As there is paucity of studies comparing fentanyl and dexmedetomidine in spinal anaesthesia, we have undertaken the study to evaluate and compare the effects of dexmedetomidine and fentanyl as intrathecal adjuvants to hyperbaric bupivacaine.

Method

This Randomized Controlled study was carried after obtaining approval from the Hospital Ethical Committee and written informed consent from the patients. Ninety ASA grade I or II patients of either sex, aged 18 to 60 years, weighing 50 to 70 kg and with a height of 150 cm to 180 cm, scheduled for lower abdominal surgery were included in the study. Patients on therapy with adrenergic receptor antagonist, calcium channel blocker, and/or ACE inhibitor, patients with known hypersensitivity to any of the study drugs, patients with history of heart block or dysarrythmia, patients who refused to consent to be part of study and patients with pregnancy were excluded from study. The study population was randomized using random number table generated from computer software. All the patients were kept for 6 hrs fasting prior to surgery. Tablet Alprazolam (0.25 mg) was given as a premedication on the night prior to surgery. Preloading was done with Ringer lactate solution (10 ml/kg body weight). Routine monitoring including non invasive blood pressure (NIBP), ECG, heart rate and pulse oximetry was done. Under proper aseptic conditions, spinal anaesthesia was performed at the level of L3-L4 interspace in sitting position using a midline approach by a 25G Quincke spinal needle. The study drug was injected slowly over 10-15 seconds with the bevel of the needle pointing upwards and the patients were made supine immediately. 90 patients were randomly divided into 2 groups (n = 45).Group D: Hyperbaric Bupivacaine (2.5ml) + Dexmedetomidine 5µg (diluted up to 0.5ml with normal saline) administered intrathecally.Group F: Hyperbaric Bupivacaine (2.5ml) + Fentanyl 25 µg (diluted up to 0.5 ml with normal saline) administered intrathecally. The study drug was prepared by a separate anaesthesiologist under strict aseptic conditions. The anaesthesiologist who administered anaesthesia was blinded to the group allocation. Vitals were recorded every 2 minutes up to the 10th minute and every 5 minutes there after up to 20 minutes. Beyond 20 minutes the vitals were recorded every 20 minutes till the time of discharge from post anaesthesia care unit.

The sensory dermatome level was assessed by pin prick method using 23G hypodermic needle at

every 2 min.[7] Surgery was allowed when T8 level was achieved. The motor dermatome level was assessed according to the modified Bromage Scale: 0-Patient able to move hip, knee and ankle. 1- Patient unable to move hip, but able to move knee and ankle.2- Patient unable to move hip and knee but able to move the ankle, 3- Patient unable to move hip, knee and ankle.[8]

The sensory and motor status was assessed prior to the spinal injection, then every 2 minutes after the spinal injection for the first 10 minutes, every 5 minutes for the next 10 minutes and thereafter every 20 minutes until the time to regression of sensory level to dermatome S2 and motor scale to bromage 0.Time to reach the sensory block up to highest dermatome level and time of regression to dermatome S2 level and time to reach bromage 0 was noted in post operative care unit.

Postoperatively, the pain scoring was done by using visual analogue scale. (0 = no pain, 10 = severe pain)[9]. VAS was monitored 1hrly for first 2 hrs,2hrly for next 8 hrs and 4hrly there after. Paracetamol was given intravenously as rescue analgesia when VAS was greater than 4. Time of administering the first dose of rescue analgesia was noted. Sedation was assessed by using modified Ramsay sedation score-1-anxious, agitated, restless. 2-cooperative, oriented, tranquil.3- responds to commands only.4- brisk response to light glabellar tap or loud noise.5- sluggish response to light glabellar tap or loud noise.6- no response.[10] Hypotension was defined as a decrease in systolic blood pressure more than 20% of the baseline value, which was treated by ephedrine 6 mg i.v. and bradycardia was defined as heart rate less than 60/min but the intervention with iv atropine 0.6mg was done only when heart rate fell below 50/min. Side effects including nausea, vomiting, bradycardia, hypotension, respiratory depression, urinary retention and shivering were assessed both intra-operatively as well as post-operatively. All the patients were examined by the anaesthesiologist after 24 hrs of the spinal block and were assessed for any neurological impairment.

Sample size calculation was done by taking duration of analgesia as primary outcome variable of interest. It was estimated that n = 40 (recruitment target achieved - n = 45 in each group) will be required per group to detect 60 minutes difference in this parameter with 80% power and 5% probability of Type I error. This calculation assumed a standard deviation of 75 minutes in duration of analgesia. For statistical analysis, raw data entered into a MS Excel spread sheet and analyzed by SPSS 21 (statistical software version 21). Unpaired student's t– test was used to compare normally distributed numerical variables. All analysis were two-tailed and p value <0.05 was taken to be statistically significant.

Result

Both groups were comparable regarding age,sex,weight,height, ASA status and duration of surgery.(table-1)

Table 1: Demographic characteristics

Parameters	Group D(n=45)	Group F(n=45)	P value
Age (Years)	43.6±10.5	41.63±9.85	0.81
Sex (M/F)	19/11	16/14	0.548
Weight (kg)	66.24±7.82	64.83±7.50	0.58
Height (cm)	164.43±5.92	163.6±5.62	0.94
ASA physical status (I/II)	18/12	20/10	0.614
Duration of surgery	47.67±15.24	45.17±11.99	0.86

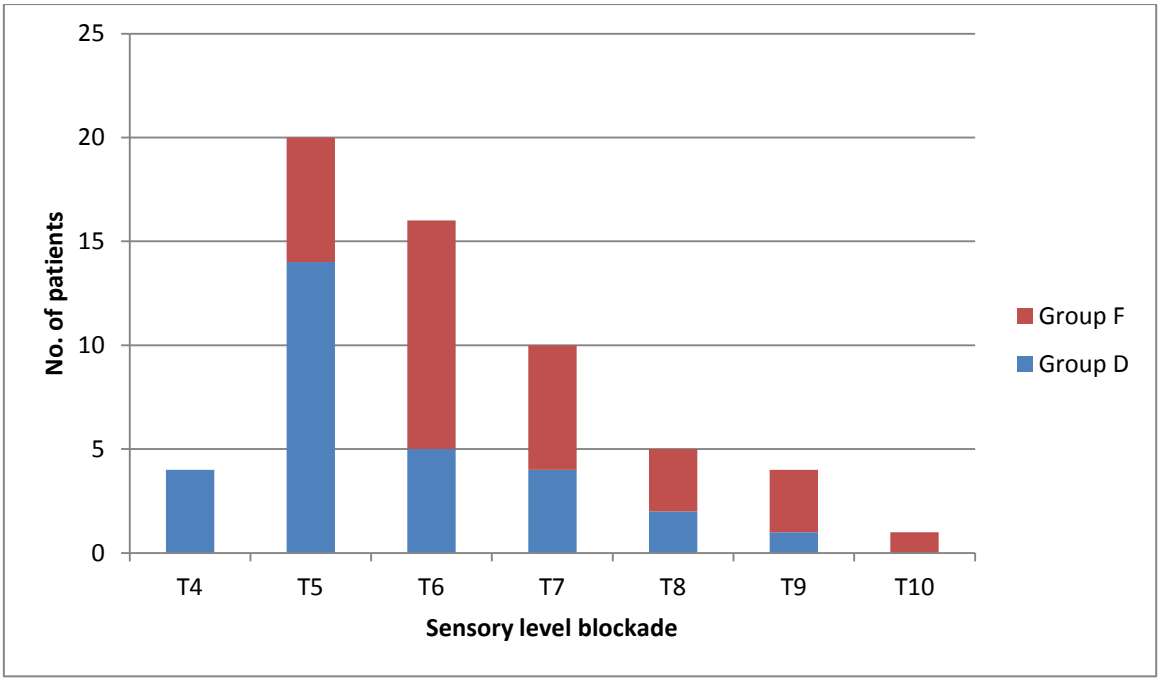
There was no significant difference in time taken for reaching peak sensory and motor block.Time taken for sensory regression to S2 level was longer in group D compared to group F which was statistically significant.Time taken to motor regression to bromage 0 was prolonged in group D compared to group F which was statistically significant.(table-2)

Table 2: Intrathecal block characteristics

Parameters	Group D	Group F	P value
Time taken for reaching peak sensory block (min)	9.33±3.50	10.67±3.65	0.509
Time taken for reaching peak motor blockade	8.57±2.63	9.07±2.79	1.00
Time taken for sensory blockade regression to S2 level	396.67±24.12	190.60±26.12	0.0001
Time taken for motor block regression to bromage 0	388.5±21.24	134.8±19.76	0.0001
Time to first dose of rescue analgesia	299±33.92	166.73±20.66	0.0001
Sedation score	1.5±0.09	1.44±0.08	0.09

In group F time of 1st dose of rescue analgesia was less compared to D group.There was no significant difference between highest level of block achieved among two groups.(fig-1)

Fig 1: Highest dermatome level of sensory block



Haemodynamic parameters like heart rate and mean arterial pressure was comparable in both groups.

Fig 2: Mean Arterial Pressure (MAP) variability in both the groups

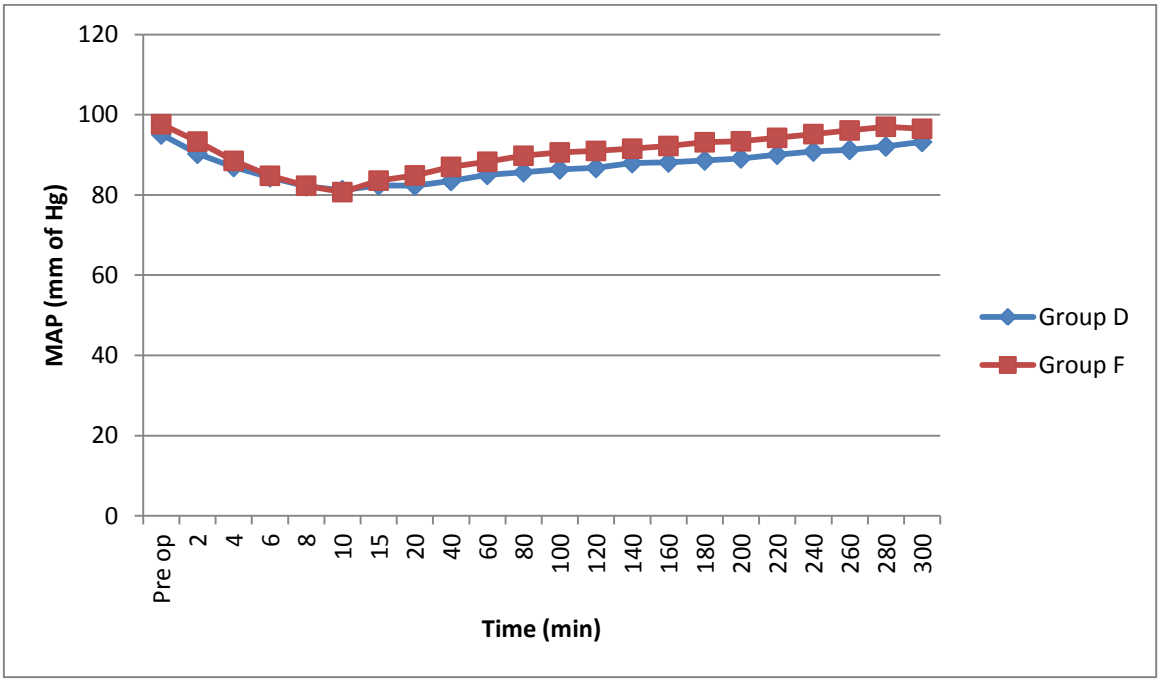
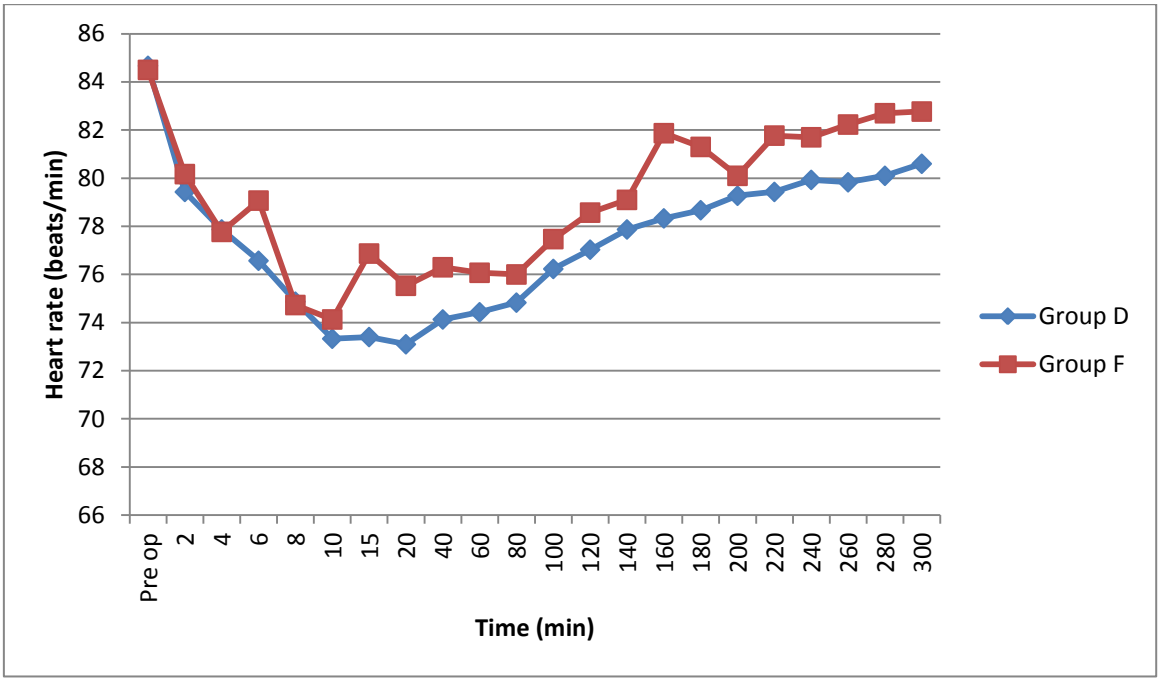


Fig 3: Heart rate variability in both the groups



Few complications like nausea, vomiting, pruritus, shivering and sedation were in both groups which were not significant. There was not a single case of respiratory depression.

DISCUSSION

The results of our study show that the supplementation of spinal bupivacaine with 5µg dexmedetomidine significantly prolonged both sensory and motor block compared with intrathecal 25 g fentanyl. No hemodynamic instability or adverse effects were reported in any group. Time taken to achieve peak level of sensory and motor blockade was comparable among both groups. These findings were in concordance with the results of Al Ghanem et al, who evaluated the effect of adjuvant like 5 µg dexmedetomidine or 25 µg fentanyl when added intrathecally to 10 mg isobaric bupivacaine in vaginal hysterectomy. They observed that the onset time of bromage 3 motor block was also not different between dexmedetomidine and fentanyl group and the time to regression of sensory block to S2 segment was significantly longer in group D than in group F ($p < 0.001$). Regression time to reach bromage 0 in dexmedetomidine group was significantly longer than that for fentanyl group ($p<0.001$) which was similar to our study.[11]

Eid MD et al concluded that 10 µg and 15 µg dexmedetomidine as adjuvant, increased the duration of analgesia provided by spinal bupivacaine. Eid Md et al found no statistically significant difference in mean heart rate when 10 µg or 15 µg Dexmedetomidine was added to bupivacaine.[12] Similarly, in our study the mean heart rate was comparable in both groups and found to be statistically not significant. Many previous studies also have shown that intrathecal dexmedetomidine was better than opioids in providing postoperative analgesia.[13-17]

Kanazi et al noted that dexmedetomidine or clonidine when added to intrathecal bupivacaine did not cause a significant reduction in blood pressure but dexmedetomidine had better sensory motor block characteristics.[18]

In his study Gupta et al compared dexmedeto-midine and fentanyl as intrathecal adjuvant to hyperbaric bupivacaine to evaluate their impact on the quality and duration of spinal anaesthesia. They observed that both dexmedetomidine and fentanyl reduced the dose of intrathecal hyperbaric bupivacaine. 5µg dexmedetomidine produced remarkably significant prolongation of subarachnoid block, increased the duration of postoperative analgesia and provided more

sedation in comparison to 25µg intrathecal fentanyl.[19] Likewise our study concluded that dexmedetomidine can be used as an intrathecal adjuvant to prolong the duration of analgesia provided by subarachnoid block and to provide a comfortable postoperative period delays the requirement of rescue analgesia.

Conclusion

We concluded from our study that supplementation of bupivacaine spinal block with a low dose of 5µg intrathecal dexmedetomidine produces a significantly longer duration of sensory and motor blockade than 25µg intrathecal fentanyl. It provided intraoperative hemodynamic stability, minimal side effects, and better quality of postoperative analgesia in comparison to fentanyl. Thus, 5 µg dexmedetomidine seems to be an attractive alternative to 25 µg fentanyl as an adjuvant to spinal bupivacaine in surgical procedures involving lower abdomen.

Source of support-nil
Conflict of interest-non

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