

Original Research Article

A comparative evaluation of efficacy of epidural dexmedetomidine and fentanyl as adjunct to 0.2% ropivacaine for post-operative analgesia in elective abdominal surgeries

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ABSTRACT

Background: Epidural analgesia as a central neuraxial technique which involves use of local anesthetics injected into the epidural space to produce a reversible loss of sensation and is the one of the most common regional technique used for lower abdominal and lower limb surgeries epidural analgesia provides excellent pain relief for surgical procedures below the umbilicus. This study compared the efficacy of epidural dexmedetomidine and fentanyl in addition to 0.2% ropivacaine for post-operative analgesia in elective abdominal surgeries.

Methods: Total of 150 patients American Society of Anesthesiologists (ASA) I and II between 20-60 years, undergoing major abdominal surgery were included in this study. The patients divided in three groups of 50 patients each. First group R (ropivacaine 0.2% 9 ml with 1ml normal saline) second group RF (ropivacaine 0.2% 9 ml with fentanyl 1 ml) and third group RD (ropivacaine 0.2% 9 ml with dexmedetomidine 1 µ/kg).

Results: There is no significant difference in age, weight, sex, and ASA grade in all three groups.

Hypotension was observed in 4 (8%) patients of R group, 2 (4%) in RD group and 4 (8%) in RF group. The shivering was present in 2 (4%) R group and 2 (4%) in RD group. Nausea, vomiting was present in R group 2 (4%) and 2 (4%) in RF group. There was no significant difference between the three groups with respect to hemodynamic parameters like heart rate, systolic and diastolic blood pressure and respiratory rate.

Conclusions: Dexmedetomidine is a better adjuvant to ropivacaine through epidural route when compared to fentanyl for providing early onset prolonged post-operative analgesia, sedation and stable hemodynamic parameters in intra-abdominal surgeries.

Keywords: Abdominal surgeries, Epidural analgesia, Ropivacaine, Dexmedetomidine, Fentanyl

INTRODUCTION

Epidural anesthesia with local anesthetics is performed for providing intraoperative surgical anesthesia and postoperative analgesia.¹ The specialty of anesthesia has seen major advances, thanks to the development of safer techniques and safer anesthetic agents, improved knowledge of pain physiology and pain management, and incorporation of better understanding of perioperative pathophysiology into perioperative care. The addition of

opioids to local anesthetics has disadvantages of respiratory depression and pruritus. Dexmedetomidine, an alpha-2 adrenoceptor agonist, acts on the spinal cord and has been used as an effective adjuvant to ropivacaine for regional and central neuraxial blocks.² Epidural opioids are proven to be very effective for postoperative analgesia. Because of its greater lipophilic nature, fentanyl offers some advantages for epidural analgesia. Fentanyl undergoes rapid vascular absorption from the epidural space, and it spreads less rostrally than other normally used opioids.³ Dexmedetomidine is a highly selective alpha 2

agonist which has both analgesic and sedative properties and is devoid of side effects caused by opioids. It also enhances the effects of local anaesthetics. Dexmedetomidine suppresses the activity in the descending noradrenergic pathway, which modulated nociceptive neurotransmission, terminates propagation of pain signals leading to analgesia. The hypnotic and supraspinal analgesic effects are mediated by the hyperpolarization of noradrenergic neurons, which suppresses neuronal firing in the locus ceruleus along with inhibition of norepinephrine release and activity in the descending medullospinal noradrenergic pathway, secondary to activation of central alpha-2 adrenergic receptors. This suppression of inhibitory control triggers neurotransmitters that decrease histamine secretion producing hypnosis analogous, to normal sleep, without ventilator depression, making dexmedetomidine a near ideal sedative.²

Various drugs have been used for the same in addition to local anaesthetics like ropivacaine of which opioids and alpha-2 agonist have become increasingly popular. Addition of an adjuvant has a dose sparing effect on local anaesthetics and prolongs the analgesia. In this study we comparative evaluate the efficacy of epidural dexmedetomidine and fentanyl in addition to 0.2% ropivacaine for post-operative analgesia in elective abdominal surgeries.

METHODS

This study was conducted in department of anesthesiology at Sri Aurobindo Institute of Medical Sciences and PG Institute, Indore (M.P). The duration of this study was February 2019 to March 2020. Total of 150 patients ASA I and II between 20-60 years, undergoing major abdominal surgery were included in this study. The patients divided in three groups of 50 patients each. First group R (ropivacaine 0.2% 9 ml with 1 ml normal saline) second group RF (ropivacaine 0.2% 9 ml with fentanyl 1 ml) and third group RD (ropivacaine 0.2% 9 ml with dexmedetomidine 1 µ/kg).

All the recruited patients were explained about the study and effects of drugs being used; written consent was taken from every patient dually signed by her. The patients underwent routine pre-operative investigation work-up including hemoglobin, completed blood count, random blood sugar, serum urea and creatinine, urine routine examination, blood grouping, HIV/HBsAg status, chest X-ray and electrocardiogram (ECG). Patients were kept nil per orally according to the fasting protocol before surgery and each received tablet alprazolam 0.5 mg at bed time.

Inclusion criteria

History was taken of all the patients during the pre-anaesthetic checkup, American Society of Anesthesiologists (ASA) grade I and II, both male and

female, age group 20-60 years scheduled for lower abdominal surgeries.

Exclusion criteria

Patient not fulfilling inclusion criteria, patient refusal, with infection at the site of injection, with coagulopathy, patients on alpha-2 antagonist treatment and patients with history of allergy to local anaesthetics or alpha-2 adrenergic agonists and pregnant women.

Technique

All the equipments necessary to administer epidural anaesthesia were checked and kept ready. The patient was placed in left lateral position and the back draped with 10% povidone iodine solution. With all aseptic measures the skin over T11-T12 interspace in anaesthetized with 2 ml of 2% lignocaine. An 18G Touhy needle passed through this epidural space which is confirmed by loss of resistance to air technique. Then a 19G epidural catheter was threaded through the needle into epidural space and advanced minimum of 3-4 cm within the space. 4 ml of xylocaine with adrenaline 1:200000 was administered as test dose to confirm the proper placement of catheter. Incubating position was given thereafter. Standard induction, maintenance and extubation regimen was followed in each case. A multimodal approach for pain by WHO ladder of pain management was followed by administering intravenous (IV) paracetamol and IV diclofenac. Patient was then shifted to post-anaesthesia care unit (PACU), on the first complaint of pain, visual analogue scales (VAS4) was administered the drug via epidural route which was one among the three groups R/RF/RD and the interested parameters were recorded. Group R [ropivacaine alone] (n=50) received ropivacaine 0.2% 9 ml+normal saline 1 ml, group RF [ropivacaine+fentanyl (RF) group] (n=50) received ropivacaine 0.2% 9 ml plus fentanyl 50 mcg, group RD [ropivacaine+dexmedetomidine (RD) group] (n=50) received ropivacaine 0.2% 9 ml plus dexmedetomidine 1 mcg/kg. After administering the drug, the following parameters were noted by the independent observer for 10 hrs in PACU. Pain score by using VAS every 5 min for 15 mins and then at 30, 60, 120, 240, 360, 480 and 600 minutes. Onset of analgesia (fall of VAS<4 after epidural drug). Duration of analgesia (starting from epidural drug administration to once the patient asked for additional epidural analgesia with VAS4). Haemodynamic parameters-pulse rate, blood pressure systolic/diastolic, respiratory rate. Number of rescue analgesics required and side effects. Sedation score assessed using a 5 point scale (deep sedation>3). The monitoring devices used in the observation period were NIBP, pulse oximetry, VAS scale and continuous electrocardiogram. Hypotension (defined as systolic arterial pressure falling more than 20% from the pre-operative level) was treated with injection ephedrine 6-12 mg IV bolus and heart rate<50 beats/min was treated with 0.01 mg/kg of injection atropine. Post-operative maintenance IV fluids were given as per body weight.

Nausea and vomiting were treated with 0.1 mg/kg of IV ondansetron. Shivering was treated with injection tramadol 50 mg IV.

Statistical analysis

Statistical analysis was performed by the statistical package for the social sciences (SPSS) program for Windows. Continuous variable are presented as mean±SD, and categorical variables are presented as absolute numbers and percentage. Data were checked before statistical analysis using Shapiro Wilk test. Normally distributed continuous variables were compared using analysis of variance (ANOVA). If the F value was significant and variation was homogeneous, Tukey multiple comparison test was used to assess the differences between the individual groups; otherwise, Tamhane's T2 test was used. Categorical variables were analyzed using by Chi-square test. Spearman's correlation was also used among various variables. A p value <0.05 was taken to indicate a significant difference.

RESULTS

A total of 150 patients were included in the study. There is no significant difference in age, weight, gender, and ASA grade I and II in all three groups (Table 1). The mean age

in R group was 44.40±12.29, whereas it was 40.17±13.49 in RD group and 42.60±10.91 in RF group. The p value (0.475) shows that the three groups are comparable. The mean weight in R group was 54.60±6.83, RD group 57.79±7.94, and RF group 54.51±5.92, p value was (0.170). The percentage of male and female in R group (68%), (32%), RD group (80%), (20%) and RF group (72%), (28%) p value was 0.384. The distribution as per ASA class was similar and comparable in the 3 groups (Table 1).

The indication of complications presents in three groups. Hypotension was observed in 4 (8%) patients of R group, 2 (4%) in RD group and 4 (8%) in RF group. The shivering was present in 2 (4%) R group and 2 (4%) in RD group. Nausea, Vomiting was present in R group 2 (4%) and 2 (4%) in RF group (Table 2).

The duration of analgesia in dexmedetomidine group was also longer when compared to fentanyl group and ropivacaine group. The difference between three groups is highly significant in duration of analgesia. The mean onset of analgesia in group in R group was 15 minutes, in RD group 9.6 and in RF group was 10 minutes. There is significant difference in three groups (Table 3). The total no of rescue analgesia used in the form of IV diclofenac or IV paracetamol whenever the VAS score was ≥4 (Table 3).

Table 1: Demographic characteristic according to age, weight, gender.

Characteristics	Group R (n=50)	Group RD (n=50)	Group RF (n=50)	P value
Age	44.40±12.29	40.17±13.49	42.60±10.91	0.475
Weight	54.60±6.83	57.79± 7.94	54.51±5.92	0.170
Male (%)	34 (68)	40 (80)	36 (72)	0.384
Female (%)	16 (32)	10 (20)	14 (28)	
ASA grade –I (%)	0 (0)	0 (0)	0 (0)	-
ASA grade-II (%)	50 (100)	50 (100)	50 (100)	-

Table 2: Incidence of complications.

Complications	Group R (n=50) %	Group RD (n=50) %	Group RF (n=50) %	P value
None	42 (84)	46 (92)	44 (88)	0.468
Hypotension	4 (8)	2 (4)	4 (8)	0.651
Shivering	2 (4)	2 (4)	0 (0)	NS
Nausea/vomiting	2 (4)	0 (0)	2 (4)	NS

Table 3: Comparison the onset of analgesia and rescue analgesia between group R, group RD, group RF.

	Group R (n=50) %	Group RD (n=16/50) %	Group RF (n=50) %	P value
Requirement of rescue analgesia				
1	8 (16)	14 (87.5)	38 (76)	<0.001
2	22 (44)	2 (12.5)	10 (20)	<0.001
3	18 (36)	0 (0)	2 (4)	<0.001
4	2 (4)	0 (0)	0 (0)	<0.001
Duration or onset of analgesia				
Duration	230.40±91.13	561.60±66.81	379.20±82.56	<0.001
Onset (min)	15	9.6	10	<0.001

The mean heart rate in R, RD and RF groups suggested not significant. The mean SBP and DBP in three groups suggesting result are comparable. The mean respiratory rate suggesting the three groups are similar (Figure 1).

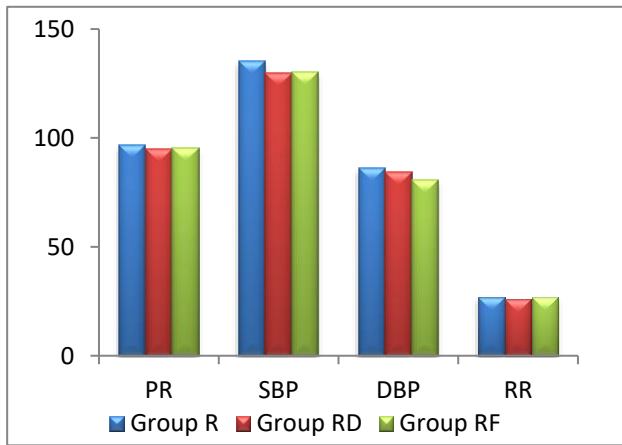


Figure 1: Vitals wise distribution (PR: pulse rate; SBP: systolic blood pressure; DBP: diastolic blood pressure; RR: respiratory rate).

The variation in VAS at different time interval. At the time 10 min in three groups which suggested significant result. Comparison between group R and RD, R and RF was significant and comparison between RD and RF groups are not significant. At 240 min between all three groups was significant. At 360 min the inter group comparison between each revealed significant result. At 480 and 600 min the result of VAS score was comparable (Figure 2).

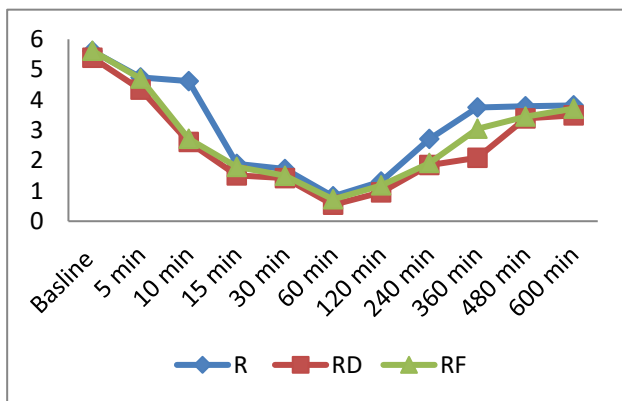


Figure 2: Comparison of VAS between group R, group RD, group RF (R: ropivacaine; RD: ropivacaine dexmedetomidine; RF: ropivacaine fentanyl).

DISCUSSION

Epidural analgesia is a good regional technique that provides us many advantages like graded level of analgesia, good hemodynamic stability, and prolonged duration of action for post-operative pain relief etc. In this study Addition of dexmedetomidine to ropivacaine as an adjuvant resulted in an earlier onset (9. 6±1. 7 min) of analgesia as compared to fentanyl (10.00±0.0 min).

Dexmedetomidine not only provided early onset, but also helped in achieving the peak analgesic level (VAS - 0) in a shorter period compared with group RF. Similar results obtained by various studies like Gupta et al and others.⁴⁻⁸ In present study the incidence of hypotension was observed in 4 (8%) patients in R group, 2 (4%) in RD group and 4 (8%) in group RD. This was treated with IV fluid boluses. Shivering occurred in 2% patients in group R and RD which was managed by warm IV fluids and blankets. Nausea and vomiting was present in 2 patients in group R and RF which was treated with IV ondansetron 0.1 mg/kg. These differences were however not statistically significant. Thus the addition of dexmedetomidine to ropivacaine in this study did not result in an increase in the incidence of side effects. These observations are supported by most studies.^{2-5,7,8} The changes in heart rate, systolic and diastolic blood pressure were comparable amongst both the groups. No significant difference in the respiratory rate between the two groups was observed. In previous study there were no cases of respiratory depression in patients of either group.⁹ In RF group 38 (76%) required one, 10 (20%) patients required two and 2 (4%) three doses of rescue analgesics. In dexmedetomidine group 14 (87.5%) required one and 2 (12.5%) required two doses of rescue analgesics. Thus the requirement of rescue analgesics was significantly higher in the fentanyl group compared to dexmedetomidine group. Similar observations were also noted by previous studies comparing epidural dexmedetomidine and fentanyl with placebo.^{4,10-12} The total duration of post-operative analgesia in fentanyl group was 379.20±82.56 minutes and in dexmedetomidine group it was 561.60±66.81 minutes. This difference between the two groups is highly significant (p<0.001). Thus dexmedetomidine had a longer duration of analgesia compared to fentanyl. Previously reported data in different studies show widely varying duration of analgesia for both epidural fentanyl (3-6 hours) and epidural dexmedetomidine (6-16 hours) when compared to placebo. This could be related to the different doses of drug used and the different types of surgeries. Also supported by Bajwa et al and various other studies.^{5,7,8,11}

CONCLUSION

All groups were comparable with respect to age, weight and gender distribution. There was no significant difference between the three groups with respect to hemodynamic parameters like heart rate, systolic and diastolic blood pressure and respiratory rate. Dexmedetomidine is a better adjuvant to ropivacaine through epidural route when compared to fentanyl for providing early onset prolonged post-operative analgesia, sedation and stable hemodynamic parameters in intra-abdominal surgeries.

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