Journal of Clinical and Biomedical Sciences

Original Article

Epidural Bupivacaine with Dexmedetomidine or Fentanyl for Lower Abdominal and Lower Limb Surgeries - A Randomized Prospective Study

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Abstract

Background: Epidural anaesthesia with catheter insertion offers a useful anaesthetic technique for lower abdominal and lower limb surgeries. Further it can also be used to offer effective post operative analgesia. Adjuvants added to local anaesthetics improve the quality of epidural block and prolong blockade. **Objectives:** To assess and compare the effects of dexmedetomidine and fentanyl as adjuvants to epidural bupivacaine in lower limb and lower abdominal surgeries **Materials and Methods:** This randomized prospective study was conducted in a referral teaching hospital in Kolar, Karnataka. Sixty adult patients of either sex belonging to ASA physical status I and II and aged between 18 to 50 years undergoing elective lower abdominal and lower limb surgeries under epidural anaesthesia were studied. Patients were randomly allotted to group D who received epidural bupivacaine with dexmedetomidine and to Group F who received bupivacaine with fentanyl. The onset and duration of sensory and motor blocks with haemodynamic variability were assessed. The requirement of rescue analgesics and side effects were recorded. Continuous data is analysed using student t-test and categorical data using Chi-square test and Mann-Whitney U test. P value <0.05 was considered as statistically significant. **Results:** Time to attain adequate sensory and motor block was faster in Group D in comparison to Group F ($p<0.001$). Two segment regression, the duration of analgesia and time to complete motor recovery was prolonged in Group D when compared to Group F. Onset of sensory blockade and motor blockade were faster in group D compared to group F. Duration of sensory and motor blockade were prolonged in group D compared to compared to group F. **Conclusion:** Epidural bupivacaine with dexmedetomidine is associated with faster onset of and prolonged sensory and motor blockade with lesser requirement of rescue analgesia compared to bupivacaine with fentanyl.

Keywords: Epidural analgesia, Bupivacaine, Dexmedetomidine, Fentanyl, RCT

Introduction

Bupivacaine is commonly used in epidural anaesthesia for lower limb and lower abdominal surgeries. Epidural block being volume dependent requires larger doses of bupivacaine to achieve anaesthetic and analgesic effects.[1,2] Opioids such as Fentanyl are commonly used as an adjuvant to bupivacaine to reduce the dose, to increase the onset and prolongue the duration of anaesthesia.[3-5] α-2 agonists such as clonidine and dexmedetomidine are also being used as adjuvants to local anaesthetics in place of opioids.[6] Epidural blocks with dexmedetomidine is found to exhibit synergism with local anaesthetics and result in prolonged sensory and motor block and offers postoperative analgesia.[7,8] This study compares the efficacy of using fentanyl and dexmedetomidine with bupivacaine in epidural block for lower limb and lower abdominal surgeries. The time to onset of sensory and motor blockade, the duration of these blockade, time to two segment regression of sensory block, time to rescue analgesia and adverse events were measured.

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Materials and Methods

This prospective randomized clinical trial was undertaken on 60 adult patients undergoing lower limb and lower abdominal surgeries in a medical college teaching hospital at Kolar, Karnataka. Both the patients and the anaesthetist recording the observations following the epidural block were blinded. Patient of ASA Grade I and II were included for the study and those with spinal deformity, neurological diseases, psychiatric conditions, renal, cardiac, pulmonary and hepatic disease, localized skin sepsis and haemorrhagic diathesis were excluded from the study. Institutional ethical clearance was obtained before the start of study. Written informed consent was obtained from all the participating patients. Patients were randomly divided in two groups of 30 each. Patients in group D received bupivacaine with dexmedetomidine and in group F received bupivacaine with fentanyl anaesthesia. Epidural space was identified in sitting position in either L_{2-3} or L_{3-4} space with 18 gauge Touhy needle using loss of resistance technique and a epidural catheter was secured. Three ml of 2% lignocaine with adrenaline 1:2,00,000 was given through the catheter and observed for any intravascular or intrathecal injection. After confirming correct placement of the catheter, epidural anaesthesia was activated with 18ml of 0.5% bupivacaine with dexmedetomidine 1 µg/kg made upto 2ml by adding sterile water in patients under group D. Similarly patients in the other group received 18ml of 0.5% bupivacaine with fentanyl 1 µg/kg made up to 2ml. Epidural catheter was secured 3-5cm into the epidural space.

Surgical procedure was initiated after establishment of adequate surgical anaesthesia. Sensory blockade was assessed by bilateral pin prick method and modified Bromage scale was used to measure motor blockade. Onset of analgesia, the highest dermatomal level of sensory blockade, time to achieve highest sensory level, the complete establishment of motor blockade, time to two segment regression and time to complete motor recovery were recorded. Time for rescue analgesia was assessed by VAS score.[9] Sedation was assessed using Ramsay sedation score.[10] Pulse oximetry, ECG and non invasive arterial blood pressure were monitored. Intraoperative heart rate, non-invasive arterial blood pressure and oxygen saturation were recorded every 5mins for first 20 mins, then every 15 mins.

Intravenous fluid input, urine output and blood loss were monitored. Hypotension was defined as >20% decrease in systolic BP from baseline and were treated with IV fluids and IV mephenteramine 3-6 mg in incremental boluses, bradycardia defined as pulse <50 beats/min were treated with IV atropine sulphate 0.6mg bolus doses and other adverse effects such as anxiety, nausea, vomiting, pruritus, urinary retention and shivering were monitored for and the need for any additional medications was attended.[11] Duration of analgesia was assessed by VAS score and ≥ 4 was considered for requirement of rescue analgesia. The onset of pain was managed with top up doses of 10 ml 0.25% bupivacaine through Epidural catheter if needed. The sample size was determined by power analysis based on previous literature. Keeping the mean difference of 5.1 and standard deviation in group 1 as 6.9 and group 2 as 3.7, a sample size of 26 patients per group was required. Considering 10% of non compliance, a sample size of 30 patients were selected for each group in our study.

Statistical analysis

SPSS 15.0 is used for statistical analysis of the data. Microsoft word and Excel is used to generate graphs and tables. Continuous data is analysed using student t-test and categorical data using Chi-square test and Mann-Whitney U test. P value <0.05 was considered as statistically significant.

Results

The demographic profile is comparable in the study groups (table 1). Time to attain adequate sensory and motor block was faster in Group D in comparison to Group F which is statistically significant as seen in table 2 ($p<0.001$). Bradycardia was observed in 7 patients in group D and 3 patients in group F which required a single dose of injection atro-

Table 1. Characteristics of patients receiving Subarachnoid block

Characteristic	Group D	Group F
Age - No. (%)		
18-40 yrs	18 (60.0)	20 (66.7)
41-50 yrs	12 (40.0)	10 (33.3)
Mean age ± SD	36.4±9.6	37.4±9.6
Sex - No. (%)		
Female	17 (56.7)	19 (63.3)
Male	13 (43.3)	11 (36.7)

Table 2. Characteristics of sensory and motor blockade in the study groups

Characteristics	Group D (mean ± SD mins)	Group F (mean ± SD mins)
Onset to sensory blockade	8.8±1.1	10.7.±1.3*
Onset to motor blockade	15.5±1.9	16.9±1.4*
Time to two segment regression	164.2±15.2	124.6±15.9*
Effective duration of analgesia	295.2±23.1	263.0±16.9*
Time to complete motor recovery	213.9±17.9	165.7±13.8*

*p<0.001

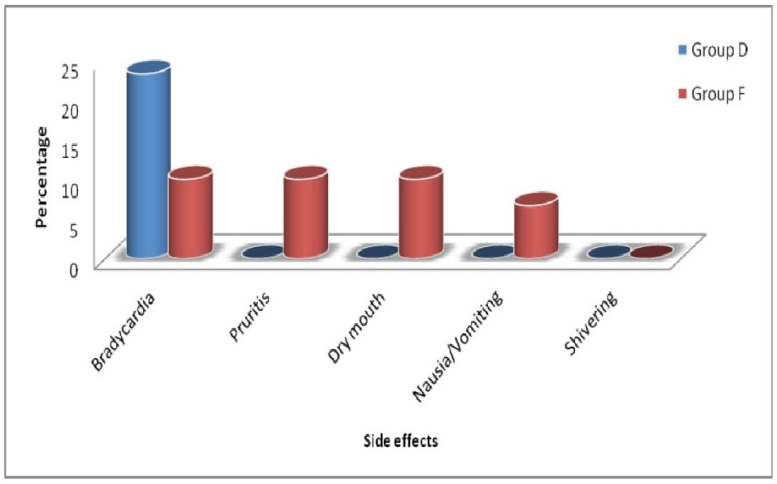

Fig 1. Side effects among patients in the study group

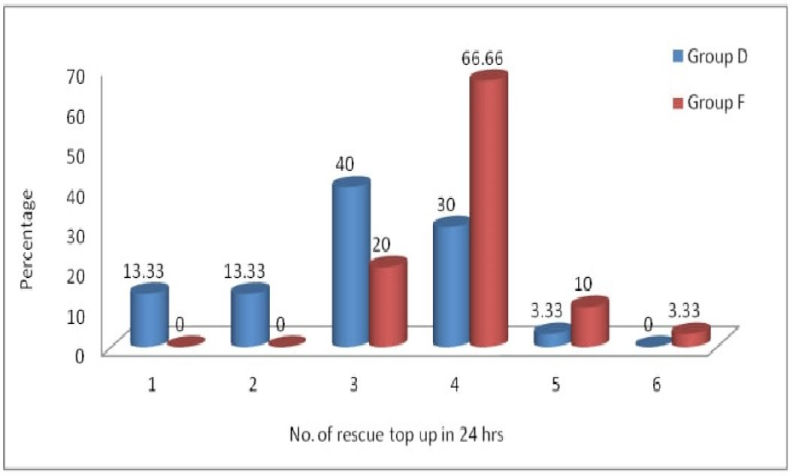

Fig 2. Rescue top up received by patients in 24 hr in the study group

pine 0.6mg IV. Two segment regression, the duration of analgesia and time to complete motor recovery was prolonged in Group D when compared to Group F. Number of rescue analgesic top ups given in 24 hours was less in Group D when compared to group F (Fig 2).

The fall in heart rate was statistically significant in Group D when compared to Group F between 10 min and 180 min (P value<0.001). Statistically significant difference in mean arterial blood pressure was observed in between Group D and Group F at 5, 10, 120 and 180 mins. More patients in group D had a sedation score of 3 and among group F sedation score of 2 was commonly observed. Patients in both the groups maintained saturation above 95% and none of them required oxygen support.

Discussion

This prospective randomized clinical found that dexmedetomidine as an adjuvant to bupivacaine in epidural block for lower limb and lower abdominal surgeries has effective analgesia and prolonged motor recovery when blockade compared to fentanyl as an adjuvant. Epidural anaesthesia with catheter insertion for lower abdominal surgeries are found to avoid the stress of general analgesia, are useful for prolonged surgeries and helpful to provide postoperative pain relief.[1]

Many adjuvants have been studied by various authors for prolonging epidural anaesthesia as well as during postoperative analgesia. Among them are opioids, alpha 2 agonists, non opioid like tramadol and neostigmine. Opioids like fentanyl has been a popular choice in that it offers faster onset and prolongs the duration of analgesia. Recently alpha 2 agonists like clonidine and dexmedetomidine have also been used in prolonging the duration of epidural analgesia. Studies comparing epidural bupivacaine with dexmedetomidine and bupivacaine with fentanyl are limited. Hence our study involved comparison of epidural bupivacaine 0.5% plus dexmedetomidine and bupivacaine plus fentanyl for lower abdominal and lower limb surgeries with major emphasis on onset of sensory blockade, onset of motor blockade, time to two segment regression, total duration of analgesia, time to complete motor recovery, haemodynamic variables. Fentanyl an opioid analgesic is a lipid-soluble, strong μ-receptor agonist and phenyl piperidine derivative with a rapid onset and short duration of action. It has been commonly used as adjunct to local anesthetics in epidural anaesthesia in doses of 50 μg to 100 μg with minimal side effects. They hasten the onset, improve the quality of the block and prolong the duration of analgesia.[12,13,14] In our study we have used fentanyl in dose of 1 μg/kg as an additive to bupivacaine. Alpha 2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia. Dexme-

detomidine is a highly selective alpha 2 agonist when compared to clonidine. It exerts its analgesic effects at the spinal and supraspinal sites. Various studies have stated that the dose of clonidine is 1.5-2 times higher than dexmedetomidine when used in epidural route. A dose of 1.5μg/ kg has been used in epidural anaesthesia in various studies without any significant side effect. The stable haemodynamics and decreased oxygen demand due to sympathoadrenal stability makes it a very useful pharmacologic agent.[15] In our study we have used dexmedetomidine in a dose of 1μg/kg. Since there is a diminished hemodynamic response and also a high thoracic spread of analgesia following epidural block patients above 50 years were not include in the study.[16]

In a study by Kumkum Gupta and her colleagues, time for onset of sensory and motor block in levobupivacaine with dexmedetomidine group was faster compared to levobupivacaine with fentanyl group. The duration of sensory analgesia and duration of motor block between groups was statistically significant being greater in levobupivacaine with dexmedetomidine group. In the study it was also found that mean arterial blood pressure decreased from baseline in both groups with maximum decline at 30-35 minutes after the epidural injection but it was never below acceptable physiological limit of 65 mmHg.[6] In our study, we have got similar results with dexmedetomidine and bupivacaine group where onset of sensory and motor block was faster and also duration of sensory and motor block was prolonged compared to fentanyl and bupivacaine group. In a similar study by Mohamed Fouad Selim and his colleagues, onset of sensory blockade was faster and duration of analgesia was longer in bupivacaine with dexmedetomidine group compared to bupivacaine with fentanyl group. Mean arterial pressure decreased significantly at 20 min in both epidural groups. Nausea and pruritis were significantly higher in fentanyl and bupivacaine group compared to bupivacaine and dexmedetomidine. The incidence of respiratory depression was nil in both the groups.[17] In our study significant difference in mean arterial blood pressure was observed between dexmedetomidine and fentanyl groups at 5,10, 120 and 180 mins. Nausea, pruritis and dry mouth were higher in fentanyl group compared to dexmedetomidine in our study.

In a similar study by Bajwa SJ and his colleagues, dexmedetomidine with ropivacaine had faster onset of action compared to fentanyl with ropivacaine when given in epidural anaesthesia. The side effect profile of both these drugs were quite favourable. More number of patients in dexmedetomidine group reported higher grade of sedation.[18] Our study also exhibited similar results with more sedation in dexmedetomidine group. In a study done by Paranjpe SJ et al for the expanding role of dexmedetomidine in anaesthesia, it was found that dexmedetomidine produces a dose dependant increase in the duration of sensory and motor blocks induced by local anaesthetics in spinal, epidural or caudal route.[19] Our study is in correlation with this study as the duration of both sensory and motor blocks were longer in dexmedetomidine group compared to fentanyl group. In a study done for the efficiency and safety of alpha 2 agonists in regional anaesthesia practice, it was suggested that monitoring for bradycardia, hypotension, possible excess sedation and subsequent fall in SpO_2 should be done.[20] In our study we monitored all the vital parameters and the common side effects found were hypotension, bradycardia and sedation.

Conclusion

Epidural dexmedetomidine with bupivacaine produces a faster onset of sensory and motor blockade, with significantly prolonged sensory and motor blockade and lesser requirement of rescue analgesia compared to fentanyl with bupivacaine in lower abdominal and lower limb surgeries.

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