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Original Research Paper

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COMPARATIVE EVALUATION OF DEXMEDETOMIDINE AND FENTANYL FOR EPIDURAL ANALGESIA IN LOWER LIMB ORTHOPEDIC SURGERIES

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ABSTRACT A study conducted between two groups to compare: Ropivacaine + Dexmedetomidine (RD) and Ropivacaine + Fentanyl (RF), comprising 50 patients each. Inj. Ropivacaine, 15 ml of 0.75%, was administered epidurally in both the groups with addition of 1 μg/kg of dexmedetomidine in RD group and 1 □g/kg of fentanyl in RF group. Besides cardio-respiratory parameters and sedation scores, various block characteristics were also observed. The study was compiled systematically and analyzed using ANOVA with post-hoc significance, Chi-square test and Fisher's exact test. Value of $P<0.05$ is considered significant and $P<0.001$ as highly significant.As compared both groups.RD group was significantly earlier in establishment of complete motor blockade, sensory analgesia at T10. Postoperatively sedation better in RD group. Incidence of nausea and vomiting was significantly high in the RF group, while incidence of dry mouth was significantly higher in the RD group. At the end of study Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant.

KEYWORDS :

INTRODUCTION

Ropivacaine has minimal cardio-vascular and central nervous system toxicity as well as a lesser propensity of motor block during post-operative epidural analgesia. Opioids like fentanyl have been used traditionally as an adjunct for epidural administration in combination with a lower dose of local anaesthetic to achieve the desired anaesthetic effect. The addition of opioid does provide a dose sparing effect of local anaesthetic and superior analgesia but there is always a possibility of an increased incidence of pruritis, urinary retention, nausea, vomiting and respiratory depression. Dexmedetomidine is a new addition to the class of alpha-2 agonist which has got numerous beneficial effects when used through epidural route. It acts on both pre and post synaptic sympathetic nerve terminal and central nervous system thereby decreasing the sympathetic outflow and nor-epinephrine release causing sedative, anti-anxiety, analgesic, sympatholytic and haemodynamic effects. Dexme detomidine does cause a manageable hypotension and bradycardia but the striking feature of this drug is the lack of opioid-related side effects like respiratory depression, pruritis, nausea, and vomiting.

MATERIALS AND METHODS

Patients with diabetes mellitus, cardiac disease, hypertension, chronic obstructive respiratory disease, coagulation abnormalities, spinal deformities, and patients allergic to amide type of local anesthetics were excluded from the study. All patients were premedicated with oral ranitidine 150 mg and alprazolam 0.25 mg a night before and 2 hour before on the morning of surgery. Patients were thoroughly counseled during the pre-operative evaluation and were properly explained about the nature of study before taking the written consent. In the operation theatre, a good venous access was secured with 18G cannula and all the patients were prehydrated with 10 ml/kg of lactated Ringer's solution. All the baseline parameters were observed and recorded which consisted of electrocardiography (ECG), heart rate (HR), non-invasive blood pressure (NIBP), and pulse oximetry (SpO_2). Lumbar epidural anesthesia was induced using 18G Touhy needle with patients in the sitting position in L3-L4 interspace and location of epidural space was confirmed by loss of resistance technique. A test dose of 3 ml of 2% lignocaine with adrenaline was administered into epidural space and thereafter epidural catheter was secured 3–5 cm into the epidural space and patients were placed supine. The following parameters were observed immediately after the administration of epidural block.

Time to onset of analgesia at T10
Maximum sensory level achieved
Time to achieve the maximum sensory level
Time to complete motor blockade
Time to two segmental dermatomal regression
Regression to S2
First feeling of pain/rescue analgesia
Total dose consumption of local anaesthetic used over 24 hours.

Sedation was also assessed at intervals of 20 minutes intra-operatively and at intervals of 1 hour during post-op period using subjective sedation scale. Motor blockade was assessed using modified Bromage scale. before surgery and at regular intervals of 1 hour post-operatively.

Statistical Analysis

At the end of study data was compiled systematically and was subjected to statistical analysis using statistical package for the social sciences (SPSS) version 15.0 for windows and employing analysis of variance (ANOVA) with post hoc significance, Chi-square test and Fisher's exact test for sedation and analgesia. Value of $P<0.05$ was considered significant and $P<0.001$ as highly significant.

RESULTS

A total of 100 patients who underwent lower limb surgery

were enrolled for the study and were randomly divided into two groups. The demographic characteristics in both the groups exhibited marked similarities and did not show any statistical significant difference ($P>0.05$) Table 1

The demographic profile of the patients of both the groups

Demographic characteristics	RD (n=50)	RF (n=50)	P
Age (years)	38.68±9.72	34.06±7.86	0.52
Weight (kg)	69.84±11.42	64.36±9.54	0.33
Body mass index	26.48±2.91	27.02±3.14	0.46
ASA (I/II)	31/19	33/17	0.78
Male/Female (M/F)	38/12	42/8	0.81
Mean duration of surgery (min)	102.48±12.36	108.78±14.49	0.21

RD = Ropivacaine+Dexmedetomidine; RF = Ropivacaine+Fentanyl; ASA = American Society of Anaesthesiologist

The onset of analgesia at T10 dermatomal level was significantly earlier in the RD group (7.12±2.44) as compared to the RF group (9.14±2.94). (P=0.016) The other early block characteristics also exhibited similar results as dexmedetomidine not only provided a higher dermatomal spread but also helped in achieving the maximum sensory anaesthetic level in a shorter period (13.38±4.48) as compared to Fentanyl (16.61±4.36). (P=0.021) Motor block was assessed using modified Bromage scale and complete motor block was achieved significantly earlier in the (18.16±4.52) patients who were administered dexmedetomidine as compared to RF group (22.98±4.78). (P=0.033) Table 2

The comparison of initial block characteristics in both the groups

Initial block characteristics	Group RD (n=50)	Group RF (n=50)	P
Onset time of sensory block at T10 (in minutes)	7.12±2.44	9.14±2.94	0.016
Maximum sensory block level	T4-6	T5-7	-
Time to maximum sensory block level (in minutes)	13.38±4.48	16.61±4.36	0.021
Time in minutes for complete motor block	18.16±4.52	22.98±4.78	0.033
Mean total dose of Mephenteramine requirement (mg)	11.8	8.3	0.18

RD = Ropivacaine+Dexmedetomidine; RF = Ropivacaine+Fentanyl

Dexmedetomidine has gained a lot of popularity as a sedative agent and similar findings were observed in our study as 38% and 42% of patients exhibited grade II and grade III sedation as compared to 16% and 2% of patients in the RF group, respectively. These sedation scores were highly significant on statistical comparison (P<0.001). Only 12% of the patients in the RD group had sedation scores of 1 as compared to 82% wide and awake patients in RF group which was a highly significant statistical entity (P<0.001)

The comparison of intra-operative sedation scores in patients of groups RD and RF

Sedation scores during surgery	Group RD No. of patients (%)	Group RF No. of patients (%)	P
1	8(16)	41** (82)	<0.001
2	19**(38)	8(16)	<0.001
3	21** (42)	1(2)	<0.001
4	2	0	-
5	0	0	-

**P<0.001-HS; RD = Ropivacaine+Dexmedetomidine; RF = Ropivacaine+Fentanyl

The finding of Table 4 reveals statistically significant values on comparison of post-operative block characteristics among the two groups. Though both the adjuvants provided smooth and prolonged post-operative analgesia but the effects of dexme detomidine were more significant on statistical comparison as compared to fentanyl. The evidence was very much visible in the prolonged time to two segmental dermatomal regression (140.32±10.21 in RD vs 110.84±9.48 in RF) (P=0.004) as well as earlier return of motor power to Bromage I in the RF group (178.52±23.29) as compared to RD group patients (259.62±21.38) (P=0.009). As a result, the time for rescue analgesia was comparatively shorter (242.16±23.86) in the patients who were administered fentanyl as compared to RD group who experienced prolonged pain free period (366.62±24.42) (P=0.012). The superior block characteristics by the addition of dexmedetomidine were clearly evident from the lesser dose consumption (76.82±14.28) of ropivacaine for postoperative analgesia for the next 24 hours (P=0.026).

The comparison of post-op block characteristics in both the groups

Post-op block characteristics (in minutes)	Group RD (n=50)	Group RF (n=50)	P
Mean time to two segmental regression	140.32±10.21	110.84±9.48	0.004
Mean time for regression to bromage 1	259.62±21.38	178.52±23.29	0.009
Mean time to sensory regression at S1	328.28±28.14	204.64±26.38	0.0082
Time to first rescue top-up	366.62±24.42	242.16±23.86	0.012
Total dose of ropivacaine used (mg)	76.82±14.28	104.35±18.96	0.026

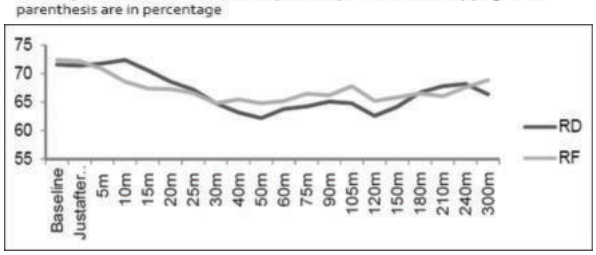
RD = Ropivacaine+Dexmedetomidine; RF = Ropivacaine+Fentanyl

shows the comparative incidence of various side effects in both the groups which were observed in the intra-op and post-op period. Nausea (26%) and vomiting (12%) were observed to a significant extent in the RF group with a comparative population of just 14 and 4%, respectively, in the RD group (P<0.05). The incidence of dry mouth was significantly higher in the RD (14%) group as compared to the RF group. (P=0.006) The incidence of other side effects like headache, shivering, dizziness, and urinary retention were comparable in both the groups and statistically non-significant (P>0.05). We did not observe respiratory depression in any of the patient from either group.

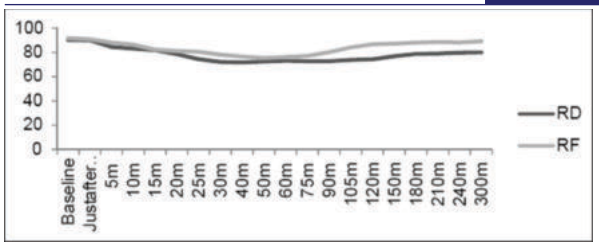
The comparison of side effects observed in both the groups during and after the operative period

Side effects	Group RD (n=50)	Group RF (n=50)	P
Nausea	7 (14)	13 (26)	0.028
Vomiting	2 (8)	6 (12)	0.036
Shivering	1 (2)	2 (4)	0.32
Headache	2 (4)	1 (2)	0.68
Dizziness	2 (4)	3 (6)	0.46
Dry mouth	7 (14)	1 (2)	0.006
Respiratory depression	0	0	
Urinary retention	5 (10)	4 (8)	0.14

RD = Ropivacaine+Dexmedetomidine; RF = Ropivacaine+Fentanyl; Figures in parenthesis are in percentage



The comparison of heart rate (HR) in the group RD and RF covering the pre-, intra-, and post-operative period



The comparison of mean arterial pressure (MAP) in the group RD and RF covering the pre-, intra-, and post-operative period

CONCLUSIONS

Dexmedetomidine seems to be a better alternative to fentanyl as an epidural adjuvant as it provides comparable stable hemodynamics, early onset and establishment of sensory anesthesia, prolonged post-op analgesia, lower consumption of post-op LA for epidural analgesia, and much better sedation levels.

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