A Comparative Study of Anaesthetic Efficacy of 0.75% Ropivacaine and 0.75% Ropivacaine with Dexmedetomidine in Epidural Anaesthesia for **Inguinal Hernia Repair**

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Abstract

Introduction: Ropivacaine is nowadays replacing bupivacaine as the drug of choice in epidural anesthesia It has a high therapeutic index in a study conducted in humans it is less neurotoxic and cardiotoxic than bupivacaine. One among the disadvantage in adding opioids is respiratory depression. To overcome this many studies emphasized adding clonidine with the local anesthetic drugas epidural anesthesia. This provides a marked reduction in the need for using hypnotics, inhaled opioids analgesics for treating postoperative pain. Aim of the Study: The clinical characteristics of epidural anesthesia performed with 0.75% repivacaine and to evaluate the synergistic effect between dexmedetomidine and 0.75% ropivacaine in epidural anesthesia. Materials and Methods: After approval of the study by our institutional ethics committee, the study was conducted on 50 patients of both sexes, aged between 25 to 55 years and physical status according to the American Society of Anesthesiologists (ASA) Ior II, undergoin gelective inguinal hernia repair surgeries. Lumbar epidural anesthesia was performed to all the patients. Weight was ranging from 55-70 kg and height ranging from 150-172 cm. Group I: (n = 25): Patients received 1 ml of 0.9% normal saline + 19 ml of 0.75% hyperbaric ropivacaine. Group II: (n = 25): Patients received dexmedetomidine 1 μ g /Kg + 0.9% normal saline so that total volume was completed to 1 ml + 0.75% hyperbaric ropivacaine 19 ml was given. Results: The mean time required for the onset of sensory block Group -R 9.0800, Group-R Dex 8.0900 in both groups was not statistically significant. Group RDex achieved complete motor blockade (Bromage scale) much earlier than group R 22.8400 and Group-R Dex 19.0000 there was statistically significant difference noticed in between these two groups ('p' value < 0.05). Out of 25 patients, there are 2 in group-R and group-R Dex 5 had bradycardia with the heart rate of <55 beats /minute and it as treated with 0.3 mg of atropine. The sedation score between R and R Dex groups reveals a statistically significant difference (P<0.001). The side effects in both the groups were comparable; no statistical difference was noticed between the group-R and RDex. Conclusion: Present study obviously reveals that an apparent synergism between the two drugs namely dexmedetomidine and ropivacaine without any additional morbidity, which has been proved statistically significant using quantitative and qualitative analysis.

Keywords: Ropivacaine; Dexmedetomidine; Heart Rate; Blood Pressure.

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Introduction

Epidural anesthesia is one of the central neuraxial blocks as well as versatile anesthetic technique, with many applications. Corning was the first man who described the epidural space in 1901 followed by epidural anesthesia was first used by Fidel Pages inhuman in the year 1921 and the in

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1945 epidural needle was introduced by Tuohy, it is stillnow most commonly used needle for epidural anesthesia [1]. Epidural anesthesia became popular by the improvements in equipment; drugs. It has got many applications in various surgeries like obstetrics and pain control. It can be used as either a single injection technique or catheter technique [2]. This can be used as an anesthetic, as an analgesic adjuvant to general anesthesia, and it can be used for postoperative analgesia procedures involving thorax, abdomen, pelvis, perineum and lower limbs [3]. It also improves the postoperative outcome and attenuates the physiologic response to surgery, in particular, a significant reduction in pulmonary infections, pulmonary embolism, ileus, acute renal failure, and blood loss. Ropivacaine is nowadays replacing bupivacaine as the drug of choice in epidural anesthesia. It shows the high therapeutic index in humans. It is less neurotoxic and cardiotoxic than bupivacaine. Various drugs like a adrenergic agonists, opioid, ketamine, midazolam, magnesium sulfate, adrenaline have been added along with local anesthetics in epidural anesthesia to improve the duration and quality of analgesia [4]. One among the disadvantage in adding opioids is respiratory depression. To overcome this many studies emphasized adding clonidine with the localanesthetic drug as epidural anesthesia [5]. This provides a marked reduction in the need for using hypnotics, inhaled opioids analgesics for treating postoperative pain. In animal models, studies were conducted using clonidine, dexmedetomidine as adjuvant drugs in epidural anesthesia to prolong its effect thereby reducing the need for opioids [6]. In humans, in the year 1997, the dexmedetomidine was administered epidurally by adding with lignocaine 1.5% in patients undergoing hysterectomy, to prolong the postoperative analgesia. Compared with clonidine, dexmedetomidine is an α_3 -adrenergic agonist with high selectivity ratio between α_2 and $\alpha 1$ (1620:1), seven to ten times more selective for α_2 receptor and has got the shorter duration of action [7]. Because its sedative, analgesic and sympatholytic activity it is being used widely in critical care. There have been only fewer studies in the perioperative effect of epidural dexmedetomidine [8].

Materials and Methods

A randomized double-blind controlled study was conducted in 50 patients undergoing inguinal hernia surgeries in KAPV Govt medical college hospital. After getting institutional ethical committee approval, the procedure was explained

to the patients in detail. Informed valid consent was obtained from all patients who are included in the study and they randomly allocated into two groups, 25 in each group. Group R (n=25) = patients receiving 0.75% Ropivacaine (hyperbaric) 19 ml +1 ml of 0.9% normal saline. Group RDex (n=25)= patients receiving Dexmedetomidine 1 μ g/kg +0.9% of normal saline so that total volume was completed to 1 ml along with 0.75% Ropivacaine (hyperbaric) 19 ml.

Selection Criteria: Patient selected for the study are male gender between the age group of 25 -55 years with ASA I and ASA II physical status scheduled for elective inguinal hernia repair under epidural anesthesia.

Inclusion Criteria:

- 1. ASA grade I & II status
- 2. Male gender
- 3. 25 -55 years of age
- 4. Patients giving informed written consent.
- 5. Patients scheduled to undergo elective inguinal hernia repair under epidural anesthesia.

Exclusion Criteria

- 1. ASA III or greater
- 2. Age more than 55 years, and less than 25 years
- 3. Patients with known h/o allergy to local anesthetic drugs
- 4. Uncooperative patients with hypotension, previous spinal surgeries, spine abnormalities, local site infection and coagulation abnormalities
- Poorly controlled hypertension, angina, cardiopulmonary disease
- 6. Patients with hematological disease, neurologic, psychiatric disease, severe renal or hepatic derangement
- 7. Patients taking tricyclic antidepressants, any antipsychotic drugs, alpha-2 adrenergic agonists, opioids, anti-arrhythmic, beta blockers, and anticoagulants.

Procedure

In the operation theatre a good intravenous line secured with 18 G cannula to administer Ringer's lactate, 8 ml/Kg/hr as a preloading solution. Baseline pulse rates, blood pressure, ${\rm SpO}_2$, ECG

were recorded. The patient was placed in the Rt lateral position. Under aseptic precaution skin over L3-L4 space infiltrated with 2 ml of 2% lignocaine. 17G Tuohy needle was introduced at L3-L4 interspace through the midline approach, entry of the needle into epidural space is confirmed using the loss of resistance technique. After negative aspiration for blood and CSF, 3 ml of 2% lignocaine with adrenaline 1 in 200000 dilutions was given into epidural space as a test dose. After 5-7 minutes of observation for effects of intravascular or intrathecal injection (like change in pulse rate, unable to dorsiflex great toe), Group-R received 20 mL of 0.75% ropivacaine, whereas Group-Rdex received 20 mL of 0.75% ropivacaine and dexmedetomidine 1 μg/ kg epidurally at a rate of 1 ml per 3 second. Time of administration of the drug is noted.

Results

Table 1: Showing Demographic Profile of Patients in Both Groups

Patient's Profile	Group-R (Mean± SD)	Group-R Dex (Mean±SD)	p value > 0.05 Not Significant
Age in years (25-55)	42.76±9.85	39.32±9.11	0.155
Weight in Kg (50-70)	58.46±5.25	61.24±6.83	0.21
Height in Cm (156 -172)	160.36±7.27	158.28±6.64	0.303

The 50 patients were involved in this study, and they randomly allocated into two groups namely R & RDex consisting of 25 patients in each group. The demographic profile regarding age, height, and weight were comparable in both R and RDex groups and did not show any significant statistical difference (Table 1).

Table 2: Showing Onset of Sensory Block of Patients (in min.)

The onset of sensory block (min.)at T 10	Group-R	Group-RDex
Mean	9.0800	8.0900
S.D	0.75939	0.65940
'p'	0.1000 Not Significant	

The mean time required for the onset of sensory block Group -R 9.0800, Group-RDex 8.0900 in both groups was not statistically significant. Group RDex achieved complete motor blockade (Bromage scale) much earlier than group R 22.8400 and Group-RDex 19.0000 there was statistically

significant difference noticed in between these two groups ('p' value < 0.05) (Table 2).

Table 3: Showing time Taken for Complete Motor Block (in min.)

The onset of motor block (min.)	Group-R	Group-RDex
Mean	22.8400	19.0000
S.D	3.77200	3.93649
'p'	0.033 Significant	

Group RDex achieved complete motor blockade (Bromage scale) much earlier than group R 22.8400 and Group-RDex 19.0000 there was statistically significant difference noticed in between these two groups ('p' value < 0.05) (Table 3).

Table 4: Showing the Duration of Sensory Block (in hrs.)

Duration of sensory (hrs.)	Group-R	Group-RDex
Mean	2.7600	6.8400
S.D	0.43589	0.68799
'p'	0.001 Significant	

Meantime of postoperative analgesia in group-RDex (6.8400) was significantly higher than group-R (2.7600) and statistically significant ('p' value < 0.05) (Table 4).

Table 5: Showing the Pulse Rate of Patients in Both the Groups

S1. No.	Pulse	Group-R Mean± SD	Group-RDex Mean± SD	ʻp' value
1.	0 min	83.8400±11.01393	81.1600±10.14347	0.375
2.	2 mins.	83.9600±9.91833	78.6400±9.66902	0.061
3.	5 mins. 80.4000±8.13941		75.9600±10.54546	0.102
4.	10 mins.	78.2400±8.23752	73.6000±9.03696	0.064
5.	15 mins.	78.5200±9.38580	71.0400±8.61916	0.117
6.	30 mins.	78.7600±8.30803	70.8800±9.36447	0.145
7.	60 mins.	78.0400±8.56582	72.2000±9.74679	0.059
8.	120 mins.	78.3200±8.59612	72.8800±9.66230	0.061
9.	180 mins.	78.2400±9.12086	75.1600±9.58158	0.250

Pulse rate variables in both the groups were comparable in both the groups. After the 15th minute in RDex group, there was a slight fall in pulse rate but it was not statistically significant. This can be possible due to the effect of dexmedetomidine. The decrease in the heart rate remained up to 2 hours. The heart rate remained stable without any fluctuation in either of the groups which is statistically not significant (P> 0.05). Out of 25 patients, there are 2 in group-R and group-RDex 5 had bradycardia with the heart rate of <55 beats /minute and it as treated with 0.3 mg of atropine (Table 5).

Table 6: Showing Sedation Score of Patients in both the Groups

Sedation	Gro	Group-R		Group-RDex	
score	n	0/0	n	%	
0	16	64.0	1	4	
1	6	24.0	7	28	
2	2	8	13	52.0	
3	1	4	3	12.0	
4	0	0	1	4	
5	0	0	0	0	
Total	25	100	25	100	
Mean	1.4	1800	3.4	1800	
SD	0.5	0222	0.4	0490	
'p'		0.001 Sig	nificant		

It reveals a statistically significant difference (p<0.001). The side effects in both the groups were comparable; no statistical difference was noticed between the group-R and RDex (Table 6).

Table 7: Showing the two Segment Regression time (in min.)

Two segment regression time (min.)	Group-R	Group-RDex
Mean	118.2800	167.0000
SD	5.36594	43.62912
'p'	0.001 Significant	

IT reveals that the two regression time was prolonged in group-RDex than group-R, statistically significant difference was noticed ('p' value < 0.05) (Table 7).

Discussion

this study, the hypothesis dexmedetomidine enhances the clinical effects of the ropivacaine on epidural administration without altering the hemodynamics was evaluated [9]. According to the results obtained from the present study, there is a definite synergistic interaction between ropivacaine and dexmedetomidine drugs [10]. Many studies have been published in national and international journals regarding the use of any local anesthetics along with dexmedetomidine for epidural anesthesia in humans by analyzing the time of onset of the epidural block and its duration [11]. In the present study, it was observed that there was no significant difference between the ropivacaine group (R) as control and ropivacaine plus dexmedetomidine (RDex) as a study group. Results obtained from our study regarding onset of sensory block in dermatomes T10, T12 and T8 are closely correlated with the study made by Li X, Eisenach et al. by administering clonidine 150 mg or dexmedetomidine 100 µg with 1% ropivacaine and they also found that there was no significance in the onset of sensory block using the above drugs in their study [12]. The administration of dexmedetomidine with ropivacaine also increases the duration of sensory block in dermatome T10 and T12 significantly. In addition, a significant increase in the duration of sensory block was noticed in our study by adding dexmedetomidine 1 microgram per kg along with 0.75% of ropivacaine [13]. Our study is also supported by Silva et al., 2002. He also found that the postoperative analgesia was increased when adding dexmedetomidine 2 µg/Kg with 0.5% bupivacaine for epidural anesthesia in patients undergoing a hysterectomy. Our results regarding the onset of sensory block and duration of the sensory block are similar with reports made by Hogue CW et al. They studied the synergistic effect of dexmedetomidine 1 µg /Kg with 0.75% ropivacaine in orthopedic surgeries [14]. In our study, the maximum level of sensory blockade was comparable and it was T4 in both groups. There was no statistical difference observed. This finding correlates with the study of Fukushima Ket al (1995) [15]. In their study, 20 ml volume of 0.75% ropivacaine and 0.5% bupivacaine were used for epidural anesthesia and it was found that the maximum cephalad spread was T4. In this study, the assessment of motor blockade was performed before surgery using modified Bromage scale and the time to achieve complete motor blockade was significantly earlier in the (19.0±3.94) patients who have received dexmedetomidine (group-RDex) as compared to group-R (22.84±3.78). (p=0.033), this finding correlates with the results of the study by which evaluate effects of adding dexmedetomidine (1 μg/Kg) with 0.75% ropivacaine (15 ml) (RD- group) comparing with that of 0.75% ropivacaine with fentanyl 1 μg/kg (RF) in epidural anesthesia in lower limb orthopedic surgeries. In that study time to complete motor blockade is much [16]. In our study, hemodynamic parameters were comparable between both groups during the intraoperative and postoperative period. In RDex group a fall in pulse rate was observed comparatively. But there was no significant intergroup variation. Likewise, fall in systolic blood pressure noticed in RDex group but it was not below the level of the baseline and did not require any active treatment. Diastolic pressure was stable and it was stable and comparable between both groups without any statistically significant difference [17]. Kalso EA, et al. studied the synergistic effect of dexmedetomidine with ropivacaine without any morbidity and hemodynamic instability due to drug association [18]. The intensity of

bradycardia and fall in blood pressure after the epidural administration of dexmedetomidine is dependenton the dose, as well as the spinal level where the drug¹ is injected. Thus, higher doses and the thoracic level administration may increase the occurrence of these hemodynamic events. [19] Douglas AG, et al. studied the highest incidence of bradycardia in patients receiving dexmedetomidine in higher dosage like 2 μ g/Kg [20].

Conclusion

We conclude that ropivacaine 0.75% with dexmedetomidine $1~\mu g$ /Kg in epidural anesthesia has good anesthetic efficacy, increases the duration of postoperative analgesia without significant variation in hemodynamic or any additional morbidity; when compared to plain ropivacaine 0.75%.

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