Indian Journal of Public Health Research and Development
Volume 14 No. 2, April-June 2023

Evaluation of Dexmedetomidine and Fentanyl as Additives to Ropivacaine for Epidural Anaesthesia and Post-Operative Analgesia in Lower Abdominal and Lower Limb Surgeries

Vijaya Rekha Koti[1], Syeda Saniya Shireen[2], Shaheera Rahman[3]

[1]Head Of the Department, [2]Final Year PG, [3]Final Year PG, Department of Anaesthesiology, Deccan College Of Medical Sciences, Hyderabad, Telangana, India.

How to cite this article: Vijaya Rekha Koti, Syeda Saniya Shireen, Shaheera Rahman. Evaluation of Dexmedetomidine and Fentanyl as Additives to Ropivacaine for Epidural Anaesthesia and Post-Operative Analgesia in Lower Abdominal and Lower Limb Surgeries. Indian Journal of Public Health Research and Development 2023;14(2).

Abstract

Background: The regional anaesthesia has lot of benefits compared to general anaesthesia for lower abdominal and lower limb surgeries. Epidural anaesthesia is an ideal anesthetic technique for lower abdominal and lower limb surgeries. The additives are used with Anesthetics for Early onset of action, To prolong the duration of action, Analgesia and Improving the quality of block.

Aims and Objectives: The aim of this study was to study the clinical efficacy of Dexmedetomidine versus Fentanyl as an additive to Ropivacaine for lumbar epidural anaesthesia and post-operative analgesia.

Materials and Methods: This study is a prospective randomised controlled study involving 90 patients undergoing infraumbilical and lower limb surgeries who will be divided randomly into three groups Group R (n = 30): received 18 ml of 0.5% ropivacaine for epidural anaesthesia and 10 ml of 0.2% ropivacaine boluses for postoperative analgesia; Group RF (n = 30): received 18 ml of 0.5% ropivacaine with 25µg fentanyl for epidural anaesthesia and 10 ml of 0.2% ropivacaine with 10 µg fentanyl boluses for postoperative analgesia; and Group RD (n = 30): received 18 ml of 0.5% ropivacaine with 25 µg dexmedetomidine for epidural anaesthesia and 10 ml of 0.2% ropivacaine with 5 µg dexmedetomidine boluses for postoperative analgesia.

Results: Addition of additives have enhanced the onset of action, prolong duration of analgesia. Quality and duration of epidural anaesthesia provided by ropivacaine with dexmedetomidine is more effective than fentanyl. Better efficacy of analgesia evidenced with Dexmedetomidine than with Fentanyl.

Conclusion: It can be concluded that RD (Ropivacaine and Dexmedetomidine) when given epidurally can be a safe and effective combination for epidural blockade in lower abdominal and lower limb surgeries.

Key Words: Ropivacaine, Fentanyl, Dexmedetomidine, Epidural

Corresponding Author: Rana Tamkanth Khatoon, Senior Resident, Department of Anaesthesiology, Deccan College Of Medical Sciences, Hyderabad, Telangana, India.

Introduction

The regional anaesthesia has lot of benefits compared to general anaesthesia for lower abdominal and lower limb surgeries. Epidural anaesthesia and Intrathecal anaesthesia are currently most used and patient friendly regional anaesthetic techniques applied for lower abdominal and lower limb surgeries. Intrathecal anaesthesia has some limitation to it like, shorter duration of anaesthesia, therefore epidural anaesthesia is an ideal anesthetic technique for lower abdominal and lower limb surgeries. The additives like Opioids, Ketamine, Neostigmine, Midazolam, α 2 agonists (Clonidine and dexmedetomidine) are being with Local Anesthetics for Early onset of action, To prolong the duration of action, Analgesia and improving the quality of block. **Fentanyl,** is an opioid analgesic which when added to Ropivacaine in epidural, delivers better duration of analgesia and lesser systemic toxicity and central side effects. The addition of Opioids to local anesthetics has its own disadvantages like, pruritus and respiratory depression.[1] **Dexmedetomidine,** an Alpha-2 Adrenoreceptor agonist, acts on the spinal cord and has been used as an effective adjuvant to Ropivacaine for regional and central neuraxial blocks.[2] Different local anesthetics are used for epidural anaesthesia, most popular in India being Lidocaine and Bupivacaine. The drawback of lidocaine is its intermediate duration of action and the drawback of bupivacaine though long acting, is increased incidence of fatal cardiac toxicity after accidental intravascular injection, because of narrow cardiovascular collapse/central nervous system toxicity (cc/cms).[3] For this reason, there has been a search for alternative drugs with desirable blocking properties of bupivacaine but with a greater margin of safety. Ropivacaine and levobupivacaine are the newer long acting amide local anesthetics which have a wide margin of safety compared to bupivacaine, with all its advantages. Recently Ropivacaine has been introduced and since Ropivacaine has all the advantages of bupivacaine with less cardiac toxicity. It appears that it may be an ideal local anaesthetic for epidural anaesthesia.[4] Various studies have found, Ropivacaine to be an effective local anaesthetic for epidural anaesthesia, in their comparative pharmacokinetics of bupivacaine and ropivacaine have found that when applied directly to an isolated vagus nerve preparation, ropivacaine was less potent than bupivacaine in terms of conduction blocks of Aβ fibers, but ropivacaine blocked Aδ and C fibers to a greater extent than did bupivacaine. It is also been found that, lipid solubility of Ropivacaine is 2.9 compared with 3.9 of bupivacaine. Hence in our study ropivacaine was selected as the study drug. The fear of surgery, the strange surroundings of the operation theatre, the sight and sound of sophisticated equipment, dynamicity of an operation during regional anaesthesia and the masked faces of so many strange personal makes the patient panic to any extent. The intense sensory and motor block, continuous supine position for a prolonged duration and the inability to move the body during regional anaesthesia brings a feeling of discomfort and phobia in many of the patients. The high cephalic spread of analgesia with local anesthetics may be significant but still its quality sometimes may not correlate with the level of sensory analgesia. At this stage, the impulsive use of large doses of sedation or even general anaesthesia with mask, defeats the novel purpose of regional anaesthesia, whereby a continuous verbal contact with the patient is lost. Sedation, stable hemodynamics and an ability to provide smooth and prolonged post-operative analgesia are the main desirable qualities of an adjuvant in neuraxial anaesthesia. α-2 adrenergic agonists have both analgesic and sedative properties when used as an adjuvant in regional anaesthesia.

Dexmedetomidine is a highly selective α2 adrenergic agonist with an affinity of eight times greater than clonidine. Various studies have shown that the dose of clonidine is 1.5 – 2 times higher than dexmedetomidine when used in epidural route.[5]

The anesthetic and the analgesic requirement get reduced to a huge extent by the use of dexmedetomidine because of its analgesic properties and augmentation of local anesthetic effects as they cause hyperpolarization of nerve tissues by altering transmembrane potential and ion 4 conductance at locus coeruleus in the brainstem. The stable hemodynamics and the decreased oxygen demand due to enhanced sympathoadrenal stability make it a very useful pharmacologic agent. Hence a study was undertaken to compare dexmedetomidine and

fentanyl as additives to ropivacaine for epidural anaesthesia and post-operative analgesia in lower abdominal and lower limb surgeries.

Materials and Methods

Study Setting: The present study was conducted at Department of Anaesthesiology, Deccan College Of Medical Sciences, Hyderabad, Telangana, India.

Study Duration: 18 Months (January 2020 to July 2021)

Study Design: This was a prospective randomized control study.

Sample Size: A total of 90 patients were included in the study.

Inclusion Criteria:

1. Patients between ages 18 and 60yrs.
2. BMI <40
3. Patients with ASA Physical status 1 & 2
4. Elective lower abdominal and lower limb surgeries

Exclusion Criteria:

1. Patient not willing for regional anaesthesia.
2. Patient allergic to local anesthetics.
3. Patients with coagulation abnormality.
4. Emergency surgeries.
5. Difficulty airway, spine deformities.
6. Cutaneous infection on the back.
7. Full stomach and pregnant patients.
8. Patients with GERD.
9. Surgery involving prone position.

The patients were divided randomly into three groups Group R (n = 30): received 18 ml of 0.5% ropivacaine for epidural anaesthesia and 10 ml of 0.2% ropivacaine boluses for postoperative analgesia; Group RF (n = 30): received 18 ml of 0.5% ropivacaine with 25µg fentanyl for epidural anaesthesia and 10 ml of 0.2% ropivacaine with 10 µg fentanyl boluses for postoperative analgesia; and Group RD (n = 30): received 18 ml of 0.5% ropivacaine with 25 µg dexmedetomidine for epidural anaesthesia and 10 ml of 0.2% ropivacaine with 5 µg dexmedetomidine boluses for postoperative analgesia.

Statistical Analysis: Statistical analysis was performed using the statistical software IBM SPSS Version 22.0. The data was collected and compiled in Microsoft Excel. To analyze the data, descriptive statistics was used to draw the graphs and frequencies and percentages, and quantitative data was analyzed using One- way ANOVA test. Then qualitative data was analyzed using chi square test. If p- value is <0.05, it is considered statistically significant.

Observation and Results

Table No. 1: Onset Of Sensory Block In The Study Groups

	N	Mean	Std. Deviation	F value	p-value
Group R	30	5.67	1.322	22.804	0.001*
Group RF	30	4.80	.847		
Group RD	30	3.73	1.112		
Total	90	4.73	1.356		

Analysis of parameter **onset of sensory block** was analysed, and it shows that in **group R (Ropivacaine)** the mean value is **5.67 minutes,** and in **groupRF (Ropivacaine and Fentanyl)** the mean value is **4.80 minutes** and in **group RD (Ropivacaine and Dexmedetomidine)** the mean value is **3.73 minutes,** respectively. The output of One-way ANOVA analysis shows that there is a statistically significant difference in the onset of the sensory block i.e., the onset of sensory block was faster in the group RD, followed by group RF and group R, respectively (F value= 22.804; p-value= 0.001)**.**

Table No. 2: Onset Of Motor Block In The Study Groups

	N	Mean	Std. Deviation	F value	p-value
Group R	30	11.37	1.351	93.505	0.001*
Group RF	30	7.73	1.285		
Group RD	30	6.77	1.478		
Total	90	8.62	2.411		

Analysis of parameter **onset of motor block** was analysed, and it shows that in **group R (Ropivacaine)** the mean value is **11.37 minutes,** and in **group RF (Ropivacaine and Fentanyl)** the mean value is **7.73 minutes** and in **group RD (Ropivacaine and Dexmedetomidine)** the mean value is **6.77 minutes,** respectively. The output of One-way ANOVA analysis shows that there is a statistically significant difference in the onset of the motor block i.e., the onset of motor block was faster in the group RD, followed by group RFand group R, respectively (F value= 93.505; p-value= 0.001).

Table No. 3: Time For Complete Sensory And Motor Block In The Study Groups

	N	Mean	Std. Deviation	F value	p-value
SENSORY BLOCK					
Group R	30	15.53	1.776	154.484	0.001*
Group RF	30	11.13	1.306		
Group RD	30	8.93	1.311		
Total	90	11.87	3.124		
MOTOR BLOCK					
Group R	30	27.03	1.810	76.221	0.001*
Group RF	30	23.63	1.921		
Group RD	30	20.83	2.102		
Total	90	23.83	3.195		

Analysis of parameter **time for complete sensory block** was analysed, and it shows that in **group R (Ropivacaine)** the mean value is **15.53 minutes,** and in **group RF (Ropivacaine and Fentanyl)** the mean value is **11.13 minutes** and in **group RD (Ropivacaine and Dexmedetomidine)** the mean value is **8.93 minutes,** respectively. The output of One-way ANOVA analysis shows that there is a statistically significant difference in the time for complete sensory block between the study groups, respectively (F value=154.484; p-value=0.001). Analysis of parameter **time for complete motor block** was analysed, andit shows that in **group R (Ropivacaine)** the mean value is **27.03 minutes,** and in **group RF (Ropivacaine and Fentanyl)** the mean value is **23.63 minutes** and in **group RD (Ropivacaine and Dexmedetomidine)** the mean value is **20.83 minutes,** respectively. The output of One-way ANOVA analysis shows that there is a statistically significant difference in the time for complete motor block between the study groups, respectively (F value= 76.221; p- value= 0.001).

Table No. 4: Total Duration Of Analgesia In The Study Groups

	N	Mean	Std. Deviation	F value	p-value
Group R	30	180.38	37.36	43.276	0.001*
Group RF	30	200.17	25.94		
Group RD	30	218.83	40.68		

Analysis of parameter **time of first rescue analgesia** was analysed, and it shows that in **group R (Ropivacaine)** the mean value is **200.12 minutes,** and in **group RF (Ropivacaine and Fentanyl)** the mean value is **220.78 minutes** and in **group RD (Ropivacaine and Dexmedetomidine)** the mean value is **250.35 minutes,** respectively. The output of One-way ANOVA analysis shows that there is a statistically significant difference in the time of first rescue analgesia between the study groups, respectively (F value= 63.141; p-value=0.001).

Table No. 5: Maximum Sensory Levels Achieved In The Study Groups

	Group			Total	Chi-square	p-value
	R	RF	RD			
T10	4	3	0	7	28.864	0.001*
	13.3%	10.0%	0.0%	7.8%		
T8	19	16	5	40		
	63.3%	53.3%	16.7%	44.4%		
T6	7	11	20	38		
	23.3%	36.7%	66.7%	42.2%		
T4	0	0	5	5		
	0.0%	0.0%	16.7%	5.6%		
Total	30	30	30	90		
	100.0%	100.0%	100.0%	100.0%		

Analysis of the parameter, **Maximum sensory level** shows that in **group R (Ropivacaine), T8** showed maximum sensory level **(63.33%)** and in **group RF (Ropivacaine and Fentanyl) T8** showed maximum sensory **level (53.33%)** and in **group RD (Ropivacaine and Dexmedetomidine)**, **T6** showed maximum sensory level **(66.67%)**, respectively. The output of chi- square test shows that there is a statistically significant association between the study groups and the maximum sensory level (Chi- square= 28.864; p- value= 0.001)**.**

Discussion

Onset Of Sensory And Motor Blockade:

In our study, the mean time for onset of sensory block in Group R was 6.87 ± 0.68, In group RF was 5.93 ± 1.47 and in group RD was 3.65 ± 0.72. The mean time of motor block in Group R was 26.14 ± 4.71, group RF was 23.37 ± 2.58, group RD was 19.52± 2.51.

There was statistically significant difference with regard to onset of sensory and motor block.

Arindam Sarkar et al,[6] Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant due to early onset of sensory anesthesia, prolonged postoperative analgesia, and lower consumption of rescue analgesia.

Different trials have shown that multimodal analgesia through different techniques is associated with superior pain relief. Opioids as epidural adjunct to local anesthetics have been in use for long and α2

agonists are being increasingly used for same. The present study aims at comparing the hemodynamic, sedative, and analgesic effects of epidurally administered fentanyl and dexmedetomidine when combined with bupivacaine.

Casati et al.[7] in their study reported that patients receiving 0.5% Ropivacaine more frequently had an inadequate motor blockade during surgery than those receiving bupivacaine.

Amba paul et al,[8] dexmedetomidine as an adjuvant to epidural bupivacaine is a better alternative to fentanyl as it shows faster onset of sensory block, lesser time to attain maximum sensory level, prolonged duration of analgesia, and longer motor blockade with higher sedative property.

The sedative effect of dexmedetomidine is probably mediated by the activation of presynaptic α-2 adrenoreceptors in the locus coeruleus, leading to inhibition of release of norepinephrine, along with it, inhibition of adenylate cyclase may lead to hypnotic response.From the above studies, we conclude that group RD have faster onset of motor and sensory blockade.

We have seen that dexmedetomidine group had higher sedation scores which was supported by Salgado et al. who found that patients were more sedated with lower bispectral values in dexmedetomidine group

HIGHEST LEVEL OF SENSORY BLOCK:

In our study, patients of group R attained the following level of sensory block 23.33 % attained T6 level , 63.33% attained T8 level and 13.33% attained T10 level. In group RF 36.67 % attained T6 level followed by 53.33% attained T8 level and 10% attaining T10 level. In group RD 66.67% attained T6 level followed by 16.67% attaining T8 level.

Kaur S et al,[9] in their study has revealed that, Dexmedetomidine has augmented motor and sensory blockade, during epidural anesthesia with Ropivacaine and prolonged the post-operative analgesic effect.

From the above study highest level of sensory block was more in RD group than the other 2 groups.

TOTAL DURATION OF ANALGESIA:

In our study, the mean duration of analgesia in group R was 180.38±37.36, In group RF it was 200.17±25.94 and in group RD it was 218.83±40.68. There was statistically significant difference with regard to total durationof analgesia.

Meister *et al.*, in a randomized study involving 50 labouring women compared epidural analgesia with 0.125% ropivacaine versus 0.125% bupivacaine both combined with fentanyl during labour using a patient- controlled epidural analgesia technique, with settings of: 6-mL/hr basal rate, 5-mL bolus with 10-min lockout interval and 30-mL/hour dose limit. They found that Ropivacaine 0.125% with Fentanyl 2 microgram/mL produces similar labour analgesia with significantly less motor block than an equivalent concentration of Bupivacaine/Fentanyl.[10]

Berti *et al.*, (2000) in a Prospective, randomized, double-blind study involving 32 patients evaluated the effects of addition of low dose Fentanyl (2 microgram/ml) to either 0.2% Ropivacaine or 0.125% Bupivacaine on postoperative analgesia through PCA pumps after major abdominal surgery. They used a basal epidural infusion of 4ml/hour with incremental dose of 1.5ml and 20 minutes lockout interval. They found no differences in pain relief, motor block, degree of sedation and recovery of gastrointestinal motility between the two groups. However, they reported the request for incremental doses and more analgesic solution consumption in patients receiving Ropivacaine alone than patients receiving the Ropivacaine/ Fentanyl mixture and also a significant decrease in peripheral SpO2, lasting up to 48 hours after surgery in the latter group. They concluded that 0.2% Ropivacaine with or without Fentanyl provided adequate pain relief in most patients with a very low degree of motor blockade and adding 2 microgram/ml Fentanyl to 0.2% Ropivacaine reduced total consumption of local anesthetic and also need for incremental doses. But there were no clinically relevant advantages in quality of pain relief and incidence of motor block with addition of Fentanyl.[11]

Rabie Soliman et al,[12] Epidural analgesia is a common method for the management of postoperative pain after total knee replacement. The

aim of the study was to compare the postoperative analgesic effect of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in adult patients undergoing total knee replacement. Dexmedetomidine is an ideal adjuvant to epidural bupivacaine for postoperative analgesia compared to fentanyl in patients undergoing total knee replacement. It provides a better postoperative analgesia and reduces the postoperative narcotics requirements and complication such as nausea and vomiting, pruritis, urinary retention, and respiratory depression compared to fentanyl.

Conclusion

It can be concluded that RD (Ropivacaine and Dexmedetomidine) when given epidurally can be a safe and effective combination for epidural blockade in lower abdominal and lower limb surgeries.

Ethical Clearance: Ethical clearance was obtained from Institutional Ethical Committee.

Source Of Fnding: None

Conflict Of Interest: No Conflict of interest.

References

1. Smet I, Vlaminck E, Vercauteran M. Randomized controlled trial of patient controlled epidural analgesia after orthopedic surgery with sufentanyl and ropivacaine 0.165% or levobupivacaine 0.125%. Br J Anaesth 2008;100: 99-103.
2. Paranjpe SJ. Dexmedetomidine : Expanding role in anesthesia. Med J DY Patil Univ 2013;6:5-11.
3. Gudin MA, López R, Estrada J, Ortigosa E (2011-11-28). "Neuraxial Blockade: Subarachnoid Anesthesia". Essentials of Regional Anesthesia. New York, NY: Springer New York. pp. 261–291. doi:10.1007/978-1-4614-1013-3_11. ISBN 978-1-4614-1012-6.
4. Marhofer D, Kettner S.C, Marhofer P, Pils S, Weber M, Zeitlinger M; Dexmedetomidine as an adjuvant to ropivacaine prolongs peripheral nerve block: a volunteer study. Br J Anaesth. 2013 Mar; 110(3):438-42.
5. Al-Ghanem SM, Massad IM, Al-Mustafa MM, Al-Zaben KR, Qudaisat IY, Qatawneh AM, Abu-Ali HM. Effect of Adding Dexmedetomidine versus Fentanyl to Intrathecal Bupivacaine on Spinal Block Characteristics in Gynecological Procedures: A Double Blind Controlled Study. Am J Appl Sci. 2009;6:882–7. [Google Scholar]
6. Sarkar. A, Bafila N. S, Singh R. B., Rasheed M. A, Choubey S, Arora , Comparison of Epidural Bupivacaine and Dexmedetomidine with Bupivacaine and Fentanyl for Postoperative Pain Relief in Lower Limb Orthopedic Surgery. Anesthesia, essays and researches, 2018,12(2), 572–580.
7. Casati A, Putzu M. Bupivacaine, levobupivacaine and Ropivacaine: are they clinically different? Best Practice and Research Clinical Anaesthe siology 2005; 19:247-68.
8. Paul Arnab, Nathroy Aparajita, Paul Thakurdas: A comparative study of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine in lower limb surgeries. Paul Arnab, Nathroy Aparajita, Paul Thakurdas.2017;37(6):221-22.
9. Kaur S, Attri J.P, Kaur G, Singh T.P; Comparative evaluation of ropivacaine versus dexmedetomidine and ropivacaine in epidural anesthesia in lower limb orthopedic surgeries Saudi J Anaesth.2014 Oct; 8(4):463-9.
10. Meister, Greg C, D' Angelo R, Owen M, Nelson K E, Gaver R. A comparison of epidural analgesia with 0.125% Ropivacaine with Fentanyl versus 0. 125% Bupivacaine with Fentanyl during labor. Anesth Analg 2000; Vol 90: issue 3-p 632-37.
11. Berti M, Fanelli G, Casati A, et al. Patient supplemented epidural analgesia after major abdominal surgery with bupivacaine/fentanyl or ropivacaine/ fentanyl. CanJ Anaesth 2000; 47: 27-32.
12. Soliman R and Eltaweel M. Comparative study of dexmedetomidine and fentanyl as an adjuvant to epidural bupivacaine for postoperative pain relief in adult patients undergoing total knee replacement: a randomized study. J Anesthesia Clin Sci. 2016; 5:1.