Original Research Article

Indian Journal of Anesthesia and Analgesia
2018; 5(10): 1687-1693
DOI: http://dx.doi.org/10.21088/ijaa.2349.8471.51018.16

Comparison of Dexmedetomidine and Fentanyl as Adjuvants to Ropivacaine in Epidural Anaesthesia for infraumbilical Surgeries: An Observational Study

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Abstract

Aims: To assess the efficacy and compare the duration of analgesia, level of sedation and side effects of 0.75% ropivacaine with 50 mcg dexmedetomidine to 0.75% ropivacaine with 50 mcg fentanyl given epidurally. *Study setting:* Department of Anaesthesiology, MOSC Medical College, Kolenchery. *Study period*: An observational descriptive study on 66 patients over a period of one year. *Methods and Material*: 66 patients of ASA physical status I and II of either sex in the age group of 18-65 years undergoing abdominal hysterectomy or inguinal hernioplasty were observed in the study under two groups of 33 patients in each. Epidural anaesthesia was given after a test dose of 3ml 2% lignocaine with adrenaline followed by 15 ml 0.75% ropivacaine with Group I receiving 50 mcg fentanyl as adjuvant and Group II receiving 50 mcg dexmedetomidine. Two groups were compared with respect to sensory and motor block characteristics, hemodynamic changes, level of sedation and side effects. *Statistical analysis used:* The data was analyzed using Chi-square test, Fisher's exact test and Student *t*-test. $p < 0.05$ was considered to be significant and $p < 0.001$ as highly significant. *Results:* Significant prolongation of analgesia, motor blockade and two point regression time was observed in Group II as compared to group 1. A maximum sedation score of 4 was attained in 78.8% patients in Group II vs 3% in Group I, which was highly significant. *Conclusions:* Dexmedetomidine is a very good epidural adjuvant to ropivacaine providing prolonged duration of analgesia, excellent sedation with minimal side effects as compared to fentanyl.

Keywords: Dexmedetomidine; Fentanyl; Epidural Anaesthesia; Lower Abdominal Surgeries; Ropivacaine.

How to cite this article:

Roshin K. Mathew, Sunitha K. Zachariah, Saramma P. Abraham. Comparison of Dexmedetomidine and Fentanyl as Adjuvants to Ropivacaine in Epidural Anaesthesia for infraumbilical Surgeries: An Observational Study. Indian J Anesth Analg. 2018;5(10):1687-93.

Introduction

Adjuvants are used in epidural anaesthesia which potentiates the effects of the local anaesthetic thereby reducing the anaesthetic and analgesic requirement to a huge extent. Opioids synergistically enhance the analgesic effects of epidural local anaesthetics, without prolonging motor block while at the same time allowing a reduction in the dose and side effects of both. Epidural opioids cross the dura and arachnoid membrane to reach the CSF and exert their spinal analgesic effects at the level of the spinal cord dorsal horn [1]. The onset of blockade is hastened with opioid additives [2]. However, the incidence of side effects following the use of epidural opioids tends to increase in parallel with the dose used which include nausea and vomiting, pruritus, urinary retention and hypoventilation [3].

Dexmedetomidine, is a highly selective alpha 2 agonist drug, introduced into clinical practice in the 1990's as an adjunct to regional, local and general anaesthesia. Epidural dexmedetomidine has been

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Received on 12.06.2018, **Accepted on** 14.07.2018

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shown to reduce intraoperative anaesthetic requirements, improve postoperative analgesia, and prolong both sensory and motor block, without side effects of opioid additives [4,5].

Here, an attempt is made to evaluate the potentiating effects of analgesia and side effects of dexmedetomidine in comparison to fentanyl, when used as an adjuvant to ropivacaine in epidural anaesthesia for lower abdominal surgeries.

Subjects and Methods

Study Design

An observational descriptive study was conducted after obtaining written informed consent from the patients and approval from the Institutional Ethics Committee. Patients with ASA physical status I and II, aged 18-65 years and posted for inguinal hernioplasty or total abdominal hysterectomy were included in the study Those with contraindications to epidural anaesthesia – uncooperative patients, previous spinal surgeries, spine abnormalities, allergy to amide local anaesthetics, local site infection and coagulation abnormalities, Body mass index (BMI > 30), patients on any antipsychotic drugs, anti-arrhythmic agents, betablockers or anticoagulants were excluded from the study.

Study was conducted at the Department of Anaesthesiology, MOSC Medical College, Kolenchery over a period of one year.

Sample Size

Considering duration of analgesia as the primary outcome, a superiority margin of 41 minutes for dexmedetomidine was taken, with regard to a previous similar study [6]. The number of cases required were 66 with an alpha error of 5% and power of study 90%. The Sample size was calculated using nMaster computer software.

The patients were observed under two groups of 33 in each. Both the groups received a test dose of 2% lignocaine 3ml along with a bolus 0.75% Ropivacaine 15 ml. Group I received 50 mcg fentanyl and Group II 50 mcg dexmedetomidine.

Data collection

Data was collected over a period of one year and recorded as mentioned in the proforma

Statistical Analysis

Statistical analysis was done using Statistical Package for Social Sciences (SPSS Inc., Chicago, IL, USA) version 20.0. The qualitative data were presented as percentage and quantitative data as mean and standard deviation. For the comparison of quantitative data, independent sample t-test was used. Chi square test / Fisher's exact test was used for the comparison of qualitative variables.

Methodology

Pre-anaesthetic evaluation of the patients was performed by the investigator, the day before the surgery and a written informed consent was obtained. The selected patients were premedicated with ondansetron 4 mg and ranitidine 150 mg tablets orally the night before and in the morning of surgery. Tablet Alprazolam 0.5 mg was also given on the night before the surgery.

In the operating room peripheral intravenous access was secured using 18 gauge cannula and monitors were placed. Baseline noninvasive blood pressure, pulse rate, electrocardiograph and pulse oximetry were recorded. Oxygen was administered through simple face mask. All patients were preloaded with ringer's lactate solution 10 ml/kg 30 minutes before the block. Maintenance fluid was given as per body weight and operative loss requirements. The drug to be given was decided by the concerned anaesthesiologist. After positioning the patients in the left lateral position with the skin over the desired site infiltrated with 2% lignocaine, epidural was attempted at L3-L4/L2-L3 spaces using 18G Tuohy needle by loss of resistance to air technique. The epidural catheter was placed 4 cm within the space. After exclusion of blood and cerebrospinal fluid in the needle with negative aspiration, 3ml of 2% lignocaine with adrenaline 1:200000 was administered as test dose to exclude intrathecal or intravascular placement of the needle. Five minutes later either 0.75% ropivacaine 15 ml with 50 mcg fentanyl (Group I) or 0.75% ropivacaine 15ml with dexmedetomidine 50 mcg (Group II) was administered. Cardiorespiratory parameters were monitored continuously and recordings made every 5 minutes until 30 minutes and at 10 minutes interval, thereafter upto 60 minutes and then at 15 minutes interval for the rest of the surgery. Heart rate less than 50 beats per minute was treated with intravenous injection atropine 0.6 mg and systolic blood pressure less than 20% of baseline was treated with intravenous injection of ephedrine in 3-6 mg bolus doses.

After epidural administration of the anaesthetic, the onset of sensory block at T10 and T8 dermatome was evaluated in midclavicular line bilaterally by pin prick using sterile 26G needle every two minutes. At complete loss of cutaneous sensation at T8, surgery was allowed to proceed. Maximum sensory level attained was noted.

Degree of motor block was assessed every 5 minutes after giving the drug, using Bromage scale. Time of onset of motor block and time taken to reach complete motor blockade were noted. Duration of motor blockade was taken as the time from maximum degree of motor blockade to full recovery of motor power (Bromage scale 0).

Table 1: Bromage Scale

Score	Bromage Scale
0	Able to move the hip, knee and ankle
1 and	Unable to move the hip but is able to move the knee ankle
2 the	Unable to move the hip and knee but is able to move ankle
3	Unable to move the hip, knee and ankle

Duration of analgesia was recorded as the time interval from the completion of anaesthesia to the time when the patient first complained of pain. During surgical procedure, adverse effects like respiratory depression, anxiety, nausea, vomiting, dizziness, headache and pruritus were recorded. Postoperatively patients were assessed at 15 minutes, 30 minutes, 45minutes, 1hour and thereafter every hour. Intensity of postoperative pain is assessed using visual analogue scale, 0=no pain to 10=maximum pain [7]. Rescue analgesia was provided postoperatively by epidural bolus of 5ml 0.2% ropivacaine followed by infusion, when patients complain of pain or with a visual analogue score of more than 4.

Sedation score was recorded just before the initiation of surgery and at 5, 20 and 30 minutes and thereafter every 15 minutes upto 2 hours and then hourly until the end of surgery. Level of sedation was assessed using Ramsay Sedation Score.

Table 2: Ramsay Sedation Score

Patient anxious or agitated or both	1	
Patient cooperative and tranquil	2	
Patient responds to verbal command only	3	
A brisk response to a light glabellar tap		4
A sluggish response to a light glabellar tap	5	
No response	6	

Results

66 ASA I / II patients of age group 18-65yrs undergoing elective bilateral inguinal hernioplasty and total abdominal hysterectomy were studied. They were observed under two groups of 33 in each who received 0.75% Ropivacaine 15 ml+ 2% lignocaine with adrenaline +50 mcg fentanyl in Group I or 0.75% Ropivacaine 15 ml + 2%lignocaine with adrenaline + 50 mcg dexmedetomidine in Group II. The groups studied were similar in terms of age, height, weight and duration of surgery (Table 1).

Time of onset of sensory blockade was taken as the time interval from the conduct of epidural block to attaining a sensory level of T10. Time of onset of sensory blockade was similar between the groups - 6.7±2.39 minutes in Group I and 7.4±2.03 minutes in Group II (p = 0.226).

Time to reach maximum sensory level was 16.9± 2.73 minutes in Group I and 18.1±2.64 minutes in Group II (p = 0.065) . Median maximum sensory

Table 1: Distribution of age, height, weight and duration of surgery

Parameters	Group I [n=33] Mean ± SD	Group II [n=33] Mean ± SD	P-value*
Age (yrs)	49.2 ± 9.98	45.0 ± 6.74	0.051
Weight (Kg)	55.6 ± 9.47	59.9 ± 9.29	0.065
Height (cms)	159.2 ± 8.84	157.4 ± 5.55	0.313
Duration of surgery (mins)	144.8 ± 45.1	159.2 ± 53.43	0.241

*P value < 0.05 is considered significant

Table 2: Sensory characteristics

Parameters	Group I Mean ±SD	Group II Mean ±SD	P - value
Time of onset of sensory blockade at T10 (mins)	6.7 ± 2.39	7.4 ± 2.03	0.226
Time to reach maximum level (mins)	16.9± 2.73	18.1 ± 2.64	0.065
Median maximum sensory level	T5	T5	0.124
Time for 2 dermatome regression (mins)	261.7± 55.73	291.7 ± 61.98	**0.042**
Duration of analgesia (mins)	328 ± 58.38	381.1 ± 75.86	**0.002**

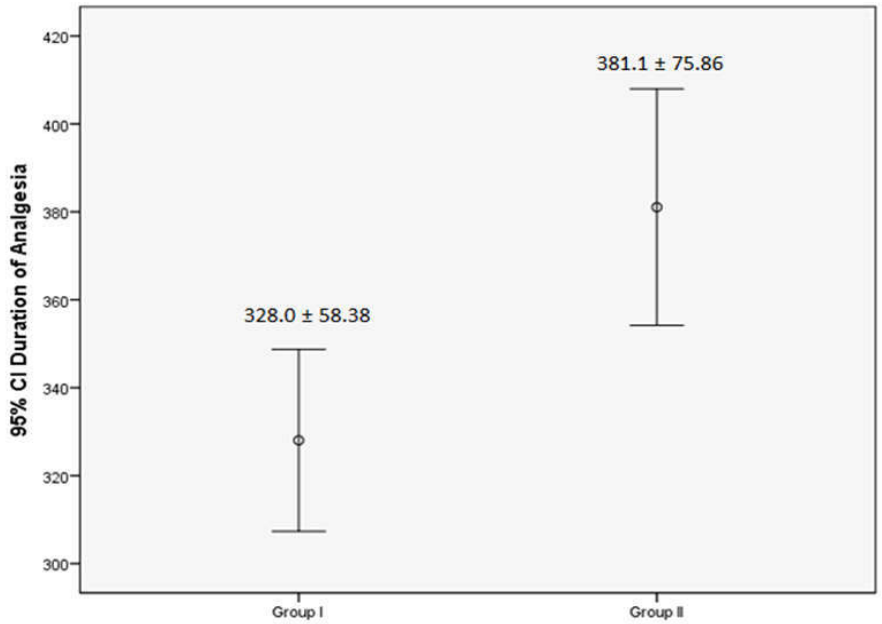
level attained was at T5 in both groups - 15 (45.5%) in Group I and 22 (66.7%) in Group II. The time taken for two point regression is the time interval between time to reach maximum sensory level and the time of achieving sensory regression by two dermatomal segments. Time taken for two point regression was significantly prolonged in Group II compared to Group I (291.7±61.98 mins vs 261.7± 55.73 mins, P = 0.042). Duration of analgesia is the time interval between the time of administration of study drug to the time till the patient complains of pain. Duration of analgesia is taken as the primary endpoint of this study (Table 2).

There was significant difference between the two groups. The duration of analgesia in Group II was prolonged in comparison to Group I (381.1±75.86 mins versus 328±58.38 mins) which was highly significant (p = 0.002) (Graph 1).

Motor block was assessed using Bromage scale. Time of onset of motor block was the time to achieve Bromage scale 1 which was 8.2±3.26 mins in Group I and 8.9±3.48 mins in Group II respectively (p = 0.365). Time to attain complete motor block is from the time of administering epidural block to the time to attain a Bromage scale of 3. Time to reach complete motor block was comparable with no statistical significance, 25.5±5.06 minutes and 27.8±5.73 minutes in Group I and Group II respectively (p = 0.073). Duration of motor block is the time interval between time of maximum degree of motor blockade to full recovery of motor power (Bromage 0). The duration of motor block varied significantly between both the groups. Prolongation of motor block was highly significant in Group II, in comparison to Group I. (267.7±72.4 minutes vs 230.5±48.9 minutes, p = 0.017) (Table 3).

Heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), Mean blood pressure (MBP) respiratory rate and oxygen saturation were continuously monitored intraoperatively as well as post operatively and compared with the preoperative values. Cardiorespiratory parameters were comparable between both groups with no statistical significance. (Graph 2,3). Any hypotension and bradycardia was observed within the first 60 minutes intraoperatively and responded to treatment with intravenous ephedrine and atropine.

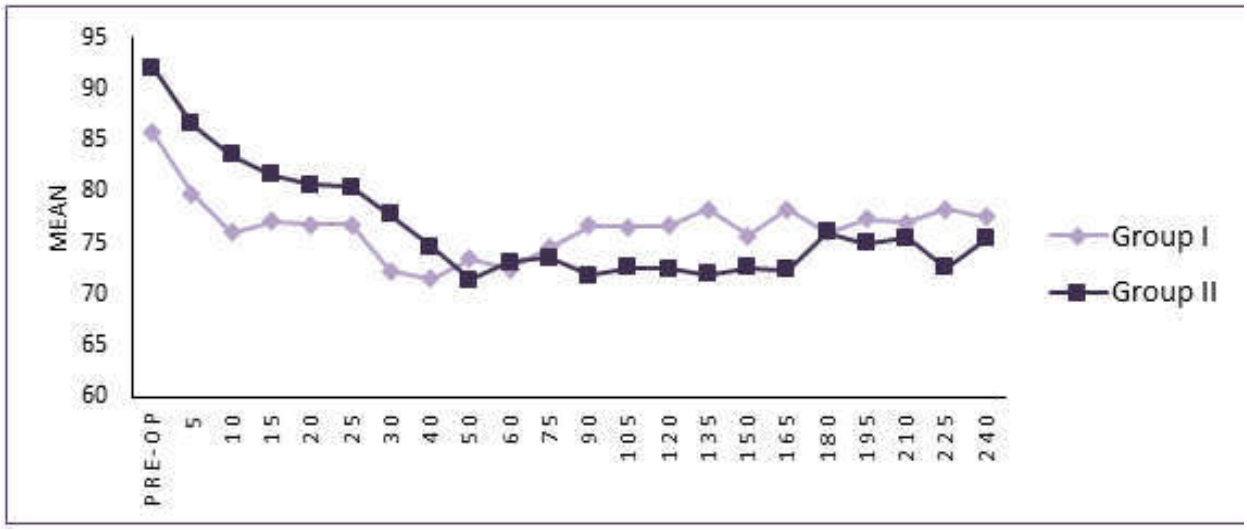
Level of sedation was assessed using a six point sedation score (Ramsay Sedation Score). 26 (78.8%) patients in Group II attained a sedation score of 4 intraoperatively while only 1 (3%) patient in Group I attained a sedation score of 4. This was a highly



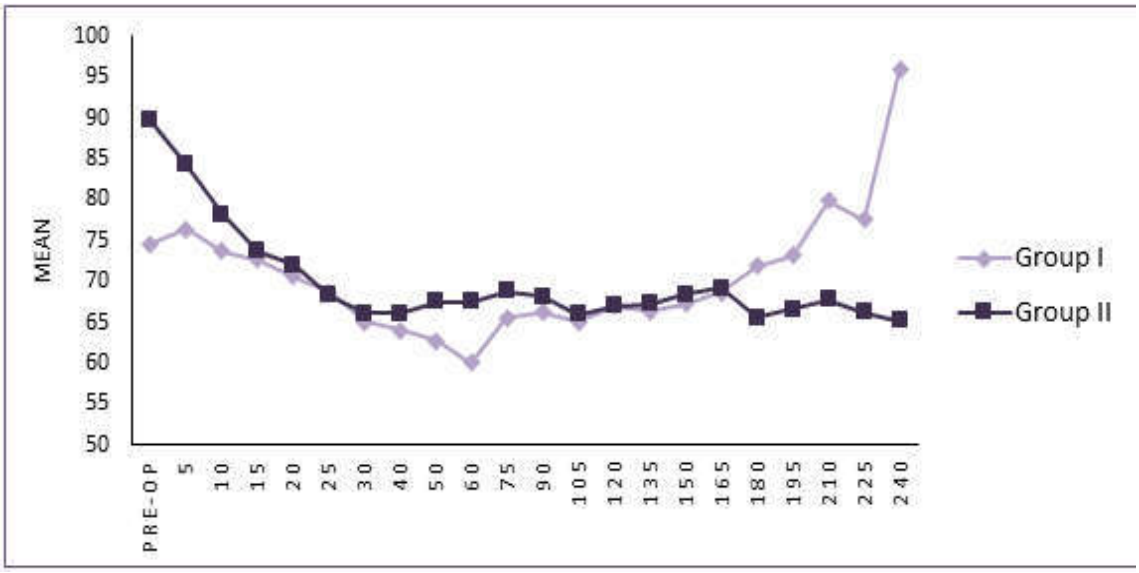
Graph 1: Duration of analgesia

Table 3: Motor characteristics

Parameters	Group I Mean ±SD	Group II Mean ±SD	P - value
Time of onset of motor block (mins)	8.2 ± 3.26	8.9 ± 3.48	0.365
Time for complete motor block(mins)	25.5 ± 5.06	27.8 ± 5.73	0.073
Duration of motor block(mins)	230.5 ±48.9	267.7±72.4	**0.017**



Graph 2: Comparison of Mean blood pressure



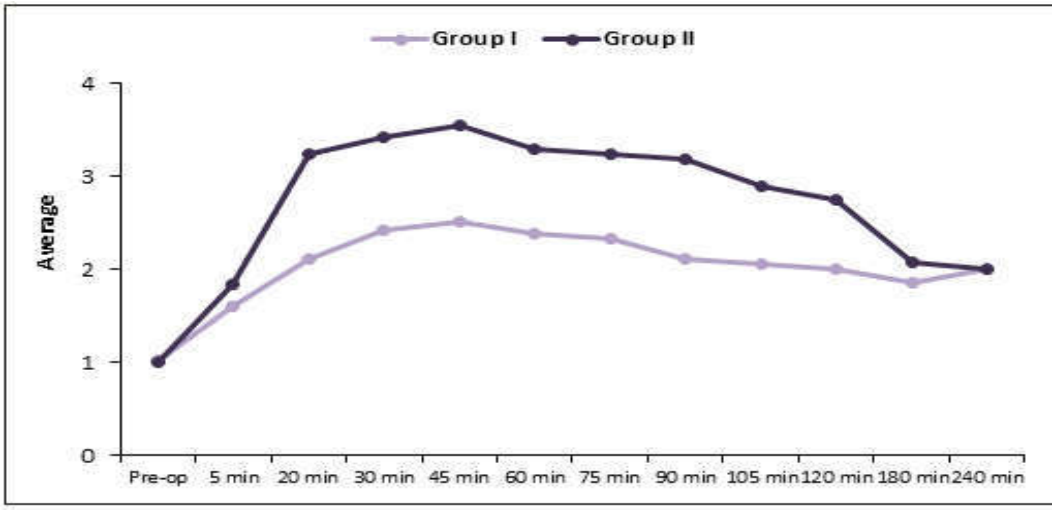
Graph 3: Comparison of heart rate

significant finding (p = 0.000). The level of intraoperative sedation was excellent in Group II. Postoperative pain was assessed using visual analogue scale (VAS). The mean VAS score reached 3.95 in Group I within four hours postoperatively as compared to 2.01 in patients in Group II which was statistically significant (p =0.032). (Graph. 4)

The incidence of hypotension and bradycardia seemed to be more in Group II. The incidence of pruritus, nausea and vomiting were observed more in Group I as compared to Group II, but this observation was of statistical significance (Table 4).

Table 4: Complications

Parameters	Group I	Group II	P – value
Hypotension	14m (42.4%)	16 (48.5%)	0.621
Bradycardia	9 (27.3%)	10 (30.3%)	0.786
Nausea and Vomiting	7 (21.2%)	1 (3.0%)	0.054
Pruritus	7 (21.2%)	0 (0.0%)	**0.011**



Graph 4: Level of sedation

Discussion

The patient characteristics in this study were comparable with respect to the ASA grading, mean age, sex, height, weight, type of surgery and duration of surgery. The primary objective of this study was assessment of duration of analgesia which determined the efficacy of the adjuvant. The results of this study show that the duration of analgesia was significantly prolonged in the group of patients who underwent lower abdominal surgeries and received 50 mcg dexmedetomidine along with 0.75% Ropivacaine 15 ml for epidural anaesthesia as compared to the patients who received 50 mcg fentanyl with 0.75% Ropivacaine 15 ml (381.1 ± 75.86 mins vs 328 ± 58.38 mins). This finding was consistent with that of Bajwa et al. and Gupta et al. [6,9]. This along with prolonged two dermatomal regression clearly indicates the effectiveness of epidural dexmedetomidine over fentanyl. Dexmedetomidine acts by binding to G-protein coupled α-2 adrenergic receptors, which are found in central, peripheral, and autonomic nervous systems and also in various vital organs and blood vessels throughout the body. Similar findings were reported by Salgado et al., while comparing epidural dexmedetomidine with ropivacaine and ropivacaine alone but observed no change in the onset of sensory blockade and time to reach maximal sensory level between groups [5].

The hemodynamic parameters as well as respiratory rate and oxygen saturation were comparable between both the groups. Fall in mean blood pressure occurred around 30 to 40 minutes and around 50 to 60 minutes after epidural administration of fentanyl and dexmedetomidine respectively. Bradycardia, a known side effect of both opioids and α2 agonists, was seen in a few patients of both groups. Postsynaptic activation of central α2-A receptors results in sympatholytic effect leading to hypotension and bradycardia, an effect judiciously used to attenuate the stress response of surgery [8].

As premedication, only a night dose of 0.5 mg alprazolam was given orally to both groups of patients, avoiding the morning dose of anxiolytic agent so that the level of sedation is not affected by the premedicants. Dexmedetomidine provided excellent sedation making it an ideal adjuvant, alleviating the anxiety and discomfort of lying awake for a long time with the inability to move the body in an unfamiliar environment [9].

Nausea and vomiting was significantly high among the fentanyl group as compared to dexmedetomidine. The antiemetic property is attributed to the decrease of noradrenergic activity as a result of binding to α2 presynaptic inhibitory adrenoreceptor in the locus coeruleus, as high level of catecholamine concentrations can induce vomiting [10].

The incidence of pruritus in the fentanyl group was higher than the dexmedetomidine group as was shown in a previous study [11].

Limitations of our Study

Our study involved two types of surgeries. Hence the onset of postoperative pain at the incision site for bilateral hernioplasty and total abdominal hysterectomy might be slightly varied which may have slightly affected the duration of analgesia.

Conclusion

- Dexmedetomidine as an excellent adjuvant to ropivacaine for epidural anaesthesia provides prolonged duration of analgesia.
- Epidural Dexmedetomidine has good hemodynamic stability with minimal side effects as compared to fentanyl

Key Messages

Dexmedetomidine is a very good epidural adjuvant to ropivacaine as it provides superior analgesia and sedation than fentanyl and associated with minimal side effects.

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