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Original Research Article

A prospective, randomised double blinded comparative study of epidural ropivacaine with fentanyl and ropivacaine with dexmedetomidine in lower limb orthopaedic surgeries in epidural anaesthesia

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ABSTRACT

Background: Opioids as epidural adjuvants have been used with local anaesthetics since long and now, α-2 agonists are being used for same purpose. Current study aims to compare the effects of ropivacaine combined with dexmedetomidine versus ropivacaine combined with fentanyl in patients undergoing lower limb orthopaedic surgeries.
Methods: Total of 90 American society of anaesthesiologists (ASA) I, ASA II patients scheduled to undergo lower limb orthopaedic surgeries under epidural anaesthesia were randomly divided into 2 groups. Group RF (n=45) received 20 ml of 0.75% ropivacaine with 1 µg/kg fentanyl and group ropivacaine with dexmedetomidine RD (n=45) received 20 ml of 0.75% ropivacaine with 1µg/kg dexmedetomidine as adjuvants. Onset of action, duration of analgesia, adverse effects and hemodynamic were monitored.
Results: Results show that age, sex, ASA grade did not differ significantly between two groups. Mean duration of sensory block (426.6 vs 520.43 mins; $p<0.01$), motor block (412.0 vs 503.37 mins; $p<0.01$) and analgesia (451.43 vs 552.93 mins; $p<0.01$) was significantly faster in RD group. No difference was observed between the study groups in hemodynamic parameters during and after the procedure. Incidence of nausea was significantly higher in RF group (15.6% vs 0%).
Conclusions: Administration of dexmedetomidine as adjuvant in epidural anaesthesia for orthopaedic surgical procedures reduces the onset time of sensory, motor block and extends duration of analgesia. Sedation with dexmedetomidine found superior to fentanyl in terms of efficacy, with lower incidence of adverse effects and greater effectiveness as a pre-emptive analgesic.

Keywords: Epidural anaesthesia, Ropivacine, Analgesia, Dexmedetomidine, Fentanyl

INTRODUCTION

Epidural anaesthesia stands as the predominant technique for providing not only peri-operative surgical anaesthesia but also post-operative analgesia in lower abdominal and limb surgeries.[1] The duration of action of ropivacaine can be extended through the addition of an additive. Several medications have been experimented as an additive with the local anaesthetics like opioids, α2-agonists, midazolam, ketamine, neostigmine, gabapentin, tramadol, adenosine etc., with various outcomes. Opioids, like fentanyl have been used frequently as an adjunct for epidural administration in combination with a lower dose of local aesthetic to attain the desired aesthetic effect.[2] The addition of opioid does offer a dose-sparing effect of local aesthetic and superior analgesia, but there is always a possibility of an increased incidence of pruritus, urinary retention, nausea, vomiting and respiratory depression.[3]

Dexmedetomidine represents a novel member of the alpha-2 agonist class, possessing a multitude of beneficial effects when administered via epidural route.[4] It effects on both pre-synaptic and post-synaptic sympathetic nerve terminal sites, as well as the central nervous system. This action results in a reduction of sympathetic outflow and nor-epinephrine release, thereby leading to sedation, anti-anxiety, analgesic, sympatholytic and hemodynamic effects.[5] Dexmedetomidine is known to cause a manageable hypotension and bradycardia but the striking feature of this drug is the lack of opioid-related side effects like respiratory depression, pruritus, nausea, and vomiting.[6]

Present study aims to compare the effectiveness of fentanyl and dexmedetomidine for epidural anaesthesia during lower limb orthopaedic surgeries in terms of side effects, duration of analgesia, maximum dermal level and time to onset of sensory and motor blocks.

METHODS

Study design

It was a prospective, randomized, double blinded, comparative controlled study.

Study sample

This prospective study included 90 ASA grade I and II patients, regardless of sex, between the ages 20 to 45 years who were having lower limb orthopaedic surgeries under epidural anaesthesia. The computerized randomized table was used to randomly assign 45 patients of any sex to the RF or ropivacaine with dexmedetomidine (Group RD) groups.

Inclusion criteria

The study includes ASA grade I and II patients without any co-morbidities, between 20 to 45 years of age and scheduled for lower limb orthopaedic surgeries were included.

Exclusion criteria

The study excludes patients with co-morbidities like uncontrolled diabetes mellitus, asthma, hypertension, cardiac disease, haematological disease, allergy to local anaesthetics, ASA class III, IV and V and with a body mass index exceeding 28 kg/m^2. Additionally, individuals with absolute contraindications to epidural anaesthesia, such as elevated intracranial pressure, bleeding diathesis and local infection are also excluded.

Study site

The current study is a single-centre, hospital-based investigation conducted from September 2020 to May 2021 in the department of anaesthesia, Yashoda hospital, Secunderabad, which is accredited by NABH and NABL.

Upon receiving approval from the institutional ethical committee, the entire procedure was thoroughly explained to the patients and informed written consent was taken. A thorough preoperative assessment was done for each patient prior to the procedure. Patients were kept nil per oral for solids 6hrs and for clear fluids 2 hrs before surgery. Intravenous line was obtained with 18G cannula and was preloaded with ringer lactate 500 ml (10 ml/kg body weight) half an hour before anaesthesia. Patients were connected to multi-channel monitor for monitoring pulse rate (PR), oxygen saturation (SpO_2), electrocardiograph (ECG), non-invasive blood pressure (NIBP) and mean arterial pressure (MAP). Patient positioned in sitting position. Under aseptic precautions; skin infiltration with 2ml of 2% lignocaine; epidural space is identified at L2-L3 space by loss of resistance to air technique; 18 G Tuohy's needle inserted and catheter is fixed at 4 cm in the epidural space. Test dose of 3ml of 2%lignocaine HCL with adrenaline 1:200,000 was injected, followed by total volume of 20 ml of either of the study drug was injected through the epidural catheter. Continuous measurement of the hemodynamic parameters for every 5 min in first one hour and every 10 min for second hour and for every 30 minutes till 12 hours were assessed.

Statistical analysis

The statistical analysis was performed by using IBM SPSS V21. Mean±SD was used to present the quantitative data, Mann-Whitney test was used if the data failed the "normality test," and the unpaired t test was used if the data passed. Number (%) was used to present the results of categorical measurements. Fisher's exact test and the Chi-square test with continuity correction were used to evaluate the associations between the qualitative variables in all two-by-two tables. A $p<0.05$ was considered statistically significant.

RESULTS

Table 1 shows that, the current study group's mean age distribution was 37.26 years and there was no significant difference between the study groups (p=0.08). Out of the total 90 cases, 54.4% were females while 45.6% were males with no significant difference between two study groups (p=1.0). Table 1 results also explained that, a total of 73.3% cases were in ASA grade I while 26.7% were in ASA grade II with no significant difference between the study groups (p=1.0). Bradycardia and arterial punctures were reported in 4.4% of the RD group while they were reported in 0% of the RF group. Adverse events like nausea and vomiting were noted in 0% and 1% of patients in RD group whereas in RF group it was 7% and 0%. There were no adverse events in 89% and 84.4% of RD and RF groups. These values in these groups do not significantly differ from one another.

Table 2 explains that mean onset of sensory block (3.63 v/s 4.67 mins; p<0.01) and time to attain complete sensory block (19.6 mins v/s 22.7; p<0.01) was significantly faster in RD group as compared to RF group. Also, total duration of sensory block was significantly greater in cases of dexmedetomidine group (520.43 v/s 426.6 mins; p<0.01). Similarly mean onset of motor block (5.23 v/s 6.43 mins; p<0.01) and time to attain complete motor block (23.03 v/s 25.77 mins; p<0.01) significantly faster in RD group as compared to RF group. Also, total duration of motor block was significantly greater in cases of RD group (503.37 v/s 412.0 mins; p<0.01). Mean duration of analgesia was significantly longer in cases of dexmedetomidine group as compared to RF group (552.93 v/s 451.43 mins; p<0.01).

Table 3 shows that T6 was the maximum level for dermatomal spread (86.7%) in the RD group, which is statistically significant when compared to T5, T8 and T10 (p<0.01). In contrast, T8 was the maximum level for dermal spread in the majority of cases (77.8%) in the RF group, as opposed to T6, T5 and T10 levels which shows a statistically significant difference (p<0.01).

Table 4 explains that the mean heart rate (MHR) at baseline and during procedure was comparable between fentanyl and dexmedetomidine groups (p>0.05). Results also shows that, the mean systolic blood pressure (SBP) was also comparable without any significant difference between fentanyl and dexmedetomidine groups (p>0.05).

Table 5 explains that the mean diastolic pressure at baseline and during procedure was found to be equivalent across the two groups (RD and RF) with no significant difference (p>0.05). Similarly results also explains that the MAP was also comparable with no significant difference among these two groups (p>0.05).

Table 1: Age, gender and ASA grade, adverse reactions comparison among study groups.

Characteristics	Group		Total	P value
	RF	RD		
Age (Mean ±SD) (years)	39.30±12.91	35.27±9.18	90	0.08
Gender	**N (%)**	**N (%)**	**N (%)**	
Female	21 (46.7)	20 (44.4)	41 (45.6)	1.0
Male	24 (53.3)	25 (55.6)	49 (54.4)	
Total	45 (100.0)	45 (100.0)	90 (100.0)	
ASA grade				
Grade 1	29 (64.4)	37 (82.2)	66 (73.3)	0.094
Grade 2	16 (35.6)	8 (17.8)	24 (26.7)	
Total	45 (100.0)	45 (100.0)	90 (100.0)	
Adverse events				
Arterial puncture	0 (0.0)	2 (4.4)	2 (2.2)	0.135
Bradycardia	0 (0.0)	2 (4.4)	2 (2.2)	
Nausea	7 (15.6)	0 (0.0)	7 (7.8)	
Vomiting	0 (0.0)	1 (2.2)	1 (1.1)	
None	38 (84.4)	40 (89.0)	78 (86.7)	
Total	45 (100.0)	45 (100.0)	90 (100.0)	

Table 2: Comparison of sensory block, motor block and duration of analgesia among study groups.

Parameters	Group	N	Mean±SD	P value
Sensory block				
Time of onset (mins)	RF	45	4.67±0.55	<0.01
	RD	45	3.63±0.56	
Time to attain complete sensory block (mins)	RF	45	22.70±0.79	<0.01
	RD	45	19.60±1.22	
Total duration (mins)	RF	45	426.60±17.40	<0.01
	RD	45	520.43±16.31	
Motor block				
Time of onset (mins)	RF	45	6.43±0.73	<0.01
	RD	45	5.23±0.77	
Time to attain complete motor block (mins)	RF	45	25.77±1.01	<0.01
	RD	45	23.03±4.12	
Total duration (mins)	RF	45	412.00±17.15	<0.01
	RD	45	503.37±16.87	

Continued.

Parameters	Group	N	Mean±SD	P value
Analgesia				
Time for first rescue analgesia (mins)	RF	45	451.43±23.50	<0.01
	RD	45	552.93±28.69	
Number of rescue analgesia in 12 hours (mins)	RF	45	1±0.00	NA
	RD	45	1±0.00	

Table 3: Maximum dermatomal level reached among study cases.

Max dermatomal spread	Group N (%)		Total (%)
	RF	RD	
T5	0 (0.0)	2 (4.4)	2 (2.2)
T6	5 (11.1)	39 (86.7)	44 (48.9)
T8	35 (77.8)	4 (8.9)	39 (43.3)
T10	5 (11.1)	0 (0.0)	5 (5.6)
Total	45 (100.0)	45 (100.0)	90 (100.0)

P value<0.01.

Table 4: Comparison of changes in heart rate and SBP among study groups.

Time (Mins)	Heart rate		P value	SBP		P value
	Group RF, mean±SD	Group RD, mean±SD		Group RF, mean ±SD	Group RD, mean ±SD	
Base line	83.43±6.27	82.20±7.46	0.183	123.73±8.31	120.63±7.45	0.317
5	82.70±6.41	81.53±7.21	0.384	124.13±8.59	120.43±7.64	0.226
10	81.93±6.81	81.40±7.18	0.658	124.13±8.19	120.90±7.62	0.314
15	81.20±6.44	79.37±6.33	0.425	124.63±8.98	120.33±7.32	0.13
20	80.13±6.02	79.53±5.76	0.675	124.33±9.14	120.97±5.69	0.151
25	80.17±6.25	79.20±5.44	0.587	123.27±9.33	121.67±6.87	0.713
30	81.83±6.98	78.97±6.04	0.239	124.03±8.56	122.23±8.03	0.574
45	81.30±7.41	78.20±5.54	0.219	124.40±7.68	122.33±7.51	0.6
60	80.30±6.89	78.30±5.21	0.359	124.47±8.45	121.50±6.87	0.225
90	79.67±6.55	77.87±5.46	0.498	124.23±7.65	120.50±5.96	0.065
120	78.97±6.22	78.13±5.14	0.852	124.27±8.55	120.37±6.85	0.117
150	78.30±6.84	78.83±6.01	0.891	123.13±8.33	120.90±6.22	0.436
180	78.47±6.93	79.10±5.81	0.852	123.00±7.81	120.70±7.71	0.503
210	78.83±6.82	79.47±5.60	0.927	123.07±7.25	119.03±7.05	0.067
240	78.37±6.32	79.23±5.91	0.857	123.77±7.87	119.33±6.95	0.052
270	77.87±6.37	79.87±6.94	0.463	123.47±7.51	120.97±7.25	0.39
300	77.73±5.85	79.83±6.95	0.232	122.37±7.70	120.97±7.15	0.541
360	79.33±6.29	80.63±6.40	0.748	121.47±7.65	120.97±7.65	0.691
420	80.03±6.32	81.17±6.44	0.714	121.93±7.84	120.27±6.93	0.535
480	81.17±7.53	80.50±6.17	0.897	122.23±6.73	120.93±5.98	0.307
540	80.53±7.06	81.30±6.78	0.767	123.53±8.14	120.13±6.64	0.169
600	80.80±7.53	82.33±6.24	0.467	123.90±7.07	120.07±7.64	0.102
660	81.80±7.85	83.00±5.87	0.686	123.63±8.12	120.27±7.05	0.219
720	81.17±6.43	81.83±6.13	0.42	123.63±7.37	119.87±4.88	0.09

Table 5: Comparison of changes in diastolic pressure and arterial pressure among study groups.

Time (Mins)	Diastolic pressure		P value	Arterial pressure		P value
	Group RF, mean±SD	Group RD, mean±SD		Group RF, mean±SD	Group RD, mean ±SD	
Base line	74.50±7.38	71.70±4.26	0.195	89.53±8.19	86.97±4.86	0.347
5	74.87±7.16	71.50±4.87	0.104	89.97±7.23	86.67±5.59	0.142
10	73.57±7.40	71.30±4.76	0.279	89.03±7.25	86.90±5.70	0.391
15	74.40±6.66	71.57±5.26	0.177	89.67±7.28	87.07±5.30	0.279

Continued.

Time (Mins)	Diastolic pressure		P value	Arterial pressure		P value
	Group RF, mean±SD	Group RD, mean±SD		Group RF, mean±SD	Group RD, mean ±SD	
20	73.87±6.02	71.53±4.98	0.221	89.80±6.34	87.27±4.95	0.163
25	73.63±5.46	72.33±4.20	0.547	88.93±6.38	87.70±5.63	0.676
30	72.90±4.49	71.30±3.83	0.409	88.60±5.73	87.10±5.13	0.582
45	73.80±4.96	71.20±3.50	0.113	89.40±5.79	87.30±5.34	0.38
60	73.90±5.35	71.27±3.84	0.155	89.37±6.38	87.10±4.35	0.259
90	74.47±6.66	72.23±4.47	0.229	90.20±6.13	87.80±4.24	0.057
120	73.63±6.08	72.27±3.41	0.594	89.43±6.02	87.20±4.16	0.227
150	74.43±6.45	72.40±3.97	0.181	89.77±5.91	87.27±5.06	0.071
180	73.47±5.62	71.40±4.80	0.365	89.17±5.68	86.43±5.28	0.164
210	74.77±6.72	71.07±4.95	0.064	89.70±6.44	86.00±5.41	0.063
240	74.43±6.88	71.40±3.01	0.085	89.43±7.60	86.37±4.51	0.126
270	75.27±7.47	72.70±3.78	0.237	90.50±7.50	87.63±4.20	0.181
300	74.93±7.10	72.00±4.68	0.051	89.90±7.31	87.37±4.78	0.087
360	75.40±7.67	71.17±4.67	0.06	90.03±7.02	86.70±4.58	0.062
420	74.13±6.32	72.07±4.86	0.233	89.20±6.42	87.20±5.01	0.177
480	75.30±4.89	71.80±4.32	0.051	89.77±6.73	87.33±4.57	0.062
540	73.57±5.18	71.90±4.30	0.437	88.57±7.16	87.20±4.55	0.514
600	73.77±5.69	71.97±4.86	0.35	89.00±6.09	87.20±5.05	0.244
660	74.50±6.00	71.87±4.80	0.121	89.50±5.89	86.70±5.31	0.07
720	74.00±5.45	71.50±4.94	0.108	89.37±5.48	86.77±4.59	0.069

DISCUSSION

Ropivacaine represents a relatively novel medication, frequently employed in the context of central neuraxial blockades. However, it has gained widespread acceptance for peripheral nerve blocks, as evidenced by extensive research. Furthermore, it has been demonstrated to be superior to bupivacaine in terms of efficacy. Additionally, ropivacaine is less lipid-soluble, resulting in its decreased potential for cardiotoxicity and neurotoxicity. Ropivacaine offers an extended duration of block and post-operative analgesia as compared to bupivacaine. However, it is noted that the motor effect of ropivacaine is not as good as bupivacaine. So, to mitigate this limitation, adjuvants such as fentanyl and dexmedetomidine are incorporated to augment the analgesic quality and prolong the duration of both sensory and motor block.[7]

A number of research studies have found that the onset of sensory block and motor block and its duration of postoperative analgesia were accelerated and extended by the administration of dexmedetomidine and fentanyl as adjuvants in brachial plexus block procedures.[8,9] In our research, it was observed that, the patients in group RD experienced sensory block and motor block much earlier than patients in group RF. Moreover, it was observed that duration of sensory block and motor block was found to be significantly longer in instances involving the RD group. Present study is in correlation with study drug and adjuvant findings of Soma et al, Kumar et al and Sarkar et al.[10-12]

Maximum dermatomal level of analgesia with the addition of dexmedetomidine was obtained in contrast to fentanyl.[13] Our findings are consistent with this investigation.

In our study, the mean onset of motor block and time to attain a complete motor block was significantly faster in RD group as compared to RF group. Also, total duration of motor block was significantly longer in cases of RD group. When it comes to delivering sufficient sedation, a prolonged post-operative analgesia, and an early onset of sensory analgesia, dexmedetomidine is a superior neuraxial adjuvant than clonidine.[14] In patients undergoing upper abdominal surgery, the addition of dexmedetomidine to bupivacaine in a thoracic epidural, produce effective perioperative analgesia comparable to fentanyl without causing any appreciable side effects.[15] In terms of epidural adjuvants, dexmedetomidine appears to be a superior option than fentanyl because it offers similar stable hemodynamics, early onset and establishment of sensory anaesthesia, prolonged post-operative analgesia and significantly better levels of sedation.[16]

The action of dexmedetomidine on the α2 receptors within the locus coeruleus and dorsal horn of spinal cord diminishes the central sympatholytic activity, resulting in increased firing of inhibitory neurons and hence producing analgesia.[17] In this research, the mean duration of analgesia was significantly longer in cases of RD group as compared to RF group. Number of rescue analgesia in 12 hours was comparable between RD and RF group. Using dexmedetomidine as an adjuvant to bupivacaine for spinal anaesthesia in lower limb surgeries has longer duration of sensory and motor block and longer postoperative analgesia.[9] Dexmedetomidine is an ideal adjuvant to epidural bupivacaine for analgesia compared to fentanyl and provides a better postoperative analgesia.[7] Our study's conclusions concur with these published results.

In this research the MHR, SBP, diastolic blood pressure (DBP) and MAP of all the study groups was comparable at the baseline and also throughout the procedure on most occasions (p>0.05). A comparable study conducted by Sahi et al found no variation in SBP, DBP, and MAP changes over time across all groups (p>0.05).[18] Sayak et al in their studies also observed change in PR among all the groups at any point of time was also not significant (p>0.05).[19]

In our study the occurrence of adverse events, including arterial puncture, bradycardia, and vomiting, was found to be equivalent among the two study groups. Whereas, incidence of nausea was notably elevated in the group receiving fentanyl, in contrast to those administered dexmedetomidine. Saikia et al in their study observed that the incidence of nausea and vomiting was higher in fentanyl group compared to dexmedetomidine.[20]

Limitations: In this study we included a small number of subjects. Large number of subjects can be added in further studies, which would result in less sampling bias. Our study was done on patients of age group between 20 to 45 years with ASA physical status I and II only. Hence results may not be extrapolated to ASA physical status III and IV patients. Further studies are required to investigate the efficacy of dexmedetomidine over fentanyl in ASA III and IV and medically compromised patients also.

CONCLUSION

In conclusion, fentanyl and dexmedetomidine will improve surgical readiness and offer comparable hemodynamic stability. As an epidural adjuvant to ropivacaine for lower limb surgeries, dexmedetomidine appears to be a better option than fentanyl as it offers more prolonged duration of motor and sensory block and postoperative analgesia.

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